Evaluation of the Efficacy and Tolerability of Sequential Intravenous/Oral Esomeprazole 40 Mg Once Daily in Adult Indian Patients with Erosive Esophagitis
Vidyagauri P. Baliga, PhD, Sanjay Chaudhary, MS, N. Dinakaran, MD, J.S. Rajkumar, MS, V.H. Kumaraswamy, MD, Mohnish Chabra, MD, Akhilesh Sharma, MD,* Anish Desai, MD. Medical Services, Glenmark Pharmaceuticals Ltd, Mumbai, India; Department of Surgery, Mumbai Medical Center, Thane, India; Gastroenterology, Government Medical Hospital and K.S. Hospital, Chennai, India; Surgical Gastroenterology, Rigid Hospitals Pvt. Ltd, Chennai, India; Medicine, M R Medical College, Gulbarga, India and Endoscopy; Gastroenterology and Hepatology, Gastroenterology & Liver Clinic and Fortis Multi-Speciality Hospital, Mohali, India.

Purpose: To evaluate the efficacy and tolerability of sequential intravenous/Oral Esomeprazole 40 mg once daily in adult Indian patients with erosive esophagitis.

Methods: This was a prospective, open-label, non-comparative, multicentre (5) study in 118 male and female patients with endoscopically confirmed erosive esophagitis (Los Angeles grade A-D), unable to take oral medication. Study was approved by respective Institutional Review Boards. Patients fulfilling selection criteria were treated with Injection Esomeprazole 40 mg administered intravenously once daily (7 days) followed by Oral Esomeprazole therapy (21 days) after obtaining their informed consent. Primary and secondary efficacy outcomes included improvement in severity of symptoms of erosive esophagitis and healing (assessed endoscopically and defined as no mucosal breaks) respectively. Tolerability and safety were assessed by physical examination and evaluation of adverse events.

Results: A total 111 patients completed the study with 7 drop-outs. At the end of therapy, there was a significant reduction in the mean scores of heartburn (91.6%), acid reflux (96.0%), belching (96.8%), epigastric pain (88.4%) and dysphagia (84.7%) compared to baseline values. As per the investigators’ and patients’ overall assessment of efficacy of treatment with esomeprazole, 89.2% of the study cases had excellent to good response. Following therapy with esomeprazole, there was complete healing of the esophageal lesions in 82.0% of the patients and no mucosal breaks were found healed at the end of therapy. Nineteen patients reported adverse events like headache, diarrhoea, nausea and abdominal pain which were mild to moderate in severity and disappeared with continued therapy.

Conclusions: Therapy with sequential intravenous/oral esomeprazole 40 mg is efficacious, safe and well tolerated and may be a suitable option in the treatment of patients with erosive esophagitis, for whom oral therapy is not appropriate.

Utilization and Acceptance of Wireless Esophageal Capsule Endoscopy for Evaluation of Self-Referral Subjects with Chronic Heartburn
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Purpose: Upper endoscopy is recommended for patients with GERD at risk for Barrett’s esophagus (BE) because of the association with adenocarcinoma of the esophagus. Patients with BE are less likely to report severe heartburn and may be less inclined to seek medical care and undergo invasive screening. The aim of this study is to assess the clinical utility of esophageal capsule endoscopy (ECE) for screening of adults at risk for BE.

Methods: Forty subjects over the age of 50 with a minimum of 2 episodes of heartburn a week during the past 6 months were recruited from local newspaper ads to undergo ECE. None of the subjects were currently under the care of a gastroenterologist or had undergone an upper endoscopy in the past five years. The average age of the study group was 61. There were 24 male subjects (62%) and 35 (90%) subjects were white. Subjects completed a pre-study questionnaire rating their heartburn severity, frequency and duration.

Results: Erosive esophagitis was identified in 13 studies (32%) (7 males, 6 females). Three subjects had circumferential ulcerations. Subjects with normal studies reported more severe heartburn (33% vs. 15%), and were more likely to use medications for relief of heartburn on most or all days (59% vs. 46%) than subjects with esophagitis. BE appearing mucosal changes were identified in 15 (38%) studies (9 males, 6 females). Subjects with possible BE were more likely to report heartburn over five years in duration (73% vs. 56%) and nocturnal heartburn on most or all nights (40% vs. 24%).

Conclusions: This study suggests that esophagitis and BE are common in adults who are self-referral for investigation of chronic heartburn. BE may be more prevalent in a community population with chronic heartburn than reported in clinical studies with referred GERD patients. Subjects with normal studies reported more severe heartburn than subjects with esophagitis or BE. A possible approach for evaluation of patients with chronic GERD without warning symptoms could be to perform an ECE study and then proceed with upper endoscopy and biopsy in only the minority of patients with possible BE.

24 Hour pH-Multichannel Intraluminal Impedance Monitoring in Patients Successfully Treated with Endoluminal Therapy for Reflux
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Purpose: pH-multichannel intraluminal impedance monitoring (pH-MII) provides a physiologic assessment and symptom correlation of gastroesophageal reflux disease (GERD) and contributes to understanding mechanisms of reflux. We analyzed pH-MII readings before and after endoluminal therapy (ET) of symptomatic GERD patients experiencing PPI failure.

Methods: Pre and post (mean of 9 mo., range 2-17 mo.) pH-MII tests were performed on 4 symptomatic GERD failing PPI therapy who underwent ET with Enteryx (2) and Plicator (2).

Results: All 4 patients reported elimination of reflux symptoms (see table 1). 3 patients discontinued PPI therapy. 1 patient required PPIs for dyspepsia. Impedance showed decreased total impedance events (reflux) and a reduction in the proximal extent of reflux post-ET (see table 2).

Conclusions: All 4 patients had a symptomatic response to ET associated with a total decrease in reflux events as measured by pH-MII. 2 patients had nonacid reflux pre-ET and a decrease in total reflux events post-ET. Clinical response was directly related to decreased reflux despite decreased esophageal clearance post-ET. The success of endoluminal therapy in these 4 GERD patients who did not respond to medical therapy with PPIs was due to an augmented antireflux barrier leading to a reduction of impedance detected reflux events. Larger studies of such patients will further clarify this mechanical phenomenon.
To identify if refractory GERD patients have symptom improvement, we conducted a study.

**Methods:**
- Patients referred to the esophageal clinic with symptomatic GERD on PPI ± H2RA and prescribed IR-OME between Oct 04 to Oct 05 were contacted. One of the investigators contacted them by phone. Patients who were prescribed and took IR-OME were included if they responded yes.
- Five questions were asked without coaxing, and these included an assessment of overall symptoms, night-time symptoms, and sleep disturbance rated on a 5-point scale: 1) much worse, 2) slightly worse, 3) same, 4) slightly better, 5) much better. In addition, patients were asked about frequency and duration of IR-OME use.

**Results:**
- 30 patients were prescribed IR-OME between Oct 04 to Oct 05. Three never took it, and three could not be contacted. 24 patients answered the questionnaire (18 female; mean age 49, range 31-75 yrs). More than 90% (22/24) of the patients were on a twice a day PPI, and all had persistent symptoms. A diagnosis of GERD was made by either a pH study or endoscopy. 58% (14/24) of the patients reported overall symptoms got better with addition/replacement of IR-OME while 30% (7/24) remained the same. 58% (14/24) of the patients had better nighttime symptoms while 30% (7/24) remained the same. 54% (13/24) of the patients had better sleep disturbance improved and 33% (8/24) had the same response on IR-OME. 20% (5/24) of the patients were taking it once at night, 66% (16/24) twice daily, and 16% (4/24) were using it more than twice. 83% (20/24) of the patients had used IR-OME for more than a month, the longest being on it for a year.

**Conclusions:**
- These results indicate that immediate-release omeprazole with a bedtime dose improves symptoms in most patients with refractory GERD.

### Immediate-Release Omeprazole Powder: An Effective Alternative Approach to Refractory GERD

**Purpose:**
To identify if refractory GERD patients have symptom improvement with the use of IR-OME powder.

**Methods:**
- Patients referred to the esophageal clinic with symptomatic GERD on PPI ± H2RA and prescribed IR-OME between Oct 04 to Oct 05 were contacted. One of the investigators contacted them by phone. Patients were asked if they were prescribed and took IR-OME. If they responded yes, five questions were asked without coaxing.

**Results:**
- 30 patients were prescribed IR-OME between Oct 04 to Oct 05. Three never took it, and three could not be contacted. 24 patients answered the questionnaire (18 female; mean age 49, range 31-75 yrs). More than 90% (22/24) of the patients were on a twice a day PPI, and all had persistent symptoms. A diagnosis of GERD was made by either a pH study or endoscopy. 58% (14/24) of the patients reported overall symptoms got better with addition/replacement of IR-OME while 30% (7/24) remained the same. 58% (14/24) of the patients had better nighttime symptoms while 30% (7/24) remained the same. 54% (13/24) of the patients had better sleep disturbance improved and 33% (8/24) had the same response on IR-OME. 20% (5/24) of the patients were taking it once at night, 66% (16/24) twice daily, and 16% (4/24) were using it more than twice. 83% (20/24) of the patients had used IR-OME for more than a month, the longest being on it for a year.

**Conclusions:**
- These results indicate that immediate-release omeprazole with a bedtime dose improves symptoms in most patients with refractory GERD.
Hatlebakk, Katz and Castell reported in 1999, “The oral bioavailability of PPI varies considerably between subjects, by a factor of at least 6... The considerable intersubject variation in pharmacologic response means that the clinician must be prepared to individualize the dosage regimen to obtain adequate treatment response in each patient”.

Cough, hoarseness, sore throat and a mirad of detrimental autonomic manifestations are associated with GERD. These findings are consistent with Reilly’s Syndrome where vasomotor disorders, increased capillary permeability, edema and lesions of the reticuloendothelial system result from “sympathetic stimulation” with “physic agents.” Regurgitated digestive juices evoke a protective response from the Vagally innervated gastroesophageal junction. Activation of efferent nerve trunks results in aerodigestive tissue responses beyond the endangered esophagus. With successful therapy, chronic Vagal response moderates and normal physiology ensues. The alerted clinician can monitor signs of GERD such as: sternal tenderness to palpation, nasal turbinate hypertrophy, exaggerated gag reflex, uvular edema and more. The clinical findings suggest cessation of reflux due to normalized function/physiology of the esophagus.

The 2003 abstract reported a 71% regression rate (5 of 7 cases). I understand the unprecedented nature of the findings. These 15 patients represent a reproducible clinical phenomenon in disease management of GERD and Barrett’s Esophagus.

Complete Esophageal Obstruction Following Ingestion of Nelfinavir – A Case Report
Pikeshkumar Patel, MD, Bhavna Balar, MD.* Medicine, Bronx Lebanon Hospital Center, Bronx, NY.

Purpose: A 43-year old man presented one-day of dysphagia and inability to swallow liquids including saliva after ingesting 3 tablets of nelfinavir in a suicidal attempt.

Oropharyngeal exam was normal and multiple attempts to pass a nasogastric tube were unsuccessful.

An esophagram showed complete obstruction of esophagus.

Upper endoscopy showed white pills obstructing the entire lumen of the esophagus at 20 cm from the incisors (Fig. 1). The pill was fractured using biopsy forceps. A Schatzki ring was found in the lower third of the esophagus 38 cm from the incisors. After the procedure he was able to tolerate liquids followed by full diet. Repeat endoscopy 5 days later showed a stricture at the site of previous obstruction which could only be traversed with a pediatric scope (Fig. 2). Endoscopy 1 month later revealed no stricture.

Conclusions: Discussion
Medication bezoars are a rare but potentially serious complication of medication use in patients [1]. It is even rarer for pills to lodge in the esophagus. Reports of cellulose fiber, bulk laxatives, sucralfate and protein-rich tube feedings and guar gum pills have been reported to cause esophageal obstruction[2, 3].

To our knowledge this is the first case report of acute esophageal obstruction and acute stricture following single use of nelfinavir.

The large size and the tablet formulation may have played a role in lodging these pill in the esophagus.

Patients using this nelfinavir should be educated about importance of drinking ample fluids when medicating.

patients were treated with Prevpac and after four weeks of treatment, these patients were examined with second EGD and multiplex PCR was performed again on the biopsies.

Results: Of the 29 patients, *H. pylori* infection was found in the 22 individuals at the distal esophagus, 25 individuals at the corpus/antrum, 4 cases at only the distal esophagus, 7 cases at only the corpus/antrum and 18 cases at both stomach and distal esophagus.

After treatment with Prevpac, 59% (17/29) cases became *H. pylori* negative. In the 22 esophageal infection cases, 11 (50%) cases were still positive on PCR results and in the 25 gastric infection individual, only 7 (28%) cases were positive. In the 18 cases with both gastric and distal esophagus infection, 10 (56%) cases were still positive, but all of the 7 with gastric only infection cases became *H. pylori* negative (100%).

Conclusions: Our results indicate that the *H. pylori* could live in the distal esophagus. It is suggested that multiple biopsies, especially the specimens from distal esophagus may be needed for the diagnosis of *H. pylori* infection in some situation. More importantly, our initial results showed that *H. pylori* located at distal esophageal mucosa are not as sensitive as those at gastric mucosa to the treatment with Prevpac.

### *H. pylori* Positive Location Before Treatment

<table>
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<th>Clinical Status</th>
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<th>H. pylori Positive Location</th>
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<th>G only</th>
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<td>Total</td>
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</table>

E: distal esophageal mucosa, G: gastric mucosa

### *H. pylori* Positive Location After Treatment

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E: distal esophageal mucosa, G: gastric mucosa

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Epidemiology and Risk Factors for Gastroesophageal Reflux Disease (GERD) in Italy

Maria P. Dore, MD, PhD, Emmanouil Maragoudakis, MD, Kennard J. Fraley, MS, Giuseppe Realdi, MD, PhD, David Y. Graham, MD, Hoda M. Malaty, MD. *Istituto di Clinica Medica, University of Sassari, Sassari, Italy; Medicine and Pediatrics, Baylor College of Medicine, Baylor College of Medicine, Houston, TX and Clinica Medica Prima, University of Padova, University of Padova, Padova, Italy.

**Purpose:** To determine the natural history and risk factors associated with GERD patients presenting in tertiary GI clinics, Italy.

**Methods:** Patients with a first diagnosis of GERD between 2004 and 2005 were included. The diagnosis of GERD was based on classic symptoms of heartburn and/or acid regurgitation. The cases were classified endoscopically as erosive, non-erosive esophagitis, or Barrett’s esophagus. A control group was enrolled from the same hospital without GERD symptoms. A detailed questionnaire collected data regarding demographic information, life style such as exercise, alcohol, coffee, chocolate, and soda consumption, smoking, having abundant meals, and frequency of bowel movement. Height and weight were recorded and Body Mass Index (BMI) was calculated. Obesity was scored using the gender/age specific body mass index Z-score (standard deviation score) and BMI calculated as Wt (kg)/Ht (cm)/1000. Obesity was based on a BMI of ≥95th percentile and was age/ gender specific.

**Results:** A total of 300 subjects were enrolled. There were 300 GERD patients between the ages of 12-80, and 200 controls. Females had a significantly higher prevalence of GERD than males (66% vs. 48%, p = 0.001, OR = 2.1, 95% CI = 1.5-3.1). The level of education had an inverse effect on GERD; 76% of those who only completed elementary school had GERD compared to 43% of those completed college (p = 0.001, OR = 2.1, 95% CI = 1.7–4.9). Obese individuals were significantly more likely to have GERD compared to those not obese (66% vs. 56%; respectively; OR = 1.8, p = .01). None of the other studied variables showed significant association with GERD. Logistic regression analysis including all the study variables in the model showed that BMI > 95th percentile, gender and low educational level were significant risk factors for GERD.

**Conclusions:** GERD is more prevalent among Italian women than men and associated with a high BMI and a low socioeconomic status (as measured by educational level). None of the dietary factors assessed were associated with GERD. Identification of the epidemiology and risk factors allows targeted studies regarding the pathogenesis and current management of GERD.

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Views and Practice of Gastroenterologists Regarding Life Style Changes for Patients with Reflux Esophagitis

Nirmal S. Mann, MD, F ACG,* Suk Seo, MD. Gastroenterology, Univ. of Calif, Davis Medical Center, Sacramento, CA.

**Purpose:** The role of life style changes (LSC) in the management of reflux esophagitis (RE) is controversial. We wanted to find out how many practising gastroenterologists prescribe LSC after doing EGD if RE is found on endoscopy. Also we wanted to find out if there is difference between the younger and older gastroenterologists in this respect.

**Methods:** Full members of AGA and ACGI were randomly contacted by phone or by interview to know about their views and practices about this issue of LSC in RE patients. The trainee members were not contacted. Information about the age of respondents was obtained from AMA Directory and ABMS Directory. None of the physicians contacted declined to participate in the survey; participation was 100%.

**Results:** There were 103 gastroenterologists in this survey. There were 8/103 (7.7%) women. The mean age was 52.7 years (range35–95). There were 56/103 (54.3%) gastroenterologists who prescribed LSC in RE patients; 39.2% gave the instructions verbally; 41% gave them as written material and 21.4% gave instructions both verbal & written. In 37.5% the instructions were given by the physician; in 66.0% they were given by the nurses. 47/103 (45.6%) did not prescribe LSC to RE patients; 46.8% believed they were not effective; 53.1% felt do not follow the instructions; 12.7% said they did not have time for it and 44.6% believed the availability of proton Pump Inhibitors has made LSC unnecessary. The respondents were divided into two groups. Group I had 41 respondents who were 49 years or younger in age; their mean age was 42.6 years (range 39–45). Group II had 62 respondents 50 years or older in age; their mean age was 59.4 years (range50–89). In Group I 13/41 (31.7%) prescribed LSC but 27/41 (65.8%) did not. In Group II LSC was prescribed by 43/62 (69.3%) respondents; 20/62 (32.2%) in Group II LSC did not prescribe LSC. The difference between the two groups in this regard is significant (Chi SQ.; P = 0.05).

**Conclusions:** A majority of practising gastroenterologists still prescribe life style changes in Reflux esophagitis patients but a significant minority do not. Younger gastroenterologists are less likely to prescribe such changes in RE patients.

Comparison of Acid Reflux Characteristics throughout the Sleep Period among the Different Gastroesophageal Reflux Disease (GERD) Groups

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Purpose: To compare extent of esophageal acid exposure during sleep time among patients with non-erosive reflux disease (NERD) and abnormal pH test, erosive esophagitis (EE) and Barrett's esophagus (BE).

Methods: Consecutive patients who underwent 24-h esophageal pH testing off proton pump inhibitors for GERD were enrolled. The extent of esophageal acid exposure was assessed every two hours of the sleep period (0-2, 2-4, 4-6, 6-8 hrs.). Each period of two hours was evaluated for the mean total number of acid reflux events, mean duration of an acid reflux event (in minutes), mean frequency of acid reflux events (per hour) and mean percentage time pH < 4 (in minutes).

Results: A total of 50 GERD patients were enrolled (NERD - 20, EE - 17, BE - 13). Mean age and gender were similar among the different GERD groups (mean age and M/F ratio for EE, NERD and BE were: 62, 52, 62, and 15/2, 15/5, 12/1, respectively). The mean time (minutes) elapsed from the last meal before the onset of sleep among the GERD groups: BE: 152, EE: 125, NERD: 92 (p = NS). All 3 groups demonstrated a decline in esophageal acid exposure throughout the sleep period as assessed by the 4 sleep intervals. Mean percent time pH < 4 in BE: 32.3, 49.0, 29.2, 2.4; EE: 11.9, 11.5, 7.1, 7.7 and NERD: 9.7, 9.1, 4.0, 2.3. Mean number of reflux events in BE: 16.2, 15.4, 10.9, 8.9; EE: 7.1, 3.5, 3.2, 4.4 and NERD: 8.1, 6.6, 2.3, 3.5 (all p < 0.05). Mean frequency (per hour) of acid reflux events in BE: 8.1, 7.7, 4.1, 4.1; EE: 3.6, 1.8, 1.6, 2.2 and NERD: 4.1, 3.1, 1.2, 1.8 (all p < 0.05). All GERD groups demonstrated a significantly higher esophageal acid exposure in the first versus second half of the sleep period as assessed by the mean percent time pH < 4 (BE: 40.6 vs.15.7, EE: 11.7 vs. 7.4, NERD: 9.2 vs. 3.1, all p < 0.05). Patients with BE had a significantly higher distribution of esophageal acid exposure throughout the sleep period as compared to those with NERD and EE (p < 0.05). There was no statistical difference in esophageal acid exposure during the different sleep intervals between patients with NERD and those with EE (p = NS).

Conclusions: Esophageal acid exposure declines during the sleep period regardless of the GERD group. Patients with BE demonstrated the greatest decline during sleep period. There is no difference in esophageal acid exposure during sleep period between EE and NERD (with abnormal pH test) patients.

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The Effect of Additional Acupuncture Versus Doubling the Proton Pump Inhibitor (PPI) Dose on Symptoms Report of Patients Who Continued To Be Symptomatic on Standard Dose PPI – A Randomized Trial

Ram Dickman, MD,* Isaac Malagon, Bing Han, Jeannette Powers, Ronnie Fass, MD, FACCP, FACC. Neuro-Enteric Clinical Research Group, Southern Arizona VA Health Care System, Tucson, AZ.

Purpose: To determine the efficacy of adding acupuncture as compared to doubling the PPI dose in GERD patients unresponsive to standard dose PPI.

Methods: Thirty consecutive patients with classic heartburn symptoms unresponsive to standard dose PPI were enrolled into the study. Patients were evaluated by a demographics questionnaire, the validated GERD Symptom Checklist, GERD Symptom Assessment Score (GSAS) and the quality of life questionnaire (SF-36). All participants underwent an upper endoscopy on PPI once a day. Patients were excluded if erosive esophagitis or GERD-related complications were documented. Patients were randomized to either adding acupuncture or doubling the PPI dose over a period of 4 weeks. Acupuncture was delivered twice a week by an expert. Patients filled diary on a daily basis that documented severity and frequency of GERD-related symptoms. Symptom score (frequency x severity) was calculated for previous 7 days at baseline and at 2 and 4 weeks of treatment in both groups.

Results: The two groups did not differ in gender (M/F), age and BMI (High PPI dose - 1/0.5, 48.9 ± 8.11, 31.4 ± 8.7, NERD group – 9/6, 52.7 ± 10.8, 32.3 ± 6.2, respectively, p = NS). The acupuncture group demonstrated a significant decrease in the mean daytime heartburn scores from baseline to week 2 and 4 as compared to the high-dose PPI group (18.3, 8.5, 3.2, p < 0.05 versus 12.8, 11.9, 16.4, p = NS, respectively). Mean nighttime heartburn scores were significantly improved only in the acupuncture group as compared to the high PPI dose group (18.07, 7.2, 3.6, p < 0.05 versus 12.8, 14.4,15.6, p = NS, respectively). Mean regurgitation scores were significantly improved only in the acupuncture group as compared to the high PPI dose group (14.8, 7.3, 3.67, p < 0.05 versus 8.9, 6.2, 7.4, p = NS, respectively).

Conclusions: Adding acupuncture as compared to doubling the PPI dose was more effective in controlling GERD-related symptoms in GERD patients unresponsive to standard dose PPI.

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Prevalence of Barrett’s Esophagus among Symptomatic Patients in a Community GI Practice

Douglas J. Sprung, MD,* GI, The Gastroenterology Group, Maitland, FL.

Purpose: The prevalence of Barrett’s Esophagus (BE) in the community setting is not well established. The aim of this study was to evaluate the prevalence of BE in a community practice, using the cohort of all patients undergoing endoscopy in a one year period.

Methods: We prospectively gathered data on all patients who had EGD’s done between 1/1/04-12/31/04 in our private GI practice in Orlando, FL. Most were symptomatic with chronic GERD, unresolved dyspepsia or new epigastric pain. There were 849 consecutive patients who underwent gastroscopy. Long segment BE (LSBE) was defined as > 3 cm of columnar lined epithelium (CLE) with specialized intestinal metaplasia (SIM) on biopsy. Short segment BE (SSBE) was < 3 cm of CLE with SIM. BE was established by multiple biopsies.

Results: Of 849 consecutive patients undergoing gastroscopy, 31 were done for Barrett’s surveillance, leaving 818 patients, of whom 3 (0.37%) had LSBE and 9 (1.1%) had SSBE. The combined prevalence of BE was 1.47%. All of these were newly diagnosed cases of BE. There were 5 patients who were felt to have CLE on gastroscopy, but biopsies did not reveal SIM.

Conclusions: The prevalence of BE in our private GI practice was 0.37% for LSBE and 1.1% for SSBE. This was a cohort of patients who had some criteria for gastroscopy, and not a random population. Nonetheless, these results mirror the most recently published population based data from outside the USA. This suggests reproducibility among community based practices, as opposed to the higher prevalence data reported from more selected populations.

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Findings on Esophageal Manometry Are Not Predictive of Symptomatic Non-Acid Reflux

Amine Hila, MD, Amit Agrawal, MD, Wojciech Blonski, MD, Donald O. Castell, MD,* Gastroenterology and Hepatology, Medical University of South Carolina, Charleston, SC.

Purpose: 24-hour multichannel intraluminal impedance and pH (MII-pH) esophageal monitoring allows detection of both acid and non-acid gastroesophageal reflux (GER) episodes. This technology is useful in patients who have persistent GER symptoms on PPIs permitting association of symptoms with the presence of acid or non-acid GER. MII and esophageal manometry (MII-EM) allows both functional and manometric evaluation of the esophagus. It is not known if patients with a positive MII-pH study for non-acid reflux (NAR) have different esophageal MII-EM findings than those who do not have NAR.
Aim: To compare MII-EM characteristics between patients with and without abnormal NAR as proven by MII-pH.

Methods: Review of 60 consecutive MII-pH studies on PPI therapy with a positive symptom index (SI) for NAR (65% females; mean age = 49.75 yrs) and 90 consecutive studies on PPI therapy with a negative SI for NAR (73% females; mean age = 52.5 yrs). All studies performed between 9/02 and 10/05. All patients also had an MII-EM study, which was analyzed for manometric diagnosis, transit abnormalities and LES characteristics.

Results: Table 1 shows prevalence of manometric diagnoses in patients with positive SI for NAR (+NAR) and those with negative SI for NAR (−NAR). There was no significant difference between the manometric diagnoses in the 2 groups (p = 0.47). Table 2 shows prevalence of transit defects by MII in patients with +NAR and −NAR. There was no significant difference in transit abnormalities between the 2 groups (p = 0.35). Also, there was no difference in LES resting pressure (+NAR: meaN = 29 mmHg; −NAR: meaN = 28.3 mmHg) or LES length (+NAR: meaN = 4.5 cm; −NAR: meaN = 4.3 cm) between the 2 groups (p = 0.73 and p = 0.2 respectively). Patients with +NAR had a significantly higher total number of NAR episodes compared to those with −NAR (p < 0.0001; meaN = 46.3 vs 23.2). Mann-Whitney test used.

Conclusions: Patients with a positive symptom index for NAR have similar esophageal manometric and transit characteristics as those with a negative symptom index for NAR.

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<th>Table 1. Manometric Diagnosis</th>
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<th>Incomplete bolus transit for liquid only</th>
<th>Incomplete bolus transit for viscous only</th>
<th>Incomplete bolus transit for liquid and viscous</th>
</tr>
</thead>
<tbody>
<tr>
<td>+ NAR (%)</td>
<td>64</td>
<td>8</td>
<td>14</td>
<td>14</td>
</tr>
<tr>
<td>− NAR (%)</td>
<td>60</td>
<td>7</td>
<td>8</td>
<td>25</td>
</tr>
</tbody>
</table>

24 Hr Esophageal Manometry and pH Recording Results with Symptom (Sx) Correlation in Patients (Pts) with Gastroesophageal Reflux (GERD) Resistant to Proton Pump Inhibitor (PPI) Therapy

Suean Ramdhany, MD; Manojkumar Singh, MD; Vijaya Boyella, MD; Venkat Pavan Kancharia, MD; Yatin Zhang, PhD; Halya Levendoglu, MD.*

Gastroenterology, SUNY Downstate Medical Center, Brooklyn, NY and Gastroenterology, Brookdale University Hospital, Brooklyn, NY.

Purpose: Many pts with GERD following PPI therapy continue to have sx. Because the etiology of their sx is not clearly known, adequate treatment is not possible. We evaluated 247 pts for their sx correlating it with 24 hr pH and motility findings.

Methods: Major sx were heartburn and regurgitation in 112 pts (A), atypical chest pain in 29 (B), dysphagia not related to achalasia and diffuse esophageal spasm in 28 (C), heartburn plus atypical chest pain in 66 (D), and combination of heartburn, atypical chest pain and dysphagia in 9 (E). A pts had significant acid reflux, alkaline reflux, combined acid and alkaline reflux and no significant acid or alkaline reflux in 33%, 42% 11%, 14%; B pts in 17%, 41%, 8%,34%; C pts in 28%, 43%, 8%, 21%, D pts in 21%, 45%, 7%, 27% and E pts in 22%, 66%, 0%, 11% respectively. Esophageal wave activity was greater in E pts (>D>B>A>C; the common sx in E,D,B was atypical chest pain).% peristaltic activity was lowest in C pts (<B<D = E = A; common sx C and B were chest pain and dysphagia).% simultaneous waves was highest in C pts (>B>D>A>C>E); common sx in C, B and E were chest pain and dysphagia).% isolated contractions were elevated in C>A>B=E>D pts. Median amplitude of contractions were lowest in D and E (common sx were chest pain and heartburn). Contractions were most prolonged in the chest pain group (B>D>A>C=E) and percent repetitive waves were highest in D>C>B=E>A. (Common sx in C,D,B were atypical chest pain). Subgroup analysis of heartburn pts showed significantly decreased # of contractions and significant increase in median amplitude of waves in the distal esophagus (p < 0.0001) in the high alkaline reflux group.

Conclusions: We conclude that alkaline reflux is the most common reflux pattern in all sx groups and is associated with increased amplitude of waves in the distal esophagus. Acid reflux and combined reflux occurred most in A pts, whereas B pts has mostly no reflux. Esophageal contractility is most preserved when atypical chest pain was present as a major sx. Peristaltic activity is least present in C pts with increased isolated and simultaneous contractions; followed by D pts. In view of various reflux patterns in all sx groups, we conclude that not the reflux pattern, but the motility changes, characterize these sx.

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Esophageal Varices Ligation (EVL) Versus Esophageal Variceal Sclerotherapy (EVS) in Esophageal Bleeding in Liver Cirrhosis

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Gastroenterology Internal Medicine, University of Indonesia/Cipto Mangun Kusumo Hospital, Jakarta, Java Island, Indonesia.

Purpose: The most frequent cause of upper gastrointestinal bleeding in Indonesia is rupture of esophageal varices. Recently EVL is classified as the best treatment to eradicate esophageal varices. This study was done to know the differences between EVL and EVS outcome in the treatment of esophageal varical bleeding.

Methods: All medical reports of upper gastrointestinal bleeding due to rupture of esophageal varices in liver cirrhosis who were done EVL or EVS in the year 2003 – 2006 were included in this study. Exclusion if the data was incomplete. Patients were divided into three groups, who were done: EVL alone, EVS alone, and combination of EVL- EVS. Data were assessed with chi-square test or anova.

Results: We got 96 (75.6%) cases who were done EVL, 23 (18.1%) cases who were done EVS and 8 (6.3%) who were done combination of EVL- EVS. There were no differences of patients characteristics between this three groups statistically. The complications of the EVL group (29.2%) is less frequent than the complications in the EVS (60.9%) or combination EVL-EVS (37.5%). The mean duration of admission in the hospital after the procedure of EVL, EVS, Combination EVL-EVS were 11.83 ± 11.23 days, 13.86 ± 10.18 days and 14.25 ± 12.82 days, respectively. The mean survival of patients who were done EVL, EVS and combination EVL-EVS are 463.05 ± 409.20 days, 200.25 ± 303.51 days, and 32.50 ± 38.89 days, respectively.

Conclusions: EVL is still the best treatment for esophageal varices bleeding. EVL has the lowest complications and the longest duration of patients survival.

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Prior Endoscopy Does Not Improve Long-Term Survival from Esophageal Adenocarcinoma among United States Veterans

Joel H. Rubenstein, MD, MSc, Amon Sonnenberg, MD, Jennifer Davis, MHSA, Laurence McMahon, MD, MPH, John M. Inadomi, MD,* Veterans Affairs Medical Center, Ann Arbor, MI; Oregon Health Sciences University, Portland, OR and University of California, San Francisco, CA.
Purpose: The efficacy of surveillance esophagogastroduodenoscopy (EGD) for esophageal adenocarcinoma (EAC) is controversial. We aimed to examine the effect of EGD at least 1 year prior to the diagnosis of EAC on survival after the diagnosis of EAC among United States veterans with gastroesophageal reflux (GER).

Methods: The national administrative database of the Veterans Administration was accessed, and patients diagnosed with EAC from 1995 through 2003 who had a prior diagnosis of GER were identified. Data were collected for EGDs performed up to 5 years prior to cancer diagnosis. Electronic medical records were abstracted for confirmation of EAC, date of diagnosis, stage at diagnosis, therapy, and date of death.

Results: 155 confirmed cases of EAC were identified. Mean age at diagnosis was 68.9; 154 were male, and 3.5% were African American. Cancer mortality was associated with increasing stage at diagnosis (HR 1.74, 95% CI 1.45-2.10), Charlson comorbidity index (HR 1.18, 95% CI 1.03-1.35), and age (HR 1.02, 95% CI 1.00-1.04). Patients with a history of EGD at least 1 year prior to diagnosis of EAC (N = 25) were diagnosed at earlier stages than those without prior EGD (stages I, II, III, IV: 28%, 44%, 12%, 16% vs. 13%, 30%, 23%, 28%, p = 0.02), and were more likely to undergo surgical resection, controlling for age and comorbidity (OR 2.1, 95% CI 0.8 – 5.4). Patients with prior EGD appeared to have better short-term cancer survival than those without prior EGD, but there was no survival advantage after 6 years of follow-up (figure). Controlling for age and comorbidities, or examining all-cause mortality yielded similar results.

Conclusions: Surveillance for esophageal adenocarcinoma improved the stage at diagnosis, and the likelihood of receiving surgical resection, but did not alter long-term cancer-associated or all-cause survival among this cohort. This is likely due to the poor long-term survival of even early stage EAC. Lead-time effects may have biased prior short-term studies toward finding a benefit from endoscopic surveillance. [figure1]

Results: (See Table) Ninety-six patients enrolled between December 2005 and May 2006 (56 VAMC, 40 UH). Two patients did not undergo esophageal biopsies and were excluded from the analysis (94 total patients). Median age was 59 years, and 68/94 (72%) were male. Eleven patients (11.7%) met pathologic criteria for EoE. No significant difference in EoE cases between male and female (p = 0.42). Mean age of EoE patients 38 ± 12 vs. 61 ± 15 for non-EoE patients (p < 0.0001). EoE was diagnosed in 19% of patients less than 50 years (RR 4.5 for age <50 vs. >50). Asthma was present in 5/11 (45%) of EoE cases vs. 19/83 of controls (23%) (p = 0.31). Food allergies present in 5/11 (45%) of EoE cases vs. 10/83 (12%) of controls (p < 0.05). Two EoE patients did not have the classic EGD findings (one esophagitis, one distal stricture). There was a ringed esophagus in 6 patients whose biopsies did not meet histologic criteria.

Conclusions: EoE was diagnosed in 11.7% of patients presenting with dysphagia with relative risk of 4.5 if age <50. Food allergies is a significant risk factor for EoE. Esophageal biopsies may be warranted in patients presenting with dysphagia especially in the younger population. Patients may not present with classic endoscopic findings.

Results

<table>
<thead>
<tr>
<th>EoE (N = 11)</th>
<th>Non-EoE (N = 83)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yrs (SD)</td>
<td>38 (12)</td>
<td>61 (15)</td>
</tr>
<tr>
<td>Gender (M/F)</td>
<td>7/4</td>
<td>61/22</td>
</tr>
<tr>
<td>Asthma (%)</td>
<td>5/11 (45)</td>
<td>19/83 (23)</td>
</tr>
<tr>
<td>Food Allergies (%)</td>
<td>5/11 (45)</td>
<td>10/83 (12)</td>
</tr>
</tbody>
</table>

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Double Dose or Higher PPI Therapy Does Not Always Result in Normalization of Distal Esophageal Acid Exposure

Ari L. Bunim, MD, David A. Katzka, MD, Yu-Xiao Yang, MD, David C. Metz, MD.* Division of Gastroenterology, Department of Medicine, Hospital of the University of Pennsylvania, Philadelphia, PA.

Purpose: The role of distal esophageal pHmetry in patients receiving double dose PPI therapy has recently been questioned due to the frequent finding of normal acid exposure.

The aim of this study is to further assess the distal esophageal acid exposure in patients undergoing repeated esophageal pHmetry for pathologic acid exposure on and off PPI therapy.

Methods: Retrospective chart review of 58 patients undergoing repeated pHmetry between 1996 and 2004. 8 patients were excluded due to an uninterpretable study. 50 patients who underwent 119 studies (116 catheter and 4 flush) were analyzed according to PPI regimen (none [N = 38], half dose [4], single dose [27], double dose [36], more than double dose [14]). Distal pH exposure ≥ 4.2%/24 hrs was considered abnormal.

Results: 1) 10/33 patients (18/50 tests) had pathologic distal esophageal acid exposure on double or higher dose PPI therapy (7 on the highest dose). Endoscopy of these patients revealed Barrett’s esophagus in 2, erosive esophagitis in 2, hiatal hernias but a normal esophagus in 3, and esophageal candidiasis in 1.

2) 42/50 patients were tested on different doses of PPI therapy. 30 patients had a decrease but 12/42 (29%) demonstrated an increase in their total distal esophageal acid exposure on a higher PPI doses.

3) 4/27 (15%) patients had abnormal distal esophageal pH exposures on less than double dose PPI therapy and continued to have abnormal distal esophageal acid exposure on double dose or higher PPI therapy.

4) Distal esophageal pH exposure time is shown in the Table.

Conclusions: 1) Abnormal distal esophageal pHmetry does occur in patients with continued GERD symptoms despite double dose or higher PPI therapy.

2) Persistent acid exposure on double dose PPI therapy may suggest significant esophageal injury (Barrett’s or erosive esophagitis).

3) Upright reflux is more prevalent in this group of patients than supine reflux.

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Distal esophageal pH exposure time (%) (Total [upright/supine])

<table>
<thead>
<tr>
<th>Therapy dose</th>
<th>None</th>
<th>Half</th>
<th>Single</th>
<th>Double</th>
<th>&gt; double</th>
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</thead>
<tbody>
<tr>
<td># tests</td>
<td>38</td>
<td>4</td>
<td>27</td>
<td>36</td>
<td>14</td>
</tr>
<tr>
<td>Mean</td>
<td>9.5 (11.9/6.5)</td>
<td>2.4 (3.6/1.7)</td>
<td>2.8 (4.3/1.1)</td>
<td>4.2 (4.4/3.8)</td>
<td>8.4 (9.7/5.9)</td>
</tr>
<tr>
<td>Median</td>
<td>6.9 (8.2/2)</td>
<td>2.7 (2.5/1)</td>
<td>1.5 (2.5/0)</td>
<td>1.3 (1.6/0)</td>
<td>5.3 (5.8/2.4)</td>
</tr>
<tr>
<td>SD</td>
<td>10.8 (14.7/11.2)</td>
<td>2.4 (1.2/1)</td>
<td>3.9 (4.3/3.3)</td>
<td>7.5 (7.2/1.1)</td>
<td>8.6 (10.6/7.3)</td>
</tr>
<tr>
<td>Range</td>
<td>0.1-15.5</td>
<td>0.1-4.3</td>
<td>0.13-1.0</td>
<td>0.32-3.3</td>
<td>0.3-29.4</td>
</tr>
<tr>
<td># Abnormal tests</td>
<td>26 (29/13)</td>
<td>1 (1/1)</td>
<td>5 (0/1)</td>
<td>10 (12/5)</td>
<td>8 (9/6)</td>
</tr>
</tbody>
</table>

The Information Content of Esophageal pH Values in Vulcan Syndrome Differs from That in Normal and GERD Subjects

Jerry D. Gardner, MD,∗ Winston Young, PhD, Sheldon Sloan, MD, Malcolm Robinson, MD, Philip B. Miner, Jr., MD, Science for Organizations, Inc., Mill Valley, CA; Blossomtech, Inc., Apex, NC; Janssen Pharmaceutica, Titusville, NJ and Oklahoma Foundation for Digestive Research, Oklahoma City, OK.

Purpose: Previously, we found that up to 12% of healthy subjects may have the Vulcan syndrome, i.e., 24-hour esophageal acid exposure in the range seen in GERD subjects, but without accompanying symptoms of pathologic esophageal acidity. The aim of the present analyses was to further characterize the abnormalities in Vulcan Syndrome.

Methods: Esophageal pH was recorded for 24 hours from 3 subjects with Vulcan syndrome, 5 normal subjects and 10 GERD subjects. We used detrended fluctuation analyses (DFA; http://www.physionet.org) to characterize fractal patterns, and lag analyses (http://www.itl.nist.gov/div898/ handbook) to examine relationships among sequential pH values. The information content of sequential pH values was calculated as the value of $r^2$ from a linear, least-squares fit of the values at a given lag.

Results: On DFA, esophageal pH from the 3 subjects with Vulcan syndrome had a fractal pattern and the self-similarity coefficients during daytime (1.03 ± 0.07; mean ± SD) or nighttime (1.14 ± 0.06) were similar to corresponding values from normal (1.02 ± 0.05; 1.03 ± 0.08) and GERD subjects (1.06 ± 0.08; 1.07 ± 0.15). With increasing lag, the slope and $r^2$ of the lag plots decreased in a biphasic manner - a rapid phase with a half-life of in the range of 1 minute and a slow phase with a half-life of in the range of 15 minutes. In Vulcan Syndrome, the information content of esophageal pH values, measured as the curve for integrated $r^2$ over the range of lag values, was significantly higher at night than during the day ($p < 0.0001$, F-test).

Conclusions: Although subjects with Vulcan Syndrome have pathologic esophageal acid exposure, esophageal pH values in these subjects have the same fractal self-similarity as those in normal or GERD subjects. On the other hand, the information content of sequential esophageal pH values in Vulcan Syndrome differs significantly from that in normal as well as GERD subjects indicating that this syndrome represents a distinct pathophysiologic entity.

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Clinical Utility of the Bravo Capsule

Andrew C. Dukowicz, MD, Brian E. Lacy, PhD, MD,∗ Lisa Paquette, RN, Douglas Robertson, MD, Julia Weiss, MA, Maurice L. Kelley, MD, Gastroenterology & Hepatology, Dartmouth-Hitchcock Medical Center, Lebanon, NH; Medicine, White River VA Medical Center, White River Junction, VT and Biostatistics, Dartmouth Medical School, Hanover, NH.

Purpose: The Bravo capsule is commonly ordered to evaluate patients (Pts) with acid reflux symptoms. Despite its widespread use, the clinical utility of the Bravo capsule has not been prospectively examined.

Methods: Before placing the Bravo capsule, referring physicians (GIs, surgeons, primary care) prospectively completed a questionnaire requesting: indications for the test (primary and secondary); symptoms (primary and secondary; duration); prior testing for the problem; and medication use. Demographic information was obtained. Patients were studied either on or off acid-suppressing medications at the referring provider’s request. Two weeks after the referring physician received the results of the test a follow-up questionnaire was sent asking whether the Bravo capsule provided new information that either changed the Pt’s diagnosis or management. Results of Bravo were classified using standard criteria.

Results: During a 6 month period, 275 Bravos were performed; 240 were available for inclusion; 106 fully completed questionnaires were returned (44.2%) and are the basis for this analysis. The mean age (±SD) at time of Bravo placement was 47 (±16 years); 66% were women. 95% of patients were Caucasian. The average age of onset of symptoms was 40 years (±15). The most common primary symptom leading to referral was that of acid reflux symptoms (heartburn and regurgitation; 65%), followed by chest pain or a chronic cough (both 9%), dysphagia (5%), and ENT symptoms (3%). The average duration of symptoms was 70 months. 91% of patients had undergone prior testing for their symptoms, including EGD, barium swallow, and/or chest x-rays. 27% had undergone a previous pH test (either pH catheter or Bravo). In all, 61% of these studies were abnormal. Results of the Bravo capsule provided new information in 75% of patients and changed the diagnosis in 25% of patients. Results of the Bravo study led to a change
in management in 64% of patients. Management changes included: referral to surgery (26%), stopping a prior medication (18%), increasing dose of a prior medication (12%), adding a new medication (12%) and other (32%).

**Conclusions:** This is the first study to prospectively evaluate the clinical utility of the Bravo capsule. It appears to be a clinically useful test as it frequently provides new information and leads to a change in Pt diagnosis or management.

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**Does Treatment Satisfaction Correlate with Absence of Esophageal Mucosal Pathology (EMP) in Users of Prilosec OTC™ (Omeprazole 20 Mg) (POTC)?**

Nicholas J. Shaheen, MD, FACG, John T. Monyak, PhD, Kurt A. Brown, MD. * UNC, Chapel Hill, NC and AstraZeneca LP, Wilmington, DE.

**Purpose:** To examine the relationship between treatment satisfaction and EMP in POTC users.

**Methods:** Adults who self-initiated POTC for frequent heartburn (HB; ≥ 2 d/wk) and took > 14 POTC tablets in the past 4 mo were eligible for this multicenter study (D9612L00084). Exclusion criteria included POTC use for ≥ 15 d consecutively in the past 4 mo, medical care for HB in the past 6 mo, and history of EMP or esophagogastroduodenoscopy (EGD). At screening, subjects completed 5 relevant domains (Symptoms [symptom relief], Satisfaction [medication performance satisfaction], PRN [flexibility with dosing when needed], Expectation [treatment expectations], and Bother [bother associated with medications]) of the Treatment Satisfaction Questionnaire for GERD (TSQ-GERD). TSQ-GERD was scored using a 6-point (bother associated with medications) scale.

At screening, subjects completed 5 relevant domains (Symptoms [symptom relief], Satisfaction [medication performance satisfaction], PRN [flexibility with dosing when needed], Expectation [treatment expectations], and Bother [bother associated with medications]) of the Treatment Satisfaction Questionnaire for GERD (TSQ-GERD). TSQ-GERD was scored using a 6-point (bother associated with medications) scale. At screening, subjects completed 5 relevant domains (Symptoms [symptom relief], Satisfaction [medication performance satisfaction], PRN [flexibility with dosing when needed], Expectation [treatment expectations], and Bother [bother associated with medications]) of the Treatment Satisfaction Questionnaire for GERD (TSQ-GERD). TSQ-GERD was scored using a 6-point (bother associated with medications) scale.

**Results:** The demographics of the 1024 intention-to-treat subjects were as follows: 45%, men; 63%, white; 32%, Hispanic; mean age, 43 y; mean BMI, 28.7 kg/m²; mean (SD) duration of HB, 72.3 (83.2) mo; and 33.2%, concomitant HB medication use. HB severity was moderate or severe in 91% of subjects before and 17% during POTC use. Most had HB 4-6 d/wk (28%) or daily (32%) before using POTC; during use, most had no HB (29%) or had HB ≤ 1 d/wk (37%). Symptoms and PRN domain scores were significantly lower in subjects with than without EMP, but these differences were small and not deemed clinically relevant (Table). Symptom domain scores were ≥ 4 in 47% and 51% of subjects with and without EMP, respectively. TSQ-GERD scores for the other 3 domains did not differentiate subjects with from those without EMP.

**Conclusions:** Treatment satisfaction with POTC cannot be used clinically to distinguish between subjects with and without EMP. GERD symptoms poorly predict the presence of EMP in subjects who self-initiate POTC use.

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<table>
<thead>
<tr>
<th>Domain</th>
<th>EMP Present (N = 343)</th>
<th>EMP Absent (N = 681)</th>
<th>95% CI for Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms*</td>
<td>3.95 (0.94)</td>
<td>4.07 (0.89)</td>
<td>(0.002, 0.238)</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>4.26 (0.87)</td>
<td>4.30 (0.88)</td>
<td>(−0.070, 0.158)</td>
</tr>
<tr>
<td>PRN*</td>
<td>4.15 (0.82)</td>
<td>4.26 (0.79)</td>
<td>(0.014, 0.221)</td>
</tr>
<tr>
<td>Expectation</td>
<td>4.13 (0.87)</td>
<td>4.23 (0.98)</td>
<td>(−0.016, 0.228)</td>
</tr>
<tr>
<td>Bother</td>
<td>3.13 (1.07)</td>
<td>3.14 (1.12)</td>
<td>(−0.132, 0.156)</td>
</tr>
</tbody>
</table>

* t test, p < .05

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**Prevalence of Clinically Relevant Esophageal Mucosal Pathology in Subjects Who Self-Initiate Use of Prilosec OTC™ (Omeprazole 20 Mg)**

Nicholas J. Shaheen, MD, FACG, John T. Monyak, PhD, Kurt A. Brown, MD. * UNC, Chapel Hill, NC and AstraZeneca LP, Wilmington, DE.

**Purpose:** To assess the point prevalence of esophageal mucosal pathology (EMP) in subjects who self-initiate Prilosec OTC™ (POTC; omeprazole 20 mg) use.

**Methods:** Adults who self-initiated POTC use for frequent heartburn (HB; ≥ 2 d/wk) and took ≥ 14 POTC tablets (as per the package insert) in the past 4 months were eligible for this prospective, multicenter study (D9612L00084). Exclusion criteria included POTC use for ≥ 15 consecutive days in the past 4 months, medical care for HB in the past 6 months, and history of EMP or esophagogastroduodenoscopy (EGD). At screening, subjects completed a questionnaire about POTC use. Within 14 days of screening, an EGD was performed to assess the presence of EMP, defined as ≥ 1 condition listed in the table. All Barrett’s and carcinoma findings were confirmed via biopsy. A 95% confidence interval (CI) was constructed for the percentage of subjects with EMP.

**Results:** The demographics of the 1024 intention-to-treat subjects were as follows: 45%, men; 63%, white; 32%, Hispanic; mean age, 43 y; mean body mass index, 28.7 kg/m²; mean (SD) duration of HB, 72.3 (83.2) months; and 33.2%, concomitant HB medication use (28%, antacids; 8%, OTC H₂-receptor antagonists [H₂RA]; 2%, proton pump inhibitors; and 1% each prescription H₂RAs or other HB medication) during POTC use. Of the 60% who had discontinued POTC use, the mean time since last use was 24 days. HB severity was moderate or severe in 91% of subjects before and 17% during POTC use. Most had HB 4-6 d/wk (28%) or daily (32%) before POTC use, but during use, most had no HB (29%) or HB ≤ 1 d/wk (37%). Prevalence of EMP is shown in the table.

**Conclusions:** Though HB was relieved in most subjects who self-initiated POTC use in the past 4 months, one third had clinically relevant EMP. Polypharmacy for HB was common in subjects who self-initiated POTC use.

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<table>
<thead>
<tr>
<th>EMP*</th>
<th>Prevalence, n (%)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any EMP</td>
<td>343 (33.5)</td>
<td>30.6–36.4</td>
</tr>
<tr>
<td>EE¹</td>
<td>311 (30.4)</td>
<td></td>
</tr>
<tr>
<td>LA grade A EE</td>
<td>170 (16.6)</td>
<td></td>
</tr>
<tr>
<td>LA grade B EE</td>
<td>95 (9.3)</td>
<td></td>
</tr>
<tr>
<td>LA grade C EE</td>
<td>39 (3.8)</td>
<td></td>
</tr>
<tr>
<td>LA grade D EE</td>
<td>6 (0.6)</td>
<td></td>
</tr>
<tr>
<td>BE¹</td>
<td>18 (1.8)</td>
<td></td>
</tr>
<tr>
<td>Short segment BE¹</td>
<td>22 (2.1)</td>
<td></td>
</tr>
<tr>
<td>Esophageal stricture</td>
<td>32 (3.1)</td>
<td></td>
</tr>
<tr>
<td>Esophageal ulcer</td>
<td>6 (0.6)</td>
<td></td>
</tr>
<tr>
<td>Esophageal carcinoma¹</td>
<td>1 (0.1)</td>
<td></td>
</tr>
</tbody>
</table>

¹ BE, Barrett’s esophagus; EE, erosive esophagitis; LA, Los Angeles. *Subjects could have ≥ 1 type of EMP. † Subject was recorded as having EE, but the grade was not specified. ‡ Based on biopsy results.

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**Effect of Erosive Esophagitis (EE) at Baseline on Symptom Resolution in Gastroesophageal Reflux Disease (GERD) after 4 Weeks of Esomeprazole Treatment**

Roy C. Orlando, MD, John T. Monyak, PhD, Debra G. Silberg, MD, FACG. * Department of Medicine, Tulane University Health Sciences Center, New Orleans, LA and AstraZeneca LP, Wilmington, DE.

**Purpose:** To compare rates of GERD symptom resolution in patients with and without EE at baseline after 4 weeks of treatment with oral esomeprazole 40 mg daily.

**Methods:** Adults aged 18–70 y with a history of frequent heartburn (≥ 2 d/wk for the past week and on average for the past 3 months) were eligible for this multicenter, open-label study (D9612L00083). Baseline endoscopy established presence and severity of EE (Los Angeles [LA] grades A–D; patient-blinded). After stratification by presence or absence of EE, all patients...
received oral esomeprazole 40 mg daily for 4 weeks. When a stratum reached its predetermined quota of ~175 patients, additional patients received no treatment, but endoscopy results were retained for prevalence estimates. GERD symptoms were reassessed at 2 and 4 weeks by questionnaire; symptom resolution was defined as patients recording ‘none’ on a scale of ‘none’, ‘mild’, ‘moderate’ or ‘severe’. χ^2 Tests were performed to compare symptom resolution rates in patients with and without EE. 

**Results:** Of 399 patients who underwent endoscopy, 205 had EE, for an EE prevalence of 51.4%. Of those with EE, 29%, 38%, 26%, and 7% had LA grades A, B, C, and D, respectively. The intention-to-treat population was composed of 356 patients (men, 42%; white, 81%; mean age, 44 y; mean BMI, 30.1 kg/m^2). After 2 and 4 weeks of esomeprazole treatment, heartburn resolution rates were higher in patients with EE (N = 179) than without EE (N = 177) at baseline (table). At baseline, all patients had heartburn and most had acid regurgitation (87%) and epigastric pain (79%). Only 47% had dysphagia at baseline, which likely decreased the power to detect between-group differences in dysphagia resolution rates.

**Conclusions:** GERD symptom resolution rates were higher in patients with EE than those without EE after 4 weeks of daily esomeprazole 40-mg treatment. Given this observation, GERD symptom resolution should not be accepted as an indicator of benign esophageal mucosal pathology. Supported by AstraZeneca LP

### Table 1

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Week 2</th>
<th>Week 4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EE</td>
<td>No EE</td>
</tr>
<tr>
<td></td>
<td>(N = 179)</td>
<td>(N = 174)</td>
</tr>
<tr>
<td>Heartburn</td>
<td>59.2</td>
<td>36.2*</td>
</tr>
<tr>
<td>Acid regurgitation</td>
<td>68.7</td>
<td>51.7</td>
</tr>
<tr>
<td>Dysphagia</td>
<td>79.3</td>
<td>70.1*</td>
</tr>
<tr>
<td>Epigastric pain</td>
<td>70.9</td>
<td>44.3*</td>
</tr>
</tbody>
</table>

*p ≤ 0.05 for χ^2 comparison with EE.

### Table 2

<table>
<thead>
<tr>
<th></th>
<th>0–60 sec</th>
<th>60–120 sec</th>
<th>120–180 sec</th>
<th>180–240 sec</th>
<th>240–300 sec</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regurg (A)%</td>
<td>55</td>
<td>29</td>
<td>21</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regurg (NA)%</td>
<td>101</td>
<td>*62</td>
<td>*14</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HB (A)%</td>
<td>25</td>
<td>62</td>
<td>18</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HB (NA)%</td>
<td>22</td>
<td>*119</td>
<td>*7.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cough (A)%</td>
<td>16</td>
<td>64</td>
<td>14</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cough (NA)%</td>
<td>63</td>
<td>*125</td>
<td>*8</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

A = Acid, NA = Non-Acid; HB = heartburn, * = p < 0.05

### 27

**Swallow Evaluation during Multichannel Intraluminal Impedance and pH (MII-pH): A Valid Method To Assess Esophageal Transit**

Amine Hila, MD, Amit Agrawal, MD, Wojciech Blonski, MD, Donald O. Castell, MD.* Gastroenterology and Hepatology, Medical University of South Carolina, Charleston, SC.

**Purpose:** 24-hour esophageal MII-pH allows detection of acid and non-acid gastroesophageal reflux (GER). The MII-pH catheter contains 6 impedance segments plus a pH electrode. MII and esophageal manometry (MII-EM) allows functional and manometric evaluation of the esophagus. The MII-EM catheter contains 4 impedance segments and 5 pressure transducers. 5 cc saline boluses are given in the recumbent position when performing MII-EM. In our laboratory, all patients have an MII-EM study performed prior to an MII-pH study. In many labs, MII-pH is done without prior MII-EM.

**Aim:** To assess accuracy of swallows given prior to ambulatory MII-pH monitoring in detecting esophageal transit abnormalities.

**Methods:** 100 consecutive patients (64 females; mean age = 52.6yrs) presenting for MII-EM and MII-pH studies, also received 10 saline swallows in the recumbent position at the beginning of MII-pH. Impedance for these swallows was assessed for complete or incomplete transit, defined as bolus entry in the 17 cm segment and bolus exit in the 15, 9 and 5 cm segments (exit: impedance rise above 50% between baseline and nadir; remaining above this value > 5 seconds). Out of 10 swallows, 8 or more complete ones satisfies the MII-EM criterion for diagnosis of complete transit. These findings were blindly compared to those of the 10 saline swallows on the MII-EM study.

**Results:** The MII-pH swallows gave identical transit diagnosis to the MII-EM in 93% of patients. In 2 patients, diagnosis changed from incomplete transit on MII-EM to complete on MII-pH, and in 5 patients from complete on MII-EM to incomplete on MII-pH. With both methods there were 64 patients with complete and 29 with incomplete transit. Thus, MII-pH swallows...
had a sensitivity of 94% and a specificity of 93% for detection of transit abnormalities. Comparing swallow diagnosis for each patient, there was a highly significant correlation ($p < 0.0001$) for the number of swallowswith of complete (Pearson $r = 0.89$) and incomplete bolus transit (Pearson $r = 0.89$). There was also a significant correlation ($p < 0.0001$) in bolus transit time between both methods (Pearson $r = 0.64$).

**Conclusions:** Use of 10 saline swallows at the beginning of MII-pH studies is accurate, missing bolus transit abnormality in only 2 of 100 patients. It is also highly sensitive and specific for detection of esophageal transit abnormalities. This method allows detection of patients in whom further evaluation of esophageal function may be warranted.

**Results:** The UES HPZ measured 4.6 ± 0.5 cm manometrically and 3.4 ± 0.9 cm endosonographically. Endosonographically, the UES was characterized by 3 parameters: muscle configuration, number of muscle layers, and mean maximal muscle thickness (MMMT), which were correlated with manometric configuration of HPZ. Manometric and endosonographic correlation revealed 4 zones (Table): zone I (esophago-UES zone) were correlated manometrically to the slow ramp in distal HPZ; zone II (lower UES) corresponded to the distal half of the HPZ; zone III (upper UES) corresponded to the proximal half of the HPZ; and zone 4 (UES-pharynx zone) corresponded to slow ramp in proximal HPZ. The cricopharyngeus muscle appeared to be “C” shaped or flat. The endosonographic length of the UES comprised 75% of the entire high-pressure zone as determined manometrically.

**Conclusions:** The source of the UES HPZ is different along its length. In the distal segment, it is generated by the proximal esophagus, while in the rest, a combination of predominantly non-circular muscles are involved. The anatomic length of the UES as determined by ultrasonography is shorter than the manometric length. These findings corroborates with previous studies using radiographic techniques.

<table>
<thead>
<tr>
<th>Zone</th>
<th>Shape (%)</th>
<th>No. Layers</th>
<th>MMMMT (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Oval = 100</td>
<td>4-5 = 100%</td>
<td>2.9</td>
</tr>
<tr>
<td>II</td>
<td>C/Flat = 80%</td>
<td>4-5 = 40%; 3 = 60%</td>
<td>2.9</td>
</tr>
<tr>
<td>III</td>
<td>Oval = 20; 3 = 100%</td>
<td>3 = 100%</td>
<td>2.7</td>
</tr>
<tr>
<td>IV</td>
<td>Flatt = 100</td>
<td>Flatt = 100</td>
<td>2.7</td>
</tr>
</tbody>
</table>

**Acid and Non-Acid Reflux Is Common in Patients with Severe Pulmonary Disease**

**Purpose:** Gastroesophageal reflux disease (GERD) has been implicated as an etiology for a variety of pulmonary diseases and complaints, especially in patients with severe disease. Our aim was to use combined, ambulatory pH and impedance testing to evaluate for reflux in patients with severe pulmonary disease.

**Methods:** The records of all patients with severe pulmonary disease [pre- or post-lung transplant, idiopathic pulmonary fibrosis (IPF) or severe COPD (FEV1<50% predicted)] were reviewed for pH testing with impedance to our motility laboratories in Jacksonville and Rochester. Type of pulmonary disease, medication use and pH testing with impedance were recorded. A pH test was considered abnormal if the esophageal acid contact time was greater than 4.6% of the total time tested. Non-acid reflux (NAR) was considered positive if there were >48 episodes of liquid reflux (Tutuian, Gastroenterology 2006;130:A171).

**Results:** There were 23 patients with severe pulmonary disease who had pH testing with impedance. All but one patient were taking some form of acid between the pharynx and the esophagus. It is believed that the upper-most portion of the esophagus, cricopharyngeus muscle, and the most distal part of the inferior pharyngeal constrictors contribute to the generation of this HPZ. This information in humans is mainly derived from concurrent radiographic and manometric studies. Therefore the exact anatomical components of the UES HPZ remains incompletely determined and our purpose is to determine the anatomic structures contributing to development of UES HPZ in humans.

**Methods:** We studied 5 healthy volunteers (40 ± 12 years; 4M using endosonographic mini-probe or EUS-MP (Olympus UM-DP20-25R, 20MHz) and concurrent manometry. The recording assembly was advanced into the proximal esophagus and withdrawn by 1 cm increments until the pharynx was manometrically identified.

**Results:** The UES HPZ measured 4.6 ± 0.5 cm manometrically and 3.4 ± 0.9 cm endosonographically. Endosonographically, the UES was characterized by 3 parameters: muscle configuration, number of muscle layers, and mean maximal muscle thickness (MMMT), which were correlated with manometric configuration of HPZ. Manometric and endosonographic correlation revealed 4 zones (Table): zone I (esophago-UES zone) were correlated manometrically to the slow ramp in distal HPZ; zone II (lower UES) corresponded to the distal half of the HPZ; zone III (upper UES) corresponded to the proximal half of the HPZ; and zone 4 (UES-pharynx zone) corresponded to slow ramp in proximal HPZ. The cricopharyngeus muscle appeared to be “C” shaped or flat. The endosonographic length of the UES comprised 75% of the entire high-pressure zone as determined manometrically.

**Conclusions:** The source of the UES HPZ is different along its length. In the distal segment, it is generated by the proximal esophagus, while in the rest, a combination of predominantly non-circular muscles are involved. The anatomic length of the UES as determined by ultrasonography is shorter than the manometric length. These findings corroborates with previous studies using radiographic techniques.

<table>
<thead>
<tr>
<th>Zone</th>
<th>Shape (%)</th>
<th>No. Layers</th>
<th>MMMMT (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Oval = 100</td>
<td>4-5 = 100%</td>
<td>2.9</td>
</tr>
<tr>
<td>II</td>
<td>C/Flat = 80%</td>
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<td>2.9</td>
</tr>
<tr>
<td>III</td>
<td>Oval = 20; 3 = 100%</td>
<td>3 = 100%</td>
<td>2.7</td>
</tr>
<tr>
<td>IV</td>
<td>Flatt = 100</td>
<td>Flatt = 100</td>
<td>2.7</td>
</tr>
</tbody>
</table>
suppressing medication. 4 patients had evidence of pathologic esophageal acid exposure (1 on BID PPI, 2 on qd PPI and 1 off medications). 10 additional patients had normal acid exposure, but were positive for NAR while on PPI therapy. The findings for each indication are in the table.

**Conclusions:** GERD, predominantly NAR diagnosed with impedance testing, was very common in patients with severe pulmonary disease. GERD was particularly common in patients with IPF and in those being evaluated for lung transplantation.

### Results:

<table>
<thead>
<tr>
<th>NAR+</th>
<th>Acid reflux</th>
<th>Acid - NAR</th>
<th>Total + (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPF</td>
<td>6</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Severe COPD</td>
<td>7</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Pre-Transplant</td>
<td>6</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Post-Transplant</td>
<td>4</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>All Patients</td>
<td>23</td>
<td>4</td>
<td>10</td>
</tr>
</tbody>
</table>

**Conclusions:** 1) Minor acid/non acid reflux is a frequent cause of symptoms in FH (50/98 episodes).

2) 28% (8 of 29) had FH (+SI). 5 of these 8 (62.5%) would have had -SI without MII-pH testing and would have been missed.

3) 24 hour MII-pH was useful in determining whether FH was or wasn’t present in almost half of all patients (48%) (+SI based on total reflux, -SI and original false -24hour pH).

4) 41% of patients had too few symptoms during the exam to properly categorize.

5) Liquid, gas and mixed reflux were equally symptomatic in these FH patients.

**Conclusions:**

1) Minor acid/non acid reflux is a frequent cause of symptoms in FH (50/98 episodes).

2) 28% (8 of 29) had FH (+SI). 5 of these 8 (62.5%) would have had -SI without MII-pH testing and would have been missed.

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4) 41% of patients had too few symptoms during the exam to properly categorize.

5) Liquid, gas and mixed reflux were equally symptomatic in these FH patients.

### Purpose:

Patients with heartburn and regurgitation but normal endoscopy and 24-hour pH have FH. Causes of FH are uncertain but include a false negative pH study, sensitivity to minute amounts of acid, non-acid and gas reflux. 24-hour MII-pH allows examination of each of these potential causes. AIMS 1.Determine potential causes of FH symptoms. 2.Determine the clinical usefulness of MII-pH testing in these patients.

### Methods:

29 consecutive FH patients age 48 years (29-71 yrs), 22 F, off PPIs for 2 weeks underwent 24-hour MII-pH, noting heartburn and regurgitation. The catheter detected pH 5cm above the LES and impedance at 5cm above the LES and therefore no evidence of FH as defined. 4)12 Acid reflux detection. The catheter detected pH 5cm above the LES and impedance at 5cm above the LES and therefore no evidence of FH as defined. 4)12 Acid reflux detection. The catheter detected pH 5cm above the LES and impedance at 5cm above the LES and therefore no evidence of FH as defined. 4)12 Acid reflux detection. The catheter detected pH 5cm above the LES and impedance at 5cm above the LES and therefore no evidence of FH as defined.

### Results:

1) 8 patients (28%) had a +SI and therefore FH. 2) 4 patients (14%) had a +24 hour pH test despite an initial negative study and had GERD. 3) 5 patients (17%) had a -SI and therefore no evidence of FH as defined. 4)12 symptoms during the exam. Liquid, gas and mixed reflux were equally divided amongst the 98 total reflux episodes in the 8 FH patients. The table shows causes of reflux, SI of acid reflux and SI of all reflux in the 8 FH patients.

### Patients with FH

<table>
<thead>
<tr>
<th>Patients with FH</th>
<th>Acid reflux</th>
<th>Minor acid reflux</th>
<th>Non acid reflux</th>
<th>Related reflux</th>
<th>Unrelated</th>
<th>Acid reflux SI</th>
<th>Acid reflux SI</th>
<th>Total reflux SI</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>0</td>
<td>7</td>
<td>0</td>
<td>7</td>
<td>2</td>
<td>0%</td>
<td>78%</td>
<td>19</td>
</tr>
<tr>
<td>B</td>
<td>3</td>
<td>1</td>
<td>9</td>
<td>5</td>
<td>0</td>
<td>33.3%</td>
<td>100%</td>
<td>2</td>
</tr>
<tr>
<td>C</td>
<td>0</td>
<td>2</td>
<td>4</td>
<td>6</td>
<td>0</td>
<td>0%</td>
<td>100%</td>
<td>8</td>
</tr>
<tr>
<td>D</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>25%</td>
<td>50%</td>
<td>4</td>
</tr>
<tr>
<td>E</td>
<td>3</td>
<td>0</td>
<td>2</td>
<td>5</td>
<td>1</td>
<td>50%</td>
<td>83%</td>
<td>11</td>
</tr>
<tr>
<td>F</td>
<td>4</td>
<td>3</td>
<td>6</td>
<td>13</td>
<td>4</td>
<td>23%</td>
<td>76.4%</td>
<td>27</td>
</tr>
<tr>
<td>G</td>
<td>20</td>
<td>4</td>
<td>12</td>
<td>36</td>
<td>1</td>
<td>54%</td>
<td>97%</td>
<td>54</td>
</tr>
<tr>
<td>H</td>
<td>17</td>
<td>2</td>
<td>1</td>
<td>20</td>
<td>1</td>
<td>81%</td>
<td>95%</td>
<td>27</td>
</tr>
<tr>
<td>Total</td>
<td>48</td>
<td>19</td>
<td>31</td>
<td>98</td>
<td>11</td>
<td>81%</td>
<td>95%</td>
<td>130</td>
</tr>
</tbody>
</table>

*SI+ only with MII-pH testing

### Purpose:

Multichannel intraluminal impedance and pH (MII-pH) esophageal monitoring allows detection of both acid and non-acid gastroesophageal reflux (GER) episodes. The MII-pH catheter contains 6 impedance segments placed 3, 5, 7, 9, 15 and 17 cm above the LES, plus a pH electrode at 5 cm. Analysis of these tracings is more challenging than is the case of simple pH esophageal monitoring. Does this increase in complexity induce a subjective component to the analysis of these tracings?

### Aim:

To assess accuracy of interpretation of MII-pH tracings between 2 separate readings done by the same person.

### Methods:

For this study, thirty 12 hour MII-pH tracings were randomly selected. These were done off PPI therapy. All subjects have MII-pH proven reflux disease and received 2 standard meals and were in the right decubitus position for 2 hours after each meal. All tracings were initially read by the same person from December 2005 to March 2006. The second reading was performed by the same person in May 2006 while blinded to the results of the first reading. Data collected: number of acid and non-acid (NA) reflux episodes, symptom association with acid and NA reflux as well as% time pH4< 5 cm above the LES.

### Results:

In all studies, there was no change in diagnosis (normal vs abnormal) between both readings, whether the diagnosis was based on% time pH4< or positive symptom association with reflux. Relative to specific MII-pH findings on the tracings, the results of both readings are extremely comparable. Comparing both readings there was a significant correlation (p < 0.0001) for the number of acid (Pearson r = 0.99) and NA reflux episodes (r = 0.99), number of symptoms associated with acid (r = 0.99) and NA reflux episodes (r = 0.97), number of symptoms not associated with any reflux episodes (r = 0.99), as well as for% time esophageal pH4< during the upright (r = 0.99) and recumbent positions (r = 0.99) and during the entire study (r = 0.99).

### Conclusions:

Repeat blinded interpretations of MII-pH tracings by the same person basically yield identical results.

### Purpose:

Multichannel intraluminal impedance and pH (MII-pH) tracings allow easy detection of reflux of any type: acid, non-acid, gas or mixed. MII-pH is more sensitive, expensive and complicated than simple pH esophageal monitoring. Does this increase in complexity induce a subjective component to the analysis of these tracings?

### Aim:

To assess the accuracy of interpretation of MII-pH tracings between 2 separate readings done by the same person.

### Methods:

For this study, thirty 12 hour MII-pH tracings were randomly selected. These were done off PPI therapy. All subjects have MII-pH proven reflux disease and received 2 standard meals and were in the right decubitus position for 2 hours after each meal. All tracings were initially read by the same person from December 2005 to March 2006. The second reading was performed by the same person in May 2006 while blinded to the results of the first reading. Data collected: number of acid and non-acid (NA) reflux episodes, symptom association with acid and NA reflux as well as% time pH4< 5 cm above the LES.

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### Conclusions:

Repeat blinded interpretations of MII-pH tracings by the same person basically yield identical results.

### Purpose:

Asymptomatic esophageal dysmotility is common in diabetics, especially those with evidence of autonomic neuropathy such as gastroparesis. In idiopathic gastroparesis there is no identifiable primary abnormality to explain the delayed gastric emptying. The purpose of this study was to investigate the prevalence of esophageal dysmotility in patients with
idiopathic refractory gastroparesis (RG), as compared to those with diabetic RG.

**Methods:** Esophageal manometry (EM) studies were reviewed for consecutive patients with documented RG who had had EM performed as part of their pre-operative evaluation for placement of a gastric stimulator. 24 studies were reviewed; 3 EM studies were excluded from the analysis because of inadequate esophageal body recordings (2 studies with early termination secondary to coughing, 1 secondary to instrument malcalibration). To examine differences between normal and abnormal EM in idiopathic or diabetic RG, chi-square analysis was performed.

**Results:** 81% of the patients were female. 38% of the patients had diabetic RG, while 62% had idiopathic RG. 48% of the EM studies demonstrated abnormalities. Only the patient diagnosed with nutcracker esophagus was symptomatic. 38% of patients with diabetic RG and 62% of patients with idiopathic RG had abnormal EM. There was no significant difference between the idiopathic and diabetic RG groups ( \( X^2 (1, N = 21) = 0.03, p = NS \)). [Figure1]

**Conclusions:** As asymptomatic esophageal dysmotility is common in diabetics, it is not surprising that patients with diabetic gastroparesis also commonly have EM abnormalities. This study suggests a similar prevalence of esophageal dysmotility in patients with either idiopathic or diabetic RG. The mechanism of this finding is unclear, as is the etiology of idiopathic gastroparesis itself. A larger study is necessary to confirm these preliminary findings.

<table>
<thead>
<tr>
<th></th>
<th>NORMAL</th>
<th>NSEMD</th>
<th>IEM</th>
<th>DES</th>
<th>NUT</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDIOPATHIC</td>
<td>[1] (6)</td>
<td>(3)</td>
<td>(1)</td>
<td>(1)</td>
<td>(1)</td>
</tr>
<tr>
<td>DIABETIC</td>
<td>[1] (3)</td>
<td>(2)</td>
<td>[2]</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>

1 = male; 0 = female

NSEMD = nonspecific esophageal motility disorder; IEM = ineffective esophageal motility DES = diffuse esophageal spasm; NUT = nutcracker esophagus

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**35**

**Ambulatory Esophageal pH Monitoring Off and on a Proton Pump Inhibitor: A Standard 48 Hour Bravo Capsule Study May Be Enough Time for Both**

**Rajeev Tummuru, MD, Scott Oosterveen, MD, Ali Kashavarzian, MD, Michael D. Brown, MD. Division of Digestive Diseases, Rush University Medical Center, Chicago, IL.**

**Purpose:** Ambulatory pH monitoring is the gold standard for the diagnosis of GERD. Whether to perform this test off or on PPI therapy continues to be debated. With the advent of the Bravo pH system, prolonged monitoring sessions have become feasible. Recent data have shown that 96 hour studies using two separate receivers calibrated to one Bravo capsule can effectively document off (first 24 hours) and on (remaining 72 hours) drug response. While exciting, this approach may not be practical. Most institutions may not have the resources to allocate two receivers for one patient over a 4 day period. We have presented our experience using a standard 48 hour, single receiver, Bravo pH capsule to measure esophageal acid exposure both off and on PPI therapy.

**Methods:** All Bravo pH studies performed at our institution between 12/04 and 4/06 were reviewed. Patients were instructed to withhold PPI for 7 days prior to the study. All Bravo capsules were placed the standard 6 cm above the squamocolumnar junction. During the first 24 hours, the patient remained off a PPI. The patient was then instructed to take either 40 mg of rabeprazole or 80 mg of esomeprazole by mouth. This dose was repeated 12 hours later. The percent of time that pH was less than 4 over 24 hours (% time pH<4) was the primary variable examined. Total number of refluxes over a 24 hour period was also considered. Day 1 vs. day 2 values were compared using the Wilcoxon signed-rank test.

**Results:** Fifty-four studies were reviewed. One study was removed as the capsule was radiologically shown to have detached and fallen into the gastric chamber during the study period. Three studies had a% time pH<4 nine standard deviations above the mean and were therefore excluded. The mean% time pH<4 was significantly lower on day 2 (2.68%) as compared to day 1 (5.49%) (\( p = 0.003 \)). The total number of refluxes per 24 hours was also significantly reduced (34.4 vs. 54.2) (\( p = 0.004 \)).

**Conclusions:** We have shown that it is feasible to evaluate esophageal acid exposure both off and on PPI therapy during a single 48 hour Bravo pH study. By giving a high dose of a rapid acting PPI on day 2, the esophageal acid exposure can be significantly reduced. This may be more practical than performing two separate studies or a single prolonged study using multiple receivers.


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**36**

**Eosinophilic Esophagitis: Are Gastroenterologists and Pathologists Missing It?**

**Rekha Attigere, MD, Tony Lee, MD, Alison Schneider, MD, Marian Haber, MD, Aysia Ahmad, MD. Gastroenterology, Drexel University College of Medicine, Philadelphia, PA.**

**Purpose:** Eosinophilic esophagitis (EoE) is an inflammatory condition of the esophagus caused by the presence of high levels of eosinophils. Common presentations include dysphagia and gastroesophageal reflux (GERD). Esophageal appearance may be normal and the diagnosis must be made by histologic evaluation with esophageal biopsies. Since this is a fairly new entity many patients with EoE may remain undiagnosed. The purpose of this study was to investigate the endoscopic and histologic evaluation of EoE in patients with dysphagia, and/or GERD with no definitive endoscopic findings...
to explain their symptoms. We theorize that endoscopists frequently take biopsies. Furthermore, it is likely that some patients in whom biopsies are taken have EoE not initially diagnosed by pathologists.

**Methods:** A retrospective chart review of upper endoscopy reports (EGDs) performed for the indication of GERD or dysphagia. Patients with normal endoscopic findings were included. Exclusion criteria included endoscopic evidence that could explain symptoms (e.g., severe esophagitis, peptic stricture). Reports were reviewed to determine if the endoscopist took esophageal biopsies. Of those with biopsies, histological specimens were reviewed to see if there was appropriate evaluation for EoE by the initial pathologist.

**Results:** Two-hundred-four consecutive EGDs were reviewed; 128 EGDs were performed for the indication of GERD, 67 for dysphagia, and 9 for both. Thirty-two cases had esophageal biopsies performed (15%; 19-GERD, 12- dysphagia, 1-both). Eighty-five percent of cases had no biopsies performed. Esophageal histology specimens were reviewed for eosinophil density. Three cases of EoE were documented initially. Eighteen (56%) of the pathology reports had no mention of the presence or absence of eosinophils. After an expert pathologist re-reviewed the specimens, 2 additional cases were diagnosed leading to a total of 5 EoE cases.

**Conclusions:** In our series 16% of patients who had esophageal biopsies had EoE. Only 15% of patients that should have had biopsies to rule out EoE did; therefore many cases of EoE were likely missed. Furthermore, eosinophil density was not adequately assessed by pathologists. EoE is currently underdiagnosed; therefore many cases of EoE were likely missed. Furthermore, eosinophil density was not adequately assessed by pathologists. EoE is currently underdiagnosed by both gastroenterologists and pathologists. Better education is needed in order to properly identify this unique disorder.

### Females Consulting with GERD Symptoms Have More Often Non-Erosive Reflux Disease and Mild Erosive Esophagitis: Results from the ReQuest™ Database

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**Purpose:** It is controversial if non-erosive reflux disease (NERD) and erosive esophagitis (EE) form a continuum of a single disease or if they are manifestations of two different pathophysiological disease entities. We therefore reviewed the ReQuest™ database (of patients with well-characterized reflux disease) to determine the proportions of male and female patients with NERD and with EE of different grades of severity.

**Methods:** The ReQuest™ database contains data from 2 NERD and 12 EE clinical trials with symptom assessment based on the reflux questionnaire ReQuest™. 10 EE clinical trials enrolled patients with severity grades A-D, the other 2 EE studies included patients with severity grades B-D (Los Angeles classification). Baseline demographics and characteristics of 6,810 per-protocol patients were analyzed.

**Results:** Of these patients, 964 had NERD and 5,846 suffered from EE [grade A: 2,309 (33.9%); grade B: 2,755 (40.5%); grade C: 637 (9.4%); grade D: 145 (2.1%)]. A greater proportion of NERD patients were females (61.3%). More females with EE had mild disease (grade A), whereas a higher proportion of male patients had more severe disease (grades C and D).

**Conclusions:** GERD in females is characterized by a higher proportion of NERD compared with men; and when EE is present, the proportion of a mild disease course (grade A) is also higher than in men. The fact that women presenting with GERD symptoms have less severe alteration of the esophageal mucosa, raises the possibility that this observation reflects genetically determined differences in visceral sensitivity amongst men and women to exposure of gastroesophageal reflux.

### pH Monitoring in Asymptomatic Individuals and Its Endoscopic Correlates

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**Purpose:** To determine the prevalence, in asymptomatic individuals, of significant esophageal acid exposure and to correlate esophageal acid exposure to the endoscopic and histologic appearance of the esophagus.

**Methods:** Patients referred for routine colonoscopy for colorectal cancer screening are asked to complete a validated questionnaire (modified GERQ) designed to determine the presence of symptomatic gastroesophageal reflux disease (GERD). Patients without established GERD or GERD symptoms are invited to participate in the trial. Enrolled patients undergo an EGD with standard technique including photographs of the gastroesophageal junction, and measurement of the lower esophageal sphincter (LES) location from the gams. Biopsies of the distal esophagus and any endoscopically abnormal tissue in the esophagus, stomach, or duodenum are obtained. A catheter-free pH-monitoring probe is then placed 6 cm above the LES and patients wear a recording monitor for 48 hours which they return, along with an activity diary, within 2-5 days. A total of 150 subjects are being recruited for this study.

**Results:** To date, 31 asymptomatic individuals have been enrolled and undergone EGD. The mean age is 54.2 (26% female; 11% African-American). There have been 3 failed BRAVO capsule deployments and pH data is available on 91% of the subjects. 16/31 (52%) have tested positive for significant esophageal acid exposure defined by a Johnson-DeMeester (JD) score > 14.72 on either day 1 (13), day 2 (9), or both (6). Among these 16 asymptomatic patients, 4 (25%) had endoscopic (esophagitis) and/or histologic evidence of reflux changes. There were 3 asymptomatic patients who had evidence of acid reflux changes either endoscopically or histologically who had either a normal JD score or no JD score due to failed capsule deployment. Therefore, a total of 7/31 (22.6%) asymptomatic patients had evidence of significant esophageal acid exposure. In addition, the prevalence of esophagitis and Barrett’s esophagus were 2/31 (6.5%) and 2/31 (6.5%) respectively.

**Conclusions:** There are no statistically significant relationships identified thus far between acid exposure and BMI, sex, race, age, and ETOH/wk or coffee/day intake. Our interim analysis indicates that significant esophageal acid exposure is common in an asymptomatic population. Exposure is variable with endoscopic or histologic evidence of GERD and reassessment of our current reference standards for pHmetry may be warranted.

### Aluminum Phosphide Induced Esophageal Stricture, an Unusual Complication: Series of 12 Cases

Rajendra K. Jain, MD, DM,* Milind P Chincholkar, MCH, Gaurudd Tiwari, MD, Virendra K. Sharma, MD, Atul Shende, MD. Gastroenterology...
Purpose: Aluminum phosphide is a common popular pesticide used to preserve grain and cereals in India. There are anecdotal reports of acute poisoning in world literature with survival on supportive measures, however the prognosis is dismal despite best intensive care. There is no antidote available for counteracting the deleterious effects of Aluminum phosphide (Celphos). Awareness of its extreme lethal nature among population has brought this poison to the forefront of mode of suicide. Aluminum phosphide is very effective in preventing infestation with peots and rodents. Thus this pesticide is easily available on the agricultural accessory shop as over the counter drug.

The poisoning with Aluminum phosphide usually culminates in mortality. However, few cases have shown survival like, ingestion of old tablet, ingestion along with water and dry gulping of tablet. The various systemic manifestation of acute poisoning includes cardio respiratory failure, peripheral circulatory failure, metabolic acidosis and shock. Gastrointestinal manifestation includes nausea, vomiting, epigastric pain, diarrhea, abdominal cramps, and backache due to hypotension.

Methods: We came across 104 cases of celphos poisoning, admitted in our institution during last one year, out of which 60 cases (57.6%) died. Among the remaining 34 cases who survived, 12 (7 male 5 female, 15-45 years) cases were presented with dysphagia which was progressive initially to solids & subsequently to liquids after a mean period of 35+6 days.

Results: On endoscopic & barium sollow evaluation all had smooth narrowing with short segment esophageal stricture (6mm-25 mm) except one patient who had tracheoesophageal fistula. Ten patients were subjected to dilatation with Savary gilliard dilators, with complete relief of dysphagia after 3-4 session of dilatation. Complications like post dilatation bleeding were observed in two cases, resolved spontaneously. Two patients were subjected to surgery, one with tracheoesophageal fistula and other with tight irregular stricture, with successful outcome. Esophageal perforation was not seen in any of the cases.

Conclusions: Aluminum phosphide is a common suicidal poisoning in India with very high mortality despite best intensive care. Among the survivors, presentation with stricture esophagus is unusual finding in literature, which can be explained by dry gulping of the tablets leading to local damage to esophageus.

Achalasia and Mycobacterium Chelonae: An Unusual Association
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Purpose: The association between non-tuberculous mycobacterial pulmonary disease and achalasia, although previously documented in the literature, is not well recognized generally. We report a case of achalasia associated with Mycobacterium chelonae pneumonia.

Methods: A 42 year old African American female presented to our emergency department with breathlessness, fever, nausea, and vomiting. Further work up confirmed that she had multilobar pneumonia with sepsis. Five weeks prior, she was treated at another facility for community-acquired pneumonia with clinical improvement and discharge. During that hospitalization, she was also diagnosed with post-prandial epigastric pain and treated with esophageal savary dilation. Her sputum at that time showed acid fast bacilli and the cervical esophagus was detected in 0 of 10 RE cases, 16 of 18 NERD cases, and 2 of 10 FD cases. A delayed transit of saliva secreted into the oral cavity was detected in 10 patients (40%) with FD. A delayed transit of saliva from oral cavity to the esophagus or both of these mechanisms.

Results: Standard saliva scintigraphy was performed in 38 patients (10 with erosive esophagitis; RE, 18 with endoscopy-negative reflux disease; NERD, and 10 with functional dyspepsia; FD). After intravenous injection of 180 to 200 M bq 99mTc-pertechnetate, anterior sequential imaging was performed every minute for 40 minutes. At 20 minutes after injection of radionuclide, a lemon candy was administrated introrally to stimulate salivary secretion. Regions of Interest (ROI) were selected on the individual submandibular and parotid glands, oral cavity, and the cervical esophagus below the thyroid gland. Time activity curves were analyzed to evaluate saliva transit from oral cavity to the esophagus. Washout ratio (peak count at baseline-lowest count after administration/peak count at baseline) was examined as a functional parameter.

Conclusions: If the washout ratio of less than 50% is defined as functional disorders of salivary glands, a decreased salivary secretion was found in 8 of 10 patients (27%) with RE, 10 of 18 patients (56%) with NERD, and 4 of 10 patients (40%) with FD. A delayed transit of saliva secreted into the oral cavity was detected in 10 of 10 RE cases, 16 of 18 NERD cases, and 2 of 10 FD cases.

Saliva Transit from Oral Cavity to the Esophagus in GERD
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Purpose: Gastro-esophageal reflux disease (GERD) is associated with an increased exposure of the esophagus to gastric contents and a prolonged clearance of the refluxed material. Appropriate clearance requires normal saliva production and an adequate swallowing to neutralize the properties in the esophagus. It has been unknown whether GERD is associated with impairment of saliva production, saliva transport from oral cavity to the esophagus or both of these mechanisms.

Methods: Standard saliva scintigraphy was performed in 38 patients (10 with erosive esophagitis; RE, 18 with endoscopy-negative reflux disease; NERD, and 10 with functional dyspepsia; FD). After intravenous injection of 180 to 200 M bq 99mTc-pertechnetate, anterior sequential imaging was performed every minute for 40 minutes. At 20 minutes after injection of radionuclide, a lemon candy was administrated introrally to stimulate salivary secretion. Regions of Interest (ROI) were selected on the individual submandibular and parotid glands, oral cavity, and the cervical esophagus below the thyroid gland. Time activity curves were analyzed to evaluate saliva transit from oral cavity to the esophagus. Washout ratio (peak count at baseline-lowest count after administration/peak count at baseline) was examined as a functional parameter.

Conclusions: Saliva production was frequently diminished in GERD and NERD patients. Saliva transit from oral cavity to the esophagus was delayed more frequently in NERD cases than in RE and FD cases. We conclude that delayed saliva transit may have an important role for developing NERD.

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Esophageal Motility in Thyroid Disease
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**Purpose:** Thyroid disorders are known to be associated with GI tract dysfunction. Hypothyroidism causes alteration of motor function leading to constipation. Hyperthyroidism can be the sole etiology for chronic diarrhea. The exact pathophysiology of alteration in bowel habit due to the effects of hypo or hyperthyroidism is not known, but because of the well-established clinical findings relating thyroid hormone to intestinal motility, TSH has become part of the work up for chronic constipation and diarrhea. However, the effect of thyroid malfunction on esophageal motility is not well known. Our question is that if thyroid function plays an important role in small intestine and colon function, what role, if any, does it play in esophageal motility? We have performed a med-line search of medical literature in English language from 1966 to 2006 and were unable to find a report on esophagus motor dysfunction and thyroid disorders except for one anecdotal case report. The purpose of this study is to assess the subjective prevalence of symptoms related to esophageal motility disorder including dysphagia, GERD and non-cardiac chest pain in thyroid disease.

**Methods:** 29 consecutive patients with established thyroid disorder in an endocrinology clinic and in a medical clinic were consented and given an IRB approved questionnaire to evaluate the prevalence of subjective esophageal motility disorder symptoms of dysphagia, GERD and NCCP. Consented patients' charts were reviewed for thyroid biochemistries, other medical history and medications. The prevalence of dysphagia, GERD and NCCP in hyper and hypothyroid patients was observed.

**Results:** 29 (26 women, 3 men, age 26-79) out of 33 consecutive patients (pts) agreed to complete our questionnaire. 16 pts had hypothyroidism, 11 had hyperthyroidism and 2 pts were euthyroid but had goiter. 12 of 29 (41%) complained of dysphagia (6/12 solids, 2/12 liquids, 4/12 both). 13 of 29 (44%) had GERD. 7 of 29 (24%) had GERD and dysphagia. 7of 29 (24%) had NCCP. 3 of 29 (10%) had all 3 symptoms. 4 of 29 (13%) pts had GERD and NCCP. None of the 3 men had any of the symptoms. 5 of 16 (31%) hypothyroid pts and 6 of 11 (54%) hyperthyroid pts had dysphagia. 7 of 12 pts with dysphagia were willing to see a GI doctor.

**Conclusions:** Our study suggests that thyroid disorders may effect esophageal motility. Further investigation using manometry and EGD may be warranted to evaluate the pts with dysphagia and thyroid disease.

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**Does Pharmacotherapy Improve Quality of Life in Patients with Presbyesophagus?**

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**Purpose:** Presbyesophagus, an esophageal motility disorder seen in the elderly that includes tertiary contractions, non-peristaltic simultaneous contractions and low amplitude peristalsis, is a common cause of dysphagia. We followed a cohort of pts to determine the efficacy of therapy to resolve dysphagia.

**Methods:** Pts with dysphagia were eligible for this open-label study if imaging or manometry showed presbyesophagus. Exclusions were other causes of dysphagia unless these conditions were adequately treated and dysphagia persisted. Pts were treated with an anticholinergic agent (AChA) such as methscopolamine bromide (Paminate®, Bradley Pharmaceuticals) or hyoscynamine sulfate (NuLev®, Schwarz Pharmaceuticals) 30 minutes before meals. If symptoms persisted, a tricyclic (TCA), either desipramine or amitriptyline, was added daily at 7 p.m. For a weakened peristalsis only then was a prokinetic such as tegaserod (Zelnorm®; Novartis) or metoclopramide was added. For a weakened peristalsis and gastroesophageal reflux, was also less upright (8.6 ± 0.9 mmHg) than supine (10.8 ± 1.3; p = 0.056). Swallow-induced esophageal contractions were reduced in amplitude upright (62 ± 9 mm Hg 5 cm above LES) compared to supine (74 ± 7 mm Hg; p = 0.036). Swallows using jello in the upright position had an increase in esophageal contraction pressures (73 ± 10 mmHg) compared to water swallows upright (62 ± 9 mm Hg; p = 0.051) without change in peristaltic velocity.

**Conclusions:** This study demonstrates positional pressure changes in the GEJ high pressure zone of both the intrinsic LES and extrinsic crural components. The reduction of the GEJ high pressure zone in the upright position may be due to the additional presence of gravitational forces preventing reflux as well as anatomic changes. The decrease in the antireflux barrier upright might explain, in part, postprandial gastroesophageal reflux that occurs in normal subjects.

Satisfactory (S) was consumption of most foods and beverages with significant improvement in QOL; Unsatisfactory (U) was limited ability to eat and no improvement in QOL.

**Results:** 120 pts with dysphagia to solids and liquids had dysmotility. 16 pts were excluded. 2 pts had scleroderma esophasus; 1 had a stricture; 6, for another motility disorder; 3 for achalasia; 1 had MS; 1 had a pharyngeal neuromyopathy; 1 had ALS; 1 had a complication of a fundoplication. 9 pts with Schatzki rings with liquid dysphagia post therapy were included. 104 pts (M = 42; F = 62) were followed for a mean time of 15.4 months (range = 1-114 months). The average age was 73.4 years. 7 were lost to follow-up. 37 reported a QOL score of E; 55 had S and 5 reported U. The 92 pts reporting E or S, 56 responded to an ACHA alone; 31 required dual therapy (TCA and ACHA) and in the 5 pts with low amplitude peristalsis, all responded to a prokinetic.

**Conclusions:** 1. 94.8% of pts treated for presbyesophagus demonstrated an improved QOL (38% were in remission and only 5.2% were unimproved). 2. ACHA alone or in combination with TCA's are effective treatment. 3. Pts having diminished peristalsis only, can be treated with prokinetics. 4. The majority of pts were female (59.6%).
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Enhanced Levels of Insulin Resistance in Patients with Gastro-Esophageal Reflux Evaluated by Flat-Panel Detector Assisted Videoesophagography
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Purpose: Although it has been reported that both body mass index (BMI) and obesity were associated with symptoms of gastroesophageal reflux disease (N Engl J Med. 354: 2340, 2006, Ann Intern Med 143, 199, 2005), the relationship between insulin resistance and gastroesophageal reflux (GER) remains unclarified. The present study was designed to investigate the effect of insulin resistance on the levels of GER by using the originally developed flat panel detector-assisted videoesophagography.

Methods: Eighteen patients with GER symptoms were examined by the videoesophagography after the informed consent. On their initial visit, all patients were completed the Japanese version of the Carlsson-Dent self-administered questionnaire (Scand J Gastroenterol. 40: 1005, 2005). The findings of videoesophagography were evaluated by the Keio video X-ray reflux scores which were defined for the diagnosis of functional GER. Patients were classified into three groups according to the X-ray scores: low X-ray score group (<3; N = 5), middle X-ray score group (4-5; N = 6), and high X-ray score group (>5; N = 7). Each score of videoesophagography, BMI, levels of serum adiponectin, triglyceride and glucose, and homeostasis model assessment of insulin resistance (HOMA-IR) were examined.

Results: The X-ray score of videoesophagography was correlated with the total point of questionnaire in the overweight (BMI >24) patients. The levels of serum adiponectin (5.8 ± 2.5 μg/ml/μg/ml) in the high X-ray score group decreased significantly as compared with those in the low groups (16.1 ± 3.6 μg/ml, p < 0.05). Metabolic markers (BMI 25.7 ± 2.4, HOMA-IR 1.5 ± 0.6, triglyceride 144.9 ± 64.4 mg/dl) in the high X-ray score group increased significantly as compared with those in the low group (BMI 22.5 ± 2.2, HOMA-IR 0.7 ± 0.4, triglyceride 68.2 ± 24 mg/dl, p < 0.05).

Conclusions: Decreased levels of serum adiponectin and increased levels of HOMA-IR were shown in patients with severe GER evaluated by videoesophagography, suggesting a possible link between insulin resistance and the severity of GER.

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Pitfalls in Wireless Esophageal pH Monitoring
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Purpose: The Bravo pH monitoring system is a catheter-free pH capsule that is attached to the esophageal mucosa. Studies have compared it to conventional pH monitors, and demonstrated patient tolerability with minimal complications. There has been one case report describing an esophageal perforation that occurred during placement of the Bravo pH catheter.1 Another more recent study reported that the Bravo capsule frequently causes hypertensive contractions in the distal esophagus, and these contractions are commonly associated with chest pain.2 The aim of our study is to report our experience with wireless Esophageal pH monitoring.

Methods: Medical records of consecutive patients undergoing Bravo pH monitoring at our institution were reviewed. 160 patients underwent wireless 48 hr pH monitoring between 7/1/2003 to 6/1/2006. Indications for the study included the typical reflux symptoms, heartburn and regurgitation, as well as atypical symptoms such as non-cardiac chest pain, chronic cough, asthma, laryngitis, hoarseness, and globus.

Results: 160 patients underwent Bravo pH monitoring between 7/2003 and 6/2006. In 23 (14%) patients, complications were noted. Data was not retrievable due to computer malfunction in 9 patients (5.6%). In 6 patients (3.8%) the capsule either failed to deploy, attach, or fell off within the first 24 hours. Eight patients (5%) reported a foreign body sensation, chest pain or globus, which required repeat EGD for removal of the capsule. Adequate diagnostic data was obtained in the remaining 137 patients (85%).

Conclusions: 1. The majority of complications were related to technical difficulties, but overall the BRAVO capsule was well tolerated. 2. Five percent of our patient population experienced somatic complaints requiring endoscopic removal of the capsule 3. Bravo pH monitoring is an effective method of quantifying esophageal acid exposure. 4. Recognition of the potential technical issues and patient intolerability compared to the standard 24 hour ambulatory pH monitor is crucial for the appropriate use of this diagnostic modality.

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Low Plasma Adiponectin Is Associated with Barrett’s Esophagus, Controlling for Reflux Symptoms
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49 Does Positron Emission Tomography Add Information to Endoscopic Ultrasound Sonography and CT in the Management of Esophageal Cancer: A Prospective Single Center Study

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Purpose: EUS and CT have been standardly used for staging esophageal cancer. With the advent of PET, many centers are adding this modality to their staging armamentarium. This prospective blinded study analyzes the utility of FDG-PET as an adjunct to EUS and chest CT for the management of patients with esophageal cancer.

Methods: Between Dec 2003 and Mar 2006, patients diagnosed with esophageal carcinoma underwent EUS, CT and FDG-PET as their initial evaluation. All EUS procedures were performed by one ultrasonographer (VMS) blinded to the PET results. Two thoracic surgeons (DRJ and RS), blinded to patient identifying information and demographics, were asked to decide if the patient needed surgical resection, neoadjuvant chemotherapy followed by resection, or palliation. Both surgeons were presented the staging EUS and CT results. With each case, one surgeon was unblinded in alternating fashion to the FDG-PET results. The treatment decisions of each surgeon were compared to determine if PET altered clinical management. Coefficients of agreement (k) were calculated between readers treatment decisions. Random cases were represented to readers to assess inter- and intraobserver variability.

Results: 43 patients (40 male, 3 female) with mean age of 63 y/o (range 34-89) were enrolled and data was prospectively collected. 38 (88.4%) had adenocarcinoma and 5 (11.6%) had squamous cell carcinoma of the esophagus. EUS was completed in 88.4% (38) of cases while 5 (11.6%) were incomplete secondary to tight stenosis. No statistical difference was found in inter- and intraobserver variability (Kappa = 1.0). Of the 43 patients, 16 were treated with surgery, 22 with neoadjuvant chemotherapy and surgery, and 5 with palliative chemoradiation. In 42 of 43 patients, the readers came to identical clinical management decisions independent of PET results. In the one case that their treatment decision differed, the EUS was incomplete. The agreement on treatment strategy between readers presented with PET results and those blinded to PET results was 97% (k = 0.96, 95% CI 0.88-1.00).

Conclusions: This study shows that the addition of FDG-PET to EUS and CT offers little if any additional information to the initial treatment stratification of patients with esophageal cancer. However, in patients with incomplete EUS, FDG-PET may have some clinical utility.

50 Early Diagnosis of Columnar Metaplasia at the Esophageogastric Junction (EGJ) Using a Monoclonal Antibody and Its Reversibility with Proton-Pump Inhibitor (PPI) Therapy

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Purpose: Barrett’s esophagus (BE) is a known pre-malignant complication of gastroesophageal reflux disease (GERD), and once developed, it is resistant to PPI therapy. A biomarker that might help early diagnosis of metaplasia and allow early initiation of chemoprevention is very much needed. We developed a novel monoclonal antibody, mAb Das-1, that reacts to BE with 100% sensitivity and specificity. It does not react with normal esophagus, EGJ and stomach epithelium. With the use of mAb Das-1, we examined the reversibility of the metaplastic process with PPI therapy.

Methods: We have prospectively followed up to 2 years a cohort of 12 patients with GERD who, at initial endoscopic biopsy, showed positive reactivity with mAb Das-1. All patients were treated with PPI. Histological and phenotypic changes on yearly follow-up endoscopy were examined using formalin fixed specimens from the EGJ biopsy tissue. mAb Das-1 reactivity was detected by a sensitive immunoperoxidase assay.

Results: Initially, only 5 of 12 patients had histologic columnar metaplasia (CM) and 7 did not, although each of these 12 patients were mAb Das-1 positive. Among these 5 patients with CM, we observed the disappearance of both antibody reactivity and CM in 2 patients. The remaining 3 patients with CM on initial histology continued to have antibody reactivity, although in 2 of the 3 CM disappeared at follow-up biopsy. In only 1 of the 5 patients, CM and mAb Das-1 reactivity persisted during the follow-up. The cohort of 7 of 12 patients exhibited mAb Das-1 reactivity in the absence of CM on initial endoscopy and histology. Five of 7 patients had disappearance of antibody reactivity and there was no CM in subsequent follow-up biopsy. Each of the 5 patients were treated with a PPI, and the treatment course was continuous in 3 and intermittent in 2 patients. Two of the 7 patients with no CM on entry into the study continued to be antibody positive at the time of follow-up.

Conclusions: CM, as evidenced by mAb Das-1 reactivity, is present in some patients with symptomatic reflux in the absence of histological evidence of CM. PPI therapy may alter the disease course of this metaplasia if introduced at an early stage and probably with continued therapy.
XP19986 Decreases Reflux and Is Well Tolerated in GERD Patients

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Purpose: Continuous positive airway pressure (CPAP) effectively treats obstructive sleep apnea (OSA), however, only a few studies have examined its effects on GERD. Among those studies, CPAP has been shown to improve nocturnal GERD, but any durable effects of CPAP on reflux events have not yet been shown.

Methods: We prospectively studied the effects of CPAP therapy on GERD in 29 patients undergoing a workup for OSA. On the evening of the sleep study, patients underwent a nonsedated esophagoscopy with placement of a Bravo pH capsule 6 cm proximal to the GE junction. Patients then underwent a two-night sleep study while pH data were recorded. The first night was diagnostic, pH capsule 6 cm proximal to the GE junction. Patients were then placed in CPAP for OSA. After 1 week, patients had a second sleep study on CPAP.

Results: Of the 29 patients, 36% were women. 90% of all patients reported chronic heartburn and 45% reported past PPI use. Esophagoscopy revealed evidence of reflux esophagitis in 55% of patients. Analyses of pH data recordings are shown in the table below. Compared to the first night of the sleep study, patients had a statistically significant reduction in all nocturnal GER indices while on CPAP treatment. On the day following treatment with CPAP, effects of CPAP on GERD indices were assessed.

<table>
<thead>
<tr>
<th>Factor</th>
<th>CEP without EUS</th>
<th>CEP with EUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight loss</td>
<td>2.94</td>
<td>2.18</td>
</tr>
<tr>
<td>Dysphagia</td>
<td>3.09</td>
<td>2.59</td>
</tr>
<tr>
<td>Shorter tumor length</td>
<td>0.81</td>
<td>0.86</td>
</tr>
<tr>
<td>Poor differentiation</td>
<td>10.30</td>
<td>10.78</td>
</tr>
<tr>
<td>EUS predicts advanced disease</td>
<td>N/A</td>
<td>5.64</td>
</tr>
</tbody>
</table>

Conclusions: EUS prediction of disease extent is strongly confounded by clinical, endoscopic and pathologic (non-EUS) information, likely because both EUS and non-EUS factors strongly predict disease extent. EUS does provide unique information (i.e. stays in final model), but its exact contribution independent of non EUS information is undefined.
patients had a persistent and significant reduction in the number of GER episodes.

**Conclusions:** In this prospective study, we have shown that CPAP therapy in patients with OSA not only improves nocturnal gastroesophageal acid reflux but also has a durable effect with regard to the number of GER episodes. In patients who have OSA and GERD, CPAP may complement acid suppression in controlling symptoms of acid reflux.

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**Impedance-Manometry with Viscous Test Solution Increases Detection of Esophageal Function Defects**

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Division of Gastroenterology, Medical University of South Carolina, Charleston, SC and Department of Gastroenterology, Wroclaw Medical University, Wroclaw, Poland.

**Purpose:** Multichannel intraluminal impedance and manometry (MII-EM) is performed using ten 5 ml swallows each of both liquid and viscous solution. The manometric diagnosis is based solely on results from the 10 liquid swallows. It was recently demonstrated that manometric diagnoses based on 10 liquid and 10 viscous swallows combined were similar to those with 10 liquid swallows alone.

The aim of the study was to compare esophageal function evaluated with 10 liquid versus 10 viscous swallows using combined MII-EM in patients with various symptoms.

**Methods:** We analyzed consecutive MII-EM studies performed in 300 patients (211 women, mean age 54.5 yrs). The manometric diagnoses were separated into normal manometry and abnormal manometry. MII findings included number of complete and incomplete transits and total bolus transit time.

**Results:** The results are summarized in Tables 1-2. Manometric diagnosis for liquid and viscous was consistent in 231 (77%) and 238 (79.3%) and viscous manometry (and abnormal liquid manometry and 4 had different abnormalities in liquid had abnormal viscous and normal liquid manometry, 17 had normal viscous

Conclusions: Our results indicate that viscous solution detects more manometric abnormalities and is performed using ten 5 ml swallows each of both liquid and viscous solution. The manometric diagnosis is based solely on results from the 10 liquid swallows. It was recently demonstrated that manometric diagnoses based on 10 liquid and 10 viscous swallows combined were similar to those with 10 liquid swallows alone.

**55**

**Diagnosis of Ineffective Esophageal Motility Based on Increased Number of Ineffective Swallows Is Associated with More Frequent Bolus Transit Abnormalities**

**Wojciech Blonski, MD, Akber Safdar, Amine Hila, MD, Donald O. Castell, MD.**
Division of Gastroenterology, Medical University of South Carolina, Charleston, SC and Department of Gastroenterology, Wroclaw Medical University, Wroclaw, Poland.

**Purpose:** Ineffective esophageal motility (IEM) was previously defined by the presence of ≥30% liquid swallows with contraction amplitude <30 mmHg (ineffective swallows) in the distal esophagus (“old” IEM). Recent study with combined multichannel intraluminal impedance and manometry (MII-EM) raised the question whether the manometric diagnosis of IEM should be based on new criteria i.e. ≥50% ineffective liquid swallows (“new” IEM) (Clin Gastroenterol Hepatol 2004; 2:230).

The aim of the study was to evaluate the association between number of ineffective liquid swallows and symptom frequency and bolus transit in patients with “new” or “old” IEM.

**Methods:** We analyzed MII-EM studies performed in 150 patients (88 women, age range: 8-87 yrs, mean 54.3 yrs) who were diagnosed with IEM by “old” definition. MII-EM parameters were assessed during 10 liquid and 10 viscous swallows. Abnormal bolus transit for liquid and viscous was defined as presence of ≥30% and ≥40% swallows with incomplete bolus transit for liquid and viscous, respectively. The patients were divided into 2 groups. First group included patients with ≥30% and <50% ineffective liquid swallows (Group A, N = 49). The second group included patients with ≥50% ineffective liquid swallows (Group B, N = 101). Mild IEM was characterized by normal bolus transit for both liquid and viscous, moderate IEM by abnormal bolus transit only for liquid or only for viscous and severe IEM by abnormal bolus transit for both liquid and viscous. Statistical analysis was performed with t-unpaired test.

**Results:** Results are summarized in the table below. Heartburn (10.2% vs. 25.7%; p = 0.03) and dysphagia (12.3% vs. 24.8%; p = 0.08) showed a trend towards greater frequency in patients with “new” IEM.

**Conclusions:** Our study indicates that IEM with ≥50% manometrically ineffective liquid swallows is more likely associated with bolus transit abnormalities and esophageal symptoms. The results underscore the rationale for using the “new” definition of IEM; ≥50% manometrically ineffective liquid swallows.

Distribution of transit abnormalities in patients with IEM.

<table>
<thead>
<tr>
<th>IEM n (%)</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>22/49 (44.9)</td>
<td>20/49 (40.8)</td>
<td>7/49 (14.3)</td>
</tr>
<tr>
<td>Group B</td>
<td>19/101 (18.8)</td>
<td>35/101 (34.6)</td>
<td>47/101 (46.5)</td>
</tr>
<tr>
<td>p-value</td>
<td>0.0007</td>
<td>0.46</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

**56**

**Eosinophilic Esophagitis: Prevalence and Predictive Factors**

**Ganapathy A. Prasad, MD, FACP, Jeffery A. Alexander, MD,* Amindra S. Arora, MD, Nicholas J. Talley, MD, FACG, Yvonne Romero, MD, FACG, Alexander L. Glenn, MD, Kryzer Lori, Smyrk C. Thomas, Enders T.B. Felicity, PhD, HSR. Gastroenterology and Hepatology, Mayo Clinic College of Medicine, Rochester, MN.**

**Purpose:** Eosinophilic esophagitis (EE) is an increasingly recognized cause of dysphagia. Information on the prevalence and factors predictive of EE is lacking. We aimed to assess:

1. The prevalence of EE in patients undergoing endoscopy for dysphagia.
2. The clinical and endoscopic factors predictive of EE.

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**Eosophageal Incompetence**

**J. Michael Link, MD, Joseph L. Valla, MD, F, Charles C. Jensen, MD, FACP, F, John A. Leiendecker, MD, FACP, F, Eric W. Sutula, MD, FACP, F. University of Wisconsin, Madison, Wisconsin.**

**Purpose:** Eosophageal incompetence is associated with severe esophagitis. The prevalence and factors associated with esophagitis are not well known.

**Results:** There were 50 patients (34 men, 50 yrs). 26 (52%) had esophagitis. Factors associated with esophagitis included prior medication use (p = 0.01), prior GERD diagnosis (p = 0.001), prior surgery (p = 0.004), and female gender (p = 0.008).

**Conclusions:** Eosophageal incompetence is associated with severe esophagitis. Prior medication use, prior GERD diagnosis, prior surgery, and female gender are associated with esophagitis.

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**Eosophageal Nissen Fundoplication**

**William D. D. Maser, MD, FACG, F, Paul P. Fried, MD, FACP, F, Phillip R. Wexner, MD, FACP, F, Ronald J. Wilson, MD, FACP.**

**Purpose:** Eosophageal Nissen fundoplication is associated with severe esophagitis. The prevalence of esophagitis is not well known.

**Results:** There were 50 patients (34 men, 50 yrs). 26 (52%) had esophagitis. Factors associated with esophagitis included prior medication use (p = 0.01), prior GERD diagnosis (p = 0.001), prior surgery (p = 0.004), and female gender (p = 0.008).

**Conclusions:** Eosophageal Nissen fundoplication is associated with severe esophagitis. Prior medication use, prior GERD diagnosis, prior surgery, and female gender are associated with esophagitis.
Methods: Consecutive patients (18-60 years of age) presenting to the outpatient endoscopy unit at Mayo Clinic, Rochester for dysphagia between June 2005-6 were enrolled in this study. Patients completed the Mayo Dysphagia Questionnaire (MDQ), a validated tool. During endoscopy, mid-esophageal biopsies were obtained if there were endoscopic findings suggestive of EE, or if there was no endoscopically evident cause of dysphagia. All biopsies were read by 1 of 5 experienced gastrointestinal pathologists. EE was defined as the presence of > 20 eosinophils/HPF.

Statistical analysis was performed using standard statistical tests for continuous and categorical variables. Univariate and stepwise multivariable logistic regression was performed using JMP software.

Results: 376 patients were included. Mean age was 45 years; 236 (63%) completed the MDQ. At endoscopy, changes suggestive of EE were seen in 21 (5.6%) patients. A total of 182 (48%) patients had no endoscopically visible EE. Independent predictors following multivariate analysis are shown in Table 1:

- **Risk Factor**: Odds Ratio 95% CI P Value
- **Age**: 0.94 0.90, 0.98 0.01
- **Impaction of food for > 5 minutes**: 2.61 0.98, 7.13 0.05
- **Endoscopic features of EE**: 7.00 2.31, 21.28 0.01
- **Use of PPI**: 0.22 0.06, 0.66 0.01

Conclusions: 1) Esophageal biopsies from normal appearing mucosa in patients with unexplained dysphagia will diagnose EE in a substantial proportion of patients.
2) A history of food impaction and specific endoscopic features point to EE as the diagnosis.
3) Increasing age and the use of a PPI indicate a lower risk of diagnosing EE.

### Table 1

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Odds Ratio</th>
<th>95% CI</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>0.94</td>
<td>0.90, 0.98</td>
<td>0.01</td>
</tr>
<tr>
<td>Impaction of food for &gt; 5 minutes</td>
<td>2.61</td>
<td>0.98, 7.13</td>
<td>0.05</td>
</tr>
<tr>
<td>Endoscopic features of EE</td>
<td>7.00</td>
<td>2.31, 21.28</td>
<td>0.01</td>
</tr>
<tr>
<td>Use of PPI</td>
<td>0.22</td>
<td>0.06, 0.66</td>
<td>0.01</td>
</tr>
</tbody>
</table>

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Molecular Changes at the Esophagogastric Junction (EGJ) in Patients with Symptomatic Gastroesophageal Reflux Disease (GERD) in the Absence of Histological Columnar Metaplasia (CM)

**Purpose:** We developed a novel monoclonal antibody, mAb Das-1, that recognizes Barrett’s epithelium (BE) with 100% sensitivity and specificity. mAb Das-1 reacts with normal colon epithelium but does not react with normal esophagus, EGJ epithelium, gastric or small intestinal epithelium. COX-2 is expressed in the presence of inflammation and in BE. However, expression of these markers at the EGJ in patients with symptomatic GERD with normal histology is unknown.

**Methods:** Patients with symptomatic GERD (N = 86) were enrolled prospectively and 3 to 4 quadrantic biopsy specimens were taken from EGJ during endoscopy. Using immunoperoxidase assays, mAb Das-1 and anti-COX-2 antibody reactivity was assessed in serial sections of paraffin blocks of EGJ biopsy tissue. Thirty-six patients had normal histology, 50 had esophagitis and none had CM. Fourteen samples with adenocarcinoma of the esophagus were included. Normal biopsy specimens from the esophagus (N = 6), small bowel (N = 10) and colon (N = 15) were included as controls.

**Results:** mAb Das-1 reactivity at EGJ was observed in 4 of 36 (11%) patients with normal histology and 7 of 50 (14%) with esophagitis. COX-2 reactivity was found in 9 of 36 (25%) with normal histology and 20 of 50 (40%) with esophagitis. All 14 patients with adenocarcinoma reacted with both mAb Das-1 and anti-COX-2. Three of 4 (75%) patients with mAb Das-1 positivity with normal histology were also reactive to COX-2. COX-2 expression was absent in all control specimens. However, mAb Das-1 reactivity was present in colon epithelium but absent from esophagus and small bowel epithelium.

**Conclusions:** A metaplastic process expressing colonic phenotype of epithelium is found in 13% of EGJ biopsy tissue of symptomatic GERD patients in the absence of histologic CM. COX-2 expression was found in 34% of EGJ tissue of symptomatic GERD patients without CM. These data indicate that subclinical molecular changes at the EGJ, including metaplastic process, occur in some patients with GERD. This strongly supports the existence of molecular changes at the EGJ.
a "pre-Barrett's" metaplastic stage. Such molecular diagnosis of early meta-
plastic process may allow initiation of early interventional treatment against
further progression with PPI or other therapy.

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An In-Vitro Model of Barrett's Epithelium (BE): Studies To Examine
the Role of Environmental Factors on Columnar Metaplasia
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Brunswick, NJ.

Purpose: Chronic exposures to acid and bile in patients with gastro-
esophageal reflux disease (GERD) are implicated in the pathogenesis of
BE and esophageal adenocarcinoma. We developed a monoclonal antibody,
amAb Das-1, that reacts to BE and adenocarcinoma of the esophagus with
100% sensitivity and specificity. amAb Das-1 reacts with normal colonic
epithelium with a membrane associated protein called CEP, but not with
normal esophagus, stomach and small intestinal epithelium. Using a non-
neoplastic BE cell line immortalized by telomerase, we examined the effect
of acid and/or bile salt on the expression of CEP, cell proliferation, cell cycle
changes and apoptosis.

Methods: BE cells were exposed to an acid environment (pH 4.0) for 5 min.
and/or with bile salt (Glycochencodochylc acid, 200uM) for 20 mins. daily
for 5 days/week; up to 10 weeks. An esophageal squamous epithelial cell
line (HET-1A) was used as control in parallel. The expression of CEP was
measured by FACS using mAb Das-1. In addition, we examined by FACS
expression of COX-2 (with anti-COX-2 mAb), cell proliferation (BrdU),
apoptosis and cell cycle changes (anexin V and propidium iodide).

Results: Both acid and bile salt independently increased proliferation of
the cells by 20-40% and apoptosis by 10-20%. The BE cells constitutively
express low levels of CEP, which increased to 1.7 fold upon acid or bile
salt exposure, while combination treatment upregulated CEP expression by
2.5-3.0 fold. Maximum increase was seen at 2 weeks and that was sustained
up to 10 weeks. COX-2 expression doubled (2.3 fold) after acid-bile salt
combination within 1 week. Cell viability in all experiments was monitored
and remained unchanged. HET-1A cell did not show reactivity to mAb Das-1.

Conclusions: Our results indicate that acid and bile salt are both indepen-
dently capable of enhancing colonic metaplastic process, although, in com-
bination, the process is further amplified. This trend of increase in the marker
proteins simultaneous with the increased cell death and proliferation might
indicate death of the susceptible and selection of the resilient colonic phe-
notype cells leading to dysplasia adenocarcinoma. The model can also serve
as an important tool for chemoprevention drug development.

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Accuracy of EUS Prediction of Pathologic Lymph Node Status in
Esophageal Cancer (EC) Is Strongly Confounded by Clinical,
Endoscopic and Pathologic Factors
Gregory Zuccaro, MD,* Thomas W. Rice, MD, John J. Vargo, MD, John A.
Dumot, DO, Rocio Lopez, MS, Darvin L. Convell, MD, Tyler Stevens, MD,
John R. Goldblum, MD. Gastroenterology, Cleveland Clinic Foundation,
Cleveland, OH.

Purpose: Confounding is influence of third variables leading to inappropri-
ate estimation of the association between test and outcome. EUS is felt to
accurately predict pathologic lymph node status in EC (defined as pN0: no
regional lymph node metastases vs. pN1: regional lymph node metastases).
Additional clinical, endoscopic and pathologic (CEP) information is typi-
cally ignored, as is its potential confounding effect. Aims: Determine if EUS
prediction of lymph node status in EC is confounded by CEP information.

Methods: 314 pts with EC had clinical evaluation with endoscopy, and
EUS, followed by esophagectomy. No pt received preop chemoradiation.
Post-op pathology was gold standard. EUS was assessed as a univariable
predictor of pN1. Next, stepwise logistic regression was used to create a
non-EUS 'CEP model' using factors available to any endoscopist (age, gen-
der, weight loss, dysphagia, tumor traversibility, length, location, and mor-
phology, histopathologic type and grade). EUS was then added to the 'CEP
model' and its odds ratio recalculated (if CEP factors did not confound EUS
prediction of pN1, the odds ratio should not change).

Results: Pathology at esophagectomy (gold standard): 171 (55%) pN0, 143
(45%) pN1. The odds ratio for EUS alone in prediction of pN1 was 10.2 (i.e.
there is 10.2 times greater odds of having regional lymph node metastases
when EUS predicts it). Non-EUS risk factors for pN1 (i.e. final 'CEP model')
were: dysphagia, tumor length, and poor histologic grade. When EUS was
added to CEP model, its odds ratio fell to 3.39, but it remains in the final
model:

<table>
<thead>
<tr>
<th>Factor</th>
<th>CEP without EUS</th>
<th>CEP with EUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dysphagia</td>
<td>3.04</td>
<td>2.53</td>
</tr>
<tr>
<td>Longer tumor length (1 cm)</td>
<td>1.57</td>
<td>1.44</td>
</tr>
<tr>
<td>Poor differentiation</td>
<td>9.24</td>
<td>8.78</td>
</tr>
<tr>
<td>EUS predicts pN1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Conclusions: EUS prediction of pN1 is strongly confounded by clinical, en-
doscopic and pathologic (non-EUS) information, likely because both EUS
and non-EUS factors strongly predict pN1. EUS does provide unique infor-
mation (i.e. it stays in final model), but its exact contribution independent
of the non-EUS information is undefined.

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Normal Values for Manometry Performed with Viscous Swallows
Wojciech Blonski, MD, Marcelo Vela, MD, Amine Hila, MD, Donald O.
Castell, MD,* Division of Gastroenterology, Medical University of South
Carolina, Charleston, SC and Department of Gastroenterology, Wroclaw
Medical University, Wroclaw, Poland.

Purpose: Esophageal function testing with combined multichannel intra-
luminal impedance and manometry (MII-EM) is performed using ten 5 ml
liquid swallows followed by ten 5ml viscous swallows. The diagnosis of
bolus transit abnormalities identified by impedance is based on both liquid
and viscous swallows. On the other hand, the manometric diagnosis is based
solely on liquid swallows. Established normal manometric values for liq-
uid swallows are: <50% ineffective contractions (<30mmHg) and <10%
simultaneous contractions (onset velocity >5 cm/s) in the distal esophagus
and distal esophageal amplitude (DEA) <180mmHg. It is uncertain whether
these values can be applied to manometry performed with viscous swallows.
The aim of the study was to establish the normal values for manometry
performed with a viscous bolus.

Methods: We analyzed consecutive MII-EM studies performed in 80 healthy
volunteers (39 women, age range 19-72 yrs). Each participant received ten
5 ml liquid and viscous swallows. The analyzed MII parameters included:
bolus presence time, segmental transit times, total bolus transit time; an-
alyzed manometry parameters were: contraction amplitude, duration and
onset velocity and residual pressure of LES.

Results: There were 799 liquid and 794 viscous swallows analyzed. Mean
DEA for liquid swallows was 104 (±44) mmHg and for viscous 102 (±51)
mmHg. Among liquid swallows 92.1% were manometrically normal (97%
with complete bolus transit (CBT)), 6.3% manometrically ineffective (46%
with CBT) and 1.6% manometrically simultaneous (84.6% with CBT).
Among viscous swallows 88.2% were manometrically normal (97%
with CBT), 10% manometrically ineffective (30% with CBT) and 1.8% man-
ometrically simultaneous (42.9% with CBT).

Table below summarizes normative data for viscous manometry.

Conclusions: Our study presents normal values for manometry performed
with viscous swallows. Based on our results (95th percentile) we propose the
following values to be considered normal for manometry performed with
viscous swallows: ≤60% ineffective contractions and ≤10% simultaneous contractions and DEA <204mmHg.

Normative data for viscous swallows characterized by manometry.

<table>
<thead>
<tr>
<th>Manometric characteristics</th>
<th>Mean number of swallows per patient</th>
<th>5th percentile</th>
<th>25th percentile</th>
<th>75th percentile</th>
<th>95th percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>8.8</td>
<td>3.9</td>
<td>8</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Ineffective</td>
<td>1.0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>Simultaneous</td>
<td>0.2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

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Transoral Bravo Capsule Placement after Transnasal Manometry

Bjorn Engstrom, BS, Brian E. Lacy, PhD, MD,* Lisa M. Paquette, RN, Tracia O’Shana, ARNP, Maurice L. Kelley, Jr., MD, Christina Engstrom, BS, Julia Weiss, MA, Richard I. Rothstein, MD. Medicine, Dartmouth Medical School, Hanover, NH; Gastroenterology & Hepatology, Dartmouth-Hitchcock Medical Center, Lebanon, NH and Biostatistics, Dartmouth Medical School, Hanover, NH.

Purpose: The Bravo capsule, a wireless pH monitoring device, is usually deployed during upper endoscopy (EGD). This study compares transoral (TO), non-endoscopic (Non-Endo) placement of the Bravo capsule to endoscopic (Endo) placement.

Methods: 1003 patients (Pts) referred to the Dartmouth-Hitchcock Medical Center for pH testing over a 28 month period (1/04 to 4/06) were evaluated. Pts were scheduled for Bravo placement either with Endo or TO without endoscopy (Non-Endo) at the request of the referring provider. Endo placement of the Bravo capsule was 6 cm above the squamocolumnar junction (SCJ). After transnasal (TN) esophageal manometry, the Bravo capsule was deployed TO 5 cm above the LES without sedation using a previously described technique (O’Shana et al, Gastroenterology 2004; 126:A1381). These Pts have not previously been described.

Results: Complete data was available for 985 patients (98%). 654 (66%) underwent Non-Endo capsule deployment and 331 (34%) underwent Endo deployment. Demographic characteristics (age, gender, race) were similar among the 2 groups. In the Non-Endo group the mean age (±SD) was 49 years (±13); 66% were women. In the Endo group, the mean age (±SD) was 47 years (±17); 63% were women. For both Endo and Non-Endo groups reflux symptoms (heartburn and pyrosis) were the primary reason for referral (67% & 71%, respectively), followed by regurgitation alone (34% & 43%, respectively) and chest pain (17% & 32%, respectively). In the Endo group, 65% of Pts were studied off of medications compared to 73% in the Non-Endo group ($p < 0.01$). The fraction of time with pH < 4.0 on Day 1 and Day 2 was 8.36 and 6.12 in the Endo group, and 8.06 and 7.17 in the Non-Endo group. The difference in total time with pH < 4.0 between Day 1 and Day 2 was less within the Non-Endo group (0.89) compared to the Endo group (2.23; $p = 0.05$). Two Pts (0.2%) developed severe chest pain and requested endoscopic removal of the Bravo capsule – 1 in each group.

Conclusions: Transoral, unsedated Non-Endo Bravo capsule placement is safe, well-tolerated, and readily accomplished in the motility lab. This technique should reduce health care costs associated with acid reflux since endoscopy is not required. No significant differences were noted in pH measurements when these two techniques were compared.

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Incidence of Non-Acid Reflux Disease in Patients Referred to an Academic Medical Center for Evaluation of Atypical GERD Symptoms or Failure To Respond to PPI Therapy

Ashish Malhotra, MBBS, Khalid Aziz, MBBS, Michael J. Callahan, PhD, James W. Preston, PhD.* Gastroenterology, University of Connecticut Health Center, Farmington, CT and Novartis Pharmaceuticals, East Hanover, NJ.

Purpose: GERD is commonly associated with complaints of chronic heartburn, but it can also manifest itself through a multitude of atypical or extra-esophageal manifestations. Recent studies have addressed the prevalence and frequency of these atypical manifestations, yet to date little has been published on the incidence of Non-Acid Reflux Disease (NARD) in these patients and in those with an incomplete response to PPI therapy. We report on the relative incidence of NARD in patients referred to our center for evaluation of suspected non-acid reflux disease from Feb to Nov 2005. NARD was diagnosed by combined 24 hour multichannel intraluminal pH-impedance testing technology (PHIT).

Methods: PHIT detected gastroesophageal reflux events based on changes in resistance to electric current between a series of electrodes placed on a catheter in the esophagus. Simultaneous pH monitoring allowed a distinction between acid and non-acid reflux events. Patients recorded symptoms during the test, allowing symptom correlation with reflux events. 49 consecutive patients, 37 female, age 24 to 85 (median 48) with typical GERD symptoms unresponsive to PPI therapy or atypical GERD symptoms underwent 24-hour PHIT test. Patients were tested either on or off PPI therapy, depending on the reason for referral. NARD was defined as at least 50% symptom association with the reflux episodes, the number of reflux episodes ≥ 95% percentile of the normal and the pH of the refluxate reaching 7.

Results: Twenty-two percent (11/49) patients had NARD. The chief complaints for these included: heartburn (4); non-cardiac chest pain (1); chronic cough (1); laryngitis (2); globus (1) and pulmonary complications (2). Seventy-two percent of the NARD patients (8 of 11), had previously been on aggressive PPI therapy yet remained symptomatic. These patients remained on PPI therapy during testing. Twenty-eight percent of NARD patients (3 of 11 patients) had not been treated previously with PPIs; they were referred for testing because of the atypical nature of their symptoms. They were tested while on no antisecretory therapy.

Conclusions: Twenty-two percent of the patients with presumed GERD symptoms unresponsive to PPI therapy or atypical symptoms were found to have non-acid reflux disease. 24 hr PHIT was helpful in establishing this diagnosis and redirecting management.

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Symptom Severity Does Not Correlate with Esophageal Acid Exposure or Lower Esophageal Sphincter Pressure (LESP)

C.N. Calbanag, MD, L.B. Nguyen, MD, S. Parker, W.J. Snape, Jr., MD.* California Pacific Medical Center, San Francisco, CA.

Purpose: The aim of this study was to assess the correlation between symptom severity with esophageal acid exposure and function of the lower esophageal sphincter pressure.

Methods: Patients evaluated with esophageal manometry and either a 24-hour pH study or 48-hour Bravo pH study who had completed the Gastroesophageal Reflux Disease-Health-Related Quality of Life (GERD-HRQOL) questionnaire were identified. The GERD-HRQOL questionnaire consists of nine Likert-type questions. Each item is scored from 0 to 5. Individual item scores were added to calculate the total GERD-HRQOL score. The total possible GERD-HRQOL score ranges from 0 (asymptomatic) to 45 (debilitated). The amount of acidic reflux (determined as a percentage of the normal and the pH of the refluxate reaching 7). The following relationships were analyzed using linear regression analysis: 1) GERD-HRQOL and esophageal acid exposure; 2) GERD-HRQOL and LESP 3) LESP and esophageal acid exposure.

Results: Forty-nine patients (20 male/29 female, mean age 47 ± 2.1 [± standard error]) were included in the study. The mean GERD-HRQOL score was 20.1 ± 2.4. The mean esophageal acid exposure (percent of time pH <4) and LESP were 10.0 ± 1.6% and 14.8 ± 1.4 mmHg. There was no correlation between GERD-HRQOL total score and esophageal acid exposure or LESP. Pearson correlation coefficients were 0.18 for esophageal acid exposure and
with GERD. \( r = -0.03 \). **Conclusions:** The GERD-HRQOL scale is a poor indicator of the level of esophageal acid exposure and insufficiency of LESP. The results of this study parallel research which demonstrated that the GERD-HRQOL does not relate to physiologic parameters of endoscopy, esophageal manometry, and 24-hour esophageal pH monitoring (Velanovich et al. Am Surg 1998). GERD is a multifactorial condition, and other etiologies should be considered such as mucosal sensitivity and resistance, dysmotility, reflux of non-acidic gastric contents, dietary indiscretion, and psychological abnormalities. Better studies are needed to objectively measure visceral hypersensitivity in patients with GERD.

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**65 Mechanical Dysphagia Due to Cervical Osteophytes in a Young Female**

Sathya Jagannmohan, MD, Walker McDonald, MD, Jian Huang, MD, MD,*

**Internal Medicine, Louisiana State University Health Sciences Center, Shreveport, LA.**

**Purpose:** Disruption of transport of liquid or a fluid bolus along the pharyngo-esophageal path by mechanical obstruction or a neuromuscular dysfunction leads to symptomatic dysphagia. Dysphagia can occur at the oropharyngeal or esophageal level. The most commonly reported etiologies of dysphagia include strictures, webs, malignancies and esophageal spasm. Cervical osteophytes are rarely known to cause dysphagia by mechanical obstruction in the elderly. We report a rare presentation of symptomatic dysphagia in a young female due to impingement by a cervical osteophyte.

**Methods:** A 43 year old African American female with history of asthma and carpal tunnel syndrome presented with a two year history of worsening dysphagia initially to solids that progressed to both solids and liquids. She denied any odynophagia, globus sensation, weight loss, abdominal pain, hematemesis, nausea, or vomiting. There was no history of reflux disease, chemical ingestion, strictures or recent use of medications. Physical exam was unremarkable and laboratory studies were unrevealing. Rigid endoscopy did not reveal any oropharyngeal abnormalities. Barium swallow revealed significant posterior compression of the esophageal wall by several large anterior cervical osteophytes at the C5-6 and C6-7 level. There was no evidence of strictures, mucosal ulceration or neuromuscular dysfunction. MRI of the spine revealed significant degenerative changes in the cervical vertebrae with posterior impingement of the esophageal wall by osteophytes. Anatomical obstruction by the protruding osteophytes caused significant narrowing of the esophageal conduit explaining our patient’s dysphagia. She was scheduled for surgical excision of the osteophytes.

**Conclusions:** Asymptomatic osteophytes of the anterior margins of the cervical spine may occur in 20 - 30% of the population. Larger osteophytes have been reported to cause, odynophagia, otalgia, and globus sensation in addition to dysphagia especially in the elderly. The young age at presentation makes our case unique. Extrinsic compression by osteophytes should be considered during the evaluation and workup of a patient with dysphagia.

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**66 Photodynamic Therapy in Barrett’s Esophagus with High Grade Dysplasia and Intra-Mucosal Carcinoma**

Jorge T. Go, MD, John A. Dumot, DO,* Rocío Lopez, MS, John Vargo, MD, Greg Zuccaro, MD, Gary Falk, MD, Thomas Rice, MD, Internal Medicine, Cleveland Clinic, Cleveland, OH; Gastroenterology and Hepatology; Quantitative Health Sciences and Cardiothoracic Surgery.

**Purpose:** Photodynamic therapy (PDT) is indicated for Barrett’s esophagus (BE) with high grade dysplasia (HGD) as alternative to esophagectomy in patients unfit for surgery. Results of PDT for intra-mucosal carcinoma (IMCA) are lacking.

**Methods:** Patients with BE and HGD or IMCA confirmed by two experienced pathologists received Photofrin 2 mg/kg followed by 220-300 J/cm laser light. The outcome measure was remission (negative esophageal biopsy for intestinal metaplasia, dysplasia or cancer) at last follow-up.

**Results:** Seventeen patients (11 men) age 78.9 years (SD ± 5.1) were treated with PDT. Twelve had IMCA and 5 had HGD. Mean length of BE was 5.8 cm (SD ± 2.2). One patient had 2 sessions of PDT, time between sessions was 2 years. The second PDT session was utilized as a separate salvage treatment when the patient showed persistent disease. The rest had a single session of PDT.

Seven patients had PDT alone during the course of treatment. Ten had multimodal endoscopic therapies in the form of endoscopic mucosal resection (EMR), argon plasma coagulation (APC) or BICAP electrocautery before or after PDT.

Out of the 7 patients treated with PDT alone, 5 went into remission in a mean follow-up of 2.3 years. The remission at last follow-up in this group was 29% (5/17). Including patients who received other endoscopic therapies, the total remission rate increased to 59% (10/17).

Regardless of first treatment, the remission rate for HGD patients was 40% (2/5) compared to IMCA 66.7% (8/12), \( p = 0.59 \).

In addition, a multivariable Cox proportional hazards analysis suggested that the length of Barrett’s esophagus is significantly associated with recurrence after PDT. For every 1 cm increase in length of the Barrett’s esophagus, the hazards of having recurrence increases 1.79 times (95% CI: 1.12, 2.84).

**Conclusions:** PDT in a single session has a low remission rate (29%) even when used in conjunction with other endoscopic therapy (59%). Alternative ablative and salvage methods are needed for PDT failures. IMCA and HGD response to PDT is similar. Barrett’s esophagus length increases the risk of recurrence of HGD and/or IMCA after PDT.

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**67 The Threshold Blood Omeprazole Concentration Is 50 ng/mL for the Maintenance of Intragastric pH of at Least 4.0 after Oral Dosing with CMA-Omeprazole, AGN 201904-Z**

Edward Lee, PhD, Dale Yu, PhD, John Sefton, PhD, Dari Parizadeh, PharmD, George Sachs, MD, Diane Tang-Liu, PhD,* Clinical
Pharmacokinetics, Allergan, Irvine, CA; Clinical R&D, Allergan, Irvine, CA and David Geffen School of Medicine, UCLA, Los Angeles, CA.

**Purpose:** To determine the threshold blood omeprazole concentration for the maintenance of intragastric pH of at least 4.0 after oral dosing with AGN 201904-Z, an acid-stable, chemically metered absorption derivative of omeprazole (CMA-omeprazole).

**Methods:** Forty healthy male subjects received 240, 480, and 640 mg AGN 201904-Z and 40 mg esomeprazole orally once-daily for 5 days in a open-label, randomized, 4-way cross-over study. These doses were estimated to deliver molar equivalent omeprazole doses of 53%, 107%, and 143% of the esomeprazole dose, respectively. Pharmacokinetic (PK) blood samples were collected at 8 timepoints following the 1st and 5th dose of each treatment. Pharmacodynamic (PD) were evaluated via 24-hr intragastric pH monitoring before treatment and after the 1st and 5th doses of each treatment. Empirical PK/PD models were constructed for AGN 201904-Z data by regressing that provided the best-fit was designated the threshold concentration. The possible threshold concentrations over the same 24-hr period. The possible threshold concentrations evaluated ranged from 10 to 400 ng/mL. The concentration that provided the best-fit was designated the threshold concentration. The best-fit concentration and model was chosen based on WSSR, R², visual inspection, and AIC value.

**Results:** Among the possible omeprazole threshold concentrations evaluated, 50 ng/mL was the best-fit concentration value in all of the models evaluated. The final model suggests the threshold intragastric pH ≥4.0 is dependent on the duration of time that blood omeprazole concentrations were greater than 8 different concentrations over the same 24-hr period. The possible threshold concentrations evaluated ranged from 10 to 400 ng/mL. This agreed with the actual results which showed AGN 201904-Z maintained drug concentrations above 50 ng/mL longer than esomeprazole (80.1 vs. 68.4% of 24-hr; p < 0.0001).

**Conclusions:** The 50 ng/mL blood omeprazole concentration provided the best correlation with the percent time intragastric pH ≥4.0 over a 24-hr dosing interval and was designated as the threshold concentration of omeprazole. AGN 201904-Z, a CMA-omeprazole designed to provide sustained omeprazole exposure, was more effective than esomeprazole at maintaining 24-hour intragastric pH ≥4.0.

**Symptomatic Patients with Erosive Esophagitis Demonstrate Reduced Delta Electroencephalographic Activity during Sleep Compared to Those without Erosive Esophagitis or Abnormal Esophageal Acid Exposure**

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**Purpose:** To compare the polysomnographic and spectral sleep in patients with erosive esophagitis and a control population with symptoms of GERD but no erosive esophagitis on endoscopy or abnormal esophageal acid exposure on 24-hour esophageal pH monitoring.

**Methods:** A prospective cohort study was conducted involving 11 subjects with erosive esophagitis confirmed by endoscopy, and 6 controls with GERD-related symptoms but no esophagitis or abnormal esophageal acid exposure. All participants underwent upper endoscopy and 24-hour pH monitoring. Sleep was polysomnographically recorded in the sleep laboratory. A spectral analysis of the sleep electroencephalogram (EEG) was performed.

**Results:** The erosive esophagitis and the control groups were similar in age (mean ± S.D.); 40 ± 20 years vs. 42 ± 17 years; p = 0.80. The esophagitis group had 36.4% women (N = 4) and the control group had 66.7% women (N = 4) (p = 0.33). The two groups were similar in regard to diverse polysomnographic variables on visual scoring. There were no differences in sleep efficiency, arousals or the absolute or percentage of delta sleep. However, on spectral analysis of EEG, subjects with erosive esophagitis had a significantly lower delta power of 44.9% (95% CI 40.7-49.0%) compared to the control group, who had a delta power of 47.9% (95% CI 43.6-52.1%) (p = 0.02).

**Conclusions:** The macro architecture of sleep in symptomatic patients with endoscopically-confirmed erosive esophagitis was not different in comparison to those without erosive esophagitis. However, a more quantitative and in-depth analysis of sleep EEG demonstrated a significantly reduced delta power, an efficient indicator of sleep homeostasis, in patients with erosive esophagitis. Future studies assessing the effect of treatment of GERD on sleep disturbances should include not only polysomnographic, but also EEG spectral analysis of sleep.

**Acute Airway Obstruction Due to Untreated Achalasia**

Joe S. Heedly, MD, John Baillie, MB, ChB, FRCP.* Gastroenterology, Wake Forest University, Winston-Salem, NC.

**Purpose:** Achalasia is typically associated with the insidious onset of dysphagia, regurgitation and weight loss. However, the literature documents rare instances of a dramatic presentation with an acute airway obstruction.

**Case Report:** A 50 year old Caucasian female presented to the emergency department with the sudden development of stridor. She had been diagnosed with achalasia but declined endoscopic or surgical therapy twelve years prior to this admission. She described very few typical manifestations of achalasia in the years preceding admission, with no episodes of regurgitation and minimal dysphagia. On arrival to the emergency department, the patient lost consciousness and was found cyanotic and bradycardic. She was emergently intubated with prompt normalization of her vital signs. An arterial blood gas, blood counts and metabolic panels were normal, as was her urine drug screen. Because of concern about subglottic stenosis as an etiology of her stridor, bronchoscopy was performed, revealing a submucosal protrusion from the posterior wall of the trachea. Computerized tomography revealed no mediastinal masses but demonstrated a severely dilated esophagus with impingement on the posterior wall of the trachea. After extubation, the diagnosis was confirmed with manometry and the patient underwent a successful Heller’s myotomy with Dor fundoplication.

**Discussion:** We present a dramatic case of airway obstruction due to longstanding achalasia. While not a typical presentation of this disease, there are over 20 cases of achalasia induced airway obstruction in the literature. This presentation occurs most frequently in women in or beyond the fifth decade of life. Achalasia should be suspected in any patient with acute onset of stridor because prompt esophageal decompression can be lifesaving. After stabilization, long term esophageal decompression is optimally obtained by surgical myotomy.

**Poorer Prognosis for Early Stage Esophageal Adenocarcinoma in African Americans: Potential Implications for Surveillance**


**Purpose:** Esophageal adenocarcinoma (EAC) is one of the most rapidly rising malignancies in the US. The incidence of EAC is known to be lower in African Americans (AA) than Caucasians (Wu et al, Cancer 2006), in addition to identified precursors including esophagitis and Barrett’s esophagitis (El-Serag et al, Gastroenterology 2004). However, there is little known about the stage-matched prognosis of EAC in AA versus Caucasians (C).

**Methods:** Data was obtained from the Cancer Information Resource File of the IMPAC Medical Registry Services as we have previously described (Zisman et al, Arch Int Med 2006). We identified all diagnosis of EAC between 01-01-1993 and 12-31-2003. A log rank test of equality was used to evaluate whether individual variables (race and age) predicted mortality.
in these patients. Local disease was defined as Stage 0, 1, and 2; advanced disease was defined as Stage 3 and 4.

**Results:** Of the 9326 patients (pts) identified with EAC, 3050 were in the local category while 4150 were in the advanced group; 7052 were C and 138 were AA. As expected, pts diagnosed with local disease had a better survival compared to advanced disease (24.6 months (mos) vs. 8.1 mos, \( p < .0001 \)). In local disease when analyzed by race, C pts had improved survival (24.8 mos, 95% CI 23.0-27.1) compared to AA pts (11.5 mos, 95% CI 9.4-16.1). To avoid confounding by peri-operative deaths, separate analysis was conducted for survival at one month after diagnosis. There was a survival difference between age <70 (13.7 mos, 95% CI 13.1-14.3) and age >= 70 (9.1 mos, 95% CI 6.9-9.5, \( p < 0.0001 \)). When comparing survival by race in advanced disease, survival for AA pts (7.3 mos, 95% CI 5.7-10.5 mos) was comparable to that of C pts (8.1 mos, 95% CI 7.7-8.4 mos, \( p = 0.5618 \)).

**Conclusions:** Our large scale study of EAC shows that the vast majority of pts are Caucasian (>77%) compared to a minority of African Americans (1.5%). Despite the lower incidence, we can see from this study that African Americans have a significantly poorer prognosis than Caucasians for early but not late stage disease. Our study also reveals a definite survival disadvantage with increasing age, even when operative risk of death is taken into account. This data underscores the need for vigilance in the minority of African American patients with Barrett’s esophagus. Future studies will need to be designed to assess whether the poorer prognosis is related to treatment access or differences in the cancer biology.

### Table 1. SCE versus EGD for the suspicion of Barrett’s

<table>
<thead>
<tr>
<th></th>
<th>IM Positive</th>
<th>IM Negative</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>EGD Positive</td>
<td>25</td>
<td>20</td>
<td>45</td>
</tr>
<tr>
<td>EGD Negative</td>
<td>10</td>
<td>39</td>
<td>49</td>
</tr>
<tr>
<td>SCE Positive</td>
<td>27</td>
<td>13</td>
<td>40</td>
</tr>
<tr>
<td>SCE Negative</td>
<td>8</td>
<td>46</td>
<td>54</td>
</tr>
</tbody>
</table>

EGD: Sensitivity: 71.4%; PPV: 55.6%; Specificity:66.1%; NPV: 79.6%. Accuracy: 68.1%. SCE: Sensitivity: 77.1%; PPV: 67.5%; Specificity: 77.9%; NPV: 85.2%. Accuracy: 77.6%.

### Table 2. EGD/SCE versus Histology (Intestinal metaplasia)

SCE Negative 10 45 55
SCE Positive 27 13 40
SCE Positive 25 20 45
SCE Negative 10 39 49
SCE Positive 27 13 40
SCE Negative 8 46 54

EGD/SCE: Sensitivity: 77.6%; PPV: 55.3%; Specificity:90%; NPV: 79.6%. Accuracy: 83.3%. “kappa index” = 0.663.
Purpose: ECE has been recommended for the evaluation of patients with GERD and screening of BE. However, studies have revealed wide variation in ECE's accuracy for the detection of BE using pooled analysis.

Methods: Recursive literature search for trials prospectively comparing ECE with EGD for the diagnosis of BE was performed. The ECE reader and EGD performer were blinded to the results of the 2nd test. The 2x2 tables for each trial were extracted and the data pooled. Sensitivity, specificity, PPV, NPV and 95% confidence interval (CI) on the pooled data were calculated. The pooled test characteristic were applied to a hypothetical population cohort with Barrett prevalence of 10% and 15% to calculate NPV and PPV in a screening population.

Results: Five trials (2 full publications) with a total of 339 patient; 144 with BE (prevalence 42%) were identified. The pooled results revealed ECE sensitivity of 81% (95% CI 77-90%), specificity of 87% (95% CI 81-91%), PPV of 82% (95% CI 75-88%) and NPV of 86% (95% CI 81-91%) for the diagnosis of BE. Based on these results, in a hypothetical population with BE prevalence of 10%; the PPV and NPV of ECE would be 40% and 98%, respectively and with BE prevalence of 15%; the PPV and NPV of ECE would be 52% and 96%, respectively.

Conclusions: ECE has acceptable test characteristics for the screening of Barrett esophagus in patients with GERD. EGD as gold-standard for the diagnosis of Barrett esophagus may undermine the true accuracy of ECE.

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Downhill Varices Due to Chemotherapy and Radiation Therapy in Non-Small Cell Carcinoma of the Lung
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Purpose: A common setting of “downhill varices”.

Case: A 55 year old black male with stage IIIB non-small cell carcinoma status post chemotherapy and radiation therapy presents with hematemesis of 300-500cc’s of bright red blood. Other than tobacco and alcohol abuse the patient had no other significant past medical history. He was taking Ibuprofen 800 mg bid, Tylenol 650 mg prn, and Loratad prn. Upon examination, vital signs revealed BP of 133/68, P 119, T 98.8, R20 with O2 sat of 98% on 3L O2. Patient had bilateral exopthalmos and dilated neck veins contiguous with the chest. Tachycardia and decreased breath sounds were present with dullness to percussion on the right. Abdominal exam was unremarkable. Caput medusae were not present. Bilateral upper edema was present. Liver enzymes and coagulation studies were within normal limits. Hbg and Hct had dropped from 11.5/34.4 to 8.7/27. CT of the chest revealed mass in the anterior mediastinum encasing brachiocephalic trunk and SVC, SVC occlusion, and large anterior thoracic wall and mediastinal collaterals. Patient underwent an EGD which showed Bilroth II anatomy secondary to gunshot wound and grade III varices 25–30 cm from the incisors with a visible fibrin clot. The varices were treated with band ligation.

Conclusions: Downhill varices are caused by obstruction of the SVC. There are two main presentations of downhill varices depending on the level of obstruction in relation to SVC. The first type is when the obstruction of the SVC is located superior to the azygous vein. When the obstruction is located superior to the azygous vein, venous blood flows from the head and upper extremities, “downhill,” through the esophageal veins, and into the azygous vein. It then enters circulation via the azygous vein. This particular type of downhill varices is found mid-to-upper two-thirds of the esophagus. Secondly, when the obstruction occurs at the level of or inferior to the azygous vein blood flows caudally through the venous plexus of the esophagus and cardiac veins and enters central venous blood flow through the IVC. In these cases the varices can occur throughout the entire esophagus. The most common two causes of downhill varices are lung cancer and large mediastinal tumors. Less prevalent causes are mediastinal fibrosis, substernal goiter, or previous central line placement. Most patients do not live long enough to develop varices or variceal hemorrhages because of malignancy.

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Demographic, Clinical, and Pathologic Characteristics of Eosinophilic Esophagitis Utilizing a National Pathology Database
Robert Kapel, MD, Carlos Torres, MD, Saime Aksoy, MD, Richard Lash, MD, David Katzka, MD.* Gastroenterology, Hospital of the University of Pennsylvania, Philadelphia, PA.

Purpose: Reports on Eosinophilic Esophagitis (EE) are limited to small series of patients from single institutions. The goal of this study was to characterize demographic, clinical and pathologic features of EE over a diverse patient population.

Methods: Patients diagnosed with EE without other organ involvement were identified utilizing a national pathology database (Pathology Partners Inc., Irving, TX) from January 2002 to May 2006. EE was defined by: 1) a mean of ≥20 eosinophils in 5 HPF, or 2) when 5 HPF were not available, a mean of ≥30 eosinophils in 2-4 HPF. Eosinophils were not counted beyond 100 per HPF. Demographic and clinical information was provided by the endoscopist.

Results: 363 cases met the inclusion criteria (308 by criteria #1, 55 by #2). Patients were identified from 26 states, from a database receiving pathology specimens from 34 states. Male gender predominated 3:1, 270 males (74.4%) to 93 females (25.6%). Ages ranged from 14 months to 98 years, with 42 children (0–17 years), and 321 adults: 78 (21.5%) age 18–29, 84 (23.1%) age 30–39, 88 (24.2%) age 40–49, 32 (8.8%) age 50–59, 25 (6.9%) age 60–69, and 14 (3.9%) age 70 or greater. Dysphagia was present in 65.0% of patients, followed by GERD/heartburn (28.4%), and abdominal pain/dyspepsia (15.2%). In adults, the most commonly reported indications were dysphagia (70.1%), GERD/heartburn (27.1%), and abdominal pain/dyspepsia (13.1%) whereas children reported GERD/heartburn (38.1%), abdominal pain/dyspepsia (31.0%) followed by dysphagia (26.2%). Across adult age groups, the prevalence of dysphagia and GERD/heartburn symptoms ranged from 44–79%, and 16–43%, respectively. The mean eosinophil count per HPF was 57.5 in children and 65.3 in adults. The count ranged from 53.6 in the 70 year plus bracket to 71.2 in the 18–29 year olds. Over the study time period, EE was diagnosed in 0.1% (1/726) of all patients with dysphagia who had upper endoscopy with esophageal biopsy in 2002, 0.9% (20/2226) in 2003, 1.2% (43/3621) in 2004, and 1.9% (110/5892) in 2005.

Conclusions: 1. EE is a national disease. 2. EE can be found in any age group but more commonly in men. 3. Dysphagia is the predominant symptom in most adults followed by GERD symptoms. 4. The degree of eosinophilic infiltration remains high throughout all age ranges. 5. The prevalence and/or recognition of EE is increasing markedly in this country.

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A Novel Test of Esophageal Function during Meal Consumption
Jason Wilson, MD,* I. Mainie, MRCP, A. Hila, MD, R. Tatauian, MD, A. Agrawal, MD, D. Castell, MD. Digestive Disease Center, Medical University of South Carolina, Charleston, SC.

Purpose: Standard esophageal manometric testing evaluates swallowing in the supine position using small boluses with a recovery period imposed between swallows. Prior manometric tests of more physiologic unrestricted eating have had limited practical application due to highly variable outcomes. The purpose of this study is to apply multichannel intraluminal impedance and manometry (MII-EM) to test esophageal function during unrestricted upright meal consumption, and to determine results with limited variability in a normal healthy population.

Methods: Ten healthy volunteers with normal esophageal impedance and manometry by published criteria underwent MII-EM testing using a combined 5-channel catheter. After transnasal placement of the catheter, each subject sat upright and consumed a meal that consisted of two pieces of
toasted bread and two ounces of Gatorade. During the meal the catheter continu-ously recorded impedance and manometry signals at 50Hz. There were no restrictions placed on eating time, and all subjects completed the meal without difficulty.

Results: All data assessed by the MII-EM meal test were normally distributed. Traditional results for manometry (e.g., contraction amplitude, distal velocity) and impedance (e.g., complete bolus transit) assessed by the meal test were highly variable. Meal test impedance results with limited variability included the meal duration, number of swallows, and the percent bolus presence time (%BPT) at 10 and 5 cm above the lower esophageal sphincter (Table 1). Manometric results with limited variability included the number of peristaltic sequences, mean time between sequences, and the distal esophageal amplitudes (Table 2).

Conclusions: MII-EM can be used to collect data with minimal variability in healthy subjects during unrestricted upright meal consumption. These methods may be used to identify abnormal motility patterns during physiologic swallowing.

Table 1. Impedance Data

<table>
<thead>
<tr>
<th>IMPEDANCE RESULTS</th>
<th>DATA (MEAN ± SD)</th>
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</thead>
<tbody>
<tr>
<td>Meal Duration (sec)</td>
<td>383 ± 190</td>
</tr>
<tr>
<td>Number of Swallows</td>
<td>21.0 ± 6.5</td>
</tr>
<tr>
<td>% BPT 10 cm</td>
<td>21.7 ± 4.3</td>
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<tr>
<td>% BPT 5 cm</td>
<td>21.5 ± 3.6</td>
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Table 2. Manometry Data

<table>
<thead>
<tr>
<th>MANOMETRY RESULTS</th>
<th>DATA (MEAN ± SD)</th>
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<tbody>
<tr>
<td>Number of Peristaltic Sequences</td>
<td>12.6 ± 6.0</td>
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<tr>
<td>Mean Time Between Peristaltic Sequences (sec)</td>
<td>31.4 ± 12.9</td>
</tr>
<tr>
<td>Distal Esophageal Amplitudes (mmHg)</td>
<td>106 ± 30.4</td>
</tr>
</tbody>
</table>

Determinants of Cost-Effectiveness of Endoscopic Ablative Therapy for Non-Dysplastic Barrett’s Esophagus

Ananya Das, MD,* Christopher D. Wells, MD, David E. Fleischer, MD, Virender K. Sharma, MD, Hack J. Kim, MD. Gastroenterology & Hepatology, Mayo Clinic, Scottsdale, AZ.

Purpose: Endoscopic ablative therapy (EAT) for non-dysplastic BE (NDBE) is controversial; however, advancement in EAT may lead to acceptance in clinical practice. We performed an economic analysis of EAT for NDBE to identify the determinants of cost-effectiveness of EAT.

Methods: Markov decision analysis model evaluated two competing strategies in a hypothetical 50-year old cohort with NDBE over the lifetime of the cohort with a third party payer’s perspective. In standard strategy, the patients underwent management per ACG practice guidelines. In the ablation arm, EAT was performed up to 3 attempts resulting in complete or incomplete ablation. The model considered complications and allowed endoscopic surveillance even with complete ablation to detect malignancy in and below the neo-squamous epithelium. The EAT were modeled after photodynamic therapy and radio-frequency ablation. Incomplete ablation was managed with endoscopic surveillance as in the standard arm. Transitional probabilities, cost estimates and utility values (appropriately discounted) were obtained from published information.

Results: In a Monte Carlo analysis under ablative therapy, incremental average net health benefit ratio was achieved only with a threshold willingness to pay of $40,000 or higher. Compared to the standard arm, the odds ratio of developing high grade dysplasia (HGD) and cancer in the ablative arm were 0.86 (95% CI, 0.81-0.9) and 0.86 (95% CI, 0.79-0.94), respectively and number needed to treat for preventing HGD and cancer were 26 (95% CI, 19-41) and 68 (95% CI, 42-167). The threshold values of the determinants of the cost-effectiveness of ablative therapy were age at entry into the model less than 55 years, total cost of ablation not exceeding $11,300 and with at least 45% achieving complete ablation of non-dysplastic BE.

Conclusions: Age, cost, and efficiency of EAT are critical determinants of its cost-effectiveness and within a narrow range of these parameters, EAT of NDBE is a cost-effective strategy by currently accepted standard.

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Cost ($)</th>
<th>Effectiveness (QALY)</th>
<th>Incremental Cost-Effectiveness Ratio ($/QALY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard</td>
<td>11,739</td>
<td>17.912</td>
<td></td>
</tr>
<tr>
<td>Ablative therapy</td>
<td>20,934</td>
<td>18.122</td>
<td>43,672</td>
</tr>
</tbody>
</table>

QALY, quality adjusted life years.

Halitosis and GERD: Fact or Coincidence

Luciana Camacho-Lobato, MD, PhD,* Thiago R. Pellegrine, MD, Silvia R. Pinheiro, MD. Internal Medicine, UNIFESP, Sao Paulo, Brazil.

Purpose: Halitosis has been reported as an extra-esophageal manifestation of GERD. This relationship though has not been adequately proved.

Aim: The purpose of this study is to ascertain the relationship between halitosis and GERD as well as try to establish its frequency and characteristics.

Methods: Twenty three consecutive adult patients with GERD (mean age 54 years, SD 12, 91% female) and 17 consecutive adult patients with dyspepsia (mean age 56 years, SD 15, 88% female) (control group) seen at the Gastroesophageal Motility Outpatients Unit during the month of May 2006 were invited to participate in this study. This study was approved by the IRB and all patients gave written informed consent. All patients had their oral volatile sulfur compounds measured by Halimeter (Interscan Corporation, Chatsworth, Canada) and their charts review for demographics, comorbidities (diabetes, chronic renal and/or liver failure, constipation, pulmonary abscess, chronic ENT diseases, and periodontitis), medications, smoking, eating habits, as well as 24 hour pHmetry and upper gastrointestinal endoscopy results.

Results: 39% of Gerd patients had halitosis, 17% of extra-oral origin and 22% of oral origin, 75% and 100% were associated to IBP usage, respectively. Halitosis was found in 18% of the dyspepsia patients, 6% of extra-oral origin and 12% of oral origin, 0% and 50% were associated to IBP usage, respectively. All extra-oral halitosis patients had pathologic acid distal esophageal reflux (25% orthostatic, 75% supine). Non-erosive GERD prevailed (75%). No gender differences were observed in the GERD group. Contingency tables (Chi-Square) failed to demonstrate any statistical differences between the two groups.

Conclusions: Regarding the relationship between Halitosis and GERD:1. Oral etiologies must always be excluded, 2. Oral or gastrointestinal bacteria overgrowth associated to IBP usage may play a role, 3. It seems there is no need for proximal GERD, 4. Larger studies must be undertaken to further investigate this matter.

Does Increasing Obesity Play a Role in Acid-Related Conditions?

Initial Findings in a Morbidly Obese Population

Milan E. Folker, MD, Mae Gc, MD, Andrew Wilson, Ted Adams, Steve Hunt, John Fang, MD,* Kathryn Peterson, MD. Gastroenterology and Hepatology, University of Utah, Salt Lake City, UT; Medicine/Gastroenterology, VA Salt Lake City Health Care System, Salt Lake City, UT and University of Utah, Salt Lake City, UT.

Purpose: Obesity is an increasing epidemic in developed nations and has been associated with increased prevalence of gastroesophageal reflux disease...
Consecutive adults were asked to complete the validated Supraesophageal Otolaryngology Clinics at a tertiary care center over a 10 month period. Medications.

General population. Despite a presumed common pathway, the correlation gastroesophageal reflux disease (GERD) are commonly experienced by the Symptoms indicative of either supraesophageal reflux (SER) or Purpose: General Internal Medicine, Division of Pulmonary & Critical Care Department of Family Medicine, Department of Medicine, Division of Gastroenterology & Hepatology, Mayo Clinic, Rochester, MN; Biostatistics, Mayo Clinic, Rochester, MN; Division of Group. Otolaryngology Head & Neck Surgery, Mayo Clinic, Rochester, MN.

Patients Not on a Proton Pump Inhibitor?

Reflux Correlate Best with Gastroesophageal Reflux Symptoms in

Which Symptoms Thought To Be Associated with Supraesophageal Reflux Correlate Best with Gastroesophageal Reflux Symptoms in Patients Not on a Proton Pump Inhibitor?

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Purpose: Symptoms indicative of either supraesophageal reflux (SER) or gastroesophageal reflux disease (GERD) are commonly experienced by the general population. Despite a presumed common pathway, the correlation between SER and GERD symptoms is not known. Our aim was to examine this correlation in community subjects and health-care seeking subjects reporting SER symptoms who were not already using proton pump inhibitor medications.

Methods: Large Simple Trial design. Potential subjects were recruited from the Southern Minnesota community and from Primary Care Clinics and Otolaryngology Clinics at a tertiary care center over a 10 month period. Consecutive adults were asked to complete the validated Supraesophageal Reflux Questionnaire and key items from the validated Reflux Symptoms Questionnaire. All returned questionnaires were scored for the presence of presumed SER symptoms, and the questionnaires of subjects reporting at least one SER symptom were then scored for GERD symptoms. Logistic regression analysis was used to determine any correlation between presumed SER symptoms and presence and severity of GERD symptoms.

Results: There were 844 persons who reported at least one SER symptom (416 females and 383 males). Mean age was 55 years (range 18 to 95). Mean BMI was 28 (range 16 to 76). The frequency of reported throat clearing was 79%, dry cough 45%, hoarseness 39%, globus 31%, nocturnal cough 22%, and sore throat 16%. Frequent GERD symptoms were reported by 36% of subjects, infrequent GERD symptoms by 28%, and lack of GERD symptoms by 36%. Analysis revealed a significant association between globus and GERD symptoms (OR, 95% CI: 1.45, range 1.10-1.92) (p = 0.009) and hoarseness and GERD symptoms (OR, 95% CI: 1.36, range 1.04-1.78) (p = 0.02).

Conclusions: Based on responses to validated symptom questionnaires, a significant association was found between the presumed SER symptoms of globus and hoarseness with GERD symptoms. This correlation may help guide treatment decisions in patients with certain combinations of SER and GERD symptoms.

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The Impact of Adjustable Laparoscopic Gastric Banding on Esophageal Motility

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Purpose: Bariatric surgery particularly the adjustable laparoscopic gastric band (LAGB) has been widely and successfully used to treat morbid obesity; though, its effect on esophageal physiologic function has yet to be fully understood. The aim of this study was to evaluate the effect of adjustable laparoscopic gastric banding on esophageal motility.

Methods: Consecutive patients with a body mass index (BMI) > 35 referred for bariatric surgery were prospectively enrolled. A detailed medical history was obtained and esophageal manometric evaluation was performed preoperatively, 6 and 12 months postoperatively allowing for comparisons using the patients as their own controls. Patients with baseline motility dysfunction were excluded. The manometric parameters evaluated were lower esophageal sphincter resting pressure (LES), LES residual pressure, wave duration, wave amplitude, and propagation. Manometric abnormalities were determined by using established published values and criteria.

Results: A total of 17 patients with a mean age of 44 ± 14 years and mean pre-surgical BMI of 48 ± 9 were evaluated between April 2003 and April 2006. Eight patients with pre-surgical manometric abnormalities were excluded. The mean follow-up time was 15 months ± 4. BMI significantly decreased between baseline and 6 months (46 ± 6 vs. 39 ± 6; p = 0.001), between 6 months and 12 months (39 ± 6 vs. 35 ± 6; p = 0.004), as well as between baseline and 12 months (45 ± 7 vs. 35 ± 5; p = 0.010). At 6 months post LAGB 40% of the individuals had at least 1 manometric abnormality while 10% had at least 2 or more abnormal findings. The mean LES residual pressure differed significantly between baseline and 6 months (5 ± 3 mm Hg vs. 9 ± 3 mm Hg; p = 0.031). At 12 months post LAGB the number of individuals with 1 abnormal manometric finding was 20% while the number with 2 or more abnormal findings increased to 20%. The mean duration of the peristaltic wave increased from 4 ± 1 seconds at baseline to 7 ± 1 seconds at 12 months; p = 0.008. LES pressure, wave propagation, and effectiveness of the contractions did not differ significantly pre and post LAGB.

Conclusions: Abnormal manometric findings are frequently encountered post LAGB. Increases in LES residual pressure and wave duration were the most significant post-surgical changes. Further evaluation of the clinical significance of the manometric abnormalities associated with LAGB is warranted.
Continuous Positive Airway Pressure Ventilation for Obstructive Sleep Apnea Reduces Gastroesophageal Reflux

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Purpose: The increased prevalence of gastroesophageal reflux (GER) in patients with obstructive sleep apnea (OSA) may be caused in part by negative intrathoracic pressure during an apneic event. Our aim was to determine if continuous positive airway pressure (CPAP) decreases nocturnal GER in patients with OSA and if so to what degree.

Methods: Patients with OSA and symptoms of GER were enrolled in a two night crossover trial. Prior to testing, patients stopped any GER related medication for ≥7 days and CPAP for ≥2 days. The first night was a diagnostic polysomnography study with pH probe placed 5 cm above the lower esophageal sphincter. The second night, CPAP titration was performed with pH monitoring. Measurements included% time with esophageal pH < 4 and the total number of GER events defined as drop in pH to <4 for at least 4 seconds. Poisson and linear regression models with generalized estimating were used to analyze the data based on an eight hour study.

Results: Seventeen patients, 9 men, completed the two study nights. Twelve were obese, range of BMI 27.3 to 50.8. Mean baseline apnea hypopnea index (AHI) was 37.4, with 3 pts having mild OSA, 5 moderate OSA, and 9 severe OSA. Eleven pts had abnormal nocturnal GER (>1.4% time pH <4). Ten of these had a decrease in nocturnal GER on CPAP with 7 pts returning to normal levels (p = 0.15). The mean number of GER events per hour, which decreased in 70% of patients, was 4.85 at baseline and 2.41 with CPAP (p = 0.11). One pt had an increase in% time pH<4 from 25.7 to 53.1 with a corresponding increase in GER events from 31 to 130. Analysis of the other 16 patients demonstrated a drop in% time pH<4 from 8.77 to 3.13 (p = 0.002) and mean GER events per hr from 4.91 to 1.43 with CPAP (p = 0.002). Sleep indices improved in all 17 patients, with mean AHI values of 39.19 at baseline and 7.39 on CPAP (p < 0.001).

Conclusions: Nocturnal GER is common in patients with OSA. In addition to improving AHl, CPAP decreases GER parameters. However, 24% of the patients still had an abnormal amount of nocturnal GER while on CPAP and GER worsened significantly in one patient. Future studies should concentrate on the potential role of supplementary acid suppression in further improving the AHI and nocturnal GER parameters.

Increased Esophageal Wall Thickness in Patients with Non-Cardiac Chest Pain

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Purpose: Noncardiac chest pain (NCCP) is a common and challenging clinical problem. The pathogenesis of chest pain is multi-factorial and not well understood. A stiff, less distensible esophagus has been identified in these patients using impedance planimetry.

Hypothesis: The impaired elasticity of the esophageal wall in NCCP is due to a structural defect-i.e. enhanced esophageal wall thickness.

Aims: Evaluate the esophageal wall diameter of patients with NCCP in comparison to controls using standard radial endoscopic ultrasound (EUS).

Methods: Consecutive patients with NCCP referred for upper endoscopy to exclude gastrointestinal mucosal sources of chest pain were invited to have EUS of the esophagus at the same session. Following completion of upper endoscopy, patients with a negative mucosal exam underwent EUS evaluation of the esophageal wall. The entire esophageal wall was evaluated using the Olympus radial echoendoscope (GF UM 130 and GF-UE 160). Measurements of the esophagus were obtained at approximately 2–3 cm from the squamous columnar junction (SCJ) (distal), 8 cm from the SCJ (middle), and 2–3 cm below the UES (proximal). Control subjects were consecutive patients undergoing EUS for other indications but without esophageal symptoms and with a normal esophageal mucosa exam during EGD. Statistical analysis was done by Wilcoxon rank-sum and Fisher’s exact test.

Results: 79 patients were studied (35 consecutive patients with NCCP and 44 controls). See table 1.

Conclusions: Patients with NCCP have an increased esophageal wall thickness- as demonstrated by EUS. Since EUS is readily available and can be performed in conjunction with EGD, the identification of this structural defect may serve as a morphologic marker to study patients with NCCP.

### Table 1

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>NCCP (N = 35)</th>
<th>Controls (N = 44)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean, median</td>
<td>63.2, 60.7</td>
<td>64.2, 64.7</td>
<td>0.680</td>
</tr>
<tr>
<td>Age (Range)</td>
<td>64 (43–79)</td>
<td>64 (26–86)</td>
<td></td>
</tr>
<tr>
<td>Female Gender n (%)</td>
<td>22 (63%)</td>
<td>29 (66%)</td>
<td>0.816</td>
</tr>
<tr>
<td>Distal esophageal thickness/mm</td>
<td>3.47, 3.1, 2.39, 2.3</td>
<td>1 SD</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>mean, median, (range)</td>
<td>(1.8–7.4), 1.34</td>
<td>(1.2–3.9), 0.64</td>
<td></td>
</tr>
<tr>
<td>Mid esophageal thickness/mm</td>
<td>2.79, 2.45, 2.05, 2.0</td>
<td>1 SD</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>mean, median, (range), 1 SD</td>
<td>(1.6–6.0), 0.99</td>
<td>(1.1–3.6), 0.52</td>
<td></td>
</tr>
<tr>
<td>Proximal esophageal thickness/mm</td>
<td>2.44, 2.4, 2.04, 1.95</td>
<td>1 SD</td>
<td>0.001</td>
</tr>
<tr>
<td>mean, median, (range), 1 SD</td>
<td>(1.7–3.6), 0.53</td>
<td>(1.1–3.0), 0.47</td>
<td></td>
</tr>
</tbody>
</table>

SD: Standard Deviation.

Evaluation of Distal Baseline Impedance May Assist Esophageal Manometry in Detecting Motility Abnormalities

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Purpose: The aim of the study was to compare distal baseline impedance (DBI) between healthy volunteers (HV) with normal manometry and patients with normal and abnormal manometry.

Methods: We analyzed combined multichannel intraluminal impedance (MII-EM) studies performed in 130 patients and subjects (79 women, mean age 53 years, age range 17-85 yrs). There were 20 HV and 20 patients with normal manometry. Patients with abnormal manometry were separated into nutcracker esophagus (NUT, N = 20), distal esophageal spasm (DES, N = 20), ineffective esophageal motility (IEM, N = 20), achalasia (ACH, N = 20) and scleroderma-like esophagus (SE, N = 10). Manometric and MII parameters were assessed during 10 liquid and 10 viscous swallows. MII findings included baseline impedance and number of complete and incomplete bolus transits. The average values of baseline impedance (DBI) measured at 5 and 10 cm above LES were calculated before (DBI) and after (DBI liq)10 liquid swallows and after 10 viscous swallows (DBI vis).

The correlations between DBI liq and DBI vis and number of complete bolus transits (CBT) for liquid and viscous as well as distal esophageal amplitude (DEA) for liquid and viscous were also assessed using Pearson correlation coefficient.

Results: Significant (p < 0.0001) correlations were found between DBI liq and CBT liq (r = 0.7), DBI vis and CBT vis (r = 0.6), DBI liq and DEA liq (r = 0.5) and DBI vis and DEA vis (r = 0.5).

Conclusions: Our results indicate that evaluation of distal baseline impedance may assist esophageal manometry in separating achalasia, scleroderma-like esophagus and IEM from nutcracker esophagus, DES or normal esophageal motility.
Non-Cardiac Chest Pain (NCCP): Is There a Difference in the Cumulative Incidence of Cardiac Death in Patients with NCCP Attributed to GI Disorders Versus Patients with NCCP of Unknown Origin?

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Purpose: To estimate the cumulative incidence of cardiac death in patients with NCCP ascribed a GI diagnosis in comparison to patients with NCCP of unknown origin.

Methods: A previous study identified 2,068 Olmsted County, Minnesota residents presenting to one of the county’s three Emergency Departments with acute chest pain between January 1, 1985 and January 31, 1992. From this cohort, 359 patients were dismissed after hospitalization with a diagnosis of NCCP. Of these, 230 patients were labeled as chest pain of unknown origin (NCCP-U), while ninety-four received a gastrointestinal diagnosis (NCCP-GI). The latter 324 patients provide the population of the current study. A review of the medical record was conducted at the largest of the three medical centers (Mayo Clinic) providing follow-up from January 1, 1993 through January 1, 2006. All deaths were abstracted with particular focus on cardiac death as determined by the clinician’s report. Utilizing a competing risks survival analysis, cumulative incidence of cardiac death was calculated for the NCCP-U and NCCP-GI subsets.

Results: In the NCCP-GI group, the cumulative incidence of cardiac death at years one, five, ten, and twenty were 0.5%, 1.9%, 5.8%, 10.5% respectively. In the NCCP-U group, the cumulative incidence of cardiac death at years one, five, ten, and twenty were 0.6%, 6.9%, 9.3%, and 13.3% respectively. In the NCCP-U group, the cumulative incidence of cardiac death at years one, five, ten, and twenty were 0.5%, 1.9%, 5.8%, 10.5% respectively.

Conclusions: This study suggests an increased cumulative incidence of cardiac death in patients with NCCP. This is significantly different from most previous data on cardiac outcomes in this population. Patients with NCCP due to a GI disorder experienced a slightly higher cumulative incidence of cardiac death than the patients with NCCP of unknown origin, possibly due to overlapping risk factors for GERD and coronary disease including obesity, smoking, obstructive sleep apnea, and diabetes mellitus. Supported by an unrestricted research grant from Tap.

Effect of PPI Therapy on Symptom Association Using Four-Day Bravo pH Recordings Combining 48 Hour Periods Off and on PPI

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Purpose: Controversy exists as to whether pH studies are best done off or on PPI therapy. Off therapy testing maximizes the yield of symptom association while on therapy testing evaluates the efficacy of therapy in normalizing esophageal acid exposure. The aim of this study was to determine the effect of PPI on symptom association using 4-day pH recordings that encompassed 2 day periods before and during PPI therapy.

Methods: 15 patients underwent 4-day Bravo pH recordings (2 day off, 2 day on) using 2 separate receivers calibrated to a single Bravo capsule. Indications for pH testing were refractory heartburn, chest pain, and chronic laryngeal symptoms. Patients were off PPI therapy for days 1 and 2. Omeprazole/Na bicarbonate 40 mg PO BID was administered on days 3 and 4. Symptom association was measured by both the symptom index (SI) and Symptom Association Probability (SAP).

Results: Off therapy, 7 patients (58%) had esophageal acid exposure values exceeding 5.3%. 6 patients had abnormal pH exposure only on day 1 and 1 patient only on Day 2. 3 patients were excluded from the study due to premature detachment or malfunction. On therapy, all patients showed significant and progressive reductions is esophageal acid exposure (Figure, p < 0.01). By day 4, all patients had normal esophageal acid exposure values. 5 patients had complete symptom resolution by day 4; the remaining 6 patients continued to experience symptoms while on PPI therapy. Both the SI and SAP significantly decreased during the on therapy compared with off therapy recording period (p < 0.05).

Conclusions: (1) Prolonged 96 hour esophageal pH recordings using the Bravo system are feasible and allow for combined testing both off and on therapeutic trial of PPI. (2) Yield of symptom association indices are significantly diminished with PPI therapy. (3) 96 hour pH studies allow for acquisition of information useful in the evaluation of refractory and atypical reflux symptoms. [figure]
Purpose: Over the past several decades, there has been a noticeable rise in the incidence rate of adenocarcinoma of the esophagus as well as a dramatic increase in dietary carbohydrate consumption in the United States (US). In this ecological study, we seek to assess the correlation between the changing dietary patterns and the incidence of esophageal cancer rates in the US.

Methods: The age-adjusted incidence rates for esophageal cancer by gender, race, and histological types were calculated based on the time period of 1971–2000 using the Surveillance, Epidemiology, and End Results (SEER) data. Dietary intakes were derived from food disappearance data obtained from the National Nutrient Data Bank. The association of esophageal cancer rates and total carbohydrate intake and percentage of carbohydrate intakes from fiber and corn syrup were assessed in linear regression models adjusting for total caloric intake.

Results: The incidence rate of esophageal adenocarcinoma was found to be significantly positively associated with per capita carbohydrate intake ($p = 0.0001$). In contrast, the incidence rate of esophageal squamous cell carcinoma is declining and is significantly negatively associated with carbohydrate intake during this time period ($p = 0.03$). There is little evidence for association for the percentages of carbohydrates from fiber or corn syrup with either adenocarcinoma or squamous cell carcinoma.

Conclusions: The rising trend in the incidence of esophageal adenocarcinoma in the United States parallel the increasing consumption of total carbohydrate intake over the same period of time. This ecological study provides evidence for the hypothesis that excess carbohydrate intake in the US population may partially account for the increased trend of incidence rate of adenocarcinoma of the esophagus. It is possible that obesity resulting from excess carbohydrate intake may be an intermediate link. The opposing trends in the incidence rate of squamous cell carcinoma and carbohydrate intake lend further supporting evidence as this subtype is known to be strongly linked to cigarette smoking. Further research into esophageal cancer and dietary habits are needed to clarify these intriguing ecological associations.

Is PET Really Necessary for Locoregional Staging of Esophageal Cancer? Preliminary Results of a Regional, Multi-Disciplinary Initiative Comparing EUS, CT and PET

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Purpose: There is no established diagnostic algorithm for esophageal cancer staging. Various modalities including CT, PET and EUS have been used. The role of PET for staging is not clear. This is a preliminary comparison of the results of CT, PET and EUS with surgical pathology as part of an esophageal cancer staging algorithm.

Methods: The Cross Cancer Institute (CCI) and the University of Alberta Hospital, both in Edmonton, Alberta, Canada have collaboratively initiated an esophageal cancer triage program. Patients with biopsy-proven esophageal cancer were referred to the CCI. Each patient underwent a CT scan of the chest/abdomen and a PET scan. Patients with no evidence of metastatic disease were referred for EUS for locoregional staging. Appropriate patients underwent surgery with curative intent. Endosonographic T and N staging results were compared retrospectively to surgical pathology or results of FNA biopsy. The results for N staging with CT, PET and EUS were compared with surgical pathology or FNA biopsy.

Results: Since May 2005, 29 patients, with no evidence of distant metastasis on CT and PET, underwent EUS. There were 24 males. The mean age was 68 years (range 50-82 years). EUS was completed in 25/29 patients (86%). There were no EUS related complications. Sixteen patients had histologically proven lymph node metastasis. Sensitivity for N staging was 55% for CT, 36% for PET and 91% for EUS, respectively and specificity was 100% for CT, 100% for PET and 60% for EUS, respectively. Diagnostic accuracy was 69% for CT, 56% for PET and 81% for EUS, respectively. Fifteen patients had histologically proven T staging. The percentage of agreement between EUS and histology with respect to T staging was 80%. There was disagreement between EUS and histology by one T level in 2 patients and by two T levels in 1 patient.

Conclusions: EUS is a safe and accurate modality for T and N staging in esophageal cancer. The combination of EUS + CT for locoregional staging appears to be comparable to EUS + PET. This suggests that the utility of PET in esophageal cancer may be limited to situations where EUS staging is not available. Further clinical data is required to confirm this.

Validity of the DeMeester’s Score for the Evaluation of GERD with 24 hr Conventional pH Monitor and the Wireless Bravo Capsule

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Purpose: The traditional system for esophageal 24-h pH monitoring requires transnasal introduction of the catheter with pH sensors; this technique produces discomfort, inconvenience, and interference with daily activity. The catheter-free pH monitoring system (Bravo) has been proposed as an alternative and promising method for 24-h pH. The purpose of the study was to determine and evaluate the validity of DeMeester’s score which is used for the diagnosis in both methods.

Methods: We retrospectively analyzed the pH monitoring parameters of the 24 hour dual channel technique in 64 patients with symptoms of GERD and the parameters of wireless pH monitoring technique in 19 different patients with symptoms of GERD.

The mean values were compared with those of normal values determined by DeMeester et al. (Gastrointestinal motility: which test? 1989, pp. 43-52) from their study of 50 young healthy adults, and the t-test was applied to determine the statistical significance of differences.

Results: The study showed that the wireless pH monitoring group had 10 out of 19 patients (52%) with DeMeester’s score more than 14.72 (the cut off value of DeMeester’s (DM) score for diagnosing GERD). The 24 hour dual channel pH probe group showed a DM score of more than 14.72 in 17 out of 64 patients (26%), all patients had classical symptoms of GERD.

Conclusions: Using the same standard abnormal values for the parameters of pH monitoring produced different results between the wireless pH monitoring group and the 24 hour dual channel group, making necessity to define different parameters for each technique. A study with both technique used in the same group of patients is needed.

Correlation between Liquid and Viscous Swallows: A Study of Combined Esophageal Manometry and Multichannel Intraluminal Impedance Testing in 409 Patients

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Purpose: To analyze the correlation between the manometric diagnoses obtained by liquid versus viscous swallows, and to determine which manometric technique, viscous or liquid, better predicts abnormal impedance.

Methods: Combined esophageal manometry and multichannel intraluminal impedance testing was performed on 409 consecutive patients referred to an esophageal function laboratory for symptoms suggestive of esophageal dysfunction, atypical chest pain, or atypical symptoms of GERD. Patients underwent 10 swallows of 10 cc of normal saline followed by 10 swallows of 10 cc of a standard viscous preparation (EFT viscous, Sandhill). One investigator analyzed all studies. He was blinded to the liquid swallow results when reading the viscous swallow tracings.
Results: Patients on average were 52.6 ± 15.8 years old (females = 63%). Manometric diagnoses by liquid (viscous) swallows were: achalasia-66 (67) patients, scleroderma esophagus-5 (5), diffuse esophageal spasm (DES)-23 (28), ineffective esophageal motility (IEM)-80 (94), and normal or nutcracker esophagus-235 (215). Manometric diagnoses obtained by liquid and viscous swallows showed substantial overall agreement (78%, kappa = 0.69, CI: 0.63-0.74). The strength of agreement critically depended on the manometric diagnosis. The agreement between the techniques, using liquid swallows as the gold standard, was excellent for achalasia or scleroderma (100%); moderate for normal esophagus, nutcracker esophagus or IEM (e.g. 78% for IEM); and poor for DES (35%). The difference in strength of agreement between achalasia and DES was highly significant (66/66 vs 8/23, OR=122, ORCl: 17-799, p < 0.0001). Compared to viscous swallows, liquid swallows exhibited much better correlation between abnormal manometric diagnoses (achalasia, scleroderma or IEM) and abnormal impedance (91% vs 83%, OR = 1.99, OR CI:1.01-3.90, p < 0.05).

Conclusions: When achalasia or scleroderma is diagnosed using liquid swallows, addition of viscous swallows rarely changes the manometric diagnosis and is unnecessary. When IEM or DES is diagnosed using liquid swallows, addition of viscous swallows may change the manometric diagnosis and can be helpful. The better correlation between abnormal manometry and abnormal impedance for liquid than for viscous swallows suggests that liquid swallows provides more relevant information. Performance of viscous swallows only when liquid swallows show IEM or DES should reduce procedure time and costs.

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Reflux during Sleep in Asymptomatic Normals: Another Potential Danger in the Night* William C. Orr, PhD,* Suane Goodrich, PhD, Goran Hasselgren, MD, Paula Fernstrom. Sleep Lab, Lynn Health Science Institute, Oklahoma City, OK and Research & Development, AstraZeneca, Molndal, Sweden.

Purpose: Previous studies with 24 hour pH monitoring have documented an incidence of abnormal findings in asymptomatic individuals ranging from 2-30%. Other studies have documented the presence of Barrett’s Esophagus in approximately 3% of asymptomatic individuals. Studies from our laboratory have documented the importance of sleep related gastroesophageal reflux (GER) in the pathogenesis of complications of acid mucosal contact. In this study we have documented GER during sleep via polysomnographic (PSG) monitoring in a group of asymptomatic, healthy individuals.

Methods: 31 normal asymptomatic individuals without any history of daytime or nighttime heartburn or other medical disorders were studied in the sleep laboratory with full PSG monitoring to include the EEG, EOG, EMG, and distal esophageal pH. All subjects slept two nights in the laboratory separated by approximately 14 days.

Results: Nine (29%) of patients had sleep related GER on at least one night, and 3 (10%) had reflux on both nights. Five (16%) of these individuals had at least 1 episode greater than 5 minutes. The average duration of reflux events was 6 minutes. The average acid contact time across those with reflux was 2% (normal = approximately 1.5%).

Conclusions: 1. GER which occurs during sleep and is not associated with any heartburn symptoms would be considered “high risk” reflux, and this exists in approximately 29% of this normal population; 2. Asymptomatic reflux during sleep may serve as a precursor to the development of serious complications of GER such as esophagitis and Barrett’s esophagus.

*Supported by a research grant from AstraZeneca, Molndal, Sweden

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Endoscopic Therapy for Gastroesophageal Reflux Disease (GERD): A Comparison of Different Techniques at a Single Institution Andrew C. Dukowicz, MD, Carol Moriarty, RN, Richard I. Rothstein, MD.* Gastroenterology and Hepatology, Dartmouth-Hitchcock Medical Center, Lebanon, NH.

Purpose: Multiple interventions exist for endoscopic therapy for GERD. To compare outcomes of endoscopic antireflux therapies, we reviewed patients (pts) at our institution who were enrolled in our initial clinical trials. Comparison was made with respect to reduction in GERD symptoms and antisecretory medication use at 12 months post-procedure. Endoscopic therapies in this comparison include the BARD Endocinch (17 pts), Stretta Procedure (10 pts), Gatekeeper Reflux Repair System (9 pts), the NDO Plicator (12 pts), and the Syntheon Antireflux Device (14 pts).

Methods: Subjects had mild GERD that was responsive to antisecretory medication (used at least daily) and abnormal pH studies. No subject had a hiatal hernia >2 cm or Barrett’s esophagus. For all patients undergoing endoscopic treatment at our institution, data was collected about their pre-procedure symptoms (GERD-HRQL scores) and medication use and compared to their symptoms and medication use at 6 and 12 months post-procedure.

Results: At 12 month follow-up, patients undergoing plication procedures (NDO, Syntheon, and BARD) had the greatest reduction in GERD symptom score (57%, 64%, and 58% reduction, respectively), compared to Gatekeeper (31.5% reduction) and Stretta (47.3% reduction). With respect to medication use at one year, patients undergoing plication procedures noted the largest reduction in medication use with 37.5% of BARD patients on no antisecretory therapy and 42% of both NDO and Syntheon patients off all antisecretory therapy. In contrast, 30% of Stretta patients and 12% of Gatekeeper patients were not on antisecretory medications at 1 year. 1 patient who underwent the BARD Endocinch underwent a Nissen fundoplication prior to 6 month follow-up.

Conclusions: Our initial protocol-based experience with the endoscopic treatment of GERD demonstrated a significant but modest improvement in GERD symptom scores and decrease in antisecretory medication use in patients with mild reflux disease when evaluated at one year follow-up. Although limited, our results suggest that plication-based procedures may be more durable. However, larger cohort series, randomized clinical trials, and longer follow-up are required to make this distinction.

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Effects of Rabeprazole (RAB) 20 mg Versus Pantoprazole (PAN) 40 mg on Intragastric Acidity and Esophageal Acid Exposure (EAE): A Randomized, Crossover, Single-Dose Study in Gastroesophageal Reflux Disease (GERD) Patients with Nocturnal Heartburn P. Miner, MD,* J. Jeni, PhD, J. Xiang, PhD, J. LoCoco, MBA, S. Oosman, B. DeLemos, MD, President and Medical Director, Oklahoma Foundation for Digestive Research, Oklahoma City, OK; Medical Department, Eisai Inc., Teaneck, NJ and Medical Department, PriCura, Unit of Ortho-McNeil, Inc., Raritan, NJ.

Purpose: To compare the effects of single doses of RAB 20 mg and PAN 40 mg on 24-h intragastric acidity and EAE.

Methods: This single-center, investigator-blinded, 2X2 crossover trial randomized 52 patients with GERD and ≥6-month history of heartburn. Patients were required to have ≥3 heartburn episodes/week (≥1 nocturnal) in the month before screening and EAE (defined as pH <4) at least 10% on a 24-h esophageal pH study performed within 24 mo. Patients received placebo on day 1, single dose of RAB 20 mg or PAN 40 mg on day 2, and standardized meals throughout, with a 6- to 13-day washout between study periods. 48-h ambulatory pH monitoring was used to record pH every 8 sec. Results: Mean% time with intragastric pH >4 (1° endpoint) was significantly greater with RAB vs PAN for the 24-h interval postdose in the PP population (N = 50) (Table [PP]). Significant differences were observed in the daytime and nighttime intervals. Results were similar for the ITT population (N = 52). RAB was significantly superior in other intragastric pH parameters. For EAE (2° endpoint), there was no statistically significant difference between the 2 treatments (5.8% vs 5.8%; p = 0.97). The proportions of subjects achieving EAE normalization (pH <4 for less than 8% of daytime hrs and for less than 3% of nighttime hrs) was numerically greater for
daytime (72.0% vs 64.0%; p = 0.32) and nighttime (74.0% vs 66.0%; p = 0.52) after RAB, but results were not statistically superior vs PAN.

Conclusions: In GERD patients with nocturnal heartburn, RAB 20 mg was significantly more effective than PAN 40 mg, in% time with intragastric pH >4 during the nighttime hours, as well as the daytime and 24-h periods. Differences between treatments in EAE were not demonstrated in this single-dose study.

Table [PP]

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A 10 Year, Single Center Experience with PDT in Esophageal Lesions
Sharon S. Everette, BSN, CGRN, Amrita Sethi, MD, Gail B. DeCosta, RN, CGRN, Alvin M. Zhass, MD, MACG, FACP, *Gastroenterology, Virginia Commonwealth University, Richmond, VA.

Purpose: 67 patients with esophageal lesions received 1 or more treatments, for a total of 105 sessions of photodynamic therapy (PDT), between the years 1996 and 2006. Demographics: mean age of 69.6 years (S.D. 27-88), 67% male, 86% caucasian, 12% African American, 2% other races. Initial diagnosis: High Grade Dysplasia (HGD)/T1 lesions (N = 37), T2 (N = 11), T3/T4 lesions (N = 19).

Methods: All patients were treated and underwent surveillance at 3-6 month intervals by one physician and one nurse. Patients were treated with 632 nanometers at 150–300 J/cm.

Results: 3-month complications in 67 patients treated with 1 or more PDT sessions included stricture (17.9%), sunburn requiring steroid therapy (0.3%), non-fatall cardiac arrhythmia (0.15%), non-malignant T-E fistula (0.15%) and abdominal abscess (0.15%). Of 37 patients treated for cure (HGD/T1 lesions), 5 year data was available in 17. Median time for follow up in this group was 7 years. Four patients in this group died; one died from esophageal cancer 2 years after treatment and 3 died from unrelated illnesses. 5 year survival rate was 76.5%. Of the 13 patients alive at 5 years, complete ablation of HGD occurred in 9. Two patients had recurrence of HGD 2-3 years after initial treatment and each was successfully retreated. There is no evidence of dysplasia in these patients with 3 year follow up. Progression to adenocarcinoma was seen in 2 patients; they were successfully treated with PDT and show no evidence of adenocarcinoma at 41 and 22 months post-treatment. Of the remaining 20 patients (HGD/T1), 12 patients had a 2-4 year follow up. Total ablation occurred in 9 patients. There was recurrent HGD in 3 patients. The remaining 8 patients have a less than 2-year follow-up.

Conclusions: PDT is a safe and effective treatment for HGD/T1 lesions, with minimal side affects including photosensitivity and a 17.9% stricture rate. 86.6% of patients with a 5 year follow up did not progress to cancer. In this high risk group, there was 1 death due to progression of disease.

HGD/T1 Lesions (N = 37)
5 year or more follow-up 17
2-4 year follow-up 12
Less than 2 year follow-up 8

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Use of Polyflex Stents in Therapy of Esophageal Strictures and Tracheoesophageal Fistulas: A Single Center Experience
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Purpose: To describe our single center experience with the self expanding covered plastic stents (Polyflex, Boston Scientific, USA) in treating esophageal strictures and tracheoesophageal fistulas.

Background: Stent therapy is indicated for the treatment of refractory benign esophageal strictures, stenosis resulting from extrinsic compression of the esophagus and for palliation of esophageal stenosis and tracheoesophageal fistulas (TE fistulas) originating from esophageal cancer. New self-expanding plastic stents made from a polyester mesh coated with a silicon membrane offer an advantageous alternative to currently used metallic stents due to their ease of removal and expandable strength.

Methods: We retrospectively analyzed all cases of Polyflex stent placements at our institution between September 2004 and October 2005. Polyflex stent placements were attempted in fourteen patients (mean age 65.7 ± 16.9 years) for the following conditions: malignant stenosis (N = 8); TE fistula (N = 2); extrinsic esophageal compression (N = 3) and benign radiation induced strictures (N = 1).

Results: Stent placement was successful in all but one patient. All patients with malignant strictures reported symptomatic improvement in their dysphagia and were subsequently able to tolerate oral nutrition. The stent migration rate in this group was 20%. Migrated stents were either repositioned or replaced with a metal stent. Tumor overgrowth causing occlusion occurred in two patients. In two patients with malignant disease, placement of a Polyflex stent allowed for further disease staging and nutritional support and eventually underwent successful esophagectomy. One patient with a malignant stricture was able to tolerate oral nutrition for up to 11 months after stent placement. Both patients with TE fistulas reported symptomatic improvement and one had documented fistula closure. Patients with successful stent placement for extrinsic esophageal compression and benign esophageal strictures also reported significant improvement in their dysphagia symptoms. Overall, in more that 90% of the patients the stents were in-situ for an average of 29.4 ± 8.8 days. No major complications were noted in our series.

Conclusions: Based on our experience, the Polyflex stent is safe and effective therapy for palliation of dysphagia in the setting of malignant and benign strictures as well as for symptomatic relief from TE fistulas. Additionally they may play an important role as a bridge to surgery in patients with operable esophageal cancer.

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Circumferential Ablation of Barrett Esophagus with Persistent High-Grade Dysplasia Following Photodynamic Therapy with Halo 360
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Purpose: Photodynamic therapy (PDT) is an FDA approved treatment for Barrett esophagus (BE) with high-grade dysplasia (HGD). It is unknown

Patients Treated with PDT for Esophageal Lesions

| HGD/T1 | 37 |
| T2 | 11 |
| T3/T4 | 19 |
whether patients with persistent HGD following treatment with PDT could benefit from another ablative technique. We report initial safety and efficacy of the HALO360 bipolar balloon electrode in treatment of patients with BE and persistent HGD after treatment with PDT.

Methods: Patients previously treated with PDT with persistent HGD confirmed by two pathologists and refusing repeat PDT or surgery were treated with the HALO360 bipolar balloon electrode. Patients underwent repeat treatment at 3 month intervals until all Barrett’s epithelium was ablated. Lugol’s chromendoscopy with targeted biopsies from endoscopically visible Barrett and random biopsies from the ablated segment of original Barrett were obtained at regular follow-up interval to assess for dysplasia and residual Barrett epithelium. Endoscopic mucosal resection (EMR) was utilized for nodular HGD or early stage adenocarcinoma (ACA). Adverse events with the procedure were recorded.

Results: Five patients with residual HGD after treatment with PDT have been treated with HALO360 bipolar balloon electrode. Two patients had complete ablation of HGD, 3 were found to have residual areas of focal nodular HGD/early stage ACA on follow-up and were treated with EMR. Two out of three had complete resection of ACA with EMR. One patient had involvement of the deep margin of the EMR with ACA and opted to undergo repeat PDT. All 3 patients were cancer/dysplasia free at the last follow-up. No adverse events were recorded.

Conclusions: Ablation of BE with persistent HGD or early stage esophageal ACA following treatment with PDT is effective using HALO360 balloon electrode and EMR for nodular disease. Patient tolerance and safety with the procedure has been excellent. Long term follow-up is needed to establish the efficacy of this treatment.


The Effect of Gastroesophageal Reflux on Upper Airway Functioning in Patients with Obstructive Sleep Apnea

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Purpose: The complaint of heartburn is a symptom which is commonly encountered in patients with obstructive sleep apnea (OSA). Questions persist regarding the effect of GER on upper airway functioning, and whether or not chronic GER may predispose to an exacerbation of OSA.

Methods: Fifteen subjects were selected for study based on having documented mild (equal to or less than 15 obstructive events per hour) obstructive sleep apnea (OSA) and at least 6% total acid contact time or 3% during the sleeping interval documented via 24 hour pH monitoring. Subjects were subsequently treated with rabeprazole 20 mg bid for 8 weeks. Subjects underwent upper airway physiologic evaluation and laryngoscopy pre and post treatment. The Reflux Finding Score was used to rate laryngoscopic findings. All subjects completed the Pittsburgh Sleep Quality Index (PSQI) and the Epworth Sleepiness Scale (ESS).

Results: Acid contact time significantly reduced posttreatment (8.1% pre vs 1.9% post, p < .05). There was no significant change in the AHI after treatment (9.3% pre vs 9.3% post,). The Reflux Finding Score was reduced (p = .07) subsequent to treatment and there was a significant (p = .04) reduction in posterior commissure hypertrophy and vocal fold edema post treatment (p < .05). Subglottic pressures were not altered subsequent to treatment. In the subgroup of patients with significant improvement in laryngeal anatomy, the males (N = 8) showed a significant reduction in the vocal fundamental frequency into the normal range (p = .03). Both the PSQI and the ESS were significantly improved post treatment.

Conclusions: 1. Patients with OSA and GER showed a significant benefit from acid suppression in terms of normalizing upper airway anatomy and some parameters of upper airway physiology. 2. The AHI was not significantly altered. 3. Acid suppression in the patient population improved both subjective sleep quality and symptoms of daytime sleepiness; 4. Treatment of GER in patients with OSA will have significant benefits in terms of both daytime functioning, as well as resolving upper airway abnormalities.

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Characteristics of Silent Nocturnal Acid Reflux Induced Sleep Changes: Comparison to Spontaneous Sleep Arousal

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Purpose: In general, clinical acid reflux sleep studies focus on nocturnal symptoms, such as heartburn, as a study endpoint. However, it has been shown that most nocturnal reflux events are silent, and do not cause classic symptoms of acid reflux or heartburn. The purpose of this study is to determine if silent acid-induced sleep arousals have characteristics that differ from spontaneous sleep arousals on polysomnography.

Methods: The records of 16 patients who had previously undergone simultaneous polysomnography and overnight esophageal pH analysis, were reviewed. A sleep arousal was defined as a shift in EEG frequency lasting for at least 3 seconds, but no more that 15 seconds. An esophageal reflux event was considered to have occurred when the pH recording was < 4.0. Arousals were reflux associated if they occurred while the pH was below 4.0 and up to 5 minutes after the pH had returned to 4.0. For each acid associated arousal, a corresponding spontaneous arousal was chosen for comparison.

Results: There were a total of 33 overnight acid reflux events, which resulted in 27 acid induced arousals. Ten acid induced arousals occurred in stage 1 sleep, while 17 occurred in stage 2 sleep. No acid induced arousal occurred during stage 3 or 4 REM sleep. Of the 27 non-acid induced arousals analyzed, 5 occurred in stage 1 sleep, 18 occurred in stage 2 sleep, and 4 occurred in REM sleep. There were no arousals during stage 3 or 4 sleep. The mean duration of an acid induced arousal was 5.2 sec compared to 5.6 sec for spontaneous arousals (p > .05). Eleven acid induced arousals occurred while the patient was supine, and 16 occurred while the patient was on their right side. In comparison, eight non-acid induced arousals occurred while the patient was supine and 19 occurred while the patient was on their right side. No acid or non-acid induced arousals occurred while the patients where on their left side.

Conclusions: Silent acid induced arousals are indistinguishable from spontaneous non-acid induced arousals in duration and body position. Sleep disturbances with multiple sleep arousals may be due to silent acid reflux episodes, which are scored during polysomnography as being spontaneous arousals. Thus, silent gastroesophageal reflux may present and be diagnosed as a primary sleep disorder.

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EUS-SOS: EUS FNA/Trucut Biopsy in Patients with Previously Failed Biopsy (bx)

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Purpose: Bronchoscopy with transbronchial FNA, mediastinoscopy, CT guided bx and laparoscopy are accepted techniques for tissue sampling of intrathoracic and intra-abdominal masses. We report our experience with EUS FNA/Trucut bx (EUS FNA/TCB) as a rescue procedure in patients (pts.) who previously failed or were refused by other bx techniques.

Aim: To evaluate the accuracy of EUS FNA in pts with malignant disease and a previously failed bx procedure.

Methods: Retrospective analysis of EUS FNA/TCB results in all pts. referred for pancreatic or mediastinal bx from 10/03 to 4/05. Pts. who failed or
were refused by other bx modalities and had a final diagnosis of malignancy were included. A positive diagnosis of malignancy by EUS FNA/TCB was considered true positive. All procedures were performed only with linear array EUS by a single endosonographer. No on-site cytopathology was done. FNA was performed in all pts. and TCB was added at the discretion of the endosonographer.

**Results:** A total of 160 pts. were referred for pancreatic or mediastinal bx for solid masses. Thirty-nine pts. (24%) met exclusion criteria. The mean age was 67 years (18 F and 21 M). There were 26 pancreatic masses and 13 mediastinal masses. In the mediastinal group, 11 failed bronchoscopy with transbronchial FNA, one failed mediastinoscopy, and one was turned down for CT guided bx. In the pancreatic group, sixteen failed CT guided bx, six failed laparoscopy, three were turned down for CT guided bx and one failed prior EUS FNA/TCB. The sensitivity of EUS FNA/TCB for detecting malignancy in 39 pts. was 85%. In the mediastinal and pancreatic subgroups sensitivities were: 100% and 77% respectively. The mean number of FNA passes was 6 (range 3-10). Trucut was used in 19 pts., mean number of passes of 2.4 (range 2-5). All six pts. with pancreatic cancer missed by EUS FNA did not undergo additional EUS TCB due to technical reasons (uncinate process lesions). Four of the six pts. with pancreatic cancer missed by EUS FNA, had at least two prior failed biopsies by CT FNA.

**Conclusions:** In pts. who have failed other bx procedures, EUS FNA/TCB should still be considered an accurate and safe modality to detect malignancy. Addition of TCB to FNA appears safe and should be considered in the absence of on-site cytopathology review.

**100 The Natural History of Dysplasia in a Large Cohort of Patients with Barrett's Esophagus**

Anu Mathew, MD, Artur Miernik, DO, Richard Gerkin, MD, Francisco C. Ramirez, MD, FAIGC.* Gastroenterology, Carl T. Hayde VA Medical Center, Phoenix, AZ and Medicine, Banner Health Good Samaritan Hospital, Phoenix, AZ.

**Purpose:** For implementing a screening and surveillance program in Barrett’s esophagus, it is important to understand the natural history of the disease, in particular when dysplasia is present.

**Aim:** To describe the natural history of patients with Barrett’s esophagus and any type of dysplasia.

**Methods:** Endoscopic data from all patients with suspected BE were reviewed. Those patients with intestinal metaplasia and who were found to have dysplasia and at least 1 endoscopic follow up 12 months apart were included. Those undergoing endoscopic therapy for Barrett’s were excluded. Patients who presented with adenocarcinoma at index endoscopy were excluded unless there was a prior endoscopy with histology negative for dysplasia.

**Study period:** January 1997 to December 2004. Setting: Endoscopy Unit at a VAMC.

**Results:** Of 1714 patients with suspected BE on EGD, 940 had confirmed diagnosis (presence of intestinal metaplasia). Of these, 120 met the criteria with dysplasia (12.8%). These patients had a mean follow up of 4 years. Nineteen patients (16.2%) had no histological follow up. Fifty nine patients (49%) had negative histologies prior to diagnosis of dysplasia. When dysplasia was found, regression to no dysplasia and absence of recurrence was seen in 57 (47.5%) cases. Persistent dysplasia (without regression to a lower degree or no dysplasia was seen in 10 patients (8.5%). Two consecutive findings of dysplasia was followed to regression without recurrence of dysplasia in 10 patients (8.5%). Fluctuating dysplasia was observed in 12 cases (10.2%).

There were 13 patients (9.3%) who had adenocarcinoma (5) and/or high grade dysplasia (8) during follow up surveillance. Tobacco, alcohol, age, and BMI were not significant predictors of histology. The only predictor was Barrett’s length. [figure1]

**Conclusions:** 1) In this large, single center cohort of patients with Barrett’s esophagus and long follow up, dysplasia of any type (including adenocarcinoma) was found in 12.8% patients. 2) Once found, dysplasia regressed without further recurrence on follow up in 48% cases. 3) Adenocarcinoma and/or HGD developed in 9% patients with dysplasia.

**101 Multimodal Oxaliplatin Based Chemo- Radiation Therapy for Locally Advanced Esophageal Carcinoma**

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**Purpose:** Oxaliplatin, 5-fluorouracil and leucovorin with concurrent radiotherapy was demonstrated to be a safe regimen in a phase 1 study for locally advanced esophageal carcinoma (LAEC). We report efficacy data of oxaliplatin in multimodal therapy for LAEC in preoperative, definitive and adjuvant setting.

**Methods:** Retrospective data analysis was done after Institutional Board Review approval. Each chemotherapy cycle lasted 29 days with concurrent radiation to tumor bed and local lymph nodes and consisted of 5-Fluorouracil 180 mg/m2 protracted-infusion from day 1-29 and oxaliplatin 85 mg/m2 on days 1, 15 and 29. Post concurrent chemoradiation, 1-2 additional cycles were administered.

**Results:** Forty-two eligible patients received a total of 39.6 cycles of chemotherapy (MedianN = 1 cycle/patient) between June 2002 to July 2005. Patient demographics are shown in table 2. In pre-operative group, complete response was seen in 5 (20.8%) patients, down staging in 12 (50%) and disease progression in 4 (16.6%). In definitive setting, clinical response was seen in 1 (8.7%) patient, tumor down staging in 4 (30.7%), stable disease in 2 (15.4%) and disease progression in 6 (46.1%) patients. In adjuvant setting, 2 patients attained no evidence of disease status, while 3 had disease progression. Grade 3 toxicities included hypotension (N = 2), fatigue (N = 2), diarrhea (N = 2); mucositis, hyperglycemia, hyponatremia, angina, leukopenia, pneumonitis, dysphagia, dehydration, emesis and weight loss (N = 1, each). There was only one grade 4 toxicity (anaphylaxis). Overall median survival was 28 months.

**Conclusions:** Multimodal oxaliplatin based therapy is safe and well tolerated for LAEC.
also significantly enhanced protective potential (Gastroenterology, 110:675-81, 1996). Little is known, however, regarding the protective quality of saliva in basal conditions and during stimulation in patients with reflux esophagitis (RE). Therefore, the aim of the study was to explore the correlation between the rate of secretion of salivary volume and inorganic as well as organic protective components in various experimental conditions in patients with RE.

**Methods:** The study was conducted in 30 GERD patients with endoscopically confirmed RE (14F and 16M; mean age of 41). Salivary secretions were collected in basal conditions, during mastication, and during stimulation by the esophageal-salivary reflex (evoked by intraesophageal perfusion with HCl/pepsin, pH 2.1, using our specially designed esophageal perfusion catheter, manufactured by Wilson - Cook Medical Co.). Concentrations of bicarbonate (BIC), non-bicarbonate (NBIC), protein (P), glycojugate (GLYC), epidermal growth factor (EGF), transforming growth factor \( \alpha \) (TGF\( \alpha \)) and prostaglandin E\( _2 \) (PGE\( _2 \)) were measured using TitraLab instrumentation, various commercial assays as well as radioimmunoassays. Spearman correlation coefficient was calculated using Sigma-Stat software.

**Results:** In basal conditions, the rate of secretion of BIC and NBIC did not correlate with salivary volume. Even in saliva stimulated by mastication salivary NBIC secretion failed to correlate with salivary volume. Only esophageal-salivary reflex-induced increase in salivary volume correlated significantly \( (p < 0.01) \) with BIC, NBIC, P, GLYC, and EGF but not TGF\( \alpha \) or PGE\( _2 \).

**Conclusions:** The lack of fully synchronized increase in the content of major salivary protective factors in basal conditions as well as during stimulation of salivary flow, by mastication or esophageal-salivary reflex, in patients with RE could indicate qualitative impairment in salivary protective potential that could contribute to the development of esophageal mucosal injury by the gastroesophageal refluxate.

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**Qualitative Impairment in Salivary Protective Potential in Patients with Reflux Esophagitis: Its Potential Clinical Implications**

Tomasz Skoczylas, MD, Zbigniew Namiot, MD, Cezary Poplawski, MD, Marek Marcinkiewicz, MD, Tomasz Zbroch, MD, Richard W. McCallum, MD, Jerzy Sarosiek, MD,* Medicine, Motility Center, GI Research Laboratory, KUMC, Kansas City, KS.

**Purpose:** Heartburn symptoms in patients with gastroesophageal reflux disease (GERD) frequently result in augmented quantity of saliva as the natural defense mechanism. Salivary secretion stimulated by mastication exhibits...
treatment may require multi-modality approach including timely surgical intervention.

### Characteristics of Gastroesophageal Reflux Episodes Leading to Symptoms in Acid Suppressed Patients

**Purpose:** Studies evaluating refluxate characteristics leading to symptoms in acid suppressed patients are lacking. Multichannel Intraluminal Impedance and pH (MII-pH) can provide detailed characterization of reflux episodes (acidity, height, composition, clearance time). Our aim was to determine characteristics of reflux episodes associated with symptoms in acid suppressed patients.

**Methods:** GERD patients with persistent symptoms (heartburn, regurgitation, chest pain, cough) despite maximal acid suppression (PPI BID) underwent 24-h MII-pH on medication. Reflux episodes considered symptomatic if symptom occurred within 2 minutes of episode. Given the “repeated measures” nature of the data (multiple reflux episodes per patient), multivariate logistic regression was performed through a generalized estimating equations (GEE) model fitted to assess the relationship between the dichotomous outcome variable (symptomatic vs asymptomatic episode) and the independent variables: age, sex, and each reflux episode characteristic: acidity (acid if pH < 4), nonacid delta if pH drop > 1 unit but not to below 4, nonacid if pH change < 1 unit, re-reflux if episode occurred when pH already < 4), pH parameters (baseline, nadir, delta), height (measured in 2 cm intervals above LES), composition (liquid or liquid+gas), volume clearance time.

**Results:** 2,998 reflux episodes (402 symptomatic) recorded in 76 patients (34% male, mean age 52y). Final multivariate model: controlling for age, gender, acidity and delta pH, height was the only variable associated with producing symptoms (Table 1), with an OR of 1.10 for every 1 unit (2 cm) increase. Height increases of 2 cm and 10 cm were associated with an increase in the odds of producing symptoms by 10% and 63%, respectively.

**Conclusions:** Height reached by refluxate appears to be the most important factor leading to symptoms in patients that are already acid suppressed. Therapies to alleviate symptoms in this group of patients should aim to limit proximal extension of refluxate. [Figure1]

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### Stomach

#### Lack of Activating Mutations of the EGF Receptor in German and Japanese Gastric Cancer Specimens

**Purpose:** Gastric cancers express high levels of EGF receptor (EGFR). EGFR tyrosine kinase inhibitors (EGFR-TKI) such as gefitinib show activity in lung cancer. The response to this treatment, however, closely correlates with activating mutations of the EGFR which occur more frequently in patients of Asian ethnicity. Because of the limited treatment options for gastric cancers, we examined whether such EGFR-TKI sensitizing mutations occur in gastric adenocarcinoma.

**Methods:** Thirty-six Japanese and thirty German treatment naive gastric cancer specimens were analyzed for somatic mutations of the catalytic domain of the EGFR. DNA was extracted from paraffin-embedded specimens and subsequently PCR and sequencing of genomic DNA covering exons 18, 19, and 21 was performed. Samples of non-small cell lung cancer DNA known to contain mutations in these sequences served as positive controls.

**Results:** Direct sequencing of EGFR PCR products from thirty German and thirty-six Japanese gastric cancer patients revealed one polymorphism but no EGFR mutations. One tubular adenocarcinoma of a German patient displayed a silent single nucleotide exchange polymorphism (c.8; t; codon 896 of exon 21).

**Conclusions:** Activating EGFR kinase domain mutations are not prevalent in gastric cancer specimens in patients of Caucasian or Asian ethnicity.
High Density Microarray Analyses Reveal Specific Gene Expression Signatures for Gastroprotection by Proton Pump Inhibitors

Independent of Acid Inhibition

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Purpose: Recently it was demonstrated that the proton pump inhibitor (PPI) omeprazole protects gastric mucosa by reducing oxidative stress -- independent of gastric acid inhibition (JBC, 2003; 278:10993–11001). Aim of the present study was to elucidate underlying molecular mechanisms.

Methods: Gastric epithelial cells (AGS and KATO III) were exposed to escalating doses of the PPIs omeprazole and lansoprazole. Whole human genome expression arrays (Applied Biosystems) were used to identify genes differentially regulated by this treatment. Only genes with a > 5-fold difference in expression in all samples were regarded as significantly regulated and grouped according to their gene function.

Results: In the cell culture model used here both PPIs reduced free radical content in a dose dependent manner. Out of over 30,000 genes mRNA expression of 60 genes was found to be significantly induced, 88 to be repressed. Most importantly among the induced genes with yet known protein functions 24% were oxidoreductases. Strongest mRNA induction could be documented for heme oxygenase-1 (HO-1, 46-fold) and thioredoxin reductase (TrxR, 14-fold). Dose dependent mRNA induction of HO-1 as well as TrxR by both omeprazole and lansoprazole was proven by real-time RT PCR.

Conclusions: Induction of several oxidoreductases demonstrated in this study support the idea that reduction of oxidative stress plays a major role in gastroprotection by PPI - independent of proton pump inhibition. Thioredoxin reductase mediated induction of heme oxygenase-1 might be the key event in this process.

Relevance of cagA Genotype and the Efficacy of Antibiotic Therapy in Patients with Non-Ulcer Dyspepsia

Xiangwen Meng, PhD, Hongjuan Zhang, PhD, Tai-Kin Tsang, MD, * GI Research, Evanston Northwestern Healthcare Research Institute, Evanston, IL and Northwestern University, Feinberg School of Medicine, Evanston, IL.

Purpose: To understand the link between H. Pylori infection and non-ulcer dyspepsia (NUD), the effect of H. Pylori treatment with Prevpac based on our multiplex PCR detection and the relevancy between the cagA genotype and the antibiotic treatment efficacy.

Methods: 50 patients with dyspepsia, who were diagnosed by CLOtest and biopsy urease test). Records for patients presenting with GERD, dyspepsia, upper abdominal pain, and dysphagia from 2002–2005 were included. Data collected included demographics, symptoms, medication use, and 2.5% reported substance abuse. There were no significant gender associations with GERD or response to antibiotic therapy. The negative reports of H. pylori detected by current clinical methods need to be carefully reevaluated to ensure the correct diagnosis.

CagA Status and Treatment Results with Prevpac

<table>
<thead>
<tr>
<th>Symptom Response</th>
<th>2nd PCR</th>
<th>cagA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(-)</td>
<td>(+)</td>
</tr>
<tr>
<td>Complete Response</td>
<td>21</td>
<td>14</td>
</tr>
<tr>
<td>Partial Response</td>
<td>21</td>
<td>11</td>
</tr>
<tr>
<td>Non-response</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
<td>29</td>
</tr>
</tbody>
</table>

*p = 0.0488, Fisher’s exact test (24/25 vs 18/25).

GERD, H. pylori and Obesity in Southeastern Kentucky

Indraneel Gowdar, * Mark B. Dignan, Uday Shankar, MD. University of Pennsylvania, University of Philadelphia, PA; Markey Cancer Center, University of Kentucky, Lexington, KY and Gastroenterology Associates of Hazard, Appalachian Regional Hospital, Hazard, KY.

Purpose: This study sought to explore the patterns of GERD and related risk factors in Southeastern Kentucky.

Methods: To explore the interaction among risk factors in this unique population, we reviewed medical records on 487 patients from a large gastroenterology practice, selecting 165 H. Pylori positive patients and 322 negatives. Records for patients presenting with GERD, dyspepsia, upper abdominal pain, and dysphagia from 2002-2005 were included. Data collected included age, gender, height, weight, self-reported tobacco/alcohol/substance abuse, hiatal hernia, GERD, Barretts esophagus, and H. pylori infection (by antral biopsy urease test).

Results: The average age of the study population (60% female) was 50.1 (sd = 15.7), with average BMI at 29.3 (sd = 7.3). 61% were found to have GERD, 6% Barretts esophagus. 34.3% reported tobacco use, 12.1% alcohol use, and 2.5% reported substance abuse. There were no significant gender differences in GERD patients. However, patients with GERD were younger (average age of 48.9 vs. 51.8; p = .047) but had higher average BMI (30.2 vs. 28.0; p = .003). There were no significant age or gender associations with rates of H. pylori, BMI, or Barretts esophagus. The table shows distribution of characteristics by H. Pylori infection. Barretts esophagus was more common among H. pylori patients than controls (p = .0037), but this finding is limited by a small sample (N = 29). Additional analyses were conducted and found that patients with GERD were more likely to have a BMI > 30 regardless of H. pylori infection status. Furthermore, obese patients (BMI > 30) under 50 years of age were more likely to have GERD than obese patients 50 years or older (76.4% vs. 58.3%, respectively; p = .004). No such difference was seen in non-obese patients (55.8% vs. 56.0%; p = 0.975).

Conclusions: The GERD rate in this clinical population was significantly (60%) which may indicate that the rate in the population at large is also

summary score. Non-responders, partial responders and total responders were designated according to less than 40%, between 40% and 80% and more than 80% symptom improvement respectively.

Results: Of 50 patients, the complete, partial and non responses for the treatment were 42% (21/50), 42% (21/50), and 16% (8/50) respectively. After treatment, 58% (29/50) patients’ biopsies became H. Pylori negative detected by using the multiplex PCR. However, of the 42 patients with complete and/or partial clinical response, 17cases were still showed H pylori positive when detected with PCR. Among the 50 patients, 50% (25/50) cases are with genotype of cagA+ and the cagA+ strains seemed to be more sensitive to the Prevpac than cagA- strains (24/25 vs 18/25; p = 0.0488, Fisher’s exact test).

Conclusions: This study showed that the H. Pylori - positive patients revealed by multiplex PCR do respond well to the treatment with Prevpac. Different cagA status of H pylori may result in different clinical outcomes or response to antibiotic therapy. The negative reports of H pylori detected by current clinical methods need to be carefully reevaluated to ensure the correct diagnosis.

CagA Status and Treatment Results with Prevpac

<table>
<thead>
<tr>
<th></th>
<th>2nd PCR</th>
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</tr>
</thead>
<tbody>
<tr>
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</tr>
<tr>
<td>Total</td>
<td>50</td>
<td>29</td>
</tr>
</tbody>
</table>

*p = 0.0488, Fisher’s exact test (24/25 vs 18/25).
elevated. The population in southeastern Kentucky has high rates of obesity which may increase risk of GERD. Additional research on the unique patterns of GERD in this population is needed.

Characteristics of H. Pylori negative and positive groups

<table>
<thead>
<tr>
<th></th>
<th>HP−</th>
<th>HP+</th>
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</thead>
<tbody>
<tr>
<td>Male</td>
<td>39.44%</td>
<td>38.79%</td>
</tr>
<tr>
<td>Female</td>
<td>60.56%</td>
<td>61.21%</td>
</tr>
<tr>
<td>Mean Age</td>
<td>49.40</td>
<td>51.36</td>
</tr>
<tr>
<td>Mean BMI</td>
<td>30.38</td>
<td>29.93</td>
</tr>
<tr>
<td>Alcohol</td>
<td>12.42%</td>
<td>11.52%</td>
</tr>
<tr>
<td>Smoking</td>
<td>32.30%</td>
<td>38.18%</td>
</tr>
<tr>
<td>Barretts</td>
<td>3.73%</td>
<td>10.30%</td>
</tr>
<tr>
<td>GERD</td>
<td>62.11%</td>
<td>58.79%</td>
</tr>
</tbody>
</table>

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Oral Rabeprazole 20 Mg Provides More Effective Acid Control Than IV Pantoprazole 40 Mg

David Armstrong, MD, FACP,* Cindy James, Fernando Camacho, G.L.A. Horbay, Bruno Teixeira, Farah A. Hussein-Bhabha. Division of Gastroenterology, McMaster University & Hamilton Health Sciences, Hamilton, ON, Canada; Damos Inc., Toronto, ON, Canada and Clinical Affairs, Janssen-Ortho Inc., Toronto, ON, Canada.

Purpose: Intravenous (IV) proton-pump inhibitor therapy is used increasingly in hospitalized patients, even if, in many cases, they can take oral medication. Oral and IV pantoprazole produce equivalent acid suppression; oral rabeprazole produces greater acid suppression than oral pantoprazole. This study compares the antisecretory effects (time pH < 4) between molecular testing and treatment outcomes was not well studied. This

Methods: Double-blind, randomized, two-way crossover study in 38 Helicobacter pylori-negative healthy volunteers. Subjects received oral rabeprazole 20 mg or IV pantoprazole 40 mg once daily for 3 days, with a 14-day (∆3) washout period before the second 3-day drug administration period with the crossover drug regimen. Intragastric pH was recorded continuously for a 24-hour period after dosing on days 1 and 3 of each treatment phase.

Results: Over a 24-hour period, oral rabeprazole produced greater acid suppression than IV pantoprazole on day 1 [pH > 3.0 (51.0%, 35.7%, p < 0.001), pH > 4.0 (37.7%, 23.9%, p < 0.001), pH > 5.0 (24.9%, 14.2%, p < 0.001), pH > 6.0 (11.2%, 5.8%, p = 0.024)] and on day 3 [pH > 3.0 (68.4%, 51.5%, p < 0.0001), pH > 4.0 (54.4%, 37.7%, p < 0.001), pH > 5.0 (38.1%, 24.8%, p < 0.001), pH > 6.0 (17.3%, 11.5%, p = 0.017)]. Over a 10-hour nighttime period, oral rabeprazole produced greater acid suppression than IV pantoprazole on day 1 [pH > 3.0 (42.8%, 27.8%, p < 0.010), pH > 4.0 (30.2%, 18.2%, p = 0.017)] and on day 3 [pH > 3 (56.2%, 37.0%, p < 0.001), pH > 4 (43.4%, 26.2%, p < 0.002), pH > 5 (29.8%, 18.8%, p = 0.024).

Conclusions: In healthy subjects, oral rabeprazole provides greater intragastric acid suppression over 24 hours and during the 10-hour nocturnal period on day 1 and 3 than IV pantoprazole. Oral rabeprazole may be an appropriate substitute for IV pantoprazole in patients who can take oral medication. [figure1]
study evaluated the frequency of gyrA/B mutations after unsuccessful standard therapy in Japan and confirmed whether molecular genetic approach will be useful in levofloxacin-based rescue therapy in comparison with the E test MICs.

Methods: Seventy-five H. pylori culture-positive patients after standard therapy who received 7- or 10-day-rescue therapy with lansoprazole (30 mg b.d.), amoxicillin (1000 mg b.d.), and levofloxacin (200 mg or 300 mg b.d.) were analyzed. The E test was performed using gastric biopsy samples. The quinoline resistance-determining regions of H. pylori gyrA/B gene were amplified by PCR and directly sequenced. The impacts of clinical backgrounds (age, gender, disease, levofloxacin dosage, treatment duration, the E test MICs to clarithromycin and levofloxacin, gyrA mutations) on treatment outcomes were calculated by multivariate logistic regression analysis.

Results: Twenty-four (32%) of 75 strains showed gyrA mutations. No gyrB mutations were observed. Fifty-nine strains respectively showed point mutations in the gyrA gene at amino acid (aa) 87 (Asn to Lys or Ile) and at aa 91 (Asp to Asn or Gly). Seven out of 14 strains with MIC values to levofloxacin of $>1$ μg/mL, and 16 out of 61 strains with those of $<1$ μg/mL, were not successfully eradicated. Sixteen out of 23 refractory strains to rescue therapy showed gyrA mutations. Forty-one out of 51 strains without gyrA mutations were successfully eradicated. The existence of gyrA mutations showed a tendency toward worse results regardless of the MICs and levofloxacin dosage. No other clinical factors have a significant impact on treatment outcomes. Longer treatment duration brought about better response in wild type strains.

Conclusions: H. pylori gyrA mutations were common after failed standard therapy in Japan. In levofloxacin-based therapy for H. pylori infection, molecular genetic approach appeared to be a useful indicator for treatment outcomes.

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Cyclic Symptoms in Patients with Gastroparesis—Differences from Non-Cyclic Patients Undergoing Gastric Electric Stimulation

Jane Claire B. Williams, MD, Thomas Abell, MD, Stephen Weeks, MD, Digestive Diseases, University of Mississippi Medical Center, Jackson, MS.

Purpose: While most patients with the symptoms of gastroparesis (GP) have chronic symptoms, others have symptoms that are cyclic in nature. We investigated patients presenting with the symptoms of GP, most of whom underwent eventual placement of Gastric Electrical Stimulation (GES) to see if patients with Cyclic Symptoms differed from those with No Cyclic Symptoms.

Methods: Patients from a data base of 345 consecutive patients seen, 48 patients (8 m, 40 f; mean age 41.5 y) with Diagnosis: 18 Idiopathic, 27 Diabetes Mellitus and 3 Post-Surgical disorders, presented with the symptoms (Sx) of GP. Most patients were drug refractory and referred for possible GES. Patients were 35 (3 m, 32 f) with Cyclic Symptoms (Cyc), and 13 (1 m, 12 f) with No Cyclic Symptoms (NoCyc). 38 of 48 patients (25 Cyc and 13 NoCyc) underwent implantation of permanent GES, mean of 33 months.

Results were compared by paired t-tests, baseline vs. latest for GES patients, 11 NoCyc) underwent implantation of permanent GES, mean of 33 months.

Baseline Values

<table>
<thead>
<tr>
<th>Va</th>
<th>Na</th>
<th>TSSa</th>
<th>GET4a</th>
<th>QOLa</th>
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</thead>
<tbody>
<tr>
<td>NoCycSx</td>
<td>2.0</td>
<td>3.0</td>
<td>11.8</td>
<td>13.9</td>
</tr>
<tr>
<td>CycSx</td>
<td>0.9</td>
<td>1.6</td>
<td>9.0</td>
<td>16.4</td>
</tr>
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</table>

Values after GES

<table>
<thead>
<tr>
<th>WtnNoC</th>
<th>p</th>
<th>WtnCyc</th>
<th>p</th>
<th>Betwn p</th>
<th>&lt; 0.0001</th>
<th>0.4</th>
<th>&lt;0.0001</th>
<th>0.3</th>
<th>&lt;0.005</th>
</tr>
</thead>
</table>

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Ibuprofen-PC Induces Less Gastrointestinal Damage Than Ibuprofen in at Risk Osteoarthritic (OA) Patients Compared to Ibuprofen at Full Therapeutic Doses

Lenard Lichtenberger, PhD, Upendra Marathi, PhD, Bhupinder Anand, MD, Howard Schwartz, MD, Michael Schwartz, DO, Garth Denyer, MD, Frank Lanza, MD, Integrative Biology & Pharmacology, Univ. of Texas Medical School, Houston, TX; PLX Pharma Inc., Houston, TX; Baylor College of Medicine, Houston, TX; Miami Research Assoc., Miami, FL; Jupiter Research Assoc., Jupiter, FL; Oaks Medical Center, Spring, TX and Houston Institute of Clinical Research, Houston, TX.

Purpose: Chronic use of NSAIDs in OA patients is associated with gastrointestinal (GI) mucosal damage that increases with age. NSAIDs induce GI injury, in part, by attenuating the hydrophobic barrier of the mucosa which may be due to their association with the mucosal phosphatidylcholine (PC). Accordingly, we have developed a novel formulation of ibuprofen by pre-associating the NSAID with PC.

Methods: This was a Phase II, randomized, single-blind trial comparing the safety and efficacy of Ibuprofen-PC vs Motrin® (2400 mg ibuprofen/day) in OA patients over a 6 week period. Upper endoscopy was performed at baseline and at 6 weeks using the 0-4 Lanza scoring method. Therapeutic efficacy was assessed by the Western Ontario and McMaster Universities Arthritic Criteria (WOMAC) and Visual Analog Scale (VAS) scores and pharmacokinetic (PK) studies were performed.

Results: 125 OA patients began, of which 107 completed the trial comprising 58 and 49 in the ibuprofen and ibuprofen-PC groups respectively. Both test drugs provided equivalent therapeutic efficacy as assessed by WOMAC/VAS, and had similar PK. In the evaluable groups, there was a trend towards greater GI safety of ibuprofen-PC vs ibuprofen (1.3 vs 1.6 increase in Lanza score).

In the ibuprofen-treated group, the relative risk of multiple gastro-duodenal erosions was 2.1 times greater in subjects $>55$ years compared to those $\leq 55$, consistent with the known age-related NSAID intolerance ($p < 0.05$). No such age-dependent increase in GI toxicity was seen in the ibuprofen-PC group. In a cohort of patients over the age of 55, ibuprofen treated subjects were 3.7 times more likely to develop multiple gastro-duodenal erosions than the ibuprofen-PC treated subjects ($p < 0.02$). Ibuprofen-PC was well tolerated, with no major treatment-related adverse events.

Conclusions: Both study drugs were equally therapeutically effective. However, Ibuprofen-PC was associated with markedly improved GI safety profile in patients $>55$ years, who are most susceptible to NSAID-induced gastrointestinal injury.

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Generation of Dyspeptic Symptoms by Direct Acid Infusion to the Stomach in Healthy Subjects

Hiroto Mio, MD, Kazutaka Nakajima, MD, Yoshikazu Kinoshita, MD, Keiichi Adachi, MD, Kazuma Fujimoto, Kanako Yamaguchi, MD, Hiroaki Kasunoki, Ken Haruna. Internal Medicine, Hyogo College of Medicine, Nishinomiya, Hyogo, Japan; 2nd Internal, Shimane University Faculty of Medicine, Izumo, Shimane, Japan; Internal Medicine, Saga Medical School, Faculty of Medicine, Saga University, Nishinomiya, Saga, Japan; and Internal Medicine, Kawasaki Medical School, Kurashiki, Okayama, Japan.
Purpose: Symptom based treatment is employed to treat dyspeptic patients, and acid suppressive drugs are recommended as the first line treatment for such patients. However, it has not been reported what symptoms are actually induced by direct acid infusion to the stomach.

Methods: The study was performed as multi-center, cross-over, randomized, double-blind fashion on 27 healthy volunteers (mean age 27, male 15, H.pylori negative 25) with written informed consent. Each fasted subject received 2 tests with 150 ml of 0.1 mol/L hydrochloric acid infusion and same volume of pure water infusion (15 mL/min for 10 minutes using the automatic infusion pump with 5-French ED tube). Both procedures were done within 7 days interval. The kind and severity of symptoms was assessed by 100 mm visual analogue scale in every 2 minutes up to 30 minutes.

Results: Area under severity scale – time curve for each symptom are shown in the figure. The areas were significantly larger in acid infusion than in water in dysmotility like symptoms and most of symptoms maximized after infusion of the acid.

Conclusions: Infused acid into the stomach induced various symptoms, demonstrating the importance of acid in symptom generation of dyspepsia, and that most symptoms maximized after the infusion suggested the crucial role of duodenal acidification. [figure1]

Increased Vascular Endothelial Growth Factor and Hypoxia Inducible Factor-1α Transcription in Acquired Sporadic Gastric Angiodysplasia
Rami Haswari, MD, John Winston, PhD, Binh Pham, MD, Pankaj Pusricha, MD.* Internal Medicine/Gastroenterology Division, University of Texas Medical Branch, Galveston, TX.

Purpose: To study the role of the angiogenic factors, Vascular Endothelial Growth Factor (VEGF) and Hypoxia Inducible Factor-1-alpha (HIF 1α) in the etiopathogenesis of gastric arteriovenous malformations.

Methods: 9 patients with symptomatic sporadic acquired gastric angiodysplasia were included in the study. Mucosal biopsies were obtained from 3 locations: 0.5, 5 and 10 cm away from the lesion and mRNA was prepared for analysis of VEGF and HIF 1α expression using quantitative real time PCR. As control, biopsies of the antrum were obtained from 9 other patients with no gastric lesions but who were undergoing endoscopy for other reasons. As compared with controls, mRNA levels of both factors decreasing markedly with increasing distance away from the lesion.

Conclusions: The expression of VEGF and HIF 1α is increased near sporadic acquired angiodysplastic lesions of the stomach, implying a possible causative effect. To our knowledge this is the first demonstration of a putative role for HIF1α in gastrointestinal arteriovenous malformations.

Saliva Plays a Dual Role in the Oxidation Process in Gastric Milieu
Shlomit Gorelik, MSc, Ron Kohen, PhD, Moshe Ligumsky, MD, Joseph Kanner, PhD.* Pharmaceuticals, School of Pharmacy, The Hebrew University, Jerusalem, Israel; Gastroenterology, Hadassah Medical Center, Jerusalem, Israel and Food Science, Volcani Center; Beil Dagan, Israel.

Purpose: Food undergoes enhanced oxidation under simulated gastric conditions. (Free Rad Biol Med 2001). Chewing food stimulates saliva secretion from salivary glands, and considerable amounts of saliva enter the stomach mixed with food. Saliva contains compounds with pro and anti oxidant properties (Free Rad Biol Med 2002; J Clin Invest 2004.). Since chewing food also stimulates acid secretion, we hypothesized that saliva may have an important role in the oxidative process of food in the acidic gastric milieu. This study aimed to evaluate the effect of saliva on food oxidation at acidic pH, to examine the effects of salivary components such as thiocyanate, nitrite and lactoperoxidase on the oxidation process. and to evaluate the effect of red wine phenols on food oxidation.

Methods: Specimens of saliva (3 ml) were obtained from healthy subjects, centrifuged and supernatants were kept frozen until use.

Oxidation system: Red Turkey meat pieces heated and homogenized with simulated gastric fluid (SGF) pH 3.0, then incubated for 3h at (4°C (with either saliva, lactoperoxidase, nitrite, thioctyanate, α-tocopherol or red wine.) Generation of hydroperoxides was determined by ferrous ion oxidation-xylene orange (FOX2) method, and of malondialdehyde (MDA) by thiobarbituric acid method (J Agric Food Biochem 2005). α-tocopherol was determined following ethanol extraction, separation by HPLC, and detection by spectrophotometer (Ex 290nm, Em 332 nm).

Results: 1. Different saliva specimens exhibited either pro-oxidant, antioxidant or no effect on lipid peroxidation of heated meat in SGF. 2. Salivary lactoperoxidase enhanced peroxidation by 50% which was pH dependent, while thiocyanate and nitrite ions exhibited anti oxidative effect of 50% and 100%, respectively. 3. Saliva did not prevent oxidation of α-tocopherol, but red wine phenols totally protected it from oxidation.

Conclusions: Human saliva contains components possessing pro and anti oxidant activity, but overall does not provide adequate protection against lipid peroxidation of food at low pH. Since red wine phenols totally prevented lipid peroxidation, food rich in potent antioxidants such as polyphenols may significantly protect antioxidants such as vitamin E from degradation, and prevent generation of toxic reactive species during meals, attenuating their potential long-term harmful effects.

Intravenous Esomeprazole 40 mg Versus Intravenous Lansoprazole 30 mg in Controlling Intragastric Acidity in Healthy Adults
Joseph Pisegna, MD, FACC, Mark B. Sostek, MD, FACC, John T. Monyak, PhD, Philip B. Miner, Jr., MD, FACC.* David Geffen School of Medicine, UCLA, Los Angeles, CA; AstraZeneca LP Wilmington, DE and Oklahoma Foundation for Digestive Research, Oklahoma City, OK.

Purpose: To compare the efficacy of once-daily dosing of intravenous (IV) esomeprazole 40 mg and IV lansoprazole 30 mg for control of intragastric (IG) pH in healthy adults.

Methods: In this randomized, open-label, 2-treatment crossover study (D9612L00080), healthy, H pylori-negative adults (aged 18–70 y) were randomized to 1 of 2 treatment sequences each consisting of two 5-dosing periods of esomeprazole 40 mg or lansoprazole 30 mg separated by a 10–17-d washout period. Medications were administered intravenously over 30 min, 4 h before breakfast on dosing days 1 and 5 and 30 min before breakfast on dosing days 2–4. IG pH monitoring was conducted on days 1 and 5 of each dosing period; a calibrated pH microelectrode positioned in the stomach 10
cm below the lower esophageal sphincter recorded intragastric pH every 5 s for 24 h. Least-squares mean (LSM) percentages of time during the 24-h monitoring period that pH was above 2.5, 4.0, and 6.0 on day 1 and day 5 (primary analysis) were calculated and analyzed using a mixed model with fixed effects for treatment, sequence, and period. pH data beyond 24 h were not used in analysis.

Results: Of 101 subjects randomized, 96 had evaluable pH data for both day-5 dosing periods: 65% were men; 94% were white; mean (SD) age was 29 (11) y, and mean BMI was 25.5 kg/m². Mean time with pH data on day 5 was 23.90 h for IV esomeprazole 40 mg and 23.96 h for IV lansoprazole 30 mg. On dosing days 1 and 5, IG pH was controlled (pH > 2.5, 4.0, and 6.0) for significantly longer (p < .001 for each comparison) with IV esomeprazole 40 mg than IV lansoprazole 30 mg (Table). Most common adverse events were injection site reactions (17 [17%] esomeprazole and 16 [16%] lansoprazole recipients); no serious adverse events were reported.

Conclusions: In healthy adults, IV esomeprazole 40 mg controlled IG acidity more effectively than IV lansoprazole 30 mg both on dosing day 1 and at presumed steady state (day 5). Both treatments were well tolerated. Supported by AstraZeneca LP.

LSM percentages of the 24-h monitoring period with pH above threshold (N = 96)

<table>
<thead>
<tr>
<th>Threshold</th>
<th>Day 1</th>
<th>Day 5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IV Esomeprazole 40 mg</td>
<td>IV Lansoprazole 30 mg</td>
</tr>
<tr>
<td>pH &gt; 2.5</td>
<td>55.5*</td>
<td>47.9</td>
</tr>
<tr>
<td>pH = 4.0</td>
<td>40.0*</td>
<td>33.6</td>
</tr>
<tr>
<td>pH = 6.0</td>
<td>14.5*</td>
<td>9.8</td>
</tr>
</tbody>
</table>

*p < .001 for test of difference in LSMs.

120 Primary Levofloxacin-Resistance and gyrA/B Mutations among Helicobacter pylori in Japan
Hideyuki Miyachi, MD, Nobuo Aoyama, PhD,* Daishike Shirasaka, PhD, Ikuya Miki, PhD, Yuko Matsumoto, MD, Takeshi Azuma, PhD. Division of Diabetes, Digestive and Kidney Diseases, Department of Clinical Molecular Medicine, Kobe University Graduate School of Medicine, Kobe, Japan; Division of Gastroenterology, Kobe University Graduate School of Medicine, Kobe, Japan; Division of Frontier Medical Science in Molecular Medicine, Kobe University Graduate School of Medicine, Kobe, Japan

Purpose: To investigate the prevalence of levofloxacin-resistance of Helicobacter pylori in Japan, and to confirm the association between susceptibility testing and gyrA/B mutations. The final goal is to reveal which mutations can predict levofloxacin-susceptibility against H. pylori.

Methods: Levofloxacin-susceptibility was examined using the E-test in 632 H. pylori strains clinically isolated in Japan from 2001 to 2005. Mutation patterns in the quinolone resistance-determining regions of the gyrA and gyrB genes were evaluated performing direct sequencing of 68 levofloxacin-resistant and 50 susceptible strains.

Results: Primary levofloxacin-resistance was found in 91 (14.4%) strains. Fifty-seven (83.8%) of 68 levofloxacin-resistant strains analyzed had point mutations in gyrA at Asn-87 or Asp-91, while 7 (14.0%) of 50 susceptible strains had gyrA mutations. There was a statistically significant difference in the occurrence of gyrA mutations between levofloxacin-resistant and -susceptible strains (p < .001). In levofloxacin-resistant strains, the occurrence of gyrA mutations at Asn-87 was most common regardless of MIC levels, and that of gyrA mutations at Asp-91 tended to be associated with low-level resistance. As for gyrB, three (4.4%) of 68 levofloxacin-resistant strains and no susceptible strains had mutations (p = 0.19).

Conclusions: Primary levofloxacin-resistance of H. pylori was not rare in Japan, and related to single or double mutations in gyrA, but not in gyrB.

Considering the burden of adopting a conventional culture method into clinical practice, it may be of great use to examine only gyrA mutations at Asn-87 and Asp-91 with a PCR-based screening in levofloxacin-susceptibility testing against H. pylori.

121 Compliance with Dyspepsia Guidelines: Experience in a Primary Care General Medicine Setting
Leon P. McLean, MD,* David G. Fairchild, MD. Department of Public Health & Family Medicine, Tufts University School of Medicine, Boston, MA and Division of General Medicine, Tufts-New England Medical Center, Boston, MA

Purpose: In 1998 the American Gastroenterological Association (AGA) published guidelines recommending that patients 45 years of age or greater with new-onset dyspepsia be evaluated with upper endoscopy to rule out malignancy. We conducted a study to examine primary-care physician (PCP) compliance with this guideline.

Methods: We reviewed the medical records of 140 patients aged 45 years or older presenting to an urban academic general internal medicine ambulatory clinic with new-onset dyspepsia between 8/2001 and 10/2005 to determine guideline compliance, evaluations and treatment offered. Endoscopy and biopsy results, if available, were also reviewed.

Results: Endoscopy was recommended to 7 patients (5%) at the index visit. The majority of patients (116 [82.8%]) were offered medical therapy. Ultimately, 41 patients (29.2%) went on to receive upper endoscopy and a total of 27 biopsies (65.8%) were performed. One carcinoma (3.7%) was detected at biopsy.

Conclusions: In this academic internal medicine primary care practice, PCP compliance with AGA guidelines for dyspepsia evaluation was extremely low. Further study is required to determine if these findings are generalizable and to identify strategies for improving compliance with dyspepsia guidelines among primary care physicians.

122 Does the Treatment of Tachygastria-Associated Non-Ulcer Dyspepsia Improve Quality of Life?
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Purpose: We have previously shown that the majority of patients (pts) with non-ulcer dyspepsia (NUD) have a motility disorder. Electrogastrographic (EGG) analyses have demonstrated that tachygastria (TG) is the predominant dysmotility seen. This study was done to determine if treatment of TG actually improves quality of life (QOL).

Methods: We prospectively followed 40 pts with TG previously diagnosed with NUD after careful evaluation including a history and physical, labs, imaging studies and endoscopic examinations were all negative. The diagnosis of TG was made using the electrogastrogram unit by EZEM Corp.Pts with bradygastria or mixed patterns were excluded. Pts with TG seen just in the post-prandial phase were treated with anticholinergics (ACh), 30 minutes before meals, that included methscopolamine bromide (Pamine®), a tricyclic agent (TCA) such as desipramine or amitriptyline was used. Finally, a combination of a TCA and ACh was used in pts with baseline TG whose cycles per minute (CPM) were seen to escalate in post-prandial phases. A simple QOL questionnaire was used to determine therapeutic efficacy. Excellent (E) was no symptoms; Satisfactory (S) was a decrease in frequency and/or intensity in symptoms,
iso a pt’s lifestyle was not compromised and Unsatisfactory (U) was persistent symptoms that prohibited a normal lifestyle. **Results:** Of the 40 pts, 32 were female and 8 were male. The age range was 17-90 with a mean age of 50.3 years. The range of follow-up was 4 to 100 wks with a mean follow-up time of 13.3 weeks. 18 pts were in the (E) category; 19 in (S) and 3 in the (U). Of pts experiencing E or S results, 25 received monotherapy and 12 dual therapy (TCA and ACH).

**Conclusions:** 1. ACH and TCA’s improve QOL in pts diagnosed with TG. 2. 92.5% of pts demonstrated a significant improvement in QOL. 3. 45% were in remission. 4. Understanding the type of TG (continuous vs. post-prandial) helps dictate type of therapy. 5. Females are more likely to have TG rather than males (4:1 ratio).

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**Isolated Gastric Malakoplakia – An Extremely Rare Condition:**

**Histological and Symptomatic Resolution after Eradication of Concomitant Helicobacter pylori Infection**

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**Purpose:** A 71-year-old African American man presented with dyspepsia, epigastric discomfort, diarrhea and weight loss for two months. There was no clinical evidence of immunodeficiency or malignancy. Upper gastrointestinal endoscopy revealed mild inflammation in the gastric antrum and body with a 5mm polyp in the body. Examination of the biopsy revealed lamina propria replaced by regular, small, round nuclei with eosinophilic cytoplasm containing Michaelis-Gutmann bodies diagnostic of gastric malakoplakia. A moderate number of Helicobacter pylori like organisms were seen on warthin starry stain. Colonoscopy revealed one cecal and one descending colon tubular adenoma. There was no evidence of malakoplakia or malignancy seen elsewhere. He was treated with lanoseratiazole, amoxicillin and clarithromycin and his symptoms resolved. Repeat gastroscopy after 4 months showed no evidence of malakoplakia or H.Pylori organisms. Malakoplakia is a rare inflammatory process characterized by a mass like accumulation of histiocytes and intracellular Michaelis-Gutmann bodies. It is associated with concomitant diseases such as leukemia, lymphoma, alpha chain disease, immunodeficiency, miliary tuberculosis, villous adenoma and carcinoma. Infectious agents have been implicated as the cause of malakoplakia in the majority of cases. It most frequently involves the urinary tract with the gastrointestinal tract being the second most frequent site. The principal sites involved are the descending colon, sigmoid and rectum. Isolated gastric malakoplakia is an extremely rare diagnosis with only three reported cases in the English literature so far. To our knowledge this is the first case reported showing an extremely rare diagnosis with only three reported cases in the English literature so far. To our knowledge this is the first case reported showing an extremely rare diagnosis with only three reported cases in the English literature so far. To our knowledge this is the first case reported showing an extremely rare diagnosis with only three reported cases in the English literature so far. To our knowledge this is the first case reported showing an extremely rare diagnosis with only three reported cases in the English literature so far.

**Conclusion:** This novel next generation PPI (AGN 201904-Z) results in a long residence time of omeprazole in the blood and more prolonged and more effective gastric acid inhibition than esomeprazole, particularly at night.

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**Metastatic Testicular Choriocarcinoma: an Unusual Cause of Massive Upper Gastro Intestinal Bleeding**

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**Purpose:** Metastatic choriocarcinoma is a rare non-seminomatous germ-cell tumor with characteristic hemorrhagic tendency due to its trophoblastic origin. Gastrointestinal involvement is present in less than 5% of cases. Despite it being a highly curable malignant disease, the occurrence of gastrointestinal bleeding worsens prognosis. We report a case of testicular choriocarcinoma which manifested initially as severe upper GI bleeding from metastatic gastric lesion.

**Case:** A 48 year old white male presented with a history of intermittent hematemesis and melena for 10 days. An upper endoscopy was performed at another hospital and showed gastritis. His melena persisted and was associated with profound fatigue. The patient was transferred to OU Medical Center with a hemoglobin of 4.7 gm/dl. Upon admission the differential diagnosis for his present illness included peptic ulcer disease, Mallory Weiss tear or an A V malformation.

**Clinical course:** Endoscopy revealed a large gastric nodule (2 cm) with ulceration and bleeding was noted in the fundus. In addition several satellite lesions were seen in the body of the stomach. Temporary control of bleeding was achieved with epinephrine injection. He continued to bleed and required multiple blood transfusions and repeated endoscopies. Biopsy of the gastric lesion was performed and the histopathology was consistent with metastatic non-seminomatous germ cell neoplasm with choriocarcinomatous component. Metastatic work up showed multiple lesions in the lungs, liver and brain with primary lesion in the left testicle. Chemotherapy was begun with a combination of bleomycin, etoposide and cisplatin. Gastric metastatic lesions decreased in size and bleeding stopped during the course of chemotherapy.
Discussion: Approximately 50% of patients with testicular germ cell tumors present with metastases. Hematocritosis can be due to metastatic implants in the gastric mucosa or retroperitoneal nodal metastasis eroding into the duodenum. Beta subunit of HCG was present in high titers in this patient due to large tumor burden.

Conclusions: Metastatic testicular germ cell neoplasms are rare causes of acute massive upper gastrointestinal bleeding and should be considered in the differential. Further investigations including serum beta HCG and testicular ultrasound are valuable in establishing the diagnosis and in formulating a treatment plan.

Massive Gastric Necrosis Following Chemoembolization for Hepatocellular Carcinoma
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Purpose: Severe gastric necrosis due to trans arterial chemoembolization (TACE) for HCC has not been previously described to our knowledge.

Methods: Presentation: A 72 yr old man with HCC presented with chest and abdominal discomfort and melena 4 days after undergoing TACE for hepatocellular carcinoma. He was pale but not febrile or orthostatic. Cardiac and abdominal exam was non focal. Rectal exam revealed melenic stool. The hemoglobin had decreased from 13 to 10gm/dl.

Results: Diagnosis: Urgent EGD revealed giant, non bleeding, cratered gastric ulcers, with pigmented material, on the lesser curvature, incisura and posterior wall of the stomach. Biopsies showed extensive necrotic tissue with no malignancy. Abdominal MRI revealed a 5.2 cm mass in the left hepatic lobe similar to pre-chemoembolization images. No free air was seen. Review of the angiography at TACE revealed an aberrant take-off of the left gastric artery from the common hepatic artery, not the celiac artery. This resulted in inadvertent delivery of the chemotherapeutic agent via the left gastric artery to the lesser curvature of the stomach.

Management: The patient was made NPO, treated with high dose PPIs, IV antibiotics, and monitored closely for gastric perforation. He did well on conservative therapy and was discharged on PPIs. Serial endoscopy 1 month and 4 months later documented progressive healing of the necrotic area.

Conclusions: TACE is an increasingly used therapy for patients with HCC. Common side effects are fever, pain, increased serum amylase and transaminase levels. A 5% incidence of non-variceal bleeding after TACE has been reported (1). Gastric necrosis is a previously unreported complication of TACE with potentially significant clinical impact. Aberrant take-offs are a common occurrence (10-40%) in the mesenteric arterial system and physicians should be aware of potential vascular anomalies and use selective cannulization during chemoembolization to prevent gastrointestinal necrosis. Gastrointestinal bleeding after hepatic transcatheater arterial embolization in patients with hepatocellular carcinoma. GIE 1996; 43 (2)132-137.

Retrospective Comparison of Percutaneous Radiologic Gastrostomy (PRG) and Percutaneous Endoscopic Gastrostomy (PEG) Utilization and Complications in a Community Hospital-Clinic System
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Purpose: PRG was an emerging alternative to PEG. This study reports the 46 month experience of gastrostomy tube placement in a single hospital-clinic system.

Methods: All PRG and PEG placed during a 46 month period were retrospectively reviewed and compared for indications, hospital status, co-morbidity, and 30 day complication rates. Complications were categorized as dislodged tube, internal leaking/peritonitis, external leaking, inflammation requiring antibiotics, hemorrhage, occluded tube, surgery, and death from tube placement. PRG were placed by an interventional radiologist. PEG were placed with both a gastroenterologist and a surgeon present. PRG were typically placed in 12-16 Fr tubes. PEG were always 20 Fr tubes.

Results: A total of 126 PRG and 106 PEG were reviewed. Both groups were similar with respect to age, gender, co-morbidity, and inpatient to outpatient ratio. Indications for PRG and PEG, respectively, were Cancer (42.1% vs. 31.1%), Head/Spine Trauma (27.0% vs. 18.9%), CVA (5.6% vs. 15.1%), Other Neurologic Condition (5.6% vs. 14.2%), Bowel Obstruction (4.8% vs. 3.8%), Post-op Complication (6.3% vs. 12.3%), and Other (8.7% vs. 4.7%). The only significant differences between the groups regarding indications were in CVA (p = 0.015) and Other Neurologic Conditions (p = 0.026). In all, 111 PRG and 99 PEG records had adequate follow-up to evaluate complications. No difference in total complications were noted between PRG and PEG (16.2% vs. 9.1%, p = 0.124). No difference was noted in any individual type of complication. Three patients in each group required surgery as a result of a complication (2.7% vs. 3.0%, p = 0.887). No deaths occurred attributable to gastrostomy tube placement. Subgroup analysis of patients receiving gastrostomy tubes for cancer related purposes showed no difference in complications between PRG and PEG (5.5% vs. 17.1%, p = 0.085). However, patients with gastrectomy for non-cancer diagnoses or symptoms unrelated to their cancer showed a higher complication rate in PRG than PEG (26.8% vs. 4.7%, p = 0.001).

Conclusions: In a community hospital-clinic system, PRG and PEG are utilized for similar patients with a preference for Neurologic conditions to receive PEG. While overall complication rates are not different, more complications were noted in patients with PRG placed for non-cancer diagnoses or symptoms unrelated to their cancer. PEG may be safer in this subgroup of patients.

Relationship between P53/VEGF Expression and Gastric Carcinoma
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Purpose: In Order to investigate the relation between P53/VEGF (Vascular endothelial growth factor) expressions and the biological behaviour in gastric carcinoma.

Methods: Human Tissue Specimens and Patien Information: 65 cases with gastric carcinoma were admitted to the Hospital Affiliated of Taian Medical College from Jan. 2004 to Jan. 2006, including 39 males and 26 females. They were aged 36-87 (58.67 ± 9.10). Neither radiotherapy nor chemotherapy were taken in preoperation period. Gastric carcinoma tissue specimens were obtained from normal gastric wall tissues in the same operation. Cancer specimens were classified based on the UICC criteria in the stage of TNM, including well-differentiated adenoma 28 cases, poorly-differentiated 37 cases.

Immunohistochemistry: All the light microscope specimens were fixed with formalin, embedded with paraffin, and sectioned at 5µm. Adopting immunohistochemistry S-P staining method. By the statistical analysis, Scores for percentage of positive cells were assigned as follows: >10% of cells positive.

Weidner Analysis: Vessel count based on the criteria of Weidner. Appearing brown endothelial cells group or endothial cells group account for percentage of positive cells were assigned as follows: "plots" (40 magnification)in tumor interstitium areas. The statistical analysis of P53/VEGF adopted Chi square test, using nonparametric model to statistics analysis date.

Results: There was close correlation between P53 and VEGF expression and clinical pathology characteristics of gastric carcinoma. The expression of VEGF was close correlated to gastric carcinoma expanding, and differentiated degree of tumor cells. The poor-differentiated group expression 64.25% was obvious higher than well-differentiated group. The positive rate of VEGF was 68.26% in P53 positive group of 46 cases with gastric carcinoma tissues.
The positive rate of VEGF was 26.19% in P53 negative group of 17 cases with gastric carcinoma tissue. The former was significantly higher than the latter ($p < 0.01$). The P53 and VEGF positive expression of gastric carcinoma and WVC was significantly higher than negative, There was obvious significance ($p < 0.01$).

Conclusions: In our study, according to investigation of P53 and VEGF in expression of gastric carcinoma tissue. P53 and VEGF expression in gastric carcinoma tissue was close correlated to gastric carcinoma biological behavior.

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The Interobserver Variability among Radiologists in Diagnosing Thickened Gastric Folds on the Upper Gastrointestinal Series
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Purpose: The upper gastrointestinal series (UGI) is sometimes reported as having thickened gastric folds. In this case-control study, we assessed the inter-observer variability among radiologists of different experiences in diagnosing “thickened gastric folds” on the UGI.

Methods: We retrieved 70 UGI films that had a diagnosis of isolated thickened gastric folds from January 1997 to December 2000. We randomly selected 79 control patients who had normal gastric folds on their UGI reports done at the same facility and on the same day. The total of 149 UGI films were independently reviewed by four radiologists with variable experiences. The inter-observer variability among the radiologists was expressed as the percentage agreement and the kappa coefficient.

Results: The case patients were older than the control patients, with mean age of 51.3 versus 46.7 years. In the case group, 51.4% were male versus 29.1% in the control group. For all 149 UGI’s, the percentage agreement among the four participating radiologists was 80%. The kappa coefficient of the four participating radiologists and the original reading was 0.583 ± 0.026, of the four participating radiologists 0.578 ± 0.033, of the two attending radiologists 0.615 ± 0.080, and of the two resident radiologists 0.626 ± 0.081. In the 70 case UGI’s, the percentage agreement was only 62%. The kappa coefficient was 0.126 ± 0.038 for all four radiologists plus the original reading, 0.332 ± 0.049 for the four participating radiologists, 0.469 ± 0.114 for the two attending radiologists, and 0.338 ± 0.114 for the two resident radiologists. In the 79 control UGI’s, the percentage agreement of the four participating radiologists with the original reading was 96%. The kappa coefficient was thought to be inaccurate in the setting of very high agreement.

Conclusions: Radiologists, regardless of their professional experience, tend to agree on diagnosing normal gastric folds but vary significantly in diagnosing thickened gastric folds on the UGI. Radiologists should utilize stricter definitions of thickened gastric folds on the UGI with age and sex of the patients taken into consideration.

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Changes in Clinical Outcome of Patients with Bleeding Peptic Ulcers during the past 10 Years
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Purpose: Bleeding has still remained as one of major medical problems of peptic ulcer diseases, despite the advances of therapeutic options and endoscopic therapy. The mortality rate of peptic ulcer bleeding has remained unchanged, mainly attributable to rebleeding in an increasingly elderly populations. The aim of this study was to compare the clinical outcomes of bleeding peptic ulcer between two distinct periods during the past 10 years.

Methods: We retrospectively obtained data on all patients with acute upper gastrointestinal bleeding from January 1993 to December 2002. We excluded cases of Mallory-Weiss syndrome, variceal bleeding, previous gastric surgery, malignancy of upper gastrointestinal tract, and liver cirrhosis accompanied with varix. We divided the past 10 years into 2 distinct periods, the first period (1993-1995) and the second period (2000-2002). The clinical and endoscopic characteristics in patients with bleeding peptic ulcer were compared between two groups. We also analyzed the changes in the clinical outcomes between two periods.

Results: During this periods, 458 cases of peptic ulcer bleeding were included in the study. The age of the patients during the second period was significantly older than during the first period (50.8 years vs 56.5 years, $p = 0.001$). In subgroup analysis, proportions of patients older than 60 years and of female patients were significantly higher in former period than in the latter period (30.4% vs 43.9%, $p = 0.006$). The percentage of the patients with co-morbid illness, such as diabetes mellitus, cardiovascular diseases, or taking non-steroidal anti-inflammatory drugs, was higher in the second period. The severity of bleeding, assessed by hemoglobin levels at presentation, the amounts of transfusion, and hospital stay, was not different between both groups. The rebleeding rate of peptic ulcer bleeding was not significantly different between both periods (15.5% vs 19.7%, $p = NS$). Also, overall mortality rate and ulcer-related mortality rates were not not significantly different between both periods.

Conclusions: Despite advances in therapeutic options in the second period, significant difference could not be found in the clinical outcomes of bleeding ulcer, compared with the first period. Old age, co-morbid illness, and increased usage of NSAIDs may contribute to it. Taken together, it may be more important to apply preventive measures to the patients with risk factors.

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Gatifloxacin Based Triple Therapy in Third-Line H. pylori Eradication Regimen: A Randomized Controlled Trial
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Purpose: Higher H. pylori eradication rates (92%) were reported with the administration of a 7-day regimen of Gatifloxin (GFLX), amoxicillin (AMX) and rabeprazole (RPZ) (Helicobacter 9:255, 2004). We reported a high resistance rate (47.9%) to GFLX in H. pylori strains from Japanese patients after unsuccessful eradication therapy and significant association between MICs for GFLX equal to or above 1 μg/ml and mutations of the gyrA gene (Antimicrob. Agents Chemother. 50.4:1538, 2006). The present randomized controlled study is designed to examine the efficacy of GFLX-based triple therapy as the third line eradication.

Methods: Nine patients in whom H. pylori isolates were found to be resistant to both clarithromycin (CLR) and metronidazole (MNZ) after first-line or second-line therapy were enrolled (first-line: CLR, AMX, proton pump inhibitor (PPI); second-line: MNZ, AMX, PPI). After informed consent, they were randomly assigned to two groups: (1) RPZ 10 mg q.d., AMX 500 mg q.d. for 7 days (RA, N = 5); (2) RPZ 10 mg q.d., AMX 500 mg q.d. GFLX 400 mg o.d. for 7 days (RAG, N = 4). The MICs of GFLX, CLR and MNZ were determined by the agar dilution method. GFLX-resistance was defined by MICs equal to or above 1 μg/ml. The quinolones-resistance determinant regions of gyrA gene were examined by PCR amplification and sequencing. Successful eradication was confirmed by negative urea breath test at 12 weeks.

Results: The resistance rate to GFLX was 77.8% (7/9). The successful rate for H. pylori eradication was 0% in the RA group and 50% in RAG group. Two of 5 patients who failed with RA therapy then received RAG therapy, one of 2 patients became H. pylori negative after RAG therapy. Eradication
rate by RAG therapy for GFLX-susceptible bacteria was 100%, and for GFLX-resistant bacteria (N = 4) was 25%. Eradication rate by RAG therapy for bacteria without gyrA mutation was 100%, and for bacteria with gyrA mutation was 25%.

Conclusions: To apply GFLX for the choice of the third line eradication treatment of *H. pylori*, the introduction of gyrA gene analysis could be a reliable predicting marker for the successful eradication.

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Serum Pepsinogens as a Marker of Delayed Gastric Emptying

Yoshihisa Urita, Sasumu Ishihara, Kaoru Domon, Tetsuya Okazaki, Tadashi Maeda, Tatsuo Akimoto, Hirohito Kato, Noriko Hara, Yoshiko Honda, Yoko Nagai, Kazushige Nakashishi, Nagato Shimada, Motonobu Sugimoto, Kazumasa Miki.1 Department of General Medicine and Emergency Care, Toho University, Tokyo, Japan; Department of Gastroenterology and Hepatology, Toho University, Tokyo, Japan.

Purpose: Serum pepsinogen (PG) is a known marker of gastric mucosal status, including mucosal atrophy. Very low serum PG1 levels and a low PG1/2 ratio are accurate predictors of severe gastric atrophy. Furthermore, it has been unclear whether delayed gastric emptying (GE) has an association with the PG1/2 ratio are accurate predictors of severe gastric atrophy. Furthermore, it has been unclear whether delayed gastric emptying (GE) has an association with the PG1/2 ratio.

Methods: We therefore analyze the results of serum PG method and 13C-acetate breath test (ABT) for the evaluation of GE. 13C-ABT was performed in 46 subjects, aged 39-87 years. The patients received a liquid test meal containing 100 mg of 13C-acetate in baseline and at 5, 10, 15, 20, 30, 40, 50, 60, 75, 90, 105, 120, 135, 150, 165, 180, 210, and 240 minutes after ingestion to analyze breath 13CO2. 13C was measured as the 13CO2/12CO2 isotope ratio and was expressed as delta over baseline per mil (%). If the time when 13CO2 excretion is the maximum is later than 90 minutes, GE is defined as delayed. Venous blood samples were obtained before ingestion and serum PG1 and PG2 concentrations were measured.

Results: Delayed GE was found in 12 of 32 patients (38%) with a PG1/2 ratio of less than 3, and in 6 of 14 patients (43%) with a PG1/2 ratio of more than 3. Among atrophic gastritis group, all 3 patients who had a PG2 value of less than 15 ng/ml had delayed GE, whereas only one of 7 patients with a PG2 value of more than 15 had delayed GE. For non-atrophic group, 6 of 15 patients who had a PG2 value of less than 15 ng/ml had delayed GE, whereas 2 of 6 patients with a PG2 value of more than 15 had delayed GE.

When a PG1 value was used as a marker, the patient with delayed GE could be identified only when all the food has left the stomach. It has been unknown whether gastric emptying of indigestible solids differs from that of liquid test meal when ingested with together. We investigated gastric emptying and intragastric distribution of a liquid test meal and indigestible solids.

Methods: Eight healthy volunteers with a mean age of 24 years were studied. None had gastrointestinal symptoms. The patients received a liquid test meal (Racol, 200cc, 200kcal) containing 37MBq technetium-99m bound to antimy sulphide colloid and microspheres (mean diameter 0.5mm, range 0.2-1.0 mm) of an ion exchange resin labeled with 37MBq indium-111. The gammacamera had a large field of view head and dual isotope simultaneous scanning was carried out with the gammacamera peaked for 250KeV and 140KeV with 40% and 20% windows to detect the radiation from 111In and 99mTc, respectively. Scanning of the subject began within one minute of completing the meal. Anterior images of 30 seconds each were collected every 15 minutes for 240 minutes. A 'region of interest' was divided into two regions, the corpus and the antrum. A count of amount of radioactivity remaining in the stomach at each time was made and time activity curves were created.

Results: The time for 50% (T1/2) of 99mTc ingested to have emptied from the stomach was 113 ± 31 minutes. That of 111In ingested was 112 ± 25 minutes. For the corpus region, T1/2 values of 99 mTc and 111 In were 71 ± 31 minutes and 75 ± 24 minutes, respectively. For the antrum region, the T1/2 value of 99 mTc was significantly faster than that of 111 In (71 ± 22 v.s. 100 ± 32 minutes).

Conclusions: Microspheres moved dependently and fast from the gastric corpus to the antrum, and were retained in the antrum for longer time. From these results, when ROI was set on the whole stomach, there was no significant difference in gastric emptying between liquid test meals and microspheres.

Role of EUS in Evaluation of Gastric Submucosal Lesions

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Purpose: Gastric submucosal lesions are often seen on routine upper endoscopy. Endoscopic Ultrasound (EUS) is a valuable imaging modality for gastrointestinal submucosal lesions. It is helpful in accurately assessing layer of origin and can differentiate submucosal tumors from extragastric compression as well.

Methods: EUS procedures performed at our center from April 2002 to February 2006 were reviewed. Patients in whom the indication of EUS was endoscopic as well.

Results: 47 patients had EUS done for gastric submucosal lesions. EUS revealed stromal tumor arising from the muscularis propria in 42% (20/47). The size varied from 8 mm to 7 cm. Two patients with tumor size more than 3 cm presented with upper gastrointestinal bleeding. EUS – FNA showed malignant stromal tumor in 3 patients, which was confirmed on surgery. Other findings included pancreatic rest 3, lipoma 3, Dieulafoy 1, submucosal cyst 1, carcinoid 1 and non-specific cellular aggregate in 12 patients. Extrinsic gastric compression was seen in 6 patients (splenic artery 4, left lobe liver 1 and anomalous spleen in 1 patient).

Conclusions: EUS is a useful tool in the evaluation of both benign and malignant gastrointestinal submucosal tumors. External gastric compression mimicking as submucosal lesion, as seen on upper endoscopy can also be readily distinguished by EUS.

Comparison of Gastric Emptying and Intragastric Distribution of a Liquid Test Meal and Indigestible Microspheres Using a Two-Phase Radio-Labelled Scintigraphy

Yoshihisa Urita, Sasumu Ishihara, Kaoru Domon, Taketo Yanagiwara, Ryo Okubo, Takahito Toba, Sei Muraoka, Mai Nawata, Hiromi Igarashi, Yoshihisa Urita, Susumu Ishihara, Kazumasa Miki.1 Department of General Medicine and Emergency Care, Toho University, Tokyo, Japan; Department of Nuclear Medicine, Toho University, Tokyo, Japan and Department of Gastroenterology and Hepatology, Toho University, Tokyo, Japan.

Purpose: The radio-opaque marker method is widely available. Even though these markers do not measure gastric emptying of a meal, they can be employed only when all the food has left the stomach. It has been unknown whether gastric emptying of indigestible solids differs from that of liquid test meal when ingested with together. We investigated gastric emptying and intragastric distribution of a liquid test meal and indigestible solids.

Methods: Eight healthy volunteers with a mean age of 24 years were studied. None had gastrointestinal symptoms. The patients received a liquid test meal (Racol, 200cc, 200kcal) containing 37MBq technetium-99m bound to antimy sulphide colloid and microspheres (mean diameter 0.5mm, range 0.2-1.0 mm) of an ion exchange resin labeled with 37MBq indium-111. The gammacamera had a large field of view head and dual isotope simultaneous scanning was carried out with the gammacamera peaked for 250KeV and 140KeV with 40% and 20% windows to detect the radiation from 111In and 99mTc, respectively. Scanning of the subject began within one minute of completing the meal. Anterior images of 30 seconds each were collected every 15 minutes for 240 minutes. A 'region of interest' was divided into two regions, the corpus and the antrum. A count of amount of radioactivity remaining in the stomach at each time was made and time activity curves were created.

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Interphase FISH as a Biomarker of Gastric Cancer Risk in *Helicobacter pylori* Gastritis and Intestinal Metaplasia

Melissa Oropeza, RN, Scott Stanley, Faisal Jafri, MD, Moftaba Olyae, MD.1 Gastroenterology and Hepatology, University of Kansas Medical Center, Kansas City, KS and Baptist Hospital, Kansas City, MO.

Purpose: Gastric submucosal lesions are often seen on routine upper endoscopy. Endoscopic Ultrasound (EUS) is a valuable imaging modality for gastrointestinal submucosal lesions. It is helpful in accurately assessing layer of origin and can differentiate submucosal tumors from extragastric compression as well.

Methods: EUS procedures performed at our center from April 2002 to February 2006 were reviewed. Patients in whom the indication of EUS was endoscopic as well.

Results: 47 patients had EUS done for gastric submucosal lesions. EUS revealed stromal tumor arising from the muscularis propria in 42% (20/47). The size varied from 8 mm to 7 cm. Two patients with tumor size more than 3 cm presented with upper gastrointestinal bleeding. EUS – FNA showed malignant stromal tumor in 3 patients, which was confirmed on surgery. Other findings included pancreatic rest 3, lipoma 3, Dieulafoy 1, submucosal cyst 1, carcinoid 1 and non-specific cellular aggregate in 12 patients. Extrinsic gastric compression was seen in 6 patients (splenic artery 4, left lobe liver 1 and anomalous spleen in 1 patient).

Conclusions: EUS is a useful tool in the evaluation of both benign and malignant gastrointestinal submucosal tumors. External gastric compression mimicking as submucosal lesion, as seen on upper endoscopy can also be readily distinguished by EUS.
Purpose: The only known marker of increased cancer risk in *H. pylori*-gastritis is intestinal metaplasia (IM) of gastric mucosa, but IM is common and cancer develops in only a fraction. The aim of this study is to identify the biomarker of gastric cancer in patients with *H. pylori*-gastritis and IM.

Methods: Thirty patients without gastric cancer (non-progressors; NP) and forty one patients with gastric cancer (progressors, P) were included in this study. Endoscopic biopsy was performed in antrum with IM and epithelial isolation was done. Array-based comparative genomic hybridization (aCGH) and interphase fluorescence in situ hybridization (FISH) using bacterial artificial chromosome (BAC; 4q32.2, 10q22.1, 18q21.1, 19q12) probes and commercially available probe (9p21) were performed.

Results: aCGH did not show any difference between P and NP. Loss of 4q32.2, 18q21.1, and 19q12 was significantly high P than in NP (p < 0.05). Gain of 10q22.1 was significantly high in P than in NP (p < 0.05).

Conclusions: Interphase FISH with 4q32.2, 10q22.1, 18q21.1, 19q12 BAC probe offers promise as a biomarker of cancer risk in *H. pylori*-gastritis with IM for gastric cancer. [figure1]
Effect of Itopride Hydrochloride on Gastric Emptying in Longstanding Diabetes Mellitus
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Purpose: Delayed gastric emptying (GE) occurs in 30-50% of patients with longstanding type 1 or type 2 diabetes mellitus and may be associated with upper gastrointestinal (GI) symptoms and poor glycemic control. Current therapeutic options are limited. Itopride has been tested in functional dyspepsia (NEJM 2006; 23: 354: 832). The aim of this study was to evaluate the effect of itopride on GE in diabetes.

Methods: Twenty-five patients (20 type 1, 5 type 2; 10M, 15 F; mean age 45.2 ± 2.7 yr; BMI 27.5 ± 0.9 kg/m²; duration 20.2 ± 2.4 yr) were enrolled in a double-blind, placebo-controlled, randomized, crossover trial; 15 had autonomic neuropathy (3.0 ± 0.2). Patients received both itopride (200 mg tid) and placebo for 7 days, separated by 7-14 days. GE was assessed by scintigraphy immediately following each treatment period. Autonomic nerve function (cardiovascular reflex tests) was assessed at enrolment. The test meal comprised 100g ground beef labeled with 20MBq 99mTc-sulfur colloid and 150 ml 10% dextrose labeled with 7MBq 67Ga-EDTA.

Results: There was a trend for itopride to accelerate both solid (p = 0.09) and liquid (p = 0.09) GE. Of the 25 patients, 12 (48%) had gastroparesis (ie delayed solid and/or liquid GE) on placebo and in this group, itopride accelerated liquid (p < 0.05) but not solid (p = 0.39) GE. The magnitude of improvement in GE of liquids (0.11; p = 0.057) was related to GE on placebo (Figure).

Conclusions: Itopride accelerates GE of liquids, and possibly solids, in diabetic gastroparesis, however, the magnitude of this effect appears to be relatively modest and dependent on the basal rate of GE. [figure1]

Mucosal Amplitude Ratio of Temporary EGG (MART) Predicts Outcome of Response to Gastric Electrical Stimulation
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Purpose: Gastric Electrical Stimulation (GES) is an accepted therapy for gastroparesis (GP) with chronic nausea and vomiting. Temporary GES is a new approach applying GES endoscopically via the gastric mucosa. We previously reported that the ratio of frequency to amplitude of the serosal EGG at the time of placement might correlate with outcome of permanent GES. We investigated the hypothesis that the ratio of frequency to amplitude of the mucosal EGG (mEGG) at the time of temporary GES placement might predict outcome to therapy.

Patients: 150 Patients, (119 F, 31 M, mean age 44 yrs) with the symptoms of gastroparesis and Diagnosis: 83 Idiopathic, 41 Diabetic, and 26 Post-surgical underwent temporary GES (TempGES) as previously described (GIE, 2005).

Methods: Patients were assessed with baseline and after 3 days of TempGES in terms of symptoms (Sx) of Vomiting (V), Nausea (N), and GI Total Symptom Score (TSS) The average Frequency (F). Amplitude ratio of the temporary EGG (MART) was calculated and compared with the outcome of Temp GES in (A) and Mucosal (frequency to Amplitude terms of % change of Sx: N, V, and TSS as well as GET by Total Gastric emptying (sum of 1, 2, 4 hour GET). Results were compared by t-test and correlation and reported as mean ± SE.

Results: After 3 days of TempGES, Vomiting score changed from 2.3 ± 0.1 to 0.5 ± 0.1, nausea from 3.3 ± 0.1 to 1.2 ± 0.1, and TSS changed from 14.3 ± 0.3 to 5.3 ± 0.4 (all p < 0.05 by paired t-tests). The correlation of mEGG Frequency alone (p = 0.11) or Amplitude alone (p = 0.33) to V were not significant alone. The correlation of the mucosal frequency to amplitude (MART) significantly correlated with percent change in Vomiting (r < 0.001). Gastric emptying improved in most patients (mean 54%) and MART also correlated with % change in total GET: r = 0.7, p < 0.0001.

Conclusions: We conclude that the use of mucosal recording of the EGG at the time endoscopic mucosal electrode placement (MART) correlates with both symptom and gastric emptying outcomes of Temporary GES. The use of MART may assist in determining which patients with GP may benefit from permanent GES.

Ca2+-Activated K+ Current in Freshly Isolated Pacemaker Cell (Intestinal Cells of Cajal, ICC) in Stomach of Adult Animal
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Purpose: Spontaneous electrical activities (slow waves) are generated by interstitial cells of Cajal (ICC) in gastrointestinal (GI) tract. From ICC, slow waves spread to neighboring smooth muscle cells via gap junctions passively. Through this mechanism, GI smooth muscle produce spontaneous contraction. In this study, we try to isolate non-cultured single ICC and Ca2+-activated K+ current in adult guinea-pig stomach.

Methods: Whole-cell voltage clamp and immunohistochemical study were used.

Results: Single ICC and smooth muscle cells were dissociated by enzyme treatment from guinea-pig antrum and mouse. Single smooth muscle cell show spindle like morphology and have no branch. However, single ICC was discernible from smooth muscle cell for its morphology with many branches. Under confocal microscope, single branched cells expressed c-Kit positive activity. However, normal smooth muscle cells do not express this specific activity under confocal microscope. In tissue level, we also found ICC network and intramuscular ICC which is sensitive to c-Kit in adult guinea-pig stomach. Under K+ rich and 0.1 EGTA pipette solution, ICC produced spontaneous inward pacemaking current (~ 329 ± 107.2 pA, N = 14). When step-depolarizing pulse from −80 to +80 mV was applied at holding potential −80 mV voltage dependent outward current was produced. And spontaneous transient outward current (STOC) was superimposed on each traces. STOC was also observed by application of ramp-hyperpolarizing pulse from +80 to −120 mV at Vh = −60 mV. Both STOC and outward current was significantly affected by tetraethylammonium chloride TEA (2 (5 mM), respectively. TEA 2 mM completely blocked STOC and reduced
outward K+ current to 80% of the control. Inhibitory effect of TEA was observed at whole tested potential ranges in current/voltage (I/V) relationship.

Conclusions: These results suggested that TEA-sensitive Ca2+-activated K+ current is present in freshly isolated ICC in guinea-pig stomach.

The Pharmacokinetics of Pantoprazole Delayed Release Granules Administered by Three Different Methods in Healthy Subjects

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Purpose: A new oral delayed release granule formulation of pantoprazole was developed as an alternative for adult subjects who cannot swallow tablets. The primary objective of this study was to determine the bioequivalence of this new formulation administered by 3 different methods in healthy subjects.

Methods: This was a randomized, open-label, 3-period, crossover, in-patient study in 25 healthy adult subjects aged 18 to 50 years. Each subject received a single 40 mg dose of pantoprazole after at least a 10 hour fast for each of the following administration methods separately by a washout period: 1) granules sprinkled over applesauce; 2) granules mixed with apple juice; 3) granules mixed with apple juice and administered through a nasogastric (NG) tube. Blood samples were collected up to 24 hours post dose and analyzed for pantoprazole levels by a validated LC/MS/MS method. Standard safety evaluations were performed. The PK parameters were estimated using non-compartmental methods. The 90% confidence limits for the test-to-reference evaluations were performed. The one-sided t-test was used to test the null hypothesis that granules formed. The one-sided t-test was used to test the null hypothesis that granules were statistically different from the reference formulation (1:1).

Results: The mean Cmax, AUC, and AUC values were similar for the 3 dosing methods. For Cmax, AUC, and AUC, the 90% CIs for the ratio of the geometric means were within the bioequivalence limits of 80%–125%. Four subjects reported adverse events while on treatment including: headache, diarrhea, bronchitis, increased cough, epistaxis, and local reaction to the NG tube. There were no deaths, serious adverse events, or discontinuations.

Conclusions: Pantoprazole granules administered with apple juice orally or through an NG tube, or with applesauce are bioequivalent. Pantoprazole granules were safe and well tolerated when administered by the above methods.

Identification and Elucidation of Role of Voltage-Dependent Ca2+ Current (VDCC) in Non Cultured and Freshly Isolated Pacemaker Cell (Intestinal Cells of Cajal, ICC) in Stomach of Adult Animal

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Purpose: Electrical slow waves in gastrointestinal (GI) muscles are generated by pacemaker cells, known as interstitial cells of Cajal (ICC). The pacemaker conductance is regulated by periodic release of Ca2+ from IP3 receptor-operated stores, but little is known about how slow waves are actively propagated. We investigated voltage-dependent Ca2+ currents in non-cultured freshly isolated ICC from adult guinea-pig. Methods: Whole-cell voltage clamp and immunohistochemical study were used. non-cultured single ICC was enzymatically dispersed from guinea-pig antrum.

Results: In the presence of nifedipine (1 μM), the peak amplitude and duration of spontaneous inward current were -525 ± 128.4 pA and 3607 ± 662.7 msec, respectively (N = 30). When step-depolarizing pulse from holding potential of -80 mV to +60 mV was applied, inward Ca2+ current was produced -113 ± 14.5 pA. Nifedipine (1 μM) blocked over 90% of the total inward current. Under Ca2+ imaging system, ICC show spontaneous Ca2+ oscillation (F/F0) 0.15 ± 0.029 and 0.156 ± 0.031 in the absence and presence of nifedipine (1 μM), respectively. The frequency of Ca2+ oscillation was 3.96 ± 0.21 and 2.35 ± 0.27 in the absence and presence of nifedipine (1 μM). And 2-aminoethoxydiphenyl borate (2-APB, 100 μM) in the presence of nifedipine (1 μM) blocked spontaneous Ca2+ oscillation in ICC (N = 4).

Conclusions: Dihydropyridine-sensitive L-type Ca2+ channel is prominent in freshly isolated ICC and its function is related to reutilization of spontaneous Ca2+ oscillation. Further IP3-induced Ca2+ pool also tightly linked to spontaneous Ca2+ oscillation in freshly isolated ICC.

Comparison of Pentagastrin-Stimulated Maximum Acid Output in Patients with a History of Erosive Esophagitis Treated with 40 mg of Oral Pantoprazole Granules or Tablets

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Purpose: The objective of this study was to demonstrate the pharmacodynamic (PD) comparability between the 40 mg delayed-release pantoprazole granule and tablet oral formulations.

Methods: This was a multicenter, multiple-dose, randomized, open-label, 2-period, 2-sequence, 9-week crossover study in patients aged 18 to 65 years with gastroesophageal reflux disease (GERD) and a history of documented erosive esophagitis (EE). The primary endpoint was pentagastrin-stimulated maximum acid output (MAO) measured at steady state after once daily dosing for 1 week and 23 hours after the last dose. Basal acid output (BAO) was also measured (hour prior to MAO). Standard safety evaluations were performed. The one-sided t-test was used to test the null hypothesis that granules vs tablet were statistically different from the alternative hypothesis that this difference was < 0 for both MAO and BAO values.

Results: Seventy-six (76) patients were randomized and 60 completed the study. The mean MAO values were 7.11 ± 4.98 and 7.29 ± 4.77 mEq/hr, while the mean BAO values were 0.74 ± 0.91 and 0.58 ± 0.63 mEq/hr for the granules and tablets, respectively. No statistically significant differences between the two formulations in the mean values of MAO and BAO were observed. The two formulations were shown statistically to be pharmacodynamically equivalent in suppressing MAO (p = 0.006). Both formulations of pantoprazole were safe and well tolerated. The adverse events collected for both formulations were similar. There were no serious adverse events.

Conclusions: Both 40 mg oral formulations of pantoprazole (granules and tablets) are pharmacodynamically comparable in their ability to suppress MAO and BAO in patients with GERD and a history of EE. Patients with GERD who are unable to swallow the tablet may safely be prescribed the pantoprazole sodium granules.

Rifaximin, Omeprazole and Levofloxacin for the Treatment of Helicobacter pylori in the Treatment-Naive Population

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Purpose: Helicobacter pylori is an insidious infection with a significant link to gastric carcinoma, lymphoma and peptic ulcer disease and has been designated a WHO class I carcinogen. The prevalence has been estimated at about 70% in developing countries and 30-40% in the United States. Emerging resistance to currently used drugs (eg. metronidazole (28.9%), clarithromycin (10.9%) and amoxicillin (12%)) have become a limiting factor in the success of therapy. Triple therapy with clarithromycin, amoxicillin and a proton pump inhibitor (PPI) has been the gold standard treatment regimen. Rifaximin and levofloxacin have been used individually with good

Conclusions: Dihydropyridine-sensitive L-type Ca2+ channel is prominent in freshly isolated ICC and its function is related to reutilization of spontaneous Ca2+ oscillation. Further IP3-induced Ca2+ pool also tightly linked to spontaneous Ca2+ oscillation in freshly isolated ICC.
success in various trials as salvage therapy for recurrence of H. pylori. We present our own experience with a novel regimen of rifaximin, omeprazole and levofloxacin as first-line therapy for eradication of H. pylori in the treatment-naïve population.

Methods: Patients with dyspeptic symptoms were evaluated by means of upper endoscopy with biopsy and stool antigen testing for H. pylori (Quest Diagnostic Labs, Teterboro, NJ). Stool antigen testing has been proven to be a safe and noninvasive means of detecting H. pylori with high sensitivity and specificity. Twenty patients of diverse ethnic background with stool antigens positive for H. pylori and confirmed histologically were included in this study. Patients with use of a PPI, NSAIDs, ASA or antibiotics in the four weeks preceding detection of H. pylori were excluded. Patients were treated with rifaximin 400 mg, omeprazole 20 mg and levofloxacin 250 mg, all twice daily, for 10 days. Follow-up stool testing for H. pylori was performed after cessation of omeprazole for a minimum of 2 weeks.

Results: Of the twenty patients enrolled that were found to have stool antigen evidence of H. pylori, ten had stools negative for H. pylori on repeat testing after treatment with rifaximin, omeprazole and levofloxacin (50%). Of the twenty patients enrolled, all were able to tolerate the regimen without incident (100%).

Conclusions: Our regimen of rifaximin, omeprazole and levofloxacin had a success rate of 50% in the eradication of H. pylori and may be of limited utility as a first line therapy. It is, however, a well-tolerated regimen and may be better suited as a salvage therapy for recurrence of infection or in those patients who are unable to tolerate the current standard regimen. Further larger studies are needed to evaluate the efficacy of this regimen.

Translocation (11; 18) and Gastric High Grade Lymphoma Risk
Sonia Toracchio, PhD, Daphne de Jong, MD, Andrew Wotherspoon, MD, Massimo Rugge, MD, Hiroyoshi Ota, MD, PhD, David Y. Graham, MD, Hala El-Zimaity, MD.* Dept of Pathology & Medicine, Baylor College of Medicine, Houston, TX; Dept of Pathology, The Netherlands Cancer Institute, Amsterdam, Netherlands; Department of Biomedical Laboratory Sciences, School of Medicine Shinshu University, Matsumoto, Nagano, Japan; Department of Oncological & Surgical Sciences, University of Padova, Padova, Italy and Department of Histopathology, Royal Marsden Hospital, London, United Kingdom.

Purpose: Translocation t (11; 18) (q21; q21) is the most frequent chromosomal aberration in extranodal marginal zone lymphoma of the MALT type. This translocation has been associated with an aggressive course but has not been described in high grade gastric MALT lymphoma. Some authors propose that tumors with this translocation rarely or never progress to high grade lymphomas. However, these conclusions are based on examining few specimens. This study examines the frequency of chromosomal translocation t (11; 18) (q21; q21) in lymphomas from patients with low grade and high grade marginal zone lymphoma of the MALT type.

Methods: We examined paraffin embedded tissue of patients with gastric marginal lymphoma of MALT type. The presence of the t (11; 18) (q21; q21) was determined using reverse transcription-polymerase chain reaction (RT-PCR); B-actin transcript was amplified to ensure specimen adequacy. This study examines the frequency of chromosomal translocation t (11; 18) (q21; q21) in lymphomas from patients with low grade and high grade marginal zone lymphoma of the MALT type.

Results: Twenty percent of patients with gastric MALT lymphoma (39 high-grade MALT lymphomas and 22 low-grade MALT lymphomas) were found to have translocation t (11; 18) (q21; q21). In a subset of 37 patients, the presence of t (11; 18) was confirmed by FISH analysis.

Conclusions: Translocation t (11; 18) (q21; q21) is characteristic of extra nodal marginal lymphomas of MALT type. It was found in both low-grade and high-grade gastric lymphomas of the MALT type at an approximately same frequency. These results challenge the assumptions that this translocation is absent in high grade lymphoma or that the translocation precludes its progression to high grade lymphoma. Testing for the translocation may provide additional prognostic information or help identify a subgroup where close follow is needed.
We circumvented that problem with finger indentation to assess the approximation of the gastric and abdominal walls in the absence of translumination. Furthermore, conventional PEG kits are unsuitable for use in patients with extreme obesity. We used a longer, 18 gauge spinal needle instead of the usual Seldinger needle and performed external abdominal compression to facilitate passage of the spinal needle through the thick abdominal wall. Additionally, we used a jagwire (outer diameter 0.025 cm) instead of the guidewire available in the PEG kit. The jagwire was passed through the spinal needle and it was snared endoscopically. The gastrostomy tube was then mounted on the jagwire, pushed through the oral cavity and pulled out through the abdominal wall.

**Conclusions:** Morbidly obese patients present a specific challenge for PEG placement and our case illustrates a modified method of PEG tube placement in morbidly obese patients using alternative supplies to overcome these challenges.

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**Portal Hypertensive Gastropathy (PHG) Is a Risk Factor for Developing Gastric Polyps**

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**Purpose:** The literature on the prevalence of gastric polyps in patients with portal hypertensive gastropathy is sparse. The prevalence on gastric polyps has been estimated to be relatively low. Very little is known about the prevalence of gastric polyps in patients who have portal hypertensive gastropathy. Elevated portal pressure can induce changes of local hemodynamics, thus playing a role in polyp causing congestion in the stomach and gastric tissue damage. These changes may then activate cytokines and growth factors that may play a role in portal hypertensive gastropathy. The prevalence of gastric polyps in patients who have portal hypertensive gastropathy is sparse. The prevalence rates on gastric polyps have been estimated to be relatively low. Very little is known about the prevalence of gastric polyps in patients who have portal hypertensive gastropathy. Very little is known about the prevalence of gastric polyps in patients who have portal hypertensive gastropathy. The prevalence of gastric polyps in patients who have portal hypertensive gastropathy has been estimated to be relatively low. Very little is known about the prevalence of gastric polyps in patients who have portal hypertensive gastropathy.

**Methods:** 360 Patients who had been diagnosed with PHG endoscopically were randomly selected from our database. This included patients who were diagnosed between January 2000 and November 2005. Patients who were previously diagnosed with gastric polyps were excluded from this group of patients. Another group of 360 patients who served as controls were selected randomly, these patients were matched for age and sex and date of endoscopy. Patients who had prior diagnosis of PHG were excluded. The prevalence rates of gastric polyps were compared.

**Results:** The prevalence of gastric polyps in patients with PHG was 4.72% (17/360), it was slightly more common in males than in females. (6.25% versus 4.14%). The average age of patients with PHG was 52.8. Patients with gastric polyps tended to be slightly older but the difference was not significant. (Average age: 58.8, p = 0.28). Among the control group, the prevalence of gastric polyps was 1.38% (5/360). This finding is highly significant with p value of 0.01. Average age in this population was 52.7. The odds ratio of developing gastric polyps in patients with PHG was calculated to be 3.6. 95% CI = 1.3 to 9.6.

**Conclusions:** Portal hypertensive gastropathy seems to be a risk factor for developing gastric polyps, this may be due to changes in local hemodynamics and possible expression of cytokines and growth factors in the mucosa of these patients. Further studies are needed to elucidate this phenomenon.

<table>
<thead>
<tr>
<th>Portal hypertensive gastropathy and risk of gastric polyps</th>
<th>PHG</th>
<th>Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>360</td>
<td>360</td>
</tr>
<tr>
<td>Average age</td>
<td>52.8</td>
<td>52.7</td>
</tr>
<tr>
<td>Males</td>
<td>225</td>
<td>225</td>
</tr>
<tr>
<td>Females</td>
<td>135</td>
<td>135</td>
</tr>
<tr>
<td>Patients with gastric polyp percentage</td>
<td>5</td>
<td>1.38</td>
</tr>
</tbody>
</table>

*p = 0.01.

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**AGN 201904-Z (AGN), a Novel Enteric-Coated PPI, Produces Greater, More Prolonged Acid Suppression Than Esomeprazole (ESO) in Healthy Male Volunteers**

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**Purpose:** A significant number of patients with acid-related disorders fail to respond adequately to once or even twice daily PPIs due to their short plasma residence time. Thus, there are unmet clinical needs for longer, effective acid suppression. AGN 201904-Z is a new chemical entity, which gives more prolonged blood concentrations of omeprazole due to its novel chemistry to produce prolonged systemic exposure. The rapid conversion to omeprazole results in a prolonged residence time in the blood implying longer effective acid suppression.

**Methods:** A first randomized, open-label, parallel-group, investigator-blinded intra-gastric pH study was performed in 24 healthy H. pylori negative male volunteers. AGN enteric-coated capsules (600 mg, delivering (50 mg molar omeprazole to the systemic circulation) or esomeprazole delayed-release tablets (40 mg) were given once daily before breakfast for 5 consecutive days. Ambulatory 24-h intra-gastric pH was recorded at baseline, and days 1, 3 and 5 of treatment. Subjects maintained a standard diet.

**Results:** See table 1. On day 1, median pH and% time pH ≥4 were significantly higher with AGN than ESO during the nocturnal period (19:00-07:00). At presumed steady state (day 5), both 24-h and nocturnal pH values and% time pH ≥4 were significantly higher for AGN than ESO. AGN provided mean% of nocturnal time with pH ≥4 more than twice as long as ESO. No safety issues were associated with either drug.

**Conclusions:** AGN 201904-Z produced significantly greater and more prolonged acid suppression than esomeprazole and nocturnal acid suppression with AGN was also more prolonged over 5-days use. AGN should provide true once-a-day treatment and better clinical efficacy than current PPIs for the management of acid-related diseases responding poorly to conventional oral PPI therapy.

**Table 1.** Mean (±SD) of median pH and% time pH ≥4 at day 1 and 5 by AGN and ESO

<table>
<thead>
<tr>
<th>Median pH</th>
<th>% Time pH ≥4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>Day 5</td>
</tr>
<tr>
<td>AGN</td>
<td>ESO</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>4.0 ± 1.1</td>
<td>5.6 ± 0.4</td>
</tr>
<tr>
<td>3.1 ± 1.2</td>
<td>4.5 ± 0.7</td>
</tr>
<tr>
<td>4.0 ± 1.0</td>
<td>5.4 ± 0.7</td>
</tr>
<tr>
<td>2.5 ± 1.1</td>
<td>3.0 ± 0.9</td>
</tr>
</tbody>
</table>

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**Simplified Method in Administration of Esomeprazole through Various Feeding Tubes**

Mojgan S. Savabi, MD, Sanjeev K. Bhawot, PharmD, Angie Plummer, RN, Emad Rahmani, MD.* Gastroenterology and Hepatology, Indiana School of Medicine, Indianapolis, IN and Department of Pharmacy Practice, Purdue University, West Lafayette, IN.

**Purpose:** The aim of this study was to determine the percentage of esomeprazole enteric-coated pellets delivered during administration through commonly used feeding tubes by means of a standardized simple technique.

**Methods:** For the purposes of this study, ten esomeprazole 40 mg capsules and five feeding tubes of various sizes and lengths were used:20 F replacement gastrostomy tube,10 F naso-jejunal tube,18 F nasogastric tube,12 F jejunal feeding/gastric decompression tube and a 20 F gastrostomy tube.
Each capsule was opened and the enteric-coated pellets were counted twice by investigator #1. The pellets were then carefully placed back into the capsule. The results of baseline counts were blinded from the other investigators until completion of the study. Next each tube was immersed in 37°C sterile water for 5 minutes and flushed twice with 50cc of sterile water. A capsule was then opened and the pellets were dispersed directly into the tube cap. Immediately afterwards, the tube was flushed with 50cc of either normal saline or sterile water at room temperature. The pellets were then collected using a coffee filter at the end of the tubes. The filters were allowed to dry prior to recounting. The collected pellets were counted twice by investigators #2-4.

**Results:** As shown in Table 1, pellet recount revealed a high percent delivery through all the various tubes. A similar percent delivery was observed with the use of normal saline versus sterile water administration.

### Delivery of Esomeprazole Pellets via Five Different Tubes

<table>
<thead>
<tr>
<th>Size/Type of Tube</th>
<th>Mean Pellet Count</th>
<th>Mean Pellet Delivery</th>
<th>Pellet Count after NS*</th>
<th>Mean Pellet Delivery</th>
<th>% Delivery history (Sterile Water)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 F Replacement Gastrostomy tube</td>
<td>1567</td>
<td>1584</td>
<td>–</td>
<td>95.6</td>
<td></td>
</tr>
<tr>
<td>20 F Replacement Gastrostomy tube</td>
<td>1343</td>
<td>–</td>
<td>1333</td>
<td>99.3</td>
<td></td>
</tr>
<tr>
<td>10 F naso-jejunal tube</td>
<td>1339</td>
<td>1322</td>
<td>–</td>
<td>99.5</td>
<td></td>
</tr>
<tr>
<td>18 F nasogastric tube</td>
<td>1246</td>
<td>1239</td>
<td>–</td>
<td>99.4</td>
<td></td>
</tr>
<tr>
<td>18 F nasogastric tube</td>
<td>1343</td>
<td>–</td>
<td>1321</td>
<td>98.4</td>
<td></td>
</tr>
<tr>
<td>12 F jejunal feeding/gastric decompression tube</td>
<td>1280</td>
<td>1237</td>
<td>–</td>
<td>96.6</td>
<td></td>
</tr>
<tr>
<td>12 F jejunal feeding/gastric decompression tube</td>
<td>1260</td>
<td>–</td>
<td>1224</td>
<td>97.1</td>
<td></td>
</tr>
<tr>
<td>20 F gastrostomy tube</td>
<td>1284</td>
<td>1273</td>
<td>–</td>
<td>99.1</td>
<td></td>
</tr>
<tr>
<td>20 F gastrostomy tube</td>
<td>1290</td>
<td>–</td>
<td>1285</td>
<td>99.6</td>
<td></td>
</tr>
</tbody>
</table>

*Normal Saline.

**Conclusions:** The direct placement of esomeprazole magnesium pellets in various size enteric tubes followed by a 50cc flush of either normal saline or sterile water can effectively deliver virtually all of the contents of a capsule.

### Helicobacter pylori Infection (HP) Is Not Associated with Iron Deficiency in the Adult Population

**Purpose:** About 27% of the US population and 50% of the world population is infected with HP. Uncontrolled case series and epidemiologic studies based on sero-prevalence rates suggest an association between HP infection and iron store depletion. The aim of this study was to investigate the association between HP and iron deficiency with/without anemia in an adult population with negative endoscopic findings.

**Methods:** This was a retrospective review of patients undergoing upper gastrointestinal endoscopy at the Syracuse VA medical center from Jan 2000 to Feb 2003. CLO test and gastric biopsy results were noted in 600 consecutive patients. HP infection was defined by a positive CLO test and/or positive biopsy result. Patient demographics, medication use and alcohol consumption, laboratory data, and endoscopic findings were recorded. Patients with an identifiable cause of iron deficiency at EGD (179), colonoscopy (48) or both (16); celiac disease (3), and bowel surgery (1) were excluded. An additional 14 patients with repeat EGD and HP testing were omitted. Statistical Analysis: Iron deficiency anemia was defined as hemoglobin (Hb) <11.5 in females and Hb <12.5 in males, ferritin <30 and transferrin saturation <29%. Patient characteristics, laboratory data, and prevalence of iron deficiency anemia was compared in groups with and without HP by student t-test, chi-square and Fisher exact test.

**Table 1.** Patient characteristics in groups with and without HP

<table>
<thead>
<tr>
<th>HP Positive (N = 68)</th>
<th>HP Negative (N = 271)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age ± SE</td>
<td>62.3 ± 10.4</td>
</tr>
<tr>
<td>Males%</td>
<td>97</td>
</tr>
<tr>
<td>Caucasians%</td>
<td>85</td>
</tr>
<tr>
<td>Alcohol Use</td>
<td></td>
</tr>
<tr>
<td>None%</td>
<td>60</td>
</tr>
<tr>
<td>Moderate%</td>
<td>35.4</td>
</tr>
<tr>
<td>Excess%</td>
<td>4.6</td>
</tr>
<tr>
<td>Medications</td>
<td></td>
</tr>
<tr>
<td>ASA/NSAID%</td>
<td>66</td>
</tr>
<tr>
<td>PPI%</td>
<td>39.7</td>
</tr>
<tr>
<td>Warfarin%</td>
<td>4.4</td>
</tr>
</tbody>
</table>

*p < 0.05
Results: 339 patients (68 HP positive and 271 HP negative) were included in the final analyses. The HP negative group had significantly more Caucasians and higher use of PPI (Table 1). Hb, serum ferritin level and prevalence of iron deficiency anemia in both groups was similar (Table 2).

Conclusions: In adults with negative endoscopic findings, *H. pylori* infection is not associated with iron deficiency.

Table 2. Comparison of laboratory data

<table>
<thead>
<tr>
<th></th>
<th>HP Positive</th>
<th>HP Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Hb ± SE</td>
<td>14.3 ± 1.7</td>
<td>14.0 ± 1.9</td>
</tr>
<tr>
<td>Serum Ferritin &lt;30 (%) §</td>
<td>6.25</td>
<td>22.2</td>
</tr>
<tr>
<td>Serum Ferritin 31-100 (%) §</td>
<td>31.2</td>
<td>29</td>
</tr>
<tr>
<td>Iron Deficiency Anemia%</td>
<td>2.9</td>
<td>7.4</td>
</tr>
</tbody>
</table>

*p < 0.05, § data on 32 pts in HP positive group and 117 in HP negative group.

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The Impact of Nutrition Ground Rounds on the Knowledge and Opinion of Internal Medicine Residents Regarding PEG

Hutef Massoumi, MD, Dommad Pandey, MD, Edward Norkus, PhD, Nejat Kiyici, MD, Hilary Hertan, MD, FACG. Department of Gastroenterology and Clinical Nutrition, Our Lady of Mercy Medical Center, Bronx, NY.

Purpose: Percutaneous Endoscopic Gastrostomy (PEG) has been performed frequently to provide nutritional support in patients unable to feed by mouth. The usefulness of this type of nutritional support has been debated especially in patients with advanced dementia. However, gastroenterologists have been frequently asked by primary care physicians to perform PEG in demented patients. The aim of our study was to evaluate the effect of teaching sessions on the awareness and opinion of medical residents regarding PEG.

Methods: A series of evidence based nutrition grand round lectures including sessions on PEG was given by the division of gastroenterology and clinical nutrition. A survey was distributed among Internal Medicine Residents to assess their personal opinion and overall knowledge about PEG, prior to the conferences. Residents were asked whether they recommend PEG for their demented patients who are unable to eat by mouth. Residents were also asked to answer questions regarding indications, contraindications, benefits, side effects and ethical aspects of PEG. A second survey was done 2 weeks after the grand rounds and the results of these two surveys were compared.

Results: A total of 34 medical residents (56% male and 44% female) participated in the study. The opinions of residents were not different between residents who had been positive at baseline had a negative result at follow up. There were no adverse events. Patients reported 100% compliance.

Conclusions: Although slightly lower than standard therapy, our 73% eradication rate suggests that levofloxacin may be an alternative to be considered as a first line therapy in *Helicobacter pylori* infection. Once a day dosing and improved patient tolerability would be expected to improve patient compliance and decrease the number of patients who fail to complete therapy due to the usual gastrointestinal side effects experienced with clarithromycin.

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Once-Daily Levofloxacin for Eradication of *Helicobacter pylori*

Alvaro Reymunde, MD,* Victor Torres, MD, Nilda Santiago, MD. Gastroenterology, Ponce Gastroenterology Research, Ponce, PR.

Purpose: To evaluate the efficacy of once a day levofloxacin in combination with amoxicillin and proton pump inhibitor in eradication of *Helicobacter pylori*.

Methods: Patients without previous treatment for *Helicobacter pylori* who tested positive by 13C urea breath test were started on levofloxacin 750 mg QD, amoxicillin 1000 mg BID and lansoprazole 30 mg BID for 7 days. Patients returned 4 weeks after therapy for follow up breath test to assess eradication.

Results: A total of 30 patients (17 female, 13 male) were enrolled in the study. Mean age was 54 years old. Twenty -two of the 30 patients (73%) who had been positive at baseline had a negative result at follow up. There were no adverse events. Patients reported 100% compliance.

Conclusions: Although slightly lower than standard therapy, our 73% eradication rate suggests that levofloxacin may be an alternative to be considered as a first line therapy in *Helicobacter pylori* infection. Once a day dosing and improved patient tolerability would be expected to improve patient compliance and decrease the number of patients who fail to complete therapy due to the usual gastrointestinal side effects experienced with clarithromycin.

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Dysmotility Related Non-Ulcer Dyspepsia Is More Common Than Functional Non-Ulcer Dyspepsia

Charles Randall, MD,* Anson Liu, Carlo Taboada, MD, Russell Havrnek, MD, Franz Zurita, MD, Jamesha Craig, CORT. Research, Gastroenterology Clinic of San Antonio, San Antonio, TX; Medicine, University of Texas Health Science Center at San Antonio, San Antonio, TX and GERSA, Gastroenterology Research of San Antonio, San Antonio, TX.

Purpose: Non-ulcer dyspepsia (NUD) is a problem frequently seen in the clinics. The common perception is that NUD is a functional bowel disorder. We have shown previously that motility disorders were common in patients presenting with dyspepsia. In this study we performed electrogastrography to determine the incidence of dysmotility in patients with a diagnosis of NUD.

Methods: 44 patients diagnosed with NUD following evaluations that included a history and physical, laboratory analysis, imaging and endoscopic examinations underwent electrogastrograms (EGG®; EZEM Corp.). Motility patterns were judged as normal (2.5-3.75 CPM (”contractions per minute)), tachygastria (TG: 3.75 -10 CPM), bradygastria (BG: 1.0 – 2.5 CPM) or mixed (combination of BG or TG).

Results: 29 pts had a tachygastria pattern; 7 had a normal pattern; 5 had a mixed pattern and 3 demonstrated bradygastria.

Conclusions: 1. Motility disorders are by far more common than normal motility patterns in NUD (64% vs. 16%).

2. Tachygastria is the most common dysmotility in NUD (66%).

3. Knowing the motility pattern of NUD patients should allow prompt treatment decisions.

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Gastroparesis: A Retrospective Study of Patients in a Private Practice Setting

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Purpose: To study the relationship of demographic factors and medical conditions related to gastroparesis.

Methods: Retrospective study of all patients undergoing gastric emptying scan in a private practice setting from January 1, 2005 to April 30th, 2006 was done after obtaining an IRB approval for the study from Mercer University School of Medicine. The demographic data collected consisted of age, gender, ethnicity, medications on, presence of Diabetes Mellitus, gastro esophageal reflux disease (GERD), prior abdominal surgery, gastric emptying time.
Results: 105 patients underwent nuclear gastric emptying scan, of which 88 were normal and 17 were abnormal with gastric emptying time of 90 minutes or more. Gastric Bezoar was present in one patient in normal gastric emptying group but none in the gastroparesis group. 23 patients had gastric emptying time of 60 minutes or longer in the normal gastric emptying group and 19 of the 23 were females.

The data collected is shown in the table below.

Conclusions: All 17 patients with gastroparesis were females but among the 88 patients with normal stomach function 81% (71 of 88) were female suggesting a higher prevalence of gastroparesis among women compared to men (p = 0.068, Fisher’s exact test). The gastroparesis had highest incidence in age group of 51-60, and majority were whites. The factors of age, race, unresponsive GERD to Proton pump inhibitors (PPIs), presence of Diabetes Mellitus, medications on and prior abdominal surgery were not significantly related to gastroparesis. Symptoms of pain, nausea, early satiety and diarrhea though present in both groups, but were insignificant statistically. Statistical trend was identified for female gender and gastroparesis. Though gastric emptying time of less than 90 minutes were considered normal, there is a preponderance of female gender with gastric emptying in the upper limits of normal, consistent with the abnormal group.

Data: Gastroparesis Vs. normal gastric emptying

<table>
<thead>
<tr>
<th></th>
<th>Gastroparesis Patients</th>
<th>Normal Gastric emptying</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex Distribution</td>
<td>17 females/0 males</td>
<td>71 females/17 males</td>
</tr>
<tr>
<td>Unresponsive GERD</td>
<td>9 positive/8 negative</td>
<td>47 positive/41 negative</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>4 positive/13 negative</td>
<td>21 positive/67 negative</td>
</tr>
<tr>
<td>Prior Abd. Surgery</td>
<td>13 positive/4 positive</td>
<td>56 positive/32 negative</td>
</tr>
</tbody>
</table>

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Investigation of Sensory Properties and Accommodation Responses in Symptomatic Diabetic Gastroparesis

Ashok Attaluri, MD, Anjana Kumar, MD, Syed Hashmi, Konrad Schulze, MD, Satish S.C. Rao, MD.* Internal Medicine/GI Division, University of Iowa Carver College of Medicine, Iowa City, IA.

Purpose: Diabetic gastroparesis is often associated with symptoms that are not explained by delayed gastric emptying alone. Our aim was to simultaneously evaluate the biomechanical and sensory responses of the stomach in diabetic gastroparesis.

Methods: We performed intermittent, phasic balloon distention of the stomach after placing a gastric barostat in 18 diabetic patients with symptomatic gastroparesis (% retention at 120 minutes: 63.8 ± 9.2%). We compared the biomechanical, sensory and accommodation responses of the stomach in the fasting state and after a liquid meal and with 12 healthy volunteers.

Results: Fasting gastric tone in diabetics was not significantly different to controls (Table, p > 0.05). However, post-prandial gastric tone (accommodation response) was impaired in almost all (94%) diabetics (Table, p < 0.05). In the fasted state, 55% of diabetics had gastric hypersensitivity and post-prandially all were hypersensitive (Table, p < 0.05). Gastric hypersensitivity or impaired accommodation did not correlate with the severity of upper GI symptoms (p > 0.05), possibly due to a Type II error.

Conclusions: Diabetics with upper GI symptoms and delayed gastric emptying demonstrate impaired accommodation, gastric hypersensitivity or both dysfunctions. An objective evaluation of sensory and accommodation responses may not fully explain symptoms but may provide valuable mechanistic insights and possibly guide therapy.

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Motility Patterns Associated with Symptoms of Delayed Gastric Emptying

Charles Randall, MD.* Anson Liu, Carlo Taboada, MD, Russell Havranek, MD, Franz Zarita, MD, Jamesha Craig, CORT. Research, Gastroenterology Clinic of San Antonio, San Antonio, TX; Medicine, University of Texas Health Science Center at San Antonio, San Antonio, TX and GERSA, Gastroenterology Research of San Antonio, San Antonio, TX.

Purpose: Common complaints seen in the outpatient clinics include epigastric bloating, distention, nausea and early satiety. These symptoms are often present post-prandially and are suggestive of delayed gastric emptying or gastroparesis (GP). This study was designed to determine gastric motility patterns in these patients.

Methods: 54 patients presenting with symptoms compatible with GP underwent necessary radiographic and endoscopic evaluations to exclude mechanical obstruction. All patients then had an electrogastrogram (EGG®, EZEM Corp.) to determine their gastric motility pattern. Motility was judged as tachygastria (TG: 3.75 - 10 CPM (*contractions per minute)); normal (2.5 - 3.75 CPM); mixed (both TG and BG); and Bradygastria (BG: 1.0 - 2.5 CPM).

Results: 34 patients had tachygastria; 6 were bradygastric; 8 had mixed patterns; and 6 were normal.

Conclusions: 1. Tachygastria is the most common motility disorder in this patient population (56%).
2. Clinicians should be aware that prokinetics might worsen symptoms in these patients.
3. 89% of patients had an abnormal motility pattern.
4. Only 11% demonstrated normal motility.

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Chronic Gastric Volvulus

Rangan Murali, MD, Benjamin Go, MD, Bashar M. Attar, MD, FACP.* Gastroenterology, John H. Stroger Hospital of Cook County and Rush University, Chicago, IL.

Purpose: Gastric volvulus is an uncommon condition. Acute gastric volvulus is a medical emergency. But chronic gastric volvulus is associated with mild and non specific symptoms. It is likely that substantial cases of chronic volvulus are unrecognized. There are only a few case reports on chronic gastric volvulus.

A 92 year old lady with past medical history of well controlled diabetes, hypertension, and obesity presented with epigastric discomfort, nausea and retching for two weeks. She vomited once, two days prior to admission. No weight loss. Patient used to get similar symptoms once in a few months which were relieved in less than 24 hours with OTC H2 receptor blocker (ranitidine). Seven years ago she was told that she had volvulus of the stomach which was relieved in less than 24 hours with OTC H2 receptor blocker (ranitidine). Seven years ago she was told that she had volvulus of the stomach which needed to be corrected. She never had CT chest or barium swallow. A chest x-ray which was done to rule out pneumonia revealed a large gastric air shadow in the chest. She refused any intervention at that time. On exam there was mild epigastric tenderness. Basic lab values including lipase were normal. Patient had an upper Endoscopy which showed twisting of gastric
folds at 4 cms from the GE junction and the endoscope could not be advanced beyond. The CT scan of the abdomen and chest showed the entire body and the pylorus of the stomach was in the posterior mediastinum. Barium study showed good gastric emptying without any obstruction. Chronic gastric volvulus is treated in the same manner as acute volvulus. Endoscopic detorsion by alpha loop technique with gastrectomy by placing a PEG tube or laparoscopic reduction of the volvulus with gastrectomy are the treatment options. Endoscopic and laparoscopic treatment options were discussed with the patient. Patient’s symptoms improved without any specific treatment and she refused any intervention. Eight months after the presentation patient is asymptomatic and a chest x-ray showed intrathoracic stomach. The clinical course of chronic gastric volvulus is variable and it may be asymptomatic for long duration.

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**Hypergastrinemia and ECL. Cell Proliferation Are Independent Factors Associated with Elevated Ghrelin Production in Patients with Neuroendocrine Tumors**

**Hank S. Wang, MD, David S. Oh, MD, Gordon V. Ohring, MD, Joseph R. Pisegna, MD.** Medicine, UCLA, Los Angeles, CA and Gastroenterology and Hepatology, Veterans Administration GLAHS, Los Angeles, CA.

**Purpose:** Ghrelin has been shown to be produced by neuroendocrine cells, including enterochromaffin-like (ECL) cells. Ghrelin is known to correlate negatively with weight and is therefore elevated in anorexia nervosa and decreased in obesity. Previously, we have shown that patients with neuroendocrine tumors (NETs) have elevated levels of ghrelin that positively correlated with body mass index, suggesting that elevated endogenous ghrelin helps to maintain weight despite widely disseminated disease. In this study, we evaluate hyperplastic changes in neuroendocrine cells. Hypergastrinemia, due to either prolonged proton pump inhibitor use or due to Zollinger-Ellison syndrome, is known to cause endocrine cell growth primarily due to ECL cell proliferation. We hypothesized that patients with elevated levels of gastrin would have greater levels of mean ghrelin and greater mean BMI as compared to matched controls.

**Methods:** The study was conducted as a single-center, prospective trial enrolling 30 patients with NETs, including 15 patients with and without hypergastrinemia. Total ghrelin levels and chromogranin A (CgA) values were measured and analyzed for differences by t test \((p < 0.05)\). Patients with hypergastrinemia were paired with control patients without hypergastrinemia whereby all other variables including type of NET, disease state, tumor burden, and history of previous treatments were matched between the two groups.

**Results:** Patients with hypergastrinemia had greater mean ghrelin levels (591 pg/ml versus 386 pg/ml), greater mean CgA levels (540 ng/ml vs 226 ng/ml) and greater mean BMI (27.4 kg/m² vs 26.0 kg/m²) compared to those without hypergastrinemia. Mean ghrelin differed significantly between the two groups while no statistically significant difference was observed between body mass index or chromogranin A levels. A positive correlation is seen between ghrelin and BMI in both patients with and without hypergastrinemia. Mean ghrelin differed significantly between the two groups while no statistically significant difference was observed between body mass index or chromogranin A levels. A positive correlation is seen between ghrelin and BMI in both patients with and without hypergastrinemia. Mean ghrelin differed significantly between the two groups while no statistically significant difference was observed between body mass index or chromogranin A levels. A positive correlation is seen between ghrelin and BMI in both patients with and without hypergastrinemia. Mean ghrelin differed significantly between the two groups while no statistically significant difference was observed between body mass index or chromogranin A levels. A positive correlation is seen between ghrelin and BMI in both patients with and without hypergastrinemia. Mean ghrelin differed significantly between the two groups while no statistically significant difference was observed between body mass index or chromogranin A levels. A positive correlation is seen between ghrelin and BMI in both patients with and without hypergastrinemia. Mean ghrelin differed significantly between the two groups while no statistically significant difference was observed between body mass index or chromogranin A levels. A positive correlation is seen between ghrelin and BMI in both patients with and without hypergastrinemia.

**Conclusions:** Patients with hypergastrinemia have elevated levels of ghrelin compared to those without when all other variables are controlled. This finding suggests that ECL cell proliferation secondary to hypergastrinaemia leads to increased ghrelin production. In these patients, ghrelin was noted to exert an orexigenic effect as increasing levels of ghrelin correlated positively with increasing body mass index.
Table 2. Comparison of laboratory data

<table>
<thead>
<tr>
<th>Endoscopist Impression</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malignant vs Benign</td>
<td>6 (4.5) vs 128 (95.5)</td>
</tr>
<tr>
<td>Size</td>
<td></td>
</tr>
<tr>
<td>&lt;6 mm vs 6-9 mm vs &gt;9 mm</td>
<td>30 (22.4) vs 11 (8.2) vs 56 (41.8)</td>
</tr>
<tr>
<td>Location</td>
<td></td>
</tr>
<tr>
<td>Cardia/Fundus/Body vs Antrum/Pylorus</td>
<td>39 (29.1) vs 95 (70.9)</td>
</tr>
<tr>
<td>Biopsy</td>
<td></td>
</tr>
<tr>
<td>Malignant vs Benign vs Not done</td>
<td>0 (0) vs 99 (73.9) vs 35 (26.1)</td>
</tr>
<tr>
<td>CytoLOGY</td>
<td></td>
</tr>
<tr>
<td>Malignant vs Benign vs Not done</td>
<td>0 (0) vs 21 (15.7) vs 113 (84.3)</td>
</tr>
<tr>
<td>Hp status</td>
<td></td>
</tr>
<tr>
<td>Positive vs Negative vs Not tested</td>
<td>26 (19.4) vs 76 (56.7) vs 32 (23.9)</td>
</tr>
</tbody>
</table>

GU were unhealed in 43% (58) at a median of 2.8 mos (1-49 mos). In trasonic ultrasound a cancer was detected on FU (Index EGDB: no bx/cytology, benign endoscopist impression). Univariable analysis showed that baseline GU size (p = 0.04), antral/pyloric location (p = 0.028) and Hp + on FU EGD (p = 0.008) were predictors of non healing but not age, gender, pathology, endoscopists impression of malignancy, indication for EGD or time between EGDs. Multivariable analysis showed that only GU size > 9 mm vs <6 mm (OR 3.00, 95% CI 1.15-7.80, p = 0.02) and antral/pyloric vs other location (OR 2.11, 95% CI 0.88, 5.05, p = 0.094) predicted nonhealing. No cutoff point for time between index and FU EGD was predictive of healing (area under the ROC curve is 0.53).

Conclusions: ACG guidelines for GU are not followed universally. Only large size but no other endoscopic or patient related factor can predict healing or the presence of gastric cancer. If bx/cytology is not obtained on index EGD, FU EGD should be done to confirm healing.

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Is Intragastric pH Control Maintained over Time on Constant High Dose Proton Pump Inhibitor (PPI)? A Retrospective Pilot Study

Olufunmilayo Olugbesan, MD, Sherry Pomerantz, PhD, Philip O. Katz, MD, *Medicine, Albert Einstein Medical Center, Philadelphia, PA and Medicine, UMDNJ-SOM, Stratford, NJ.

Purpose: Relapse of GERD symptoms and erosive esophagitis is seen in a substantial minority of patients on stable long-term doses of PPI. The reason for relapse and the relationship to maintenance of intragastric pH control over time is not known. No study has systematically investigated intragastric pH control in long-term use (over 30 days) of stable doses of PPI (tachyphylaxis)?

Aim: To evaluate maintenance of intragastric pH control during long-term steady state PPI therapy.

Methods: Retrospective single center database review. Data from dual channel ambulatory pH monitoring (24 hour) performed with pH electrodes 5 cm above the lower esophageal sphincter; and 15 cm below the esophageal electrode and gastric fundus were reviewed. Data from individuals with at least 2 consecutive pH studies on a constant dose of PPI for >28 days were selected. All patients were required to be on 7 days of PPI prior to the pH studies to achieve steady state dosage during testing. Individuals on H2 blocker and PPI, pediatric population, escalating doses of PPI and concurrent motility agent therapy were excluded. Patients were completely de-identified. Upper GI symptoms were recorded at the onset of the pH studies as is standard in our lab. Percent time pH <4 was recorded for upright, supine and total. Difference in mean% time pH <4 was calculated between first and second study. Two tailed paired T tests were calculated (p < 0.05 significant).

Results: 17 study patients met inclusion criteria: scleroderma (n = 11), heartburn (n = 5), and chest pain (n = 1). Patients were either taking lansoprazole or omeprazole at least twice daily. Duration of therapy ranged from 2-25 months (mean 10.7). The mean difference in% time gastric pH < 4 increased from study one to two: (15.79%; CI: 1.03 - 30.56; p = 0.038). There was also a trend towards decrease in pH control in the second study for total time pH <4 (mean difference 9.42%; CI 0.92 - 19.78; p = 0.07). There was no significant difference in mean% time gastric pH < 4 upright.

Conclusions: This pilot study suggests that there may be a fall off in efficacy of PPI in acid control as assessed by intragastric pH while patients are supine. Whether this represents true “tachyphylaxis” will require a prospective study. The clinical implication of these data remains to be established.

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Comparative Efficacy of Rabeprazole and Pantoprazole in the Control of Nocturnal Gastric Acid Output and Intragastric Acidity—A Randomized, Two-Way Crossover Study

Hank S. Wang, MD, David S. Oh, MD, Gordon V. Ohning, MD, Jose Nieto, MD, Phuang Tien, MD, Joseph R. Pisegna, MD, *Medicine, UCLA, Los Angeles, CA and Gastroenterology and Hepatology, Veterans Administration GLAHS, Los Angeles, CA.

Purpose: Rabeprazole and other proton pump inhibitors (PPI) have been shown to be highly effective in the treatment of gastro-esophageal reflux disease (GERD). However, there has never been a rigorous investigation as to the comparative ability of PPIs when taken as per FDA label to control night-time GERD. In this study, we sought to evaluate the relative efficacies of rabeprazole and pantoprazole in controlling nocturnal gastric acid secretion.

Methods: The study was conducted as a double-blinded, randomized crossover study enrolling 23 patients with a history of GERD without previous PPI treatment. The patients first underwent a baseline 12 hour overnight gastric analysis (2000 to 0800) whereby 30 minute samples were collected and assessed for acid output and intragastric pH. The subjects were randomized into 1 of 2 groups to receive either rabeprazole 20 mg or pantoprazole 40 mg on the morning of the next visit (Treatment 1). At that time, a second gastric analysis was completed in the above fashion. Following a 4 week washout, the subjects were given the other study drug (Treatment 2) and a third gastric analysis was completed. Acid output was determined using the titration method. Nocturnal acid breakthrough (NAB) was defined as persistence of gastric pH < 4 for greater than 1 hour between the hours of 22:00 and 06:00.

Results: Rabeprazole achieved greater evening and nocturnal acid control compared with pantoprazole (median pH: 4.2 vs 3.9; mean time pH > 4: 5.5 vs 4.5 hours; NAB 50% vs 67%). A significantly greater percentage of patients on rabeprazole maintained an intragastric pH greater than 4.0 for more than 6 hours compared to pantoprazole (47% vs 27%). Rabeprazole achieved greater acid output control compared to pantoprazole (mean acid output: 78 vs 1.18 mEq/hr (p < .005); mean percentage of time acid output < 2: 92% vs 78%).

Conclusions: Rabeprazole achieved significantly greater control of evening and night-time acid output, suggesting that it is a highly effective treatment for night-time GERD. In addition, a significantly greater percentage of patients on rabeprazole maintained an intragastric pH > 4 for more than half the study time with fewer incidences of NAB. These results demonstrate for the first time that control of nocturnal gastric acid secretion can be improved with rabeprazole compared to pantoprazole.

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The Risk of Bleeding for Percutaneous Endoscopic Gastrostomy Procedure in Patients with Aspirin

Mark Coronel, MD, Kenneth Banner, MD, Samuel Davidoff, MD, Prasun K. Jalal, MD, Simmy Bank, MD, *Division of Gastroenterology, Long Island Jewish Medical Center - Albert Einstein College of Medicine, New Hyde Park, NY.

Purpose: The incidence of bleeding following the placement of a percutaneous endoscopic gastrostomy (PEG) tube has been reported as 2.5%. Aspirin is increasingly being used for associated co-morbid conditions in
patients requiring PEG placement. The aim of the study is to determine the risk of bleeding for PEG tube placement in patients with aspirin.

**Methods:** The records of 596 consecutive patients who had a PEG procedure as an inpatient were reviewed retrospectively. The incidence of bleeding was noted in patients who remained on aspirin or received aspirin within 5 days before the procedure (Group A) and compared with patients who did not receive aspirin or in whom aspirin was stopped more than 7 days prior (Group B). The primary outcome was overt bleeding within 48 hours, and secondary outcomes were drop of hemoglobin by 2 grams, any requirement of blood transfusion, or intervention including endoscopy, during the hospital stay. Fisher’s exact test was used to calculate the difference between the groups.

**Results:** 42 patients were excluded due to discharge within 48 hours of the procedure. Out of 554 patients, 190 (34.3%) patients were included in group A (Ages 27-98, median 79), and 364 (65.7%) were in group B (Ages 22-100, median 78). Bleeding was seen in 15 (2.7%) patients; 11 (5.8%) in group A, and 4 (0.01%) in Group B (p value = 0.004). Among patients with bleeding, 3 patients in group A and 1 in group B were on coumadin (INR 1.8-2.2). In addition, 3 patients in Group A and 1 patient in group B were on clopidogrel. The risk of bleeding on aspirin remained statistically significant (p < 0.05) even after excluding patients with bleeding who had been on clopidogrel or coumadin. Bleeding patients were managed by stopping the respective drugs, transfusion (required in 2 patients, 1-3 units of pRBC), and 3 patients in group B required intervention with endoscopic therapy or gastric artery embolization. None of the patients in either group died from bleeding related complications.

**Conclusions:** In this study, aspirin increased the risk of bleeding in patients undergoing PEG procedure compared with patients who were not on aspirin. However, the absolute risk of bleeding on aspirin following PEG placement was small and all cases were managed without endoscopic intervention. Concomitant use of coumadin or other anti-platelet agents further increased the risk of bleeding.

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**High-Frequency Gastric Electrical Stimulation (GES) Is Effective in Treatment of Patients with Chronic Functional Nausea and Vomiting and a Normal Gastric Emptying**

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**Purpose:** Previous reports have shown that long-term GES can improve symptoms and quality of life in up to 70% of patients with refractory gastroparesis. The aim of this study was to investigate the effectiveness of GES (Enterra™ Therapy) in patients with symptoms suggestive of gastroparesis but who had a normal gastric emptying and were given the diagnosis of functional nausea and vomiting not responding to standard approaches.

**Methods:** We studied 16 such patients (3M, 13F, median age: 39 years, 5 diabetic and 11 idiopathic) who had a documented normal baseline 4-hr gastric emptying test (GET) (normal value at 4 hrs <10% gastric retention) and received GES therapy for at least 1 year. The GET, total symptom score (TSS) derived from 7 upper GI symptom sub-scores (0-4), quality of life (QOL) using SF-36 Health Status Survey including physical composite score (PCS) and mental composite score (MCS) and nutritional status were generated to optimize sensitivity and specificity for differentiating gastroparetic patients from subjects with normal gastric emptying for the percent retention (%R) at 2, 3, and 4 hours imaging time. The concordance statistic (c-statistic) denoting the area under the ROC curve was used for a global measure of diagnostic utility.

**Results:** Based on the normal range of gastric retention established at University of Kansas Medical Center, i.e., 60% or less, 28% or less, and 10% or less at 2, 3 and 4 hours, respectively, the c-statistic for%R at 4 hours (c = 0.954) is greater than that either at 2 hours (c = 0.598) or at 3 hours (c = 0.643). The currently used cutoff points for%R at 10%, 28%, and 60% at 4, 3, and 2 hours give a sensitivity and specificity of 100% and 90.9%, 47.8% and 80.7%, and 52.2% and 67.5%, respectively.

**Conclusions:** Extending GE scintigraphy with a low fat meal from 2 to 4 hours detects more patients with delayed GE. GE data at 3 and 4 hours have advantages over 2 hours, but GE at 4 hours is the best time point for detection of delayed GE or gastroparesis in this patient population.

<table>
<thead>
<tr>
<th>Median (range)</th>
<th>2-hr gastric retention (%) (normal &lt;60%)</th>
<th>4-hr gastric retention (%)</th>
<th>Vomiting score</th>
<th>Nausea score</th>
<th>TSS (0-28)</th>
<th>Weight (kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>26 (2–74)</td>
<td>5 (1–10)</td>
<td>3 (0–4)</td>
<td>4 (1–4)</td>
<td>18 (9–26)</td>
<td>59 (41–82)</td>
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<tr>
<td>1 year</td>
<td>34 (9–70)</td>
<td>4 (1–37)</td>
<td>2 (0–4)</td>
<td>2 (0–4)</td>
<td>8 (0–19)</td>
<td>61 (44–84)</td>
</tr>
<tr>
<td>p value (t-test)</td>
<td>0.5</td>
<td>0.2</td>
<td>0.001</td>
<td>0.0001</td>
<td>0.0002</td>
<td>0.1</td>
</tr>
</tbody>
</table>
SmartPill Capsule for Assessment of Gastric Emptying – Comparison with Simultaneous Gastric Emptying Scintigraphy

Henry P Parkman, MD,* Alan Hutson, PhD, Irene Sarosiek, MD, Braden Kuo, MD, William D. Chey, MD, Leonard Katz, MD, Jack Semler, PhD, Richard W. McCallum, MD. Medicine, Temple University, Philadelphia, PA; Biostatistics and Medicine, University of Buffalo, Buffalo, NY; Medicine, University of Kansas, Kansas City, KS; University of Michigan, Ann Arbor, MI and Medicine, SmartPill Corporation, Buffalo, NY.

Purpose: Gastric emptying scintigraphy (GES) is used to measure gastric emptying. Recently, a wireless capsule (SmartPill), which measures pH and pressure, has been developed to measure GI transit. We have previously reported good correlation of the SmartPill to differentiate normal subjects from patients with gastroparesis. The aim of this analysis was to determine the ability of the SmartPill to differentiate subjects with normal and delayed gastric emptying.

Methods: In a multicenter study, simultaneous SmartPill pH/pressure recording and GES were performed in 86 normal subjects and 60 patients with previously diagnosed gastroparesis. The SmartPill capsule was ingested after an overnight fast and GES was performed with imaging every 30 min for 4 hours after a 99mTc-SC Eggbeaters meal. After 6 hours, Ensure was given. The gastric residence time (GRT) of the SmartPill was determined as the duration after capsule/meal ingestion to a rapid rise in pH upon reaching the alkaline small intestine. Delayed GES was defined as >10% gastric retention at 4 hours.

Results: Successful SmartPill recordings and GES were obtained in 77 normal subjects and 48 patients with previously diagnosed gastroparesis. In normal subjects, the median SmartPill GRT was 215 minutes with 95% confidence intervals (199, 225). In patients with a history of gastroparesis, the median SmartPill GRT was >360 minutes with 95% confidence intervals (322, >360). In patients with a history of gastroparesis, delayed GES on the study day was documented in 24 of 48 (50%). In normal subjects, GES was normal in 71 of 77 (92%). Using receiver operating characteristic (ROC) analysis, a 4 hour SmartPill GRT was best to identify subjects with gastroparesis or normal based on their history with sensitivity of 82% and specificity of 74%. A 5 hour SmartPill GRT was best to identify subjects with delayed or normal gastric emptying based on scintigraphy on the day of the test with sensitivity of 83% and specificity of 83%.

Conclusions: The SmartPill gastric residence time is able to identify abnormal gastric emptying with good sensitivity and specificity. This study suggests the SmartPill can be used as a novel nonradioactive method for assessing gastric emptying in health and disease.

Maintenance Intermittent Therapy with Rabeprazole 20 mg in Patients with Symptomatic GERD (sGERD)


Purpose: Determine the clinical value of maintenance intermittent therapy with rabeprazole (RAB) 20 mg in sGERD patients vs placebo (PBO).

Methods: This phase II trial enrolled sGERD patients confirmed by endoscopy for absence of erosions/esophageal complications (Hezel-Dent Grade 0 or 1) with ≥3-month history of GERD symptoms and heartburn ≥4 days/wk during a 2-wk PBO run-in. Patients underwent a 4-wk course of open-label RAB 20 mg QD. Those with complete heartburn control were then randomized (1:1) to a 6-month, double-blind intermittent therapy phase with RAB 20 mg or PBO. Patients were instructed to take medication QD for 7 days when heartburn recurred. If heartburn was still present on day 8, patients were to take 7 more days of treatment. Symptom and medication data were recorded in electronic patient diaries. Antacids (< 8 tablets/day) were allowed as rescue medication. The optimal long-term management of sGERD has not been established. Although some patients benefit from continuous therapy, maintenance regimens such as “intermittent” or “on-demand” treatment have also been adopted. There have been no intermittent studies in the U.S. so far.

Results: In the maintenance intermittent phase, the primary efficacy end-point, mean% of heartburn-free days (intent-to-treat, ITT; RAB:N = 96; PBO:N = 91), was significantly greater with RAB vs PBO (82.6% vs 62.2%; p < 0.0001). For secondary endpoints, RAB-treated patients experienced a significantly higher% of heartburn-free daytime (84.1% vs 63.4%; p < 0.0001) and nighttime (95.4% vs 90.3%; p = 0.0021) periods, and took fewer antacid tablets vs the PBO group (0.6 vs 1.2/day; p = 0.0021). A significantly lower% of RAB-treated patients discontinued due to insufficient control of heartburn (6.3% vs 36.3%; p < 0.0001). The safety findings were consistent with the known safety profile of RAB.

Conclusions: Based on the preliminary results from this 1st US study, intermittent therapy with RAB 20 mg was an effective regimen in maintaining control of heartburn among studied patients.

Clinical, Psychiatric, and Manometric Profile of Cyclic Vomiting Syndrome in Adults and Response to Tricyclic Therapy

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Purpose: Our goal was to prospectively investigate 31 adult patients (mean age 29 years, range 18-62) meeting Rome II criteria for cyclic vomiting syndrome (CVS).

Methods: All subjects completed a clinical questionnaire, Hamilton Rating Scale for Anxiety (HAM-A) and Zung Depression inventory. Gastric emptying time (GET) was assessed in 30 subjects and electrogastrogram (EGG) in 11 between acute attacks. 27 patients treated with Amitriptyline at a goal dose of 1 mg/kg per day completed a follow up questionnaire, which included global assessment of symptom status and quality of life score.

Results: The mean age of onset of CVS was 29, range 14-53 years and cycles of nausea and vomiting were accompanied by severe epigastric and diffuse abdominal pain. A typical attack ranged from 1 to 14 days with majority being 4-6 days. The HAM-A revealed that 84% had an anxiety disorder and based on Zung Depression inventory 78% suffered from mild to severe depression. Only 4 (13%) patients reported migraine, but 14 had a family history of migraine. GET was rapid in 23 (77%), normal in 4 and delayed in 3. The EGG was abnormal in 7 of 11 patients with 4 having tachygastria. Of 13 patients using marijuana, 7 believed it was therapeutic while 2 had resolution of CVS after stopping use. For acute attacks IV lorazepam was the most effective in our clinical experience. For long-term prevention patients were treated with Amitriptyline with a target dose of 1 mg/kg and 15 patients achieved 75 mg/day (range: 50-150 mg) for 16.8 months (range: 12-24 months). The average number of ER visits and hospitalizations were significantly diminished from 27 to 6 when annually adjusted. 26% achieved full remission and 93% had a favorable response. The major side effect of amitriptyline was hypersomnia and dizziness that caused two subjects to stop the treatment.

Conclusions: This large single center experience of CVS in adults has the following hallmarks: 1) Prominence of abdominal pain and increased prevalence of anxiety and depression. 2) Rapid gastric emptying and tachygastria EGG findings. 3) Successful suppression of attacks can be achieved by long-term high dose amitriptyline therapy.

The Extent of Abuse of Proton Pump Inhibitor Therapy and Its Potential Consequences for the Patient and Impact on Health Care Costs
**S100 Abstracts**

Harshit S. Khara, MD, Humaira Siddiqui, MD, Adnan Muhammad, MD, C.S. Pitchumoni, MD,* Department of Gastroenterology & Hepatology, St. Peter’s University Hospital, New Brunswick, NJ.

**Purpose:** Proton Pump Inhibitor (PPI) agents are relatively safe and highly effective in offering symptomatic relief in patients with GERD, as part of triple therapy for H. Pylori and as gastric protective agents during NSAID therapy. A prescription for a PPI is often initially given without much thought on its need and renewed with much less scrutiny for months.

**Aim:**
1. To evaluate the extent of abuse of PPI therapy in a medical clinic of a teaching institution.
2. To analyze the financial impact of the abusive use of PPI therapy.

**Methods:** A chart review of 500 consecutive patients was conducted for the number of prescriptions for any one of the PPI agents (Esomeprazole, Lansoprazole, Omeprazole, Pantoprazole and Rabeprazole) and for their indication or the lack of it.

Patients receiving PPI therapy were classified into three groups – Group 1 – those who had a valid indication, Group 2 – those who had a questionable indication (the Gray Zone – patients with nausea, vomiting, decreased appetite, abdominal pain of unknown etiology, viral/candida esophagitis, chronic dry cough) and Group 3 – those who had no indication or even had achlorhydria.

**Results:** Total number of patients on a PPI was 131 (26%)/500
The misuse of PPI therapy is anywhere between 15% to 42% (15% – 27%)

**Cost Analysis:**

- Group 1 = 20 patients X $4.94/day = $36,062.00/year
- Group 2 = 35 patients X $4.94/day = $63,108.50/year

Group 1 is not calculated since it was medically indicated.

**Conclusions:**
1. Once PPI therapy is initiated, for any reason, it is seldom discontinued.
2. The financial impact on healthcare is substantial due to the high cost of PPI therapy.
3. Potential side effects of PPI therapy, including increased susceptibility to C. Difficile colitis, Community Acquired Pneumonia, Vit. B12 malabsorption and Acute Interstitial Nephritis (AIN), are rarely assessed because of the feeling that PPIs are safe.
4. Patients may be spending their limited resources on PPI therapy at the expense of other life saving medications.

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**Group Results**

<table>
<thead>
<tr>
<th>GROUPS</th>
<th>Number of cases n (%)</th>
<th>Mean duration of therapy</th>
<th>Range of therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1 (Valid indications)</td>
<td>76 (58%)</td>
<td>61.8 weeks</td>
<td>48 weeks – 190 weeks</td>
</tr>
<tr>
<td>Group 2 (Gray Zone)</td>
<td>35 (27%)</td>
<td>54.29 weeks</td>
<td>48 weeks – 184 weeks</td>
</tr>
<tr>
<td>Group 3 (No indication)</td>
<td>20 (15%)</td>
<td>51.5 weeks</td>
<td>32 weeks – 240 weeks</td>
</tr>
</tbody>
</table>

Pancreatic/Biliary.

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**HMGA2 Expression in Pancreatic Cystic Lesions**

Christopher J. DiMaio, MD, Jeanine D’Armento, MD, Helen Remotti, MD, Chada Kiran, Nancy Ciau, Yuxia Jia, Timothy Wang, MD, Peter D. Stevens, MD,* Division of Digestive & Liver Diseases, Columbia University Medical Center, New York, NY; Pathology, Columbia University Medical Center, New York, NY; Medicine, Columbia University Medical Center, New York, NY and Medicine, University of Medicine and Dentistry of New Jersey, Piscataway, NJ.

**Purpose:** Pancreatic cystic lesions are being identified at an increased frequency. However, differentiating between which lesions are benign, premalignant, or malignant continues to prove difficult. Patients in whom cystic lesions are identified should be assessed for their risk of having or developing invasive carcinoma. Identification of morphologic characteristics and analysis of cyst fluid are valuable, but insufficient tools. An objective biomarker could complement histological diagnosis in assessing the presence of or risk of progression to cancer. However, no such dependable biomarker exists. HMGA2 is a member of the HMG family of DNA-binding proteins. Prior studies have demonstrated an overexpression of related HMG proteins in multiple types of neoplastic tissue, including pancreatic duct cell carcinomas (DCC) and intraductal papillary mucinous neoplasms (IPMN) of the pancreas. HMGA2 overexpression has been demonstrated in pancreatic DCC. At present, there is no data on the expression of HMGA2 in pancreatic cysts. If HMGA2 is indeed a marker of advanced histology, it may have a role in determining cys type and thus prognosis. The aim of this study is to demonstrate the presence of HMGA2 in malignant lesions of the pancreas, and its absence in benign pancreatic lesions.

**Methods:** Archived formalin-fixed pathology specimens from 2 patients with serous cystadenoma (SCA), 2 patients with mucinous cystadenomas (MCA), 2 patients with invasive IPMN, and 2 patients with pancreatic adenocarcinoma (AC) were obtained. Immunohistochemical (IHC) staining was performed using a polyclonal antibody generated against a peptide of the HMGA2 protein. Positive signaling was defined as greater than 20% of cells having diffuse and intense nuclear staining.

**Results:**
- Positive signaling for the HMGA2 protein was observed in both IPMN specimens and both pancreatic AC specimens.
- No IHC staining for HMGA2 was demonstrated in the SCA or the MCA.

**Conclusions:**
- For the first time, we demonstrated the presence of HMGA2 protein in malignant pancreatic cystic lesions, as well as its absence in benign cystic lesions. We conclude that HMGA2 is a potential biomarker to determine the nature of an indeterminate pancreatic lesion.

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**Necrotizing Panniculitis, a Skin Condition Associated with Acinar Cell Carcinoma of the Pancreas**

Aly Lakhani, MD, Luis Maas, MD, FACP FACC AGAF,* Department of Internal Medicine, Gastroenterology Division, William Beaumont Hospital, Royal Oak, MI.

**Purpose:** Pancreatic panniculitis is a rare cutaneous eruption due to leak of pancreatic lipase into the bloodstream with subsequent focal necrosis of adipose that is sometimes associated with pancreatic disease. We describe an unusual patient with this skin condition who presented to our hospital for evaluation of skin lesions of uncertain etiology with associated diarrhea and arthralgias.

**Methods:** A sixty-one year old man complained of a four month history of subjective fever, pain in his ankles, knees and wrists, and a painful rash that spread from his legs to the abdomen and arms. The cutaneous eruption comprised inflamed-looking papules and pustules on an erythematous base that drained dark, purulent, foul-smelling fluid. The patient also made note of diarrhea which had been progressive over four months. Lipase levels, drawn to investigate the patient’s chronic diarrhea, were elevated to three hundred times the reference limit. Amylase, ALT, AST and bilirubin were mildly elevated. A CT scan of the abdomen revealed a mass in the tail of the pancreas with nodules in both the liver and the base of the left lung. A CT-guided needle biopsy of one of the liver nodules revealed histology consistent with Acinar Cell Carcinoma of the Pancreas. The cancer was stage IV at the time of presentation. The skin eruption was diagnosed to be nodular subcutaneous fat necrosis, also known as pancreatic panniculitis. The patient was offered palliative treatment.

**Results:** Pancreatic panniculitis is rare, occurring in 2-3% of all patients with pancreatic disorders. Occasionally, it is associated with cancers of the pancreas, especially with acinar cell carcinoma which itself represents only one to two percent of pancreatic malignancies. As of 1995 fewer than 40
described cases of acinar cell carcinoma of the pancreas have presented with poly-arthritis and disseminated fat necrosis, both seen in our patient prior to the discovery of his pancreatic malignancy.

Conclusions: In clinical practice the skin manifestations of internal malignancies vary in their presentation. They may challenge primary care physicians and dermatologists when patients present without associated findings for malignancy. Panniculitis should be kept in mind in the differential diagnosis of inflammatory nodules and pustules with an erythematous base, such as the ones observed in our patient, particularly when they are progressive and unrelenting. They may be the clue to the discovery of a potentially serious disease.

Weight Cycling and Risk of Gallstone Disease in Men
Chung-Jyi Tsai, MD, F ACCG,∗ Michael Leitzmann, MD, Walter Willett, MD, Edward Giovannucci, MD. Div. of Digestive Diseases and Nutrition, University of Kentucky Medical Center; Div. of Cancer Epidemiology and Genetics, National Institute of Health and Channing Lab., Department of Medicine, Harvard Medical School.

Purpose: Large weight fluctuations earlier in life may represent an independent risk factor for chronic diseases including metabolic syndrome. Weight cycling is associated with overshoots of lipogenic enzymes and insulin in experiments. The long-term effect of repeated intentional weight loss and weight regain on the risk of gallstone disease in men is unknown.

Methods: We examined the relations of weight cycling to the risk of gallstone disease in a large cohort of men. As part of the Health Professionals Follow-up Study in the US, men provided information on intentional weight loss during the previous 4 years using validated questionnaires in 1992. The Pearson correlation between self-reported weight and measured weight by technicians was 0.97. Weight cyclers were men who had intentional weight loss and weight regain. Weight cyclers were further divided into three categories: light cyclers (maximum intentional weight loss per episode of 5 to 9 lb), moderate cyclers (maximum intentional weight loss per episode 10 to 19 lb), and severe cyclers (maximum intentional weight loss per episode of 20 lb or more). Men free of gallstone disease at baseline were followed from 1992 to 2002. On biennial questionnaires the participants reported newly diagnosed gallstone disease. A validation study of self-reported gallstone disease was conducted.

Results: During 264,760 person-years of follow-up we ascertained 1,222 new cases of symptomatic gallstones. We examined the effect of weight cycling on the risk of gallstone disease. The multivariate relative risk (RR) of weight cyclers, compared with weight maintainers, after adjusting for multiple potential confounding variables including body mass index, was 1.11 (95% CI, 0.94 to 1.31) in light cyclers, 1.18 (95% CI, 0.97 to 1.43) in moderate cyclers, and 1.42 (95% CI, 1.11 to 1.81) in severe cyclers. We further examined the effect of number of cycling episodes. Among weight cyclers the RR associated with having more than one weight cycle, compared with weight maintainers, was 1.10 (95% CI, 0.88 to 1.37) in light cyclers, 1.28 (95% CI, 1.03 to 1.59) in moderate cyclers, and 1.51 (95% CI, 1.13 to 2.02) in severe cyclers.

Conclusions: Our findings suggest that weight cycling, independent of weight, may increase the risk of gallstone disease in men. Larger weight fluctuation and more weight cycles are associated with greater risk.

Blood Antioxidant Status and Lipid Peroxidation in Patients with Chronic Pancreatitis
Larysa Dobra, MD, PhD, Peter Dobra, MD, PhD,* Lyudmila Kyytich, MD, PhD. Gastroenterology Department, SPA Rehabilitation, Uzhgorod, Zakarpatska, Ukraine and Health-Resorts Association, Ukrprofzorovnitsa, Uzhgorod, Zakarpatska, Ukraine.

Purpose: The role of immune system in pathogenesis of chronic pancreatitis is unclear. The aim of this study was to establish the main determinants of plasma antioxidant potential in different types of chronic pancreatitis: alcoholic pancreatitis (ACP, N = 25), biliary pancreatitis (BCP, N = 37).

Methods: We measured blood plasma levels of lipid peroxide oxidation and antioxidant defense: malondialdehyde (MD), hydroperoxide of lipids (HL); ceruloplasmine (CP) and myeloperoxidase (MPO). Measurements were performed by using colorimetric methods.

Results: In comparison to healthy volunteers (HV, N = 18) the average concentration of plasma free-radical oxidation determinants (MD and HL) in both groups of chronic pancreatitis were significantly higher (by 45%-91%). Ceruloplasmine activity was higher (approximately 35%) in patients with alcoholic chronic pancreatitis, and lower (49%) in case of biliary chronic pancreatitis. MPO levels were lower in 2.5 and 2.1 times in case of alcoholic pancreatitis and biliary pancreatitis accordingly.

Conclusions: Low levels of antioxidant defense in patients suffering from different types of chronic pancreatitis show the exhaustion of immune defense, high indices of blood plasma lipid peroxidation underline important role of immune system in pathogenesis of chronic pancreatitis and determine strategy of therapy.

Endoscopic Ultrasound-Guided Celiac Plexus Block (EUS-CPB) and Neurolysis (EUS-CPN): Evaluation of Complications: A Prospective Single Center Experience
Vanessa M. Shami, MD, Alfredo J. Hernandez, MD, Paul Yeaton, MD, Michel Kahaleh, MD,* Digestive Health Center of Excellence, University of Virginia, Charlottesville, VA.

Purpose: EUS-CPB and EUS-CPN have been increasingly used for pain control in patients with chronic pancreatitis and unresectable pancreatic cancer respectively. Significant reported complications include hemoperitoneum, perforation, peripancreatic abscess and sepsis. We have prospectively evaluated our complications using this technique.

Methods: Between December 2001 and March 2006, patients undergoing CPB and CPN were evaluated prospectively. A total of 78 patients underwent 123 procedures. All cases were performed by three dedicated pancreaticobiliary endoscopists (VMS, PY and MK) using the Olympus linear echoendoscope (GFUCT140, 130, or GFUCP140) and a 22 or 19 gauge needle. Prophylactic antibiotics were not administered. All cases were done using a single injection technique once the celiac axis was identified. The CPBs were performed by administering 18cc of 0.25% bupivacaine and 2cc of triamcinolone. The CPNs were performed injecting 5 cc of 0.25% bupivacaine and 20cc of dehydrated absolute alcohol.

Results: A total of 78 patients (47 males) with a median age of 51 ± 13 years were enrolled. Thirty four patients underwent CPB for chronic pancreatitis, and 44 patients underwent CPN for pancreatic cancer. The CPB group had a mean of 2.4 (range of 1-8) procedures performed per patient. Two had major complications; one with a periesophageal abscess requiring thoracotomy, and one with peritonitis treated conservatively with antibiotics. No major complications were noted in the CPN group.

Conclusions: EUS-CPB and EUS-CPN provide pain control in patients with chronic pancreatitis and pancreatic cancer. Although the procedure is relatively safe, severe complications may occur in the CPB group. Since chronic pancreatitis patients seem to require multiple CPB sessions for pain control, further studies identifying patients who respond the best to this treatment are required.

Cholecystocholedocal Fistula
Jeffrey Lin, Edward M. Reece, MD, Sergio Huerta, MD.* Department of Gastrointestinal and Endocrine Surgery, UT Southwestern Medical Center/VA North Texas Health Care System, Dallas, TX.

Purpose: The purpose of this study is to evaluate the treatment of cholecystocholedocal fistula as evidenced by a case study.
Methods: A patient with elevated transaminases and alkaline phosphatase was preoperatively evaluated for Mirizzi Syndrome type II using both ultrasound and endoscopic retrograde cholangiopancreatography (ERCP). Figure A is an ERCP image highlighting a contracted gallbladder (arrow) with complete obliteration of the cystic duct. Intraoperatively, a cholangiogram was performed to further resolve the anatomy, revealing a completely obliterated cystic duct. To address the cholecystobiliary fistula, a Roux-en-Y hepatojejunostomy was performed.

Results: The management of Mirizzi Syndrome requires a good surgical strategy if preoperative diagnosis is made, due to the dangers in dissecting the triangle of Calot. Early recognition of Mirizzi syndrome during laparotomy is essential to avoid complications. The diagnosis of Mirizzi syndrome is initially suggested by an impacted stone in the neck or infundibulum of gallbladder by ultrasound. Computed tomography is obtained to exclude malignancy. Neither of these tests are sufficiently sensitive or specific for the diagnosis of Mirizzi syndrome. The syndrome is best diagnosed by ERCP.

Conclusions: The management of this disease is best accomplished by an open approach. Csendes type I is typically successfully managed by an open cholecystectomy, removal of the stone and closure of the gallbladder cuff. In more severe cases of the disease (types II&III), a partial cholecystectomy with oversew of the defect (with or without flaps) in the common hepatic duct and T-tube placement may be required. Csendes type IV, as in the present case, is best managed by a choledochocoejenuostomy or a hepatojejunostomy. Gallbladder carcinoma should be excluded in all cases of Mirizzi syndrome.

[figure1]

178 Predictors of Malignancy in Ampullary Neoplasms
Prabhleen Chahal, MD, Todd H. Baron, MD, Christopher J. Gostout, MD, Bret T. Petersen, MD, Michael J. Levy, MD, Mark D. Topazian, MD. Gastroenterology and Hepatology, Mayo Clinic, Rochester, MN.

Purpose: Safety and effectiveness of endoscopic management of ampullary neoplasms (AN) has been well described. However, the specific features predictive of malignancy in AN remain elusive. We sought to assess the predictive factors of malignancy in AN.

Methods: All patients who underwent EA from Jan 2002-Sept 2005 were identified from the endoscopy database. Data were abstracted from the endoscopic procedure report and the patient records and placed in a JMP drive. Sporadic lesions were defined as those occurring in the absence of FAP or its variants. Post EA complications were defined as immediate and delayed based on a temporal cut-off of 48 hrs.

Results: 71 patients (36 males, 35 females), with the diagnosis of sporadic ampullary neoplasm (44), FAP and its variant (24), ampullary carcinoid (1), gangliocytic paraganglioma (1) and Peutz-Jeghers hamartoma (1), underwent EA requiring median of 1 attempt (range 1-5) and total of 107 endoscopies. Median age was 63 years (range 20-94) and median follow-up was 6mths (range 1-40). Patients presented with one or more of the following symptoms: abdominal pain (14), jaundice (11), GI bleeding (8), pancreatitis (7), abnormal liver enzymes (6), incidental (5), cholangitis (4), anemia (4), and surveillance in known FAP pts (20). Median tumor size was 1.5 cm (range 0.5-5 cm). Immediate complications were observed in 26/71 (37%) including pancreatitis (N = 10, mild = 9, moderate = 1), bleeding (8), abdominal pain (6), cholangitis from bile duct edema (1) and perforation (1) and delayed complication including papillary stenosis was observed in 7/71 (10%). Histological diagnosis was tubular/tubuloislet adenoma with low grade dysplasia in 48, high grade dysplasia in 8, adenocarcinoma in 6 and normal histology was found in 9 patients. Intraductal extension occurred in 8 patients. Age over 60 years (all 6 adenocarcinoma patients) and jaundice as a presenting symptom (3/6 adenocarcinoma presented with jaundice vs. 3/65 in patients with non-malignant ampullary neoplasm, p = 0.02) were found to be significant predictors of malignancy.

Conclusions: Age ≥ 60 years and jaundice are significant predictors of ampullary malignancy. Intraductal tumor growth and tumor size were not found to be significant predictors of ampullary malignancy.

179 Treatment of Biliary Strictures Secondary to Chronic Pancreatitis: Comparison of Temporarily Placed Covered Self Expandable Metal Stents (CSEMS) vs. Plastic Stents
Michel Kahaleh, MD, Bridger W Clarke, Brian Behm, MD, Reid B. Adams, MD, Paul Yeaton, MD, ∗ Digestive Health Center of Excellence, University of Virginia, Charlottesville, VA.

Purpose: Biliary strictures occur in up to 30% of patients with chronic pancreatitis. Such strictures are frequently managed with temporary placement of plastic stents. Uncoated metal stents have been used in this setting but fail long-term therapy due to mucosal hyperplasia. The use of partially CSEMS has been studied in malignancy, but their role in benign biliary diseases remains undefined. The aim of this study was to compare the benefits of temporarily placed CSEMS vs. plastic stents in the treatment of patients with chronic pancreatitis complicated by biliary strictures.

Methods: Seventeen consecutive patients with chronic pancreatitis and common bile duct strictures (13 men, 4 women, mean age 49 y/o, range 32–62) underwent endoscopic placement of CSEMS (Wallstent 40, 60, or 80mm) and were followed prospectively. CSEMS were left in place until adequate biliary drainage was achieved, confirmed by resolution of symptoms, normalization of LFTs, and imaging. CSEMS removal was achieved using a snare or rat tooth forceps. Results were compared with a group of 27 patients in whom single or multiple plastic stents were placed prior to the study (22 men, 5 women, age range 32–75). Factors assessed included symptoms, biochemical tests of liver function, number of ERCPs performed, time until resolution, and complications.

Results: CSEMS were left in place for a median time of 4 months (range: 1-14) before removal. One patient required removal within 1 month due to pain, another required removal within 1 week due to an infected pseudocyst. One patient spontaneously passed the CSEMS. Resolution of biliary stricture was confirmed in the remaining 14 patients. Of the 27 patients receiving plastic stents, removal with resolution was achieved in 22 (median time of stent placement 8 months, range: 2–72 months). Of the five patients who did not undergo stent removal, two developed pancreatic cancer, two are lost to follow up, and one died of pneumonia. The mean number of ERCPs performed on the SEMS group was 2.1, while the plastic group underwent a mean of 4.8 procedures (p < 0.0001).

Conclusions: Temporary placement of CSEMS in patients with biliary strictures secondary to chronic pancreatitis offers an excellent alternative to plastic stenting. The use of CSEMS may offer a technique that requires fewer
ERCps and less overall treatment time than conventional plastic stenting before resolution.

Prevalence of the Calcium Sensing Receptor Gene (CASR) 518T>C Polymorphism in Patients with Idiopathic Pancreatitis in the United States
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Purpose: Familial hypocalcemic hypercalcermia (FHH) is commonly caused by mutations in the calcium sensing receptor gene (CASR). Hypercalceremia is a known risk factor for acute pancreatitis. Felderbauret al (BMCGastroenterology 2004; mar 18; 4 (1): 16) reported a FHH kindred with the CASR 518 T>C polymorphism in whom chronic pancreatitis (CP) was associated with the presence of the pancreas-targeting serine protease inhibitor, Kazal type 1 gene (SPINK1) N34S haplotype.

Aim: To test the hypothesis that the CASR 518 T>C polymorphism is a common polygenic risk factor in patients with or without SPINK1 N34S or P55S haplotypes and recurrent acute (RAP) or chronic pancreatitis in a North American population.

Methods: PCR primers were designed to reliably amplify the CASR gene exon 4, which contains codon 518. The primers were: forward CTCACT CAGCACCCTCTCCTACT, and reverse GCAGCTGATGACGACTATGGG. 241 affected subjects and 126 controls were selected from the North American Pancreatitis Study 2 (NAPS2) and Hereditary Pancreatitis Study (HP).

AFFECTED SUBJECTS INCLUDE INDIVIDUALS WITH (N = 72) AND WITHOUT (N = 169) SPINK1 N34S OR P55S POLYMORPHISMS AND EITHER RAP (N = 51) OR CP (N = 190). CONTROLS INCLUDE INDIVIDUALS WITH (N = 8) AND WITHOUT (N = 118) SPINK1 N34S OR P55S. ALL SUBJECTS WERE SCREENED FOR THE CASR 518 T>C SNP BY PCR AND DIRECT SEQUENCING.

Results: The CASR 518 T>C SNP was not identified in affected patients with or without the SPINK1 N34S or P55S polymorphisms, nor was it found in controls. Furthermore, no novel genomic DNA variants in CSAR exon 3 were detected in any of the subjects.

Conclusions: The CASR 518 T>C mutation was not identified in a prospectively ascertained population of RAP and CP patients from the USA. Although the original report provides insight into pancreas-targeting polygenic disorders, the CASR 518 T>C variant does not contribute significantly to the risk of RAP or CP in the USA.

Association between Serum Insulin, Insulin Resistance, and Gallstone Disease in Korean Population
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Purpose: Diabetes is one of the major risk factors for gallstone disease. Many studies reported a positive association between insulin and gallstones in diabetes, but negative in non-diabetes. We conducted a prospective case control study to explore the association of serum insulin, insulin resistance and gallstone disease in Korean general population without diabetes.

Methods: Between May 2004 and May 2005, total 118 Korean subjects (71 men, 47 women) without diabetes were included in clinical examination, abdominal ultrasonography and blood chemistries. Fasting serum insulin was determined by radioimmunoassay, and other chemistries by standard enzymatic colorimetric methods. Insulin resistance was determined by the homoeostasis model assessment index (HOMA-IR). BMI, percentage of body fat and waist hip ratio were also measured.

Results: The prevalence of gallstone disease was 25.4% (18/71) among males and 23.4% (11/47) among females. Compared with controls (N = 89), gallstone cases (N = 29) had higher serum insulin, glucose and triglyceride levels and BMI. In t-test and chi-square test for variable, the association between serum insulin, HOMA-IR index, BMI and gallstone disease was statistically significant (p < 0.05). However, in multiple logistic regression analysis, the indices were not significantly different.

Conclusions: We could suggest that hyperinsulinemia and insulin resistance may be associated with gallstone formation even in individuals without diabetes.

Expression of Nestin and Pancreatic Fibrosis in a Spontaneous Chronic Pancreatitis Model (Male WBN/Kob Rats)
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Purpose: Although the causes of human chronic pancreatitis are quite diverse, there are many aspects of its onset that are currently unclear. WBN/Kob rat serve as a model of spontaneous chronic pancreatitis that presents with impaired internal and external pancreatic secretion in males only, and causes fibrosis and inflammatory cells infiltration consisting mainly of monocytes in the pancreas starting at age 12 weeks. The purpose of this study is examining the mechanism of the onset and development of pancreatitis.

Methods: The animals used in this study consisted of 8-, 10- and 12-week-old male WBN/Kob rats and male Wistar rats (control). Total RNA was extracted from the pancreas followed by competitive hybridization using a Rat Oligo Microarray. In addition, real-time RT-PCR, MassARRAY and immunohistostaining were carried out on genes highly expressed with the microarray.

Results: Nes was highly expressed at 10, 12 weeks as compared with the control. Increased expression was observed at age 10 and 12 weeks as compared with the control in real-time RT-PCR as well. A similar trend was also observed in analyzes using MassARRAY. According to the results of immunohistostaining, nestin was stained primarily in spindle cells observed surrounding pancreatic acinar cells, and was thought to be expressed in pancreatic stellate cells.

Conclusions: The activation of pancreatic stellate cells has attracted attention in fibrosis associated with chronic pancreatitis. Pancreatic stellate cells have been reported to be stained by nestin during pancreas damage induced by pancreatic duct ligation. Increases in expression of Nes starting at 10 weeks observed in the study rats. This expression is thought to be localized primarily in pancreatic stellate cells, thereby suggesting a correlation among increased expression of nestin, activation of pancreatic stellate cells and pancreatic fibrosis.

Hemobilia, Cholangitis, Pancreatitis, and Cholecystitis after CT-Guided Percutaneous Liver Biopsy
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Purpose: Hemobilia presents as a classic triad of gastrointestinal bleeding, right upper quadrant pain and jaundice. Incidence of hemobilia is 0.06-1% with percutaneous liver biopsy. Presented is a rare case of a hepatic biopsy-related triple complication including cholangitis, pancreatitis and cholecystitis from hemobilia.

Methods: A 48-year-old man with a history of chronic hepatitis C and alcohol abuse presented with epigastric abdominal pain, nausea and low grade fevers 7 days after a CT-guided liver biopsy. On presentation he was
Pancreatic ductal features which are associated with chronic pancreatitis were investigated. Two patients who had a history of chronic pancreatitis were studied. Optimal coherence tomography imaging of the main pancreatic duct was performed during ERCP. A catheter-based OCT probe was passed endoscopically and images were obtained. The probe was inserted into the pancreatic duct during ERCP and images were obtained. All patients underwent ERCP and OCT imaging. OCT imaging is a non-invasive technology that can be performed in the endoscopy suite. The OCT images showed the morphology of the main pancreatic duct. The OCT images showed that the pancreatic duct walls could be easily identified as could various pancreatic ductal features. The OCT images showed that the pancreatic duct walls could be easily identified as could various pancreatic ductal features. The OCT images showed that the pancreatic duct walls could be easily identified as could various pancreatic ductal features.
obstruction. Mechanism of PP drainage was via cystduodenostomy in 5 patients and cystgastrostomy in 6 patients. Trans-papillary drainage alone was used in 4 patients with small cysts communicating with the pancreatic duct. ERCP alone was used in 3 procedures, EUSCP with EUS-assistance in 6 procedures, and EUS-guided alone in 5 procedures. Mean patient age was 49 years (range: 14-73 years).

Results: Successful drainage of PP was achieved in 12/13 patients (13/14 procedures). Trans-papillary PP drainage failed in one patient. After a median follow-up of 23.3 months (range: 1.5-40), 9 patients had complete resolution of PP and 2 patients developed partial recurrence of PP without symptoms. One patient developed infection that was successfully treated with antibiotics. No patient required additional drainage procedures for recurrent PP. One patient was lost to follow-up. The PP drainage success rates among the 3 endoscopic techniques did not appear to differ.

Conclusions: In selected patients, endoscopic drainage of PP is a safe, minimally invasive, and highly effective procedure. This benefit is seen across a wide range of patients with respect to age and etiology of PP. In addition, the type of endoscopic drainage technique performed does not appear to have an effect on the outcome.

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Interventional Radiology in Pancreatic Diseases
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Purpose: In the field of gastrointestinal surgery, interventional radiology (IVR) is not only essential for treatment of complications such as postoperative abscesses, but is also serves as an alternative treatment method to surgical procedures. We conducted a study of the future outlook for IVR by presenting an IVR procedure that we have performed for various pancreatic diseases.

Methods: Percutaneous transgastric puncture was performed on a cyst following pancreaticectomy. The cyst was then eliminated by allowing the cyst fluid to flow into the stomach by implanting a drainage tube. A similar procedure was performed on an abscess following severe acute pancreatitis. The abscess wall and posterior stomach wall were gradually diluted with a balloon to drain into the gastric lumen. In the case of chronic pancreatitis associated with dilated pancreatic duct, percutaneous transgastric puncture was performed on the dilated pancreatic duct, and a new pathway for pancreatic juice was constructed by leading pancreatic juice into the stomach. This resulted in dissipation of pain. In a case of jaundice caused by chronic pancreatitis, cholangioduodenal fistulation was performed using magnets. This case had progressed favorably for seven years.

Results: Although various procedures have been performed on a total of 15 cases, favorable results have been obtained without complication. Surgery was performed on two cases following IVR.

Conclusions: In consideration of the recent trend toward selecting treatment that places a minimal burden on the patient, IVR is considered to be a reliable treatment that will lead to even closer involvement with the field of gastrointestinal surgery.

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Relationship between Severity of First Attack of Acute Pancreatitis and the Degree of Elevation of Amylase/Lipase Levels in African-American and Hispanic Patients
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Purpose: Diagnosis of acute pancreatitis is most often based upon clinical picture and serum amylase and lipase levels more than three times of normal (>3n). Some patients with acute severe pancreatitis, with smaller degree of enzyme elevations may be missed or considered to be having only mild pancreatitis, that could result in delaying intensive care management and timely interventions. Our objective was to determine the association of pancreatic enzyme elevation with the severity of first attack of acute pancreatitis.

Methods: Retrospective review of medical records of 433 patients aged 18-95 years with a diagnosis of first attack of acute pancreatitis over 15-year period (238 African-American and 195 Hispanic). Using the 3n criteria of pancreatic enzymes level, patients were divided into two groups (≤3n & >3n). Study criteria of severity included: type of acute pancreatitis (interstitial or necrotizing), presence of extra pancreatic manifestations (EPM), necessity for surgery, and mortality.

Results: Of the 433 subjects, the etiology was alcohol in 230 (53%) and gallstones in 182 (42%). Eighteen percent of patients had necrotizing pancreatitis, 15% had EPM, 3% needed surgery and 12% died. According to the amylase level, 329 patients (76%) had level >3n and 104 patients (24%) had ≤3n. For the lipase level, 355 patients (82%) had >3n and 78 patients (18%) had ≤3n. There was no association between the level of amylase or lipase enzymes and the indicators of severity of first attack of acute pancreatitis or mortality (p>0.05).

Conclusions: The magnitude of elevation of serum amylase/lipase was not associated with the severity of first attack of acute pancreatitis in our study population. The clinicians should have a high index of suspicion for the diagnosis and low threshold for computerized abdominal tomography, in order to detect obscure severe acute pancreatitis.

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Clinicopathologic Variability of Pancreatic Cancer: Analysis by Histological Types
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Purpose: The purpose of this study is to assess differences in clinical characteristics by histologic types of pancreatic cancer.

Methods: 7,653 pts. diagnosed with primary invasive pancreatic cancer from 1973-2002 were identified through 13 cancer registries that participate in the Surveillance, Epidemiology, and End Results Program. Comparisons were made between 5 histological groups of pancreatic cancer: Ductal Adenocarcinoma (DA), Solid Invasive Mucinous Adenocarcinoma (SIMA), Cystadenocarcinomas (CA), Acinar Cell Carcinoma (ACC) and Islet/Endocrine Tumors (IET). A Loglinear model was built using SAS software. Our referenc groups were cases with DA, age 30-44 yrs, white race and females.

Results: Most cases of pancreatic cancer were DA (51.3%), between 60–74 yrs (46.2%), in White patients (82.1%), between 1993–2002 (52.3%). P-values for association with variables (age, gender, race, stage at diagnosis, grade, diagnostic method and treatment) and histologic types, assessed by Maximum Likelihood Ratio testing, were <0.0001. Tumor grade had highest degree of association, followed by stage at diagnosis, age & type of diagnostic method. Race was least likely to be associated with histologic type. Compared to pts. 30–44 yrs, pts. from 60–74 yrs were less likely to be diagnosed with IET and CA, while those over 75 yrs were less likely to be diagnosed with IET compared to DA. Compared to females, males were more likely to be diagnosed with ACC and IET and less likely to be diagnosed with CA. Compared to whites, blacks were less likely to have SIMA and IET, and patients of “other races” were more likely to have CA than DA. CA are more likely to have localized disease compared to DA. SIMA (OR 2.11; 95% CI 1.91–2.33) and IET (OR 1.45; 95% CI 1.29–1.63) have more distant disease compared to DA. Compared to DA, CA were less likely to have poorly differentiated cancer (OR 0.46; 95% CI 0.31–0.68). IET (OR 8.09 95% CI 6.21–10.53) and ACC (OR 2.45 95% CI 1.14–5.26) are more likely to have Anaplastic/Undifferentiated cancer compared to DA.
Purpose: Except for smoking, the risk factors for pancreatic cancer (PC) are not well established. Studies have shown that radon and cigarette smoking have a synergistic, multiplicative effect on lung cancer rates. It is not known if radon exposure increases the risk of PC. A Swedish study demonstrated a significant correlation between PC mortality and average background radiation. Our objective was to correlate radon exposure with the incidence of PC in the USA and to ascertain the influence of race in this correlation.

Methods: Age-adjusted incidence rates (AAIRs) of PC from 1992–2002 for 210 counties, segregated by race, were obtained from the U.S National Cancer Institute’s Surveillance, Epidemiology and End Results database. The average radon levels for each county were obtained from the Environmental Protection Agency Map of Radon Zones which assigns each county in the USA to one of 3 categories based on Radon potential (a predicted average indoor radon screening level): Low (less than 2 pCi/L), Moderate (from 2 to 4 pCi/L) or Highest (greater than 4 pCi/L). We correlated the aggregate radon exposure to the aggregate AAIRs of PC in each county using Spearman’s correlation coefficient.

Results: The AAIRs of PC in the USA range from 1.4/100,000 persons in Beaver County, UT to 21.8/100,000 persons in Guadalupe County, NM. There was an aggregate radon exposure to the aggregate AAIRs of PC in each county using Spearman’s correlation coefficient.

Conclusions: This large, population-based study shows that pancreatic cancer is heterogeneous, with distinct histological types that vary in clinical presentation in relation to age, gender, stage and grade at diagnosis.

Correlation Coefficients of Pancreatic Cancer and Radon Exposure

<table>
<thead>
<tr>
<th>Race</th>
<th>r-value</th>
<th>p-value</th>
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</thead>
<tbody>
<tr>
<td>Whites</td>
<td>0.002</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Blacks</td>
<td>0.291</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>American Indians</td>
<td>0.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Asian Americans</td>
<td>0.259</td>
<td>&lt;0.001</td>
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</table>

Purpose: Pancreatic cancer is associated with the worst survival of any form of gastrointestinal malignancy. Our aim was to determine if a survival disparity remained between black and white patients after adjustment was made for treatment offered.

Methods: Patients diagnosed with primary invasive pancreatic locoregional cancer between 1988-1999 were identified through 13 population-based cancer registries that participate in the National Cancer Institute’s Surveillance, Epidemiology and End Results Program. Patients were categorized into White (N = 5952), Black (N = 872), and Other races (N = 960). We used Kaplan-Meier curves to estimate survival statistics, and Cox proportional hazards regression to estimate death rate of whites relative to that of blacks after adjustment for potential explanatory factors.

Results: Blacks were less likely to receive any form of treatment (52.2%). Across races, a combination of radiation and surgery was the least common form of treatment. Survival analysis demonstrated that 1. After adjustment for age, sex, year of diagnosis, marital status, stage, and location of tumor, the black-to-white mortality hazard ratio (HR) was 1.175 (95% confidence interval [CI] 1.086–1.271). Further adjustment for treatment reduced the excess cancer mortality to 12% (HR = 1.12; 95% CI 1.04-1.228), decreasing the overall racial difference in excess mortality by 31.4%. Patients “of other races” had better survival than whites (HR 0.995; CI 0.885–1.029).

2. The survival of all patients improved over time from 1988–99. On adjusting for treatment, the survival advantage disappeared in blacks (HR 1.011; 95% CI 0.991–1.003).

3. Improved survival was significantly associated with female gender (HR 0.894; 95% CI 0.849-0.941), younger age, and later year of diagnosis (HR 0.998; 95% CI 0.991-1.005).

4. A combination of both surgery and radiation (HR 0.338; 95% CI 0.307–0.372) was associated with longer survival, followed by surgical treatment alone (HR 0.413 95% CI 0.38–0.44). Patients that underwent radiation therapy alone had a 34% decreased mortality compared to patients that had neither surgery nor radiation (HR 0.664; CI 0.624–0.705).

Conclusions: Race is an independent predictor of survival in locoregional pancreatic cancer. Lack of appropriate treatment accounted for a third of the excess mortality observed among blacks. Further studies to specifically study the relationships among specific modalities of treatment, and race, are warranted.

Purpose: The role of laparoscopic surgery in the treatment of Mirizzi syndrome (MS) is not well defined and remains controversial. We evaluated the preoperative diagnosis and efficacy of laparoscopic procedures in the treatment of MS.

Methods: Cholecystectomy was attempted on 2,012 consecutive patients and twenty-four (1.2%) were finally diagnosed with MS. Patients without preoperative endoscopic retrograde cholangiography (ERC) underwent preoperative spiral computed tomography (SCT) after intravenous infusion cholangiography (IVC-SCT).

Results: Fourteen patients had McSherry’s type I MS (MS I) and 10 had type II MS (MS II). Open surgery was performed on patients with MS II or a preoperative suspicion of gallbladder cancer. Laparoscopic cholecystectomy (LC) was performed successfully on 10 of the 14 patients with MS I and the remaining four patients with MS I were converted to open surgery. At preoperative ERC (3) or IVC-SCT (11) on patients with MS I, 3 of 4 (75%) patients who were converted to open surgery had a nonvisualized cystic duct, whereas and 9 of 10 (90%) patients with LC had a visualized cystic duct.

Conclusions: MS I with a visualized cystic duct may be considered to be an indication for laparoscopic surgery. IVC-SCT may be a useful tool for...
Alcoholic Pancreatitis Is on the Rise While Tropical Pancreatitis Is on the Decline in South India
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Purpose: Kerala State in South West India is an endemic region for tropical pancreatitis with the highest incidence in the world. We reported in the eighties a series of chronic pancreatitis (CP) patients of whom 98% were tropical pancreatitis and only 2% alcoholic pancreatitis. During the last two decades, remarkable changes in diet and lifestyle have occurred in Kerala State. We investigated changes in the pattern of CP resulting from such dietary and lifestyle changes.

Methods: We analysed the risk factors of a current prospective cohort of 300 patients with CP.

Results: Twenty-eight percent of our present cohort are alcoholic pancreatitis and 72% non-alcoholic. M: F ratio in the study cohort is 2:1. Among the males, 41% have alcoholic pancreatitis. Classical tropical pancreatitis (age <25yrs. malnutrition, dense large intraductal calculi, diabetes mellitus, ± high cassava intake in diet, ± family history) constitutes only 6.3% of the whole group and 8.7% of the non-alcoholic group. The non-alcoholic pancreatitis patients as a group are younger by 11yrs than the alcoholic patients (23.83 ± 12.02 yrs. 35.16 ± 12.19 yrs; p = 0.001). Over the past 20yrs alcohol consumption in India has gone up by more than 100% with the highest intake in Kerala. The amount of alcohol intake in the present study is 130 ± 59.6 g/day and mean duration of imbribement 19.44 ± 9.77 yrs. Eighty percent of the alcoholics are also smokers (p = 0.001). The number of cigarettes smoked per day is 23.61 ± 14.58 and mean duration of smoking 22.3 ± 9.17yrs. Regular cassava intake in diet, which was universal in our earlier series, was present only in 76.36% of patients in the current series. Cassava ingestion in the diet is 266 ± 171 g/day in the current cohort (earlier cohort: 350g/day). Less toxic varieties of cassava are consumed now. Cereals have replaced cassava as a staple food in the majority.

Conclusions: Alcoholic pancreatitis has registered a phenomenal rise in our state, even though non-alcoholic pancreatitis is still observed in the majority of patients. Classical tropical pancreatitis has become less common now. We presume that the reduced cassava intake along with the increase in alcoholism and smoking have contributed to this change in disease pattern.

Comparison of Endoscopic Ultrasound (EUS) and Endoscopic Retrograde Pancreatography (ERP) for the Prediction of Pancreatic Exocrine Insufficiency (PEI)
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Purpose: ERP is highly sensitive for ductal changes of chronic pancreatitis (CP). EUS has been advocated as a sensitive structural test as well. Potential advantages of EUS over ERP include less risk and the ability to evaluate both ductal and parenchymal architecture. Direct pancreatic function tests are considered a valid reference standard for CP because they detect mild PEI as a surrogate for early fibrosis. The purpose of this study was to compare ERP and EUS for prediction of PEI as detected by the secretin endoscopic PFT (ePFT).

Methods: 71 patients (46 female, mean age 42 yrs) who underwent EUS, ERP and secretin ePFT for the evaluation of pancreatitis were identified from our pancreatic disease database. The ePFT was performed based on our 1-hour endoscopic technique with synthetic porcine or human secretin. PEI was defined as a peak bicarbonate concentration <80 mEq/L. EUS abnormalities were categorized as mild (1-2 criteria), moderate (3-5 criteria) or severe (6-9 criteria). ERP abnormalities were categorized as mild, moderate, or severe based on the Cambridge classification. For each EUS and ERP stage, univariate logistic regression was performed to calculate an odds ratio (OR) and 95% confidence interval (CI) for the prediction of PEI.

Results: 38/71 (54%) of patients had PEI. Severe structural changes detected by both ERP and EUS were significantly associated with the presence of PEI (OR 15.5 and 11.4, respectively).

Conclusions: Both ERP and EUS are strongly associated with PEI in the presence of severe structural abnormalities, and poorly associated with PEI in the presence of mild and moderate structural abnormalities. Clinical Implication: EUS is as valid as ERP and a safer alternative in the structural evaluation of CP.

Association of EUS and ERP Abnormalities with PEI

<table>
<thead>
<tr>
<th>Test</th>
<th>Stage</th>
<th>PBC≥80 mEq/L, N (%)</th>
<th>PBC&lt;80 mEq/L, N (%)</th>
<th>95% OR²</th>
<th>CI ³</th>
</tr>
</thead>
<tbody>
<tr>
<td>ERP</td>
<td>Mild (N=12)</td>
<td>4 (33)</td>
<td>8 (67)</td>
<td>1.8</td>
<td>0.5, 6.7</td>
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<tr>
<td></td>
<td>Moderate (N=10)</td>
<td>3 (30)</td>
<td>7 (70)</td>
<td>2.1</td>
<td>0.5, 8.9</td>
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<tr>
<td></td>
<td>Severe (N=14)</td>
<td>1 (7)</td>
<td>13 (93)</td>
<td>15.5</td>
<td>1.9, 126</td>
</tr>
<tr>
<td>EUS</td>
<td>Mild (N=19)</td>
<td>10 (53)</td>
<td>9 (47)</td>
<td>0.7</td>
<td>0.2, 1.9</td>
</tr>
<tr>
<td></td>
<td>Moderate (N=16)</td>
<td>6 (37)</td>
<td>10 (63)</td>
<td>1.5</td>
<td>0.5, 4.7</td>
</tr>
<tr>
<td></td>
<td>Severe (N=11)</td>
<td>1 (9)</td>
<td>10 (91)</td>
<td>11.4</td>
<td>1.4, 95</td>
</tr>
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1PBC = peak bicarbonate concentration, 2OR = odds ratio, 3CI = confidence interval.

Sensitivity and Specificity of Serum IgG4 Levels for the Diagnosis of Autoimmune Pancreatitis: A Study of 500 Patients
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Purpose: Serologic abnormalities are an important adjunct to diagnosis of AIP. Elevated levels of serum IgG4 have been reported to be highly sensitive and specific for AIP. These results have not been confirmed in Western populations.

Aims: a) Assess the diagnostic accuracy of elevated levels of total IgG and IgG4 for AIP and the prevalence of elevated IgG4 levels in other pancreatic diseases, especially pancreatic cancer b) Compare the characteristics of patients with elevated IgG4 levels with and without AIP, as well as AIP patients with and without elevated IgG4 levels.

Methods: We measured total IgG and IgG4 levels in 43 patients with AIP diagnosed by HISORT criteria and 457 consecutive patients attending the Pancreas Clinic with a final diagnosis of pancreatic cancer (N = 143), chronic pancreatitis (N = 77), acute pancreatitis (N = 58), benign pancreatic tumor (N = 62), miscellaneous pancreatic disorders (N = 57) and no pancreatic disease (N = 60).

Results: For diagnosis of AIP elevation of IgG4 levels had better sensitivity compared to total IgG (32/43 (74%) vs 16/43 (37%) p < 0.001). All 16 AIP patients with elevated total IgG also had elevated IgG4 elevation. Among AIP patients, those with elevated IgG4 levels were more likely to be male compared to those with normal IgG4 levels (91% vs 55%, p = 0.007); age and proportion presenting with obstructive jaundice were similar. Among various non-AIP groups, the prevalence of elevated IgG4 levels was 3 to 10%; prevalence was similar among groups. When comparing patients with elevated IgG4 levels with and without AIP, non-AIP patients (“false positives”) were more likely to be female (45% vs 9%, p = 0.001), have a normal total IgG (84%
vs 47%, p = 0.002) and have serum IgG4 levels less than 2 times the upper limit of normal (87% vs 31%, p < 0.001).

**Conclusions:** Elevated serum IgG4 levels are characteristic of AIP and present in majority (74%) of patients. Even among subjects with wide variety of pancreatic diseases, elevated serum IgG4 levels are highly specific (93%) for AIP. However elevated IgG4 levels do occur in other pancreatic diseases including pancreatic cancer. Since AIP is a relatively rare disease, elevated IgG4 levels in subjects with low pretest probability of having AIP are likely to represent false positives.

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**Long-Term Evaluation of Biliary Dyskinesia in Pediatrics**
Michael S. Halata, MD, Howard E. Bostwick, MD, Leonard J. Newman, MD, Lynette Cukaj, MD, Girish Sharma, MD, Stuart H. Berezin, MD.
Pediatrics, New York Medical College, Valhalla, NY.

**Purpose:** Biliary dyskinesia, a motility disorder of the gallbladder, causes gastrointestinal complaints. The six patients who had continuing abdominal symptoms following cholecystectomy with no other significant right upper quadrant pain before surgery had complete resolution of their symptoms. The average cyst diameter was 26 mm and predominately uniloculated. Fifty-three per cent of cysts were aspirated with a 22g needle and 67% of cases required only one needle pass for aspiration. (Table 1) All patients were given IV antibiotic prophylaxis. There were no reports of infectious complications post EUS-FNA in any of the pts. studied.

**Conclusions:** In our study no pts. developed infectious complications post EUS-FNA, which is lower then what has been reported in the literature. It is unclear if our low infection rates are secondary to prophylactic antibiotic use, and future randomized studies are needed to clarify its prophylactic role.

<table>
<thead>
<tr>
<th>Cyst Location</th>
<th>Number of Passes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head</td>
<td>42% (N = 31)</td>
</tr>
<tr>
<td>Body-tail</td>
<td>58% (N = 42)</td>
</tr>
<tr>
<td>Cyst Characteristics</td>
<td>Mean 26 mm (range 3-98 mm)</td>
</tr>
<tr>
<td>Size</td>
<td>59% (N = 43)</td>
</tr>
<tr>
<td>Uniloculated</td>
<td>30% (N = 30)</td>
</tr>
<tr>
<td>Multiloculated</td>
<td>67% (N = 49)</td>
</tr>
<tr>
<td>Number of Passes</td>
<td>19% (N = 14)</td>
</tr>
<tr>
<td>&gt;3</td>
<td>14% (N = 10)</td>
</tr>
</tbody>
</table>

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**Significant Increase in Trainee Credibility Score after Mechanical ERCP Simulator Training**
Joseph Leung, MD, FACG, Felix Leung, MD, Wen Lee, MD, Micha Rajony, MD, Robert Wilson, GI, VANCHCS, Mather, CA; GI, VAGHLACS, Sepulveda, CA; Endoscopy, Union Hospital, Tianjian, China and GI, UCDMC, Sacramento, CA.

**Purpose:** To test the hypothesis that hands-on practice improves credibility score with training using a mechanical ERCP simulator.

**Methods:** Between 4/2005 and 4/2006, 73 consecutive pts. had EUS FNA of PCL. All procedures were preformed by three experienced endosonographers. After PCL was identified by EUS, the endosonographer determined if FNA will be preformed and prior to FNA antibiotic prophylaxis was administered. (Levofloxacin 500 mg I.V.) Aspiration was preformed by using 19, 22 or 25g needles. Pts. were discharged home on a 3-day course of Levofloxacin 500 mg p.o. twice daily. Infectious complications were assessed at day 0 by direct examination and at day 30 by phone call. Inquiries were made about development of symptoms (abdominal pain, fever, bleeding, etc.), visits to the emergency room, physician office or hospitalizations.

**Results:** There were 73 patients with PCL (mean age 69 yrs.; females 66%). The average cyst diameter was 26 mm and predominately uniloculated. Fifty-three per cent of cysts were aspirated with a 22g needle and 67% of cases required only one needle pass for aspiration. (Table 1) All patients were given IV antibiotic prophylaxis. There were no reports of infectious complications post EUS-FNA in any of the pts. studied.

**Table 1.**

<table>
<thead>
<tr>
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</tr>
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<tr>
<td>&gt;3</td>
<td>14% (N = 10)</td>
</tr>
</tbody>
</table>
MRCP Frequently Misses Pancreas Divisum in Clinical Practice
Matthew L. Carnes, MD, Gregory D. Borak, MD, Joseph Romagnaolo, MD, MScEpid, Peter B. Cotton, MD.* Division of Gastroenterology and Hepatology, Digestive Disease Center, Medical University of South Carolina, Charleston, SC.

Purpose: Pancreas divisum is the most common congenital abnormality of the pancreatic anatomy occurring in 3.7-14% of the general population. Pancreas divisum occurs when the ventral and dorsal pancreatic ducts fail to fuse during embryonic development. The majority of patients remain asymptomatic; however, a small percentage develops recurrent bouts of pancreatitis from a relative obstruction to flow of pancreatic secretions through a stenosed minor papilla. MRCP has emerged as a noninvasive method of examining the pancreatic ductal anatomy and parenchyma. Secretin has been used to enhance the visualization of the pancreatic ductal system. MRCP has been reported to have equaled accuracy to that of ERCP. Our institutional experience has been that many patients referred for pancreatic disease have had MRCP which failed to correctly identify pancreas divisum.

Methods: Using our GI Trac endoscopic database, patients diagnosed with pancreas divisum at ERCP between January 2001 and February 2006 were identified. The patients who also had MRCP prior to ERCP were included for analysis. Other patient demographics such as age and gender were also accumulated. Fisher exact or Chi-square p-values and binomial 95% confidence intervals (CI) were calculated and reported.

Results: Pancreas divisum was identified in 405 patients at ERCP at MUSC during the defined period. Of these, 111 (27%) had undergone MRCP prior to ERCP and were included for analysis. 72 (65%) patients had MRCP at outside centers and 39 had MRCP at our institution. Secretin was used in 15 (38%) of the 39 MRCPs at our institution and none in those performed at referring centers (p < 0.001). Only 23 (32%) of the 72 MRCPs performed at outside centers correctly identified divisum. Additionally, 9 (18%) of the remaining 49 negative MRCPs were suspected of it by the attending gastroenterologist on review prior to ERCP. In contrast, 16 (67%) of the 24 MRCPs without secretin at our institution correctly identified divisum. In the secretin-stimulated group, 67% (10/15) were correctly identified. There was no difference between these two subgroups at our institution in terms of sensitivity (difference = 0%).

Conclusions: This analysis shows that pancreas divisum is often missed on MRCP. The absence of secretin, use of suboptimal MR techniques, and inexperienced examiners at reading these types of studies are all possible factors contributing to the poor detection rate using MRCP.

Invasive Hemolymphangioma of the Pancreas: a Case Report
Yoshikazu Toyoki, Kenichi Hakamada,∗ Shunji Narumi, Syuchi Yoshihara, Mutsumo Sasaki. Department of Surgery, Hirosaki University School of Medicine, Hirosaki, Aomori, Japan.

Purpose: Hemolymphangioma of the pancreas is very rare benign tumor. There are only five reports of this disease until May 2006. Major symptoms in this disease are abdominal pain and distension due to enlarged tumor. Herein, we report a case of hemolymphangioma of the pancreas with gastrointestinal bleeding due to invasion to the duodenum.

Results: Case report: A 53-year-old man had been admitted a referral hospital because of severe anemia due to gastrointestinal bleeding on December 2005. And then, he was transferred to our institute for invaded to duodenum pancreatic head tumor on January 2006. Laboratory data showed anemia and the others data, including tumor marker, were within normal limits. Upper gastrointestinal endoscopy revealed bleeding at the duodenum. Computed tomography also demonstrated a heterogenous mass at the pancreatic head and suspected invasion to the duodenal wall. Ultrasonography showed huge mass at the pancreatic head with mixture with high and low echoic area. We were performed pylorous-preserving pancreatoduodenectomy. Pancreatic head tumor was soft tumor and this tumor invaded to the duodenum. Pathology of this tumor showed a hemolymphangioma of the pancreas invaded to the duodenum. He had good postoperative course and discharged at 26 days after operation.

Conclusions: Hemolymphangioma of the pancreas is very rare benign tumor. In a literature review until May 2006 we found only five case reports. Major symptoms are abdominal pain and distension due to enlarged tumor. However, we experienced a case of hemolymphangioma of the pancreas with gastrointestinal bleeding due to invasion to the duodenum. This disease is very rare, but should be considered when patients have gastrointestinal bleeding.

Prevalence of the N34S Mutation in Patients with Acute Pancreatitis
Elie Asun, MD, Janette Lamb, MD, George I. Papachristos, MD, Nevir Oruc, MD, Michael M. Barmada, PhD, David C. Whitcomb, MD.∗ Department of Internal Medicine, University of Pittsburgh Medical Center, Pittsburgh, PA; Division of Gastroenterology, Hepatology and Nutrition, University of Pittsburgh Medical Center, Pittsburgh, PA; Division of Gastroenterology, EGE University, Izmir, Turkey and Department of Human Genetics, University of Pittsburgh Medical Center, Pittsburgh, PA.

Purpose: Serine Protease Inhibitor Kazal type 1 (SPINK-1) is a specific trypsin inhibitor expressed in the pancreas. It has been hypothesized that SPINK-1 acts as the first-line of defense against premature trypsin activation within the pancreas. Mutations in the SPINK-1 gene are associated with chronic pancreatitis however their role in acute pancreatitis remains unclear. This study aims at studying the prevalence of the N34S mutation in a cohort of patients with acute pancreatitis.

Methods: Blood was collected from 102 patients with acute pancreatitis and 239 controls. We tested for the presence of the N34S mutation using validated genotyping methods.

Results: The N34S mutation was detected in 5 patients (3 heterozygotes and 2 homozygotes) all of which had recurrent acute pancreatitis. 7 controls (all heterozygotes) tested positive. The calculated Odds Ratio was 2.391 with a 95% confidence interval of 0.828 – 6.906.

Conclusions: The SPINK-1 N34S mutation does not seem to play an important role in the pathogenesis of acute pancreatitis. This suggests that
previously proposed mechanism of SPINK-1 associated protection needs to be reconsidered.

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Gemcitabin in Elderly Patients with Unresectable Pancreatic Carcinoma
Motoko Izumiya, MD, Yoshiyuki Yamagishi, MD, PhD, Hajime Higuchi, MD, PhD, Hiromasa Takaishi, MD, PhD, Toshifumi Hibi, MD, PhD.*
Gastroenterology, Internal Medicine, Keio University School of Medicine, Shinjuku, Tokyo, Japan.

Purpose: Pancreatic cancer is a highly lethal disease with a rising incidence worldwide. Its prognosis is very poor and especially in the cases with unresectable tumor (Stage IV), median time survival (MST) is 3 to 4 months. Chemotherapy with Gemcitabin (GEM) has recently demonstrated better survival outcomes. We have retrospectively examined the prognosis of elderly patients treated with GEM.

Methods: 62 patients with advanced pancreas tumor with no prior therapy were divided into three groups. Group A; 19 patients under best supportive care. Group B; 26 patients under 70 years old, who received standard GEM (1000 mg/m2) on days 1,8,15. Group C; 17 patients over 70 years old with standard GEM therapy.

Results: Median age of each group were 70.6 (range 49–80), 57.9 (36–69), and 74.9 (71–84) years old. There were no significance in ratios of male: female, Stage IVa : IVb, and performance status 0 : 1. Average CA19-9 was 4301, 7661, and 11,485 with MST were 121, 292 (p < 0.01 vs. group A), and 216 days (p < 0.01 vs. group A), respectively. Among chemotherapy received patients, no complete response (CR) was observed, while 5 patients (19%) in group B and two patients (12%) in group C obtained partial response (PR), with an additional 15 patients (58%) and 10 patients (59%) demonstrated stable diseases (SD). The level of CA19-9 was improved by more than 50% in 17 patients (65.4%) in group B, eight (47.1%) in group C, CA19-9 improvement by more than 20% was seen in 17 patients in group B (65.4%) and 10 (58.8%) in group C. 5 patients (19.2%) in group B and 5 (29.4%) in group C had to have their GEM dose modified because of bone marrow suppression (4 patients) and appetite loss (1 patient).

Conclusions: Chemotherapy with GEM was well tolerated even in elderly patients over 70 years old and yielded a significantly longer MST compared to those under BST. There was no difference in reponse rates (PR + SD) between the group under 70 years old and the group over 70 years old.

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The Association between Genetic Polymorphism of 5,10-Methylenetetrahydrofolate Reductase and Thymidylate Synthase Enhancer Region and Risk of Cholangiocarcinoma
Kwang Hyun Ko, MD, Chang Il Kwon, MD, Kyu Sang Rim.* Internal Medicine, Pochon CHA University, Sungnam, Gyeonggi, Korea.

Purpose: 5,10-Methylenetetrahydrofolate reductase (MTHFR), a key enzyme in folate metabolism, plays a major role in the provision of methyl groups for DNA methylation; thymidylate synthase (TS) is a rate limiting enzyme in the synthesis of dTMP and DNA repair. The clinical role of genetic polymorphisms of MTHFR and that of TS enhancer region (TSER) were demonstrated in several clinical studies with colorectal, esophageal, gastric and breast cancer. However, there have never been any studies on the association between cholangiocarcinoma (CCC) and genetic polymorphisms of MTHFR and TSER.

Methods: We examined the polymorphism of MTHFR and TSER, that share a common substrate, 5,10-methylenetetrahydrofolate, in the CCC, concurrently. Blood samples were obtained from 85 patients with CCC and 204 healthy control donors. Using polymerase chain reaction and restriction fragment length polymorphism (PCR-RFLP), C to T transition at position 677 of MTHFR and tandem repeat of 28bp in the enhancer region of TS gene were analyzed.

Results: Characteristics of 85 CCC cases and 204 controls were as follows. Mean age of CCC was 66.8 year old with 51 males and 34 females. Mean age of control group was 45.9 years with 72 males and 132 females. In 85 CCC patients, 40 had common bile duct cancer, 25 Klatskin tumor, 12 peripheral CCC, and 8 gall bladder cancer. No statistical differences were noted among MTHFR 677CC, CT, TT and TSER 2R2R, 2R3R, 3R3R genotypes.

Conclusions: In conclusion, our data from a Korean population suggest that combined polymorphisms of MTHFR C677T and TSER are not associated with risk of cholangiocarcinoma. Large scale clinical study with folate level and other polymorphisms associated with CCC are warranted.

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Gallstone Disease in Hispanic Females: A Clinically Significant Difference in Clinical Behavior and Complications Compared to Other Ethnic Groups
Hareth M. Raddawi, MD,* Antonio Sanchez, MD.
Internal Medicine/Gastroenterology, University of Illinois/Advocate Christ, Chicago/Oak Lawn, IL.

Purpose: Gallstones are a Polygenic disorder much more predominant in females than males. It is believed to affect over 30 Million Americans. Gallstones appear to be more prevalent in Hispanics compared to other ethnic groups. Gallstone disease and complications related to gallstones contribute substantially to healthcare costs and morbidity. Identification of individuals likely to develop complications would be of great benefit in clinical practice. Our aim was to study the differences in clinical behavior of gallstones between Hispanics, especially females, and Non-Hispanic patients.

Methods: Over a 36 month period we compared the incidence of complications and the severity of gallbladder disease amongst Hispanic versus Non-Hispanic patients who had gallbladder surgery at our institution (A 700-bed tertiary Hospital in suburban Chicago). 1920 patients underwent a cholecystectomy, 1710 were Non-Hispanic, 213 were Hispanic. We randomly selected 120 matching patients from each group for comparison.

Results:

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Hispanics (120)</th>
<th>Non-Hispanics (120)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>78%</td>
<td>63%</td>
<td></td>
</tr>
<tr>
<td>Average age</td>
<td>40</td>
<td>51.5</td>
<td></td>
</tr>
<tr>
<td>Need for ERCP</td>
<td>16%*</td>
<td>6%</td>
<td>0.025</td>
</tr>
<tr>
<td>Severe GB Pathology</td>
<td>27%</td>
<td>14%</td>
<td>0.025</td>
</tr>
</tbody>
</table>

*All 16% had CBD Stones, Severe GB Pathology = Necrotizing/Hemorrhagic Cholecystitis.

Conclusions: Several studies have shown a higher prevalence of lithogenic bile genes amongst Hispanics compared to other ethnic groups. Our data show a higher percentage of Hispanic females with symptomatic gallstones, it also raises the question of a more aggressive clinical behavior of gallstones in Hispanics whereby they not only debut at an earlier age but seem to migrate more often to the bile duct with a tendency to cause more severe gallbladder inflammation. Further prospective studies involving larger numbers of patients are urgently needed to better understand and compare the natural history and clinical behavior of gallstones in different genders in different ethnic groups.

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Accuracy of Endoscopic Ultrasound for Diagnosing Vascular Involvement in Pancreatic Cancer: A Single Center Experience
Jyotsna Talapaneni, MD, Shailender Singh, MD, Strunivas Padi, MD, Melissa Oropeza, RN, Scott Stanley, Faisal Jafri, MD, Mojtaba Olyaee, MD,* Gastroenterology and Hepatology, University of Kansas Medical Center, Kansas City, KS and Baptist Hospital, Kansas City, KS.

Purpose: Endoscopic Ultrasound (EUS) has emerged as an accurate tool to diagnose and stage pancreatic cancer. The ability of EUS to detect vascular
invasion pre-operatively is helpful in management decisions and is perhaps operator dependent. The reported accuracy of EUS to detect vascular involvement in patients with pancreatic cancer is variable. The aim of the study was to evaluate the accuracy of EUS to diagnose vascular involvement in patients with pancreatic cancer at our institution.

**Methods:** Patients who had EUS performed for evaluation of pancreas for varying reasons were retrospectively reviewed. Patients found to have pancreatic cancer who underwent surgery at our institution were then identified. EUS criteria for vascular involvement were: loss of echoplane, tumor in the lumen, abnormal vessel contour, and presence of collateral vessels in the absence of a main vascular structure. Surgical definitions for vascular involvement were: tumor adherence to vessel or tumor encasing the vessel or vascular unresectability.

**Results:** Total of 379 patients were reviewed. EUS revealed pancreatic adenocarcinoma and vascular involvement in 114 patients. 65 of these patients underwent surgery. Of these surgically confirmed patient EUS correctly showed vascular involvement in 36 patients, and there was no involvement in 19 patients. The accuracy of EUS for vascular involvement is shown in table 1.

**Conclusions:** The positive predictive value of EUS to detect vascular invasion in pancreatic cancer is high, a positive result indicating likely true vascular invasion. EUS is a good minimally invasive test to diagnose vascular involvement, thus providing valuable information needed to help select patients for surgical management.

**Table 1.** Accuracy of EUS to diagnose vascular involvement in patients with pancreatic cancer

<table>
<thead>
<tr>
<th>Vascular Involvement</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>63.46%</td>
<td>78.57%</td>
<td>91.67%</td>
<td>57.89%</td>
</tr>
</tbody>
</table>

**206**

**Role of EUS-FNA in the Diagnosis of Solid Pancreatic Lesions. A Single Center Experience**

**Purpose:** Mass lesions of the pancreas include both malignant and benign tumors which are often difficult to differentiate. Differentiating these tumors is essential for optimal management and outcome. The purpose of the study is to retrospectively evaluate the accuracy of EUS-FNA in cytologic diagnosis of pancreatic solid lesions at our institution.

**Methods:** 379 patients who underwent EUS over a 3-year period based on abnormal pancreatic imaging (mass lesion, fullness or prominent head of pancreas) or obstructive jaundice were included in the review. EUS-FNA was performed using 22-gauge needle. Onsite cytopathologist was available to determine the adequacy of the sample.

**Results:** 175 of 379 patients were identified to have a finding of solid pancreatic lesion on EUS and had EUS-FNA performed. EUS-FNA results are as shown in table 1. Surgical confirmation of pancreatic adenocarcinoma was available in 71 out of 111 patients. Follow up of patients with atypical cytology on subsequent surgery revealed pancreatic malignancy in 4 patients. The sensitivity, specificity, positive predictive value and negative predictive value of EUS-FNA in the diagnosis of solid pancreatic tumors at our center is 96.52%, 100%, 100% and 92.72% respectively.

**Conclusions:** EUS-FNA is a minimally invasive and safe procedure to evaluate patients with pancreatic solid lesions and can provide accurate tissue diagnosis. Patients with atypical cell aspirates should be evaluated further for possible underlying pancreatic malignancy.

**207**

**Role of EUS in Evaluation of Patients with Obstructive Jaundice: Single Center Experience**

**Purpose:** Pancreatic malignancy is a common cause of biliary obstruction in the elderly and CT scan has been the conventional diagnostic imaging modality. However, in these patients normal pancreas on CT scan is not uncommon and in such situations surgical exploration has been suggested. EUS has emerged as a valuable tool in evaluating pancreatic malignancy and/or vascular invasion. The aim of the study was to investigate the role of EUS/EUS-FNA in patients with obstructive jaundice without any definite pancreatic mass lesion on prior CT scan.

**Methods:** Patients who had EUS performed at our center between April 2002 and February 2006 for obstructive jaundice and had biliary stricture on ERCP and prior CT scan was negative for any pancreatic mass lesion were included in the study. Final diagnosis was based on definitive cytology, surgical pathology or clinical follow up of at least 6 months. FNA reported as atypical cells or suspicious for malignancy was considered negative for this study analysis.

**Results:** 57 patients fulfilled the inclusion criteria. 46 patients had normal CT of the pancreas and 11 patients had inconclusive CT findings (enlarged or fullness of head of pancreas, heterogenous pancreas, mass cannot be excluded). EUS performed in the group with normal pancreas on CT scan revealed pancreatic mass lesion in 56% (26/46). 18 of these 26 patients had pancreatic adenocarcinoma on EUS-FNA and was confirmed on surgical pathology. Of the remaining 20 patients with obstructive jaundice and normal pancreas on CT, EUS revealed: normal pancreas 7, chronic pancreatitis 2, CBD stone 1, ampullary mass 3, cholangiocarcinoma 6 and biliary sarcoid in 1 patient. In the group of 11 patients with indeterminate pancreatic CT findings, EUS revealed a mass lesion in all and pancreatic adenocarcinoma was confirmed in 8 patients.

**Conclusions:** EUS appears to be extremely useful in patients with obstructive jaundice particularly to evaluate for pancreatico-biliary malignancy and to evaluate for other benign causes of biliary obstruction.

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**Role of EUS in Evaluating Patients with Abnormal Pancreas on CT Scan**

**Purpose:** Superiority of EUS over conventional CT scan in evaluating pancreatic lesions is now well established and accepted. However, due to easy availability, CT scan appears to be the preferred first modality for pancreatic imaging. Indeterminate or inconclusive results, difficult to distinguish from pancreatic carcinoma are often reported on abdominal CT/MRI performed for unrelated symptoms. The aim of this study was to report our experience of EUS findings in patients with such equivocal pancreatic imaging results.

**Methods:** EUS reports of all patients, from April 2002 to February 2006, who underwent EUS for evaluation of pancreas were reviewed. Patients whose indication was indeterminate pancreatic imaging results (e.g. enlarged benign pancreatic histology) 26 (14.85%)

**Table 1.** Distribution of patients based on EUS-FNA results

<table>
<thead>
<tr>
<th>Pancreatic Adenocarcinoma</th>
<th>Neuro-endocrine Tumor</th>
<th>Mucinous Adenocarcinoma</th>
<th>Intraductal Papillary Adenocarcinoma</th>
<th>Atypical Cells</th>
<th>Benign Pancreatic histology</th>
</tr>
</thead>
<tbody>
<tr>
<td>111 (63.42%)</td>
<td>14 (8%)</td>
<td>1 (0.57%)</td>
<td>2 (1.14%)</td>
<td>21 (12%)</td>
<td>26 (14.85%)</td>
</tr>
</tbody>
</table>
Variation in SPINK-1 N34S Effect Size Is Population-Dependant
Elie Aoun, MD, Chung-Chou Chang, PhD, George I. Papachristou, MD, Nevin Oruc, MD, Michael M. Barmada, PhD, Whitcomb C. David, MD.* Department of Internal Medicine, University of Pittsburgh Medical Center, Pittsburgh, PA; Division of Gastroenterology, Hepatology and Nutrition, University of Pittsburgh Medical Center; Pittsburgh, PA; Division of Gastroenterology, EGE University, Izmir, Turkey and Department of Human Genetics, University of Pittsburgh Medical Center, Pittsburgh, PA.

Purpose: SPINK-1 is a specific trypsin inhibitor expressed in the pancreas and currently thought of as the first-line of defense against premature pancreatic trypsin activation. Mutations in the SPINK-1 gene are associated with pancreatitis but their reported effect varies widely among studies. Our aim is to systematically review the effect size of the SPINK1 N34S high-risk haplotype in patients with acute pancreatitis (AP) and chronic pancreatitis (CP) in different populations using meta-analysis.

Methods: Case-control studies published by October 2005 were identified by Medline search. The significance of the association of the N34S mutation with pancreatitis was evaluated for each study separately [OR (95% CI)]. Separate meta-analyses were carried for the different disease subtypes.

Results: The N34S mutation was associated with CP in general (OR: 10.50, 95% CI: 6.92–15.92). Patients with ACP had a weaker association (OR: 5.13, 95% CI: 3.26–8.08). The strongest association was with TCP (OR: 31.15, 95% CI 13.21–73.47). The association with AP was weak (OR: 2.98, 95% CI: 1.71–5.22). There was no evidence of publication bias.

Conclusions: Majority of patients with inconclusive pancreatic imaging had underlying abnormality detected on EUS, pancreatic malignancy being found in 17% of the patients. EUS along with FNA is an effective modality for establishing a tissue diagnosis in patients with abnormal pancreatic imaging.

Results of the meta-analyses across the different disease subsets

<table>
<thead>
<tr>
<th>Subset (nb of studies)</th>
<th>Heterogeneity</th>
<th>Fixed Model (Mantel-Hanszel)</th>
<th>Random Model (Der Simonian-Laird)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CP - all etiologies (19)</td>
<td>34.19 (18.001)</td>
<td>10.12 (7.89–12.99)</td>
<td>10.50 (6.92–15.92)</td>
</tr>
<tr>
<td>ACP (10)</td>
<td>6.41 (9.069)</td>
<td>5.13 (3.26–8.08)</td>
<td>5.13 (3.26–8.08)</td>
</tr>
<tr>
<td>TCP (3)</td>
<td>0.15 (2.093)</td>
<td>31.15 (13.21–73.47)</td>
<td>31.15 (13.21–73.47)</td>
</tr>
<tr>
<td>ICP (8)</td>
<td>11.78 (7.011)</td>
<td>12.20 (7.62–19.52)</td>
<td>12.06 (6.45–22.53)</td>
</tr>
<tr>
<td>HCP (7)</td>
<td>11.28 (6.008)</td>
<td>12.20 (7.62–19.52)</td>
<td>10.96 (5.22–23.01)</td>
</tr>
<tr>
<td>AP (3)</td>
<td>0.30 (2.086)</td>
<td>2.98 (1.71–5.22)</td>
<td>2.98 (1.71–5.22)</td>
</tr>
</tbody>
</table>

ACP = Alcoholic CP; TCP = Tropical CP; ICP = Idiopathic CP; HCP = Hereditary CP.
Comparison of Peak Bicarbonate in CAP_NML and CAP_ABNML

<table>
<thead>
<tr>
<th></th>
<th>N Median</th>
<th>25th</th>
<th>75th</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAP_NML</td>
<td>35 93</td>
<td>84–104 (20)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAP_ABNML</td>
<td>9 56</td>
<td>42–74 (32)</td>
<td></td>
<td>0.0004*</td>
</tr>
</tbody>
</table>

*Non-parametric Analysis: Wilcoxon Rank Sum test

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Incidence and Risk Factors for Pancreatic Cancer in Southeast Appalachian, KY 1998-2002

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Purpose: The American Cancer Society estimates that 32,180 men and women will be diagnosed with and 31,800 men and women will die of pancreatic cancer (PC) in 2005 in our nation. Based on the NCI’s SEER cancer statistics review, in the United States, between 1998-2002, the median age of PC incidence in the United States is 72, its incidence is increasing in women, it appears to have stabilized in men. While the incidence is increasing in women, it appears to have stabilized in men. Among cases, 29% were female and 10, moderate = 10 and severe = 23) due to alcohol = 33 and other causes = 20 were studied. At baseline mean age was 48.4 yrs, 27 were males, 29 Caucasian. Over a median duration of 20 months [range 3-66], the Cambridge stage worsened in 25 (47.2%) and improved in 12 (22.6%) subjects. 11/25 subjects had a one stage worsening which was driven mainly by MPD irregularity. Those with MPD strictures did not progress more rapidly than those without. Improvement in Cambridge stage was mainly driven by decreased main PD diameter. Neither improvement nor worsening PD morphology correlated with the frequency and severity of pain flares or other clinical outcome parameters. Females gender was associated with greater risk of worsening PD morphology. There was also a trend for alcohol as an independent risk factor for progression.

Conclusions: CP morphology is a dynamic parameter and shows bidirectional changes over time. Changes in PD diameter are the principal driver of both improvement and worsening of Cambridge stage over time but do not correlate with clinical outcomes. These data highlight the need for a better method for grading and staging of CP.

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A Prospective Cohort Study of Pancreatic Duct Changes in Chronic Pancreatitis and Its Clinical Implications

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Purpose: The changes of pancreatic duct (PD) morphology in chronic pancreatitis (CP) and their relationship to clinical outcomes have not been prospectively evaluated.

Aims: (1) to perform a prospective analysis of changes in PD morphology over time in subjects with CP, (2) correlate changes in PD morphology with clinical outcomes, and (3) identify factors associated with changes in PD morphology.

Methods: Subjects with CP were followed with serial magnetic resonance cholangio-pancreatography (MRCP). PD changes were categorized according to the Cambridge classification (Axon et al, 1984). Clinical outcome parameters included pain episode frequency and severity, development of pseudocysts, stenoturbation and diabetes. Comparison of distribution of parameters between those who worsened or improved versus others was done with a T-test or Fisher’s Exact test. Cox’s regression analysis was performed to identify independent predictors of improvement or worsening. Spearman’s coefficient was used to determine relationship between clinical outcomes and changes in PD.

Results: A total of 53 subjects with CP (PD changes; equivocal = 10, mild = 10, moderate = 10 and severe = 23) due to alcohol = 33 and other causes = 20 were studied. At baseline mean age was 48.4 yrs, 27 were males, 29 Caucasian. Over a median duration of 20 months [range 3-66], the Cambridge stage worsened in 25 (47.2%) and improved in 12 (22.6%) subjects. 11/25 subjects had a one stage worsening which was driven mainly by MPD irregularity. Those with MPD strictures did not progress more rapidly than those without. Improvement in Cambridge stage was mainly driven by decreased main PD diameter. Neither improvement nor worsening PD morphology correlated with the frequency and severity of pain flares or other clinical outcome parameters. Females gender was associated with greater risk of worsening PD morphology. There was also a trend for alcohol as an independent risk factor for progression.

Conclusions: CP morphology is a dynamic parameter and shows bidirectional changes over time. Changes in PD diameter are the principal driver of both improvement and worsening of Cambridge stage over time but do not correlate with clinical outcomes. These data highlight the need for a better method for grading and staging of CP.
We have previously shown that pts with suspected SOD who are found to have normal SOM are also at high risk for post-ERCP pancreatitis (Fogel et al., Endoscopy 2002; 34:280-5). The aim of this retrospective, non-randomized study was to determine whether PD stent placement also reduces pancreatitis rates in this pt population.

**Methods:** From 1/99-12/05, all pts who underwent ERCP/SOM (for evaluation of chronic abdominal pain or unexplained pancreatitis) but had normal biliary/pancreatic SOM were identified from our ERCP database. The decision to place a temporary, 3Fr or 4Fr, unflanged 3/4-single pigtail PD stent was made by the individual endoscopist. Pts who underwent any other therapeutic intervention or received secretin at ERCP were excluded. Incidence of pt/procedure risk factors for post-ERCP pancreatitis (age, gender, prior history of post-ERCP pancreatitis, absence of chronic pancreatitis on ERP, degree of PD opacification), trainee participation and prior sphincter therapy were compared in both groups. Since difficult cannulation or number of PD injections was unknown in this retrospective study, procedure time was used as a marker for procedure difficulty.

**Results:** 410 pts met inclusion criteria: 175 had a PD stent placed (group 1), while 235 did not (group 2). Pancreatitis rates were 2.3% (4/175; 3 mild, 1 moderate) in group 1 and 8.9% (21/235; 16 mild, 4 mod, 1 severe) in group 2 (p < 0.01; OR = 4.2, 95% CI 1.4-12.5). Incidence of risk factors for pancreatitis, trainee participation or prior sphincter therapy (37% group 1, 44% group 2) was not statistically different between the two groups. Procedure time was slightly longer in group 1 (25.0 ± 10.9 min vs 21.8 ± 11.9 min; p = 0.01).

**Conclusions:** In this study, temporary PD stent placement was associated with a 4-fold reduction in pancreatitis rates, in pts with suspected SOD but normal SOM. While procedure time was longer in the stented group (mean difference 3.2 minutes), this potentially might be accounted for by stent placement alone. Routine use of PD stents is recommended when evaluating this difficult, high-risk patient population.

### Abstracts

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**Obstructive Choledocholithiasis Necessitating ERCP with Needle-Knife Sphincterotomy in a 4-Month-Old with Recent Cephalohematoma**

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**Purpose:** A four-month-old male presented with clay-colored stools for three weeks, dark urine for five days, and jaundice for two days prior to admission. The infant was otherwise asymptomatic. Perinatal history was remarkable for a cephalohematoma, which had formed secondary to a vacuum extraction. Resultant indirect hyperbilirubinemia resolved with phototherapy. The family history was negative for hemolytic disease and gallstones. The infant appeared robust and playful. Physical examination was remarkable only for jaundice. Laboratory studies showed total bilirubin 8.1 mg/dL, direct bilirubin 6.0 mg/dL, alanine aminotransferase 165 u/l, aspartate aminotransferase 151 u/l, alkaline phosphatase 641 u/l, and gamma-glutamyl transpeptidase 1,309 u/l. Complete blood count and pancreatic enzymes were normal. Abdominal ultrasound revealed a thick-walled gallbladder with a non-mobile calculus. The common bile duct (CBD) was dilated to 5 mm. Subsequent MRCP revealed a 4 mm stone in the distal CBD. The patient underwent ERCP. The cholangiogram revealed multiple filling defects in the CBD. Needle-knife sphincterotomy was performed, as deep cannulation could not be achieved by catheter or guidewire. However, despite this intervention, deep cannulation was still unsuccessful. The pancreatic duct was inadvertently injected once. ERCP was repeated four days later. The sphincterotomy required needle-knife extension because of papillary swelling. Deep cannulation was successful, sphincterotomy was extended by mini-tome, and multiple pigmented stones were extracted. There were no complications with either procedure. The patient recovered quickly and remains asymptomatic and well.

Here we describe a case of an infant with obstructive choledocholithiasis following resolution of a perinatal cephalohematoma. Several hemolytic states such as sickle cell anemia are well known to be associated withpigmented biliary calculi. Resorption of a cephalohematoma in our case may have contributed to stone formation by this same mechanism. The temporal relationship of the cephalohematoma along with the absence of other risk factors for stone formation strengthens this association. The clinician should remain vigilant for this etiologic phenomenon in the appropriate clinical setting. ERCP in children should be performed with the best available expertise.

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**Clinical Significance of Isolated Intrahepatic Ductal Dilatation Detected by Computed Tomography**

Samir Parekh, MD, Ngozi Okoro, MD, Amil Patel, MD, Yoosun Han, MD, Qiang Cai, MD, FACG. Department of Medicine Division of Digestive Diseases, Emory University School of Medicine, Atlanta, GA.

**Purpose:** Isolated intrahepatic bile duct dilatation is not an uncommon finding on computed tomography (CT) scan. However, the clinical significance of this ductal dilatation is unknown. The purpose of this study is to identify the etiology for isolated intrahepatic ductal dilatation.

**Methods:** Patients with a finding of isolated intrahepatic bile duct dilatation were identified in radiology reports of all patients who had an abdominal CT scan at The Emory Clinic or Emory University Hospital between 1/1/1998 and 8/9/2005, and the following data were recorded: age, gender, race, past medical history, chief complaint, liver enzymes, alkaline phosphatase, total bilirubin, direct bilirubin, final diagnosis, and clinical outcome. Patients who were status post liver transplantation and patients who had biliary stents or drains in place at the time of imaging were excluded.

**Results:** 17 patients with isolated intrahepatic ductal dilatation who met inclusion criteria were identified in this study period. Ages ranged from 33 to 91. 10 patients were female and 7 were male. The most common presentations were abdominal pain. The most common underlying diagnoses were idiopathic dilatation (8/17, 47%) and primary sclerosing cholangitis (6/17, 35%). It was also noted that 50% (4/8) of patients with idiopathic dilatation had previous cholecystectomies. Etiologies of dilatation for the remaining 3 patients included cholangiocarcinoma, cholecytitis, and liver metastasis status post radiofrequency ablation. All patients with benign idiopathic dilatation had normal liver enzymes and bilirubin upon presentation. In contrast, all but one patient with dilatation related to underlying pathology had elevations in bilirubin and/or liver enzymes.

**Conclusions:** This study suggests that those patients with isolated ductal dilatation and abnormal liver biochemistries should be aggressively worked up for an underlying etiology. Although most patients with normal liver biochemistries appear to have a benign idiopathic etiology, physicians must use clinical judgement in further work up to avoid too much aggressive work up. Our data may also suggest a link between prior cholecystectomy and isolated intrahepatic ductal dilatation.

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**Isolated Main Pancreatic Ductal Dilatation Detected by Computed Tomography: When To Be Concerned for Malignancy?**

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**Purpose:** The finding of main pancreatic duct (PD) dilatation on computed tomography (CT) scan is not uncommon. We previously reported that the combination of biliary duct dilatation and PD dilatation had a higher rate of malignancy than that of isolated PD dilatation (DDW, 2003). The objective of
Conclusions: Fifty-one patients with isolated PD dilatation were identified in the study period. The two most common causes of isolated PD dilatation were chronic pancreatitis (37/51, 73%) and idiopathic dilatation (8/51, 15%). The rest are 5 patients with malignancy including 2 pancreatic adenocarcinomas, 2 intraductal papillary mucinous tumors (IPMT), and 1 pancreatic sarcoma and 1 patient with acute cholecystitis. The 5 patients with pancreatic malignancy had no evidence of chronic pancreatitis. There-fore, 35% (5/14) of patients with isolated PD dilatation and without chronic pancreatitis had a pancreatic malignancy. Conclusions: General practitioners and gastroenterologists should carefully follow patients with isolated PD dilatation on CT as 6% of such patients have underlying malignancy. In addition, if patients with isolated PD dilatation have no evidence of chronic pancreatitis, an extensive work up is strongly suggested as up to one third of those patients may have a pancreatic malignancy.

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Does Gallbladder Pathology Predict Reoccurrence of Symptoms Post Cholecystectomy?—A Telephone Survey of Patients with Cholecystectomy

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Purpose: The aim of this study is to investigate histopathology findings of the gallbladder in patients who have undergone cholecystectomy and determine if there is any association between these and any residual symptoms the patient may have post surgery.

Methods: All adult patients who had cholecystectomies in a teaching hospital over a one year period were searched by a computer program. We excluded patients who had gallbladder surgery as part of any other procedure. We then contacted the patients and had them answer a standardized questionnaire detailing symptoms before and after gallbladder removal.

Results: A total of 277 open and laparoscopic cholecystectomies were screened. After inclusion and exclusion criteria were applied, 124 patients were available for analysis, and data was ultimately collected from 88 patients. The histologic findings were acute cholecystitis, chronic cholecystitis, cholelithiasis, adenocarcinoma, gallbladder polyps, and normal. Two years after surgery, 46% of patients with a histologic finding of acute cholecystitis were free of symptoms. In the chronic cholecystitis group, 38% were free of symptoms. In the cholelithiasis group, 35.7% of patients were free of symptoms after surgery. The sample sizes for patients with adenocarcinoma, polyps, and no pathology were too small for analysis.

Conclusions: Cholecystectomy provided more symptom relief in patients with acute cholecystitis than in those patients with chronic cholecystitis or cholelithiasis.

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Risk Factors for Failure of ERCP under Conscious Sedation

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Purpose: ERCPs are technically challenging procedures typically conducted under conscious sedation. However, it is not uncommon for patients to fail to achieve a satisfactory level of sedation with conscious sedation (CS) and require general anesthesia (GA) in an operating room setting. Having patients undergo multiple attempts at ERCP greatly increases both the financial cost and the risk of complications. The aim of this study is to identify potential risk factors for patient who will require GA for a safe and successful ERCP.

Methods: A retrospective analysis was conducted at Emory University Hospital of all patients between 1/1/01 and 3/15/06 who failed ERCP under CS and required GA. Data from those who required GA was then compared to data from patients whose ERCPs were successful with CS between 1/1/05 and 6/30/05. Comparisons were made based upon the following data: indication for procedure, age, gender, and history of alcohol, tobacco, and narcotic use.

Results: Of the 1,010 ERCPs performed over this five year time period, 33 (3.6%) failed CS later requiring GA. When comparing those who failed CS to those who had successful procedures with CS, there was no indication for procedure that was more prone to fail CS, and there was no significant difference in median age, alcohol use, or tobacco use. However, males were slightly more likely to fail CS as 61.1% of cases requiring GA were male compared to 50.7% of those requiring only CS. In addition, approximately 60.7% of patient requiring GA were on various narcotic medications at the time of procedure compared to only 35.5% of those who were successful on initial attempt under CS.

Conclusions: This small retrospective study suggests that male gender and chronic narcotic use appear to be significant risk factors for failure of ERCP using standard conscious sedation medications. Patients on narcotics are almost twice as likely to fail conscious sedation and require general anesthesia.

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Ursodiol for Selected Patients with Post-Cholecystectomy Abdominal Pain—A Preliminary Study

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Purpose: The aim of this study is to examine the effect of ursodiol in the management of abdominal pain for patients with microlithiasis in the common bile duct after cholecystectomy.

Methods: We studied post-cholecystectomy patients with “idiopathic” right upper quadrant abdominal (RUQ) pain. These patients had both a negative abdominal ultrasound and an upper endoscopy examination. Bile was aspirated from these patients and examined for microlithiasis. For those patients found to have microlithiasis in the common bile duct, ursodiol was then used in an attempt to control the abdominal pain.

Results: Three patients were ultimately identified for the study. They were all female, middle aged, and had a cholecystectomy 1 to 3 years prior to being enrolled into the study. They all had RUQ abdominal pain, and one also had acute pancreatitis. They tried various different medications such as proton pump inhibitors, etc., without any alleviation of their symptoms. After using ursodiol for 6 months, all reported that their abdominal pain either improved or resolved.

Conclusions: Ursodiol may be an ideal medication for management of patients with post-cholecystectomy abdominal pain and microlithiasis. However, a randomized trial is needed in the future.

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Pancreaticopleural Fistula: A Rare Complication of Chronic Pancreatitis

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Purpose: Pancreaticopleural fistula (PPF) is a rare entity in which pancreatic secretions drain directly into the pleural cavity. A case is described herein of PPF in a patient with chronic pancreatitis. A 43-year-old male presented with a 4-week history of dyspnea, chest pain, cough and a history of alcoholism. On examination he had features of pleural effusion that was confirmed by chest
Drug Induced Acute Pancreatitis: An Evidence Based Approach and Review of the Literature

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Purpose: Drug induced acute pancreatitis is a difficult diagnosis to establish. While some medications have been shown to cause acute pancreatitis with a large body of evidence, such as a rechallenge and consistent latency, many drugs have been attributed to causing acute pancreatitis merely by one case report. In order to classify the drugs based on the level of evidence, the review of literature was performed.

Methods: Classification System: Based on the analysis of the level of evidence, four classes of drugs could be identified. Class I Drugs includes medications in which at least 1 case report described a recurrence of acute pancreatitis with a rechallenge with the drug. The case report must have ruled out all other causes of acute pancreatitis, such as alcohol, gallstones, triglycerides and other known medications. Class II drugs includes drugs in which there is a consistent latency in 75% of the reported cases, however no published case reports with rechallenge. At least 4 case reports were required to be included in this category. Class III drugs have at least 2 case reports, but neither a rechallenge nor consistent latency. Class IV drugs have only one case report published.

Results: Medline search of the literature from 1955–2006 revealed 1214 case reports which allowed classification of 120 drugs. 46 medications met the criteria to be included in Class I. These drugs with the greatest evidence of causing acute pancreatitis, with rechallenges and a consistent latency, include: alphanmethyldap, all-transretinoic acid, amiodarone, mesalamine, azathioprine, bezafibrate, cannabis, carbimazole, cimetidine, clomiphene, codeine, cytokine-ribosin, dapsone, dexamethasone, enalapril, fluvastatin, furosemide, HCTZ, hydrocortison, ifosfamide, INF-alpha, INH, lamivudine, losartan, meglumine, 6-MP, methimazoel, metronidazol, nelfinavir, omerprazole, pantemidine, pravastatin, procarinomide, pyritinol, simvastatin, sulfa, stibogluconate, sulindac, tetracycline, valproic acid.

Conclusions: In summary, this classification system assists clinicians in understanding the evidence and patterns of drug induced acute pancreatitis. Future publications of drugs thought to cause acute pancreatitis should include information necessary for this classification system.

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Fatal Acute Pancreatitis: Correlation with Single Prognostic Markers of Severity on Admission

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Purpose: Acute Pancreatitis (AP) has a mortality rate of 8.57% (range 3-36%) calculated on the basis of 26 studies (Lankisch et al. Pancreas. 1999; 19:321-324). Recognition of severity of AP on admission may help in reducing the second peak of mortality that usually occurs after 2 weeks of hospitalization. Many single markers were added recently (Pitchumuni et al. J Clin Gastroenterol; 36:798-814).

Aim: The aim of this study is to identify the important single markers of severity on AP on admission, which are readily available and correlate them with fatal cases encountered by us.

Methods: Data was collected on patients presented to two institutions with AP over a 4 year period. The prognostic markers and their clinical significance were then tabulated.

Single prognostic markers of severity in AP on Admission

<table>
<thead>
<tr>
<th>Prognostic markers:</th>
<th>P-value</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Significant&lt;br&gt;HR &gt; 100/min</td>
<td>&lt;0.05</td>
<td>53%</td>
<td>76%</td>
<td>7%</td>
<td>98%</td>
</tr>
<tr>
<td>Significant&lt;br&gt;Calcium &lt;8.0 mg/dl</td>
<td>&lt;0.001</td>
<td>33%</td>
<td>97%</td>
<td>24%</td>
<td>98%</td>
</tr>
<tr>
<td>Significant&lt;br&gt;Albumin &lt;3.0 g/dl</td>
<td>&lt;0.05</td>
<td>20%</td>
<td>93%</td>
<td>8%</td>
<td>97%</td>
</tr>
<tr>
<td>Significant&lt;br&gt;Creatinine &gt;2.0 mg/dl</td>
<td>&lt;0.001</td>
<td>40%</td>
<td>93%</td>
<td>16%</td>
<td>98%</td>
</tr>
<tr>
<td>Significant&lt;br&gt;Glucose &gt;200 mg/dl</td>
<td>&lt;0.001</td>
<td>53%</td>
<td>87%</td>
<td>11%</td>
<td>98%</td>
</tr>
<tr>
<td>Significant&lt;br&gt;Presence of pleural effusion on CXR or CT scan</td>
<td>&lt;0.001</td>
<td>60%</td>
<td>71%</td>
<td>7%</td>
<td>98%</td>
</tr>
<tr>
<td>NOT significant&lt;br&gt;WBC &gt; 16,000/mm3</td>
<td>0.169</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOT significant&lt;br&gt;AST &gt; 250u/l</td>
<td>0.719</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOT significant&lt;br&gt;HCT &gt; 44%</td>
<td>0.153</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOT significant&lt;br&gt;Sex</td>
<td>0.972</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOT significant&lt;br&gt;Etiology of AP</td>
<td>0.526</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOT significant&lt;br&gt;Fall of HCT &gt; 10% in 48hr</td>
<td>0.686</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Note: Although not part of this study, initial hemococoncentration and failure to correct it was related to local pancreatic complications but NOT to mortality.
Results: Total number of patients: 486 (Males 220, Females 266)
Mean age: 54.5 ± 18.20 SD years
Mortality: 15 (3.0%) cases.

Conclusions: 1) Etiology of AP (Biliary vs. Alcohol) not significant to mortality (p-value 0.526).
2) Simple prognostic markers of severity in AP (HR > 100/min, calcium < 8.0 mg/dl, albumin < 3.0 g/dl, creatinine > 2.0 mg/dl, glucose > 200 mg/dl and presence of pleural effusion) are readily available on admission and statistically significant in predicting mortality.
3) The NPV of these single prognostic markers for mortality is 98%.

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Pancreatic Pseudocyst Drainage—Transpapillary or Transmural?
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Purpose: Endoscopic drainage by transpapillary (TP), transgastric (TG) and transduodenal (TD) route of the pseudocyst is available but there has been a paucity of data comparing the different endoscopic techniques in terms of overall success and complications. The primary aim of this study is to pool available data and provide an overall success rate stratified by the different endoscopic approaches.

Methods: Pubmed search was performed by search phrase “Endoscopic pancreatic pseudocyst drainage.” Articles having incomplete data, surgical approaches, transcutaneous approaches were excluded. 7 articles were included for this study. We looked at the technical and overall success for each of the modalities (TP, TG, TD and mixed), including complications for the procedure. The pooled data was analyzed by transpapillary and transmural (TG+TD) approaches.

Results: There were 323 pts in the 7 studies. The study period range from 1983-2000 with a mean follow up of 33.7 mths (22-43 mths). TP approach was performed in 115 patients with an overall success in 88 pts (77%). Transmural approach was performed in 183 pts with an overall success in 135 pts (74%). The overall success rate with these procedures is 75%. Outcome analysis was performed on 5 studies (1,2,5,6,7) TP v/s transmural approach (OR 1.35, 95% CI 0.7-2.5). Total complications were reported in 63/323 patients (19%), with major complications being pancreatitis (6/323, 1.8%), bleeding (17/323, 5.2%) and infections (18/323, 5.5%). There was only 1 (0.3%) reported mortality.

Conclusions: Our pooled analysis reveals that there is no difference in the outcomes of the two approaches. Individual decisions for the route of drainage should depend on the anatomical considerations (ductal disruption, distance from lumen and location), technical feasibility and expertise. Prospective controlled trials are ideally indicated to define outcome between the two approaches.

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Endoscopic Ultrasound-Guided Placement of Fiducials for the Treatment of Pancreatic Cancer
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Purpose: Alternative treatment options for locally unresectable pancreatic cancer are emerging. Radiosurgical therapy (Cyberknife, Accuray Inc, Sunnyvale, CA) is a new approach that allows for precise and flexible external beam radiation targeting of the tumor through an image-guided stereotactic radiosurgery system. Cyberknife treatment of pancreatic cancer requires placement of fiducial markers to enable computer tracking of the tumor during radiation delivery. This placement of the fiducial has traditionally required surgery. We present a novel technique of fiducial placement using endoscopic ultrasound.

Methods: After informed consent, patients were given a dose of prophylactic intravenous antibiotic. Sedation was achieved in a routine fashion using intravenous midazolam and meperidine. A Pentax 5G-3630 UR radial echo endoscope was used to localize the pancreatic tumor. Next, using a Pentax 5G-3630 linear echoendoscope, one to three 5 mm gold fiducials were deployed into the center of the tumor using a Wilson Cook 19 gauge or 22 gauge EUS biopsy needle. The position of the fiducial(s) were documented by both sonography and fluoroscopy. The patients were recovered and discharged from our outpatient facility in the usual fashion. Post-implantation follow-up occurred at day # 10 during which time placement of the fiducial(s) was assessed by computed tomography.

Results: Eleven patients underwent EUS-guided placement of sixteen fiducials. There were no intra-procedural complications with all patients being discharged from our ambulatory center. Upon follow-up, one patient had developed an infectious process which resolved with short-term oral antibiotics. Two patients experienced migration of their fiducials requiring repeat EUS-guided implantations without clinical consequences. All eleven patients went on to complete a 6 week course of radiosurgical therapy.

Conclusions: We have shown that EUS placement of fiducials in pancreatic cancer for tumor localization can be accomplished safely and effectively. It may be an appealing alternative to conventional laparoscopic or surgical placement.

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Use of CEA to Amylase Ratio for the Evaluation of Cystic Lesions of the Pancreas
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Purpose: Management of pancreatic cystic lesions remains challenging due to limitations in the ability to distinguish between mucinous, nonmucinous, and malignant cysts without surgery. A carcinoembryonic antigen (CEA) level greater than 192 has been proposed as the best marker for differentiating these lesions. However, CEA may be elevated in benign pseudocysts, making the positive predictive value of CEA less than ideal. Since pseudocysts have elevated amylase levels, we hypothesized that correcting the CEA for the amylase level would improve the predictive value. We sought to determine whether use of the ratio of cyst fluid CEA to the natural log of the amylase (CEA/ln amylase) would improve the test performance characteristics in distinguishing benign from premalignant or malignant cysts.

Abstracts
Epidemiology of Acute Biliary and Alcoholic Pancreatitis, Is There a Seasonal Pattern?

Damodar Pandey, MD, Hatem Massoumi, MD, Edward Norkus, PhD, Nejat Kiyici, MD, Hilary Hertan, MD, FACG.* Department of Gastroenterology, Our Lady of Mercy Medical Center, Bronx, NY and Department of Medical Research, Our Lady of Mercy Medical Center, Bronx, NY.

Purpose: Although the etiologies of acute biliary and alcoholic pancreatitis are known, the exact factors contributing to their occurrence are not fully clear. In this report, we questioned whether there are seasonal variations in the occurrence of these two diseases.

Methods: Data was retrospectively collected on hospitalized patients with acute biliary or alcoholic pancreatitis from 1981-2000. We intend to continue this study for another 5 years. Information regarding patient's age, sex, ethnicity, date and season of birth, date and season of the occurrence of acute pancreatitis and its relation to the holidays were recorded.

Results: A total of 527 cases of acute biliary and alcoholic pancreatitis were admitted from 1981 to 2000 with a distribution of 45% and 55%, respectively. The entire sample contained 50% males and 50% females. However, there were significant sex differences between the two diseases (p < 0.0005). Among biliary cases, 25% were male and 75% were female and in the alcoholic group, 70% were male and 30% were female. We also observed a significant age difference between the two etiologies (p < 0.0005). Mean age was 52 ± 21 (sd) years for biliary cases and 42 ± 12 (sd) years for alcoholic cases. In addition, the ethnicity of patients was significantly different between biliary and alcoholic groups (p = 0.004). Among biliary cases, the ethnicity distribution was 25% white, 35% African American, 35% Hispanic and 5% Asian. In alcoholic patients, there were 17% white, 54% African American, 23% Hispanic and 5% Asian. In this sample of 527 patients, the occurrence of biliary pancreatitis has continually increased over the 20-year period (p < 0.0005), which has followed the trend toward increasing body mass index in the population. We have found no relationship between the occurrence of acute biliary or alcoholic pancreatitis and patient's month or season of admission and whether or not more cases occurred around the major holidays.

Conclusions: Age, sex and ethnicity are different among patients with biliary versus alcoholic pancreatitis. The occurrence of biliary pancreatitis is on the rise. There is no seasonal pattern for occurrence of acute pancreatitis. There is no increase in the occurrence of alcoholic or biliary pancreatitis around major holidays.

Pancreatic Duct (PD) Stenting with the Johlin Wedge Stent (JPWS) in Pancreatic Disease

Adam Lowe, MD, Brian Applebaum, MD, Romeo Esquivel, MD, John Cunningham, MD.* Medicine, University of Arizona Health Sciences Center, Tucson, AZ and Medicine, Southern Arizona Health Sciences Center, Tucson, AZ.

Purpose: Endoscopic management in pancreatic disorders is widely accepted. PD stenting for an obstructed/disrupted duct has been described. However, these stents are often placed short-term. We describe our experience with the JPWS in a series of pts.

Methods: All pts, between October 2002 and May 2006, with findings of an obstructed/disrupted PD were evaluated for stent placement. ERCP was performed and an 8.5 or 10 Fr JPWS was placed. Pts were followed at either 12 or 24 week intervals with repeat ERCP ± stent exchange.

Results: A total of 26 patients, ages 26 to 83 years, had ERCP with placement of the JPWS. A total of 44 stents were placed; 11 patients had serial stent placements. All pts had ductography changes of chronic pancreatitis (CP) by the Cambridge Classification or malignancy with stricture. The etiology of pancreatic disease in these pts was alcohol (8), idiopathic (6), malignancy (5), gallstone (2), hereditary (2), IPMN (1), papillary stenosis (1). Indications for stent placement were 12 PD strictures, 7 PD disruptions (3 pseudocysts, 2 pseudocysts with pancreatic ascites, 2 pancreaticocelepical fistulas) and 7 PD stones. 37 were placed in the main PD; 7 were placed in the dorsal duct. Follow-up was possible in 23 of the 26 patients (88%). 3 patients had stent removal within 14 days, 2 for abdominal pain and 1 for bacteremia of unknown source. Of the remaining 20 pts, 9 had resolution of their symptoms and underlying process; 6 patients remain with a JPWS in place and continue with marked symptom improvement. 4 pts died from their underlying malignancy. The remaining pt went for surgery shortly after stent placement for pancreatic head malignancy. In 2 patients at interval ERCP the stents were noted to partially migrate distal into the duodenum, but they remained asymptomatic. There were no clinical stent occlusion events. Stents remained in the PD between 49 and 455 days with a mean length of 178 days. There were no complications related to length of time the stent remained intraductal. Conclusions: Placement of the JPWS is effective in the management of pts with symptoms due to pancreatic disease. Palliation of abdominal pain and resolution of leakage and stricturing occurred in the majority of patients alleviating the need for surgical intervention. In addition, these stents may be safely left in place for more than 24 weeks allowing for less frequent stent exchanges.

Influence of Baseline Hematocrit on Traditional Calculations of Hemoconcentration To Predict Severity in Acute Pancreatitis

Timothy B. Gardner, Todd Mackenzie, Douglas J. Robertson.* Gastroenterology, Dartmouth-Hitchcock Medical Center, Lebanon, NH and General Internal Medicine, Dartmouth-Hitchcock Medical Center, Lebanon, NH.

Purpose: We and others have evaluated admission hematocrit in acute pancreatitis (i.e. hemoconcentration) and have come to differing conclusions regarding its accuracy in predicting subsequent necrosis and organ failure. Variation in patient baseline hematocrit (e.g. because of underlying anemia) may account for some of the inconsistency observed in this measure. Therefore, we evaluated the influence of baseline patient hematocrit when using admission hematocrit as a predictor of important outcomes in acute pancreatitis.

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Methods: All patients admitted to our medical center with their first episode of acute pancreatitis who had at least one baseline outpatient hematocrit performed in the year prior to admission were identified using ICD-9 codes. If a patient had multiple outpatient values, the most recent was used. All patients had pancreas protocol CT scans. Charts were abstracted for demographics, etiology and severity of pancreatitis, and primary outcomes were necrosis, organ failure, length of hospitalization, mortality and readmission within 30 days. The Wilcoxon signed rank test was used to evaluate the effectiveness of using the absolute change in hematocrit from baseline and the percent change from baseline at admission in predicting the outcomes of interest. These predictors were then compared to the standard predictor of admission hematocrit.

Results: 71 patients were identified. 34.7% had gallstone, 33.3% had post-ERCP, and 18.1% had alcoholic pancreatitis. Mean Balthazar scores were 3.1 and mean Charlson scores were 2.1. There were 12 patients who developed necrosis (16.9%), 10 with organ failure (14.1%), 7 readmitted within 30 days (9.9%) and one death (1.4%) and the median length of stay was 7 days. Admission hematocrit, absolute hematocrit change from baseline and percent hematocrit change from baseline were not predictive of necrosis (p = 0.14, 0.25, 0.33, respectively) or 30 day readmission (p = 0.08, 0.61, 0.46, respectively). However, while admission hematocrit was predictive of organ failure (p < 0.05) and length of hospital stay (p < 0.01), absolute hematocrit change from baseline and percent hematocrit change from baseline were not.

Conclusions: In patients with acute pancreatitis, utilizing available information on baseline and admission hematocrit did not improve the predictive value for disease severity when compared to more traditional calculations of hemoconcentration.

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Prognostic Indicators of Quality of Life after Cholecystectomy for Biliary Dyskinesia

Timothy M. Geiger, MD, Ziad T. Awad, MD, Amolak Singh, MD, Wade Davis, PhD, Klaus Thaler, MD, Brent Miedema, MD, ∗ Department of General Surgery, University of Missouri-Columbia, Columbia, MO.

Purpose: Most patients who undergo cholecystectomy for the diagnosis of biliary dyskinesia have resolution of their symptoms. However, 20% to 30% of patients continue to have symptoms after surgery. The aim of this study was to determine quality of life after laparoscopic cholecystectomy in patients with biliary dyskinesia, and if preoperative variables correlate with quality of life after surgery.

Methods: Biliary dyskinesia was defined as a gallbladder ejection fraction of <35% in symptomatic patients without gallstones on sonography. All patients with biliary dyskinesia who had undergone cholecystectomy at our institution between Jan 31, 2000 and Jan 31, 2005 were identified. These patients were then contacted by telephone to complete the Gastrointestinal Quality of Life Index and a survey of preoperative symptoms. A database containing laboratory data, radiologic data, preoperative symptoms, and quality of life score was created for analysis. Main outcome measures were postoperative quality of life vs. historical standards, and preoperative variables vs. quality of life postoperative.

Results: A total of sixty-six patients were identified as fitting the inclusion criteria. Forty-three patients were contacted by phone and thirty agreed to participate. Patients were noted to have a higher quality of life postoperative than historical pre-cholecystectomy patients (p < .001). Patients included in this study had quality of life scores equivalent to historical postoperative quality of life in patients with gallbladder disease, and to historical normal populations. No laboratory, pathologic, or sonographic data was predictive of a lower quality of life. It was found that patients having postprandial nausea and vomiting had a lower quality of life (p < .029) after surgery as compared to those without these preoperative symptoms. No other symptoms had a correlation to quality of life.

Conclusions: Patients who participated in this study had a postoperative quality of life similar to both normal populations and patients following laparoscopic cholecystectomy for biliary disease. Nausea and vomiting preoperatively predicted a lower postoperative quality of life. Patients with biliary dyskinesia and have presenting symptoms of both nausea and vomiting may have a global gastrointestinal motility disorder, including gastroparesis. Preoperative gastric emptying study could be beneficial for this group before proceeding to cholecystectomy as it may alter the treatment plan.

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Linear Array Endosonography in Billroth II Gastrectomy

Pankaj Singh, MD, Richard A. Erickson, MD, ∗ Internal Medicine, Central Texas Veterans Health Care System, Temple, TX and Internal Medicine, Scott and White Memorial Hospital, Temple, TX.

Purpose: Endoscopic intervention of pancreato-biliary region in Billroth II anastomosis is technically challenging. We describe the first reports of the application of linear array endosonographic imaging/intervention (from an afferent limb) as an adjunct to ERCP in Billroth II gastrectomy.

Methods: EUS used to image pancreato-biliary region and right lobe of the liver in patients with Billroth II gastrectomy were included in this study. EUS was performed with a linear array echoendoscope. ERCP was attempted before EUS. EUS guided cholangiography (EUS-C) was performed when ERCP was unsuccessful in obtaining the cholangiogram.

Results: In these cases approach from the gastric antrum was unsuccessful. An attempt to access the afferent limb with echoendoscope was successful in 3 of the 4 cases. Of these 3 cases, pancreatobiliary examination was
attempted in 2 cases and successful imaging was obtained. Trans-duodenal EUS cholangiography was successfully attempted in one case. When afferent limb could be accessed successfully, the procedure was clinically effective in all cases. In three of the four cases, linear EUS provided information that was missed by the previous radiological tests and thus had a significant impact on the management. There was one complication of self-contained retroperitoneal duodenal perforation, which was diagnosed and repaired during surgical removal of stones from the common bile duct.

**Conclusions:** Linear array endosonography is feasible in Billroth II. Approach from afferent limb is superior to trans-gastric. Performing EUS under fluoroscopy and placement of the biliary stent prior to EUS are helpful for successful imaging. Since there is potential of complication, it should be reserved for cases where other diagnostic methods are unsuccessful.

Summary of clinical features for 4 patients undergoing attempted Linear Array EUS Imaging in Billroth II gastrectomy

<table>
<thead>
<tr>
<th>Case</th>
<th>Indication</th>
<th>Application</th>
<th>EUS Findings</th>
<th>Did EUS changed the management</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Jaundice</td>
<td>EUS-C/EUS-FNA</td>
<td>Pancreatic head mass</td>
<td>Yes</td>
</tr>
<tr>
<td>2</td>
<td>Pancreatitis</td>
<td>EUS cholangiography</td>
<td>CBD stones</td>
<td>Yes</td>
</tr>
<tr>
<td>3</td>
<td>EUS-FNA right</td>
<td>EUS-FNA</td>
<td>Hepatoma</td>
<td>Yes</td>
</tr>
<tr>
<td>4</td>
<td>Weight loss</td>
<td>EUS-FNA</td>
<td>Liver lobe</td>
<td>No</td>
</tr>
</tbody>
</table>

EUS-C: EUS cholangiography.

[figure1]

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**233 Pancreatic Cystic Neoplasms: What Is the Optimal Imaging Surveillance Interval?**  
Christopher D. Wells, MD, Ananya Das, MD,* Cuong C. Nguyen, MD. Gastroenterology & Hepatology, Mayo Clinic, Scottsdale, AZ.

**Purpose:** Incidental pancreatic cystic neoplasms (PCNs) are often encountered and are usually followed conservatively with periodic imaging with CT, MRI or EUS to confirm stability of the lesions. However, the optimal interval of imaging studies for surveillance is not known.

**Methods:** A retrospective analysis of longitudinal medical records of patients, identified through a departmental database and/or using ICD-9 codes 577.2 (Pancreatic Cyst/Pseudocyst) and 211.6 (Benign Neoplasm Pancreas), with PCNs was performed to determine the proportion of lesions that developed significant (more than 10 mm and/or 50% of baseline) growth in size (in maximal diameter) during follow up. Patients with pseudocysts and typical imaging features of main duct IPMN were excluded.

**Results:** After excluding patients with small (<10 mm) cysts (N = 244) and those with imaging follow up of less than 6 months (N = 222), a total of 308 cysts in 266 (mean age, 71.5 (11.2) years, 37.3% men) patients were available for analysis. The working diagnosis of these cystic lesions (based on clinical, radiological features, aspiration cytology, cyst fluid analysis, and surgical pathology data when available) were serous cystic neoplasm in 44 (14%), side branch type of IPMT without involvement of main pancreatic duct in 87 (28%), mucinous cystic neoplasm in 125 (41%), and neuro-endocrine pancreatic tumor in 9 (3%). 3 patients had cyst-adenocarcinoma. The mean initial size of the cysts was 2.2 (1.6) cm. Over a median period of follow up of 23 (range 6-106) months, there was a mean increase in size of 0.3 (0.6) cm. 87% of all cysts did not show significant growth during follow up. Initial size of the cystic lesion lesions had a significant positive correlation (Pearson co-efficient 0.18, p < 0.001) with increasing size of the lesion during follow up: 36% of the cysts larger than 5 cm had significant growth during follow up, compared to only 4% of the smaller cysts (p < 0.001). In a multivariate Cox proportional hazards model, the initial size of cystic lesions (>3 cm) [Relative hazard 4.7 (95% CI, 1.1-19.6, p = 0.031] and presence of solid component in the cyst on imaging [RH 4.8 (95% CI, 1.4-16.4, p = 0.001] were the only independent predictors of significant growth during follow up.

**Conclusions:** Most PCNs in this study did not have significant growth during follow up suggesting that surveillance imaging at intervals less than 2 years may not be necessary unless they are more than 3 cm or contain a solid component.

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**234 Intestinal Trefoil Factor [TFF-3] and Extracellular Signal Regulated Kinase [Erk] Expression in Pancreatic Cancer**

Vishal K. Bhagat, MD, Thaer Khoury, MD, Jihne Yu, PhD, Milind Javle, MD,* Medicine, University at Buffalo, Buffalo, NY; Pathology, Roswell Park Cancer Institute, Buffalo, NY; Biostatistics, University at Buffalo, Buffalo, NY and Medicine, Roswell Park Cancer Institute, Buffalo, NY.

**Purpose:** TFF-3 is an anti-apoptotic member of the gastrointestinal trefoil polypeptide family that is involved in mucosal restitution. Epidermal Growth Factor (EGF) and its downstream signaling intermediates (Erk, Akt and their phosphoforms) act synergistically with the trefoil peptides in the epithelium to enhance repair processes. We hypothesized that these peptides may also act synergistically in pancreatic cancer.

**Methods:** Clinical and pathological data were obtained from 35 consecutive, surgically resected, pancreatic cancer cases. Immunohistochemical staining was performed using a polyclonal antibody to TFF-3 and monoclonal antibodies to EGFR signaling proteins including EGFR, Erk, pErk, Akt and pAkt. Two surgical pathologists (TK and DFT) independently calculated the histoscore as the staining intensity [0, 1, 2, 3] x percentage of the positive cells. Histoscore > median value was considered positive. Kendall’s tau was employed to correlate expressions of these peptides with TFF-3 and logistic regression was used to correlate with grade and stage of the tumor. Biomarker expressions were correlated with survival using univariate analysis.

**Results:** Median age of these patients was 68 (range = 38-84). There were 20 females. Positive cytoplasmic TFF-3 expression was noted in 20/35 (57%) patients. There was significant association between TFF-3 and Erk expression (p = 0.006) (Table-1). Erk expression correlated with tumor grade (p = 0.0114) and tumor stage (p = 0.0097). We found no association between TFF-3 or Erk expression and survival of these patients on univariate analysis (p = 0.56).
Conclusions: TFF-3 is commonly expressed in pancreatic cancer and may have positive relationship with Erk expression.

### Table 1. Frequency of positive expression of EGF signaling proteins and their associations with TFF-3

<table>
<thead>
<tr>
<th>Signaling proteins (N = 35)</th>
<th>Positive expression</th>
<th>Median and range of histoscores</th>
<th>Association with TFF-3 (Kendall’s tau)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>EGFR</td>
<td>19 (54%)</td>
<td>20 (0–300)</td>
<td>0.050</td>
<td>0.776</td>
</tr>
<tr>
<td>Erk</td>
<td>23 (66%)</td>
<td>300 (0–300)</td>
<td>0.454</td>
<td>0.006</td>
</tr>
<tr>
<td>pErk</td>
<td>19 (54%)</td>
<td>80 (0–300)</td>
<td>0.102</td>
<td>0.558</td>
</tr>
<tr>
<td>Akt</td>
<td>22 (63%)</td>
<td>100 (0–300)</td>
<td>0.219</td>
<td>0.207</td>
</tr>
<tr>
<td>pAkt</td>
<td>16 (46%)</td>
<td>0 (0–240)</td>
<td>0.120</td>
<td>0.507</td>
</tr>
</tbody>
</table>

### Utilization of Magnetic Resonance Cholangiopancreatography (MRCP) at an Academic Medical Center

**Vikram Boolchand, MD, Srikrishna Vemana, MD, Charles Martin, III, MD, Gregory S. Cooper, MD, ∗ Department of Medicine, University Hospitals of Cleveland/Case Western University, Cleveland, OH and Department of Radiology, University Hospitals of Cleveland/Case Western University, Cleveland, OH.**

**Purpose:** While Endoscopic Retrograde Cholangiopancreatography (ERCP) is considered the traditional imaging modality for the pancreatic and bile ducts, MRCP is an accepted non-invasive alternative. Indications for MRCP are clear, but the use of MRCP has not been evaluated. The aim of this study was to evaluate the use of MRCP in an academic medical center.

**Methods:** A retrospective study was performed evaluating all patients who presented for an MRCP from 1/2004 to 7/2004 at an academic medical center. Charts were reviewed and data was collected on the demographics, MRCP findings, and further evaluation of the results.

**Results:** A total of 48 patients were included, including 29 outpatients. The average age was 55 years and 74% were female. 21 had a GI consultation. Indications and frequency of abnormal findings on MRCP are listed in the table. Abnormalities of the pancreatic duct/pancreas were found in 6 patients. Bile duct dilatation was found in 10 patients. Abnormalities of both the pancreas and the biliary system were found in 3 patients. Dilatation of the gallbladder was found in 2 patients and liver lesions were found in 2 patients. 13 ERCPs were performed after MRCP and demonstrated discordant biliary tree findings in 3 patients. In all 3, the discordant findings were observed in bile duct strictures (2 false positive, 1 false negative). The pancreatic anatomy was evaluated in 6 patients and discordant findings were observed in 1 case of pancreatic duct disruption (false negative). There were no differences in outcome between patients with or without a GI consultation and between inpatient vs. outpatient status at the time of MRCP.

**Conclusions:** At our institution, MRCP was most commonly performed in middle-aged females in an outpatient setting. The most common indications included evaluation of the common bile duct for obstruction and pancreatic duct in pancreatitis. MRCP maybe an appropriate triage technique for patients prior to ERCP and in whom there is a low suspicion for therapeutic options with ERCP. MRCP maybe limited in the evaluation of bile duct strictures, given discordant findings with ERCP.

### Jejunal Feeding in Chronic Pancreatitis

**Jill Moore, MD, John Fang, MD, Kathryn Peterson, MD, Mavdeen Ogaru, James Disario, MD, ∗ Gastroenterology, University of Utah, Salt Lake City, UT.**

**Purpose:** Determine effects of jejunal feeding on pain and body weight in chronic pancreatitis. Current therapies are largely inadequate for pain and weight loss with chronic pancreatitis. Enteral nutrition delivered deep in the jejunum does not stimulate pancreatic secretion and holds promise as therapy.

**Methods:** Retrospective case series.

**Results:** There were 30 (23 women, 7 men) patients with a mean age of 44 (21–62) years. Pain data were available on 25 patients with a mean follow up of 7.5 (0.5–42) months. 13 (36%) had endoscopic nasoenteric tubes (ENET) initially or long term. 9 (25%) had percutaneous endoscopic gastrostomy with jejunal extension (PEG-J). 14 (39%) had direct percutaneous endoscopic jejunostomy (DPEJ) and 9 (25%) had more than one type of feeding tube. 12 (40%) complications occurred in 12 (40%) patients. Minor events were pain at the stoma in 3 (10%) with PEG-J and infections at insertion site requiring antibiotics in 3 (10%) severe complications developed in 7 (23%) and included 5 (17%) with PEG-J tube malfunction requiring endoscopic intervention, one (3%) small bowel volvulus with obstruction following DPEJ requiring surgery, and one (3%) presumed perforation managed conservatively. The mean duration of jejunal feeding was 4.6 (0.5–26) months. 20/25 (80%) patients reported uncontrolled pain at initial evaluation and 9/20 (45%) had pain complete or near complete resolution with jejunal tube feeds (p = 0.008). The mean weight was 62.6 kg at baseline and 61 kg after jejunal feeding (mean decrease, 1.6 ± 14 kg, p = 0.27). 10/28 (36%) gained weight (mean increase, 8 ± 7.5 kg) with jejunal feeding. 17/28 (61%) lost weight (mean decrease, 6.1 ± 5 kg), 4 of whom had known or suspected cancer and a mean loss of 14 ± 3.6 kg. In most cases, the weight stabilized after initial loss.

**Conclusions:** 1) Jejunal feeding through endoscopically-placed tubes leads to clinically significant pain relief in many chronic pancreatitis patients. 2) Jejunal feeds do not impart a statistically significant effect on weight overall, but many patients gain weight while others have initial weight loss that stabilizes over time.

### Cytologic Assessment of EUS-FNA of Solid Pancreatic Masses

**Mohammad E. Hoque, MD, Fumio Omata, MD, Yang K. Chen, MD, ∗ Division of Gastroenterology, University of Colorado Hospital, Aurora, CO.**

**Purpose:** There is a paucity of data on the number of needle passes during pancreatic EUS. Our aim is to determine whether the characteristics of the pancreatic mass determine the number of EUS-FNA passes that are required to obtain a satisfactory cytologic assessment in patients with solid pancreatic masses.

**Methods:** Our endoscopy database was used to identify patients who underwent EUS-FNA of pancreatic masses. Cystic lesions were excluded. A cytopathologist was routinely present for FNA to determine sample adequacy. Only the index EUS was used for data analysis. A data collection instrument included symptoms, imaging, size and location of the mass, presence of at least 4 EUS criteria for chronic pancreatitis, number of needle passes, cytology results, surgical pathology, and complications.

**Results:** Between 1/01 and 10/05, 284 consecutive patients underwent EUS-FNA procedures for the evaluation of a pancreatic mass. 43 patients had cystic lesions and were excluded. 241 patients were included. All had previous non-invasive imaging. Mean age 63 years, 135M/106F, chronic pain (56%), weight loss (56%), jaundice (34%). Mass location: head 154 (64%), body 46 (19%), uncinate 20 (8%), tail 15 (6%), and neck 6 (2%). The 22G needle was used in 97% of cases. Cytology results, number of passes, size of mass, and presence of chronic pancreatitis are listed in the table. There were no false-

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positive cytology in patients undergoing surgical resection for malignancy (N = 31). There were a similar mean no. of passes (3.9 ± 1.4) in patients with chronic pancreatitis (N = 70, 29%) compared to those without chronic pancreatitis (4.1 ± 1.6). The mean number of passes based on mass location was similar: head (4.1 ± 1.1), body (3.9 ± 2.1), neck (5.2 ± 6.0), uncinate (3.7 ± 4.4), and tail (4.7 ± 4.7). Complications: pancreatitis (N = 10).

Conclusions: 1) The pancreatic pathology of the tissue being sampled does not affect the number of needle passes required to obtain a satisfactory cytologic assessment. 2) It appears that mass location, size, and the presence of chronic pancreatitis do not determine the number of needle passes required to obtain a cytologic assessment.

Cytologic Results

<table>
<thead>
<tr>
<th></th>
<th># of cases (%)</th>
<th>Mean # of passes</th>
<th>Mean mass size (mm)</th>
<th>% Chronic pancreatitis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malignant</td>
<td>131 (54%)</td>
<td>4.1 ± 1.6</td>
<td>36 ± 13</td>
<td>20%</td>
</tr>
<tr>
<td>Suspicious</td>
<td>20 (8%)</td>
<td>4.6 ± 1.2</td>
<td>35 ± 14</td>
<td>15%</td>
</tr>
<tr>
<td>Atypical</td>
<td>35 (15%)</td>
<td>3.8 ± 1.9</td>
<td>30 ± 15</td>
<td>40%</td>
</tr>
<tr>
<td>Benign</td>
<td>52 (22%)</td>
<td>3.9 ± 1.9</td>
<td>29 ± 13</td>
<td>48%</td>
</tr>
<tr>
<td>Indeterminate</td>
<td>2 (&lt;1%)</td>
<td>4.0 ± 1.4</td>
<td>35 ± 22</td>
<td>50%</td>
</tr>
<tr>
<td>Insufficient</td>
<td>1 (&lt;1%)</td>
<td>5</td>
<td>39</td>
<td>100%</td>
</tr>
</tbody>
</table>

Is Serum Lipase Elevated in Patients with Diabetic Ketoacidosis without Pancreatitis?

Savio C. Reddymanu, MD,∗ Pallavi Bellamkonda, MD, Gangadhar Vajrala, MD, Medicine, LSUHSC-S, Shreveport, LA and Medicine, Creighton Univ Med Ctr, Omaha, NE.

Purpose: Diabetic ketoacidosis (DKA) is a serious complication of diabetes mellitus which can present with nausea, vomiting and abdominal pain. These symptoms are also the chief complaints of acute pancreatitis (AP). Measurement of lipase level is a standard test used to diagnose AP. Sensitivity of lipase for the diagnosis of AP varies from 85-100%. The aim of our study was to evaluate the incidence of hyperlipasemia in patients presenting with DKA, who do not have radiographic evidence of AP, and to correlate the elevated lipase with the other metabolic parameters like anion gap (AG), glomerular filtration rate (GFR), serum glucose, and serum osmolality.

Methods: Retrospective study in a cohort of 43 patients with DKA. The criteria for inclusion were i) A diagnosis of DKA in the absence of AP, and ii) Measurement of serum lipase at presentation. A total number of 113 episodes of DKA were analyzed. Information on lipase, AG, GFR, serum glucose and serum osmolality at presentation were retrieved. Normal lipase was defined as 8-78 IU/dl. Patients were divided to two groups based on their lipase levels, i) Normal and non-significant elevation in lipase level (upto 3 times normal), and ii) Significant elevation in lipase (> 3 times normal).

Results: Elevated lipase level was found in 40% (43 episodes). 19% (21 episodes) had significant hyperlipasemia. These levels ranged from 250-6510 IU/dl. Non significant elevation of lipase level was found in 21% (24 episodes), where lipase levels varied from 80-199 IU/dl. ANOVA analysis showed no correlation between serum lipase and GFR, AG, serum glucose or serum osmolality. (Table 1)

Conclusions: In DKA, significant elevation of lipase is found in about 19% of cases in the absence of AP. Serum lipase elevation in DKA does not correlate with commonly deranged parameters in DKA like AG, GFR, or serum osmolality. Diagnosis of AP in DKA on the basis of hyperlipasemia alone, is not reliable.

<table>
<thead>
<tr>
<th>Variable</th>
<th>DKA with normal lipase (N = 92)</th>
<th>DKA with significantly elevated lipase (N = 21)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GFR† (ml/min/1.73m2)</td>
<td>2.13 ± 1.07</td>
<td>2.09 ± 0.94</td>
</tr>
<tr>
<td>AG</td>
<td>24.0± 5.95</td>
<td>25.90 ± 8.50</td>
</tr>
<tr>
<td>Serum Osmolarity (mOsm/Kg)</td>
<td>310.12 ± 11.29</td>
<td>313.66 ± 19.12</td>
</tr>
<tr>
<td>Glucose (mg/dl)</td>
<td>502.70 ± 224.29</td>
<td>525.47 ± 216.70</td>
</tr>
<tr>
<td>BUN (mg/dl)</td>
<td>23.59 ± 15.41</td>
<td>18.04 ± 10.63</td>
</tr>
</tbody>
</table>

†GFR (ml/min/1.73m2) 1- GFR >90, 2- GFR 60-90, 3- GFR 30-59, 4- 15-29, 5- GFR<15 + p value not significant for any of the above variables.
Results: 126 ERCPs were performed on 115 patients (37M/78F, mean age 58, range 14-93) during the studied period, with a mean follow-up of 6.1 months. Cholelithiasis was identified by the endoscopist in 38% (48/126) of cases, biliary strictures in 13% (17/126), chronic pancreatitis in 4% (5/126), post-operative injury in 2% (3/126), pancreas divisum in 2% (2/126), dilated common bile duct (> 1 cm) in 29% (36/126); 12% (15/126) were read as normal. The overall concordance rate between the endoscopist and the radiologist was 88% (111/126). Of the 15 cases in which there was discordance, 13 had findings reported by the endoscopist but not by the radiologist. In the remaining 2 discordant cases, one patient had “air or calculi in the common bile duct” reported only by the radiologist. This patient underwent a sphincterotomy irrespectively and would have been protected against further bouts of cholelithiasis, if calculi indeed existed. Pancreatic divisum was reported only by the radiologist in one patient who underwent ERCP for clinical gallstone pancreatitis. The patient subsequently underwent cholecystectomy. Although no additional episodes of pancreatitis occurred during follow-up, it was possible that the pancreatitis was due to pancreatic divisum and not gallstones. Therefore, this case may be one in which the radiologist’s interpretation provided additional clinical information. Conclusions: 1. The concordance rate between radiologists and endoscopists was 88%. 2. In only one of 126 cases did the radiologist’s interpretation contribute additional information to alter patient management. 3. Routine post-procedural ERCP interpretation by radiologists is not necessary. Selective consultation with radiologists seems a more appropriate strategy.

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The Utility of Screening for Autoimmune Pancreatitis Using Elevated Levels of IgG4 in Consecutive Patients Diagnosed with Pancreatitis or Pancreatic Cancer

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Purpose: Autoimmune pancreatitis (AIP) is now recognized as a treatable form of recurrent acute and chronic pancreatitis that is sometimes misdiagnosed as pancreatic cancer. Elevated IgG4 levels are reported to be diagnostic of AIP, although normal levels do not exclude the diagnosis. While the prevalence of AIP in Japan appears to be high, the prevalence of AIP in the United States is unknown. The current study was aimed at screening consecutive series of patient with recurrent acute and chronic pancreatitis and pancreatic cancer for IgG4 levels, and to determine the utility of IgG4 in screening for AIP.

Methods: Blood samples and phenotypic information on 128 consecutive pancreatitis patients ascertained from the Pittsburgh site of North American Pancreatitis Study 2 (NAPS2) study and 78 consecutive patients ascertained from the Pancreatic Adenocarcinoma Gene-Environment Risk (PAGER) study were collected using an IRB approved protocol. IgG4 levels were determined using the single radial immunodiffusion (SRID) assay (Binding Site, Birmingham, UK).

Results: One patient with chronic pancreatitis and no patients with pancreatic cancer were previously diagnosed with AIP on clinical and laboratory criteria prior to IgG4 screening. Adenocarcinoma was confirmed in all patients by histology and by clinical follow up (e.g. metastatic cancer and/or death). Seven serum samples from NAPS2 and 6 from PAGER had IgG4 level below the level of detection. Using a cut-off of > 135 mg/dl (Hamanou et al. 2012) 2 of 128 (1.6%) subjects with pancreatitis and 5 of 78 (6.5%) subjects with pancreatic cancer had elevated IgG4 levels at the time of ascertainment. The subject previously diagnosed with AIP was post treatment and had an IgG4 level of 11.6 mg/dl, which was within the normal range.

Conclusions: AIP appears to be uncommon in the United States based on this sample. Screening of consecutive patients with recurrent acute pancreatitis, chronic pancreatitis, or pancreatic cancer for unsuspected AIP with IgG4 levels in this population was neither sensitive nor specific, and therefore offers little utility as a screening tool.

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Diffuse Gastric Hyperplastic Polyposis Presenting with Profound Iron Deficiency Anemia

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Purpose: Gastric polyps are relatively common findings on routine endoscopy and are usually asymptomatic and incidentally found. Although adenomatous polyps pose a risk of malignant transformation, inflammatory and hyperplastic polyps pose significantly less risk. However, there have even been reports of focal malignancies found in large hyperplastic and inflammatory polyps. Rarely, regardless of histology, gastric polyps may cause significant symptomatology such as anemia, bleeding or obstruction. Here we present a unique case of a woman with profound iron deficiency anemia who was found to have extensive isolated gastric hyperplastic polyposis. The patient is a 26-year-old woman with no chronic medical problems who presented with weakness and fatigue. There was no abdominal pain or weight loss. Physical examination revealed pale sclera. Laboratory analysis revealed a hematocrit of 22 percent, MCV of 66, iron of 12, TIBC 487, Ferritin of <5 ng/ml. The patient underwent upper endoscopy, colonoscopy and small bowel colonoscopy. Colonoscopy and small bowel series were normal. Upper endoscopy revealed innumerable gastric polyps casing in size from 2 mm to 3 cm. The polyposis was isolated to the stomach as colonoscopy and small bowel series were normal. Pathology revealed hyperplastic changes with no evidence of adenomas, dysplasia, or carcinoma. Hyperplastic polyps are typically benign in pathology and symptomatology. However there are reports in the literature of large hyperplastic polyps causing occult bleeding (as in our patient), or large antral polyps causing gastric outlet obstruction. Extensive polyposis can be found in polyposis syndromes such as Familial Adenomatous Polyposis (FAP), juvenile polyposis, and Peutz-Jeger’s syndrome. This case is unique in that there is extensive hyperplastic polyposis causing severe anemia.

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The Relationship between Periampullary Duodenal Diverticula and Common Bile Duct Stones


Purpose: Periampullary duodenal diverticula are thought to be associated with bile duct stones. However, studies to date have not taken into account factors such as size of the diverticula, number of stones, and age of the patient. Our study analyzed the relationship between size of the periampullary diverticulum and the presence of bile duct stones while taking into account the influence of age.

Methods: We analyzed 970 consecutive patients who underwent endoscopic retrograde cholangiopancreatography (ERCP). Patients who had undergone previous biliary instrumentation were excluded. 196 of these patients were then subdivided into three groups based on their findings at ERCP: the first group (group I; N = 142) had bile duct stones without evidence of periampullary diverticula, the second group (group II; N = 35) had bile duct stones and evidence of a periampullary diverticula, and the third group (group III; N = 19) had periampullary diverticula without stones. Size of the diverticulum and number of stone(s) were then analyzed for each group. Additionally, age analysis of each of the patient groups was performed. The ANOVA and chi-squared test were used to analyze the results.
Results: Of a total of 177 patients with biliary stone disease, 35 (20%) had periampullary diverticula. Common duct stones were associated with the presence of a diverticulum in 35/54 patients (65%). Patients with periampullary diverticula and biliary stones were also more likely to have multiple stones, 20/35 (57%), as compared to patients without evidence of periampullary diverticula, 61/142 (43%) (p < 0.01). Large (>1 cm) periampullary diverticula were more commonly associated with bile duct stones, 23/28 (82%), as compared to small (<1 cm) periampullary diverticula, 11/25 (44%) (p < 0.01). Age was also a factor, as patients with bile duct stones and periampullary diverticula were older (mean age-72) as compared to patients with bile duct stones without periampullary diverticula (mean age-50) (ANOVA analysis, p < 0.01).

Conclusions: Periampullary diverticula occur more commonly in older patients and are associated with an increased incidence of multiple bile duct stones. Larger size (≥1 cm) of the diverticula was also found to correlate directly with the presence of bile duct stones. These findings may be beneficial to endoscopists in planning their treatment of choledocholithiasis.

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ERCP with Selective Biliary Stenting at T-Tube Removal in Orthotopic Liver Transplant Recipients—A Novel Approach
Visvanathan Murali-Dharan, MD, Sanjay Kulkarni, MD, David Cronin, MD, Harry Aslanian, MD, Mario Strazzabosco, MD, Uzma Siddiqui, MD, Priya Jamidar, MD,* Section of Digestive Diseases, Yale New Haven Hospital, New Haven, CT and Section of Transplant Surgery, Yale New Haven Hospital, New Haven, CT.

Purpose: Bile leaks are not uncommon following T-Tube removal in patients who have undergone orthotopic liver transplantation (OLT) and choledochocholedochal anastomoses. These can be a significant source of morbidity and may necessitate emergent endoscopic, radiologic or surgical intervention.

Methods: To decrease the number of unplanned interventions and hospital stay, in 4 consecutive patients undergoing OLT at Yale New Haven Hospital, an ERCP was performed at the time of t-tube removal (post-OLT). Once endoscopic biliary cannulation was achieved, the t-tube was removed in the ERCP suite. A cholangiogram was obtained following t-tube removal. If contrast extravasation was seen a biliary endoprosthesis was placed.

Results: See tables

Conclusions: In this small series of OLT patients with biliary fistulas, ERCP with stenting appears safe and effective. Emergent ERCP or other interventions were not required. There were no ERCP related complications and hospital stay was not prolonged. A larger prospective study is warranted.

Table 1. Patient Characteristics and Outcome

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age</th>
<th>Sex</th>
<th>Indication for OLT</th>
<th>Explant</th>
<th>Follow up</th>
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<tbody>
<tr>
<td>1</td>
<td>60</td>
<td>F</td>
<td>Alcoholic Liver Dz</td>
<td>Alive &amp; Well</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>53</td>
<td>M</td>
<td>Hepatitis C</td>
<td>Alive &amp; Well</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>50</td>
<td>F</td>
<td>Alcoholic Liver Dz</td>
<td>Alive &amp; Well</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>56</td>
<td>M</td>
<td>Alcoholic Liver Dz</td>
<td>Alive &amp; Well</td>
<td></td>
</tr>
</tbody>
</table>

Table 2. ERCP Findings and Intervention

<table>
<thead>
<tr>
<th>Patient</th>
<th>Timing of ERCP</th>
<th>Pre-op Abx</th>
<th>Findings</th>
<th>Stent</th>
<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6 wks post-OLT</td>
<td>Zosyn</td>
<td>No contrast extravasation/Stricture</td>
<td>Yes</td>
<td>None</td>
</tr>
<tr>
<td>2</td>
<td>8 wks post-OLT</td>
<td>Cipro</td>
<td>Contrast Extravasation</td>
<td>Yes</td>
<td>None</td>
</tr>
<tr>
<td>3</td>
<td>4 wks post-OLT</td>
<td>Cipro</td>
<td>Caliber Change</td>
<td>No</td>
<td>None</td>
</tr>
<tr>
<td>4</td>
<td>24 wks post-OLT</td>
<td>Zosyn</td>
<td>Extravasation</td>
<td>Yes</td>
<td>None</td>
</tr>
</tbody>
</table>

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Cost-Effectiveness Analysis of Management for Patients at Risk for Familial Pancreatic Adenocarcinoma
Joel H. Rubenstein, MD, MSc, James M. Scheiman, MD, Michelle A. Anderson, MD, MSc.* University of Michigan Medical School, Ann Arbor, MI and Veterans Affairs Medical Center, Ann Arbor, MI.

Purpose: Approximately 10% of pancreatic adenocarcinoma is familial. Screening has been recommended for first-degree relatives (FDRs) from pancreatic cancer (PC) kindreds. Approximately 50% of FDRs have EUS findings of chronic pancreatitis (CP). The management of these relatives has not been analyzed for cost-effectiveness. We aimed to model the natural history of these patients and to compare the cost-effectiveness of 4 management strategies.

Methods: We performed systematic reviews of the published literature, and created a Markov model for 45 year-old male FDRs with findings of CP on EUS. We compared 4 strategies: do nothing, prophylactic total pancreatectomy, annual surveillance for PC by EUS, and annual surveillance for PC with EUS and fine needle aspiration of mass lesions (EUS/FNA). Patients were followed until age 90 or death. Outcomes incorporated direct medical costs, quality of life, mortality from cancer, diabetes, and procedural complications.

Results: In the base case strategy (do nothing), the cumulative lifetime risk of PC was 20% (vs. 1% in the general population); in sensitivity analyses, the risk ranged from 4 to 93%. In the base case, doing nothing provided the greatest remaining years of life (29.2), the lowest cost, and the greatest remaining quality-adjusted life years (QALY’s) (18.6). Pancreatectomy provided the fewest remaining years of life (24.7), and the fewest remaining QALY’s (14.3). The results were sensitive only to the incidence of cancer, and to 29 other variables evaluated in the model. Pancreatectomy provided the longest life expectancy if the cumulative lifetime risk of PC were at least 47%, provided the most QALYs if the risk were at least 67%, and was cost-effective if the risk were at least 56%. Under no circumstances was surveillance for PC with either EUS or EUS/FNA most effective or cost-effective due to the poor survival of even early stage PC and the morbidity of pancreatectomy.

Conclusions: First degree relatives from PC kindreds who have EUS findings of CP have greatly increased risk for PC, but the precise risk is poorly quantified. Without the ability to further stratify risk, the most effective strategy is to do nothing. If the lifetime risk of cancer is at least 47%, then pancreatectomy may be the most effective strategy, even accounting for subsequent insulin-requiring diabetes. Further research is needed to characterize the level of risk in order to apply our data to individual patients.

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Primary Hodgkin's Lymphoma Masquerading as a Klatkin Tumor
David N. Socoloff, DO, Sandra Jara, MD, Prasad M. Kulkarni, MD.* Digestive Diseases and Nutrition, University of South Florida/James A Haley VA, Tampa, FL.

Purpose: Cholangiocarcinoma affects 2-2.8 per 100,000 population per year, and has a 5 year mortality rate of 90%-95%. Current limitations of pre-operative tissue sampling often make a definitive diagnosis elusive necessitating surgical exploration. We present a case of an obstructing hilar mass, initially thought to be an advanced cholangiocarcinoma, found to be a primary extraductal hilar Hodgkin's lymphoma at laparotomy.

Results: A 56 year old male presented with gradual onset of painless jaundice. Initial work-up revealed: AST 464UL, ALT 548UL, Alk Phos1697UL, T.Bili 7.90 mg/dL, and Direct Bili 6.00 mg/dL. Tumor markers including AFP, CEA, LDH, and CA19-9 were unremarkable. Triple phase CT abdomen revealed a common hepatic duct filling defect with intrahepatic ductal dilation without extrahepatic dilation, later confirmed by MRCP. ERCP was then performed revealing a moderate sized stricture involving the common hepatic duct and a short portion of both intrahepatic ducts consistent with a Bismuth II tumor. Brushings were negative for malignancy and
temporal biliary stenting was performed for decompression while surgical consultation was obtained for definitive diagnosis. Exploratory laparotomy with cholecchoscopy did not reveal cholangiocarcinoma, but rather an obstructing hilar lymph node causing extrinsic compression of the common hepatic duct. Biopsy revealed lymphocytic rich Hodgkin’s lymphoma. Resection and bilateral hepatico-jejunostomy was averted, and the patient was referred to Oncology for treatment.

**Conclusions:** Primary extranodal non-Hodgkin lymphoma of the extrahepatic bile duct mimicking Klatskin tumor has rarely been reported. Though cholangiocarcinoma accounts for 60-80% of Klatskin tumors; other causes of biliary tree obstruction such as lymphoma should be entertained as treatment may be non-surgical. [figure1]

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**ERCP in the Supine and Left Lateral Position**

Vijaypal Arya, MD.* Alex Gershenhorn, MD, Kalpana A. Gupta, MD, Siddharth Mogra, MS, Swarn V. Arya. Division of Gastroenterology, Wyckoff Heights Medical Center, Brooklyn, NY.

**Purpose:** ERCP is an acronym for Endoscopic Retrograde Cholangiopancreatography. Traditionally, with the patient in prone position, an ERCP endoscope is passed through the mouth, esophagus and stomach into the duodenum. After the ampulla is identified, a catheter is passed through the endoscope into the pancreatic and biliary ducts, contrast material is then injected into the ducts and x-rays are taken. In skillful hands, ERCP can be very useful and life saving. Sometimes patients are very ill and require intubation before ERCP. In such patients, prone position is cumbersome, not possible or unsafe. We report three patients; two with successful ERCP in supine position, and one with successful ERCP in left lateral position.

**Methods:** Case 1: A 63 year old female morbidly obese, with significant past medical history of end stage renal disease on hemodialysis, diabetes mellitus, hypertension, presented with right upper quadrant abdominal pain, fever and jaundice. The total and direct bilirubin were 20.4/17.8. AST, ALT, Alkaline Phosphatase were also elevated. Because of morbid obesity and poor respiratory status, patient could not be placed in prone position. ERCP was attempted in supine position, unsuccessful cannulation of common bile duct was achieved, biliary stricture was diagnosed and seven french 12 cm stent was placed successfully. Patient returned after 8 weeks and biliary stent was replaced again in supine position.

Case 2: A 63 year old male with significant history of COPD, coronary artery disease, pacemaker placement, presented with abdominal pain, fever, elevated LFTs and high white count. CAT scan revealed dilated common bile duct. Because of poor respiratory status, patient could not be placed in prone position. ERCP was attempted in left lateral position, ampullary mass with dilated common bile duct was diagnosed, a common bile duct stent was placed successfully.

Case 3: A 58 year old female with known history of cirrhosis, diabetes mellitus, renal stones, cholecystectomy, presented with abdominal pain, jaundice and elevated obstructive enzymes. Because of poor respiratory status, patient could not be placed in prone position. ERCP was attempted in supine position, common bile duct was cannulated successfully.

**Conclusions:** Although the success is not guaranteed with these anecdotal case reports, one should not be dogmatic, but ought to attempt ERCP in the supine and/or left lateral position if needed.

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**Endoscopic Management of Impacted Biliary Basket—A Case Report**

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**Purpose:** Endoscopic management of impacted biliary basket.

**Methods:** A 73-year-old man with cholecystectomy four years prior was admitted with biliary colic and jaundice for two weeks. He had no other medical problems. He was taking NSAIDs for pain. He had poor appetite but no weight loss. He was afebrile with normal vital signs and deeply icteric conjunctiva.

**Labs:** No leukocytosis, normal amylase and lipase, total bilirubin 23, direct bilirubin 21, alkaline phosphatase 235, AST 49, ALT 74.

**Abdominal sonogram:** dilated common bile duct (CBD). ERCP revealed periampullary mass that was biopsied and later found to be adenoma. Cholangiogram obtained after an adequate sphincterotomy, showed dilated CBD with a 2 cm stone. Lithotripsy with Olympus mechanical lithotriptor was attempted. The stone could not be crushed and the basket with stone became impacted in distal CBD (Fig). Several attempts to disimpact the stone were unsuccessful. Lithotripsy wire was then cut close to the handle and endoscope was removed. Patient underwent percutaneous transhepatic cholangiogram to relieve biliary obstruction. Instead of referring for surgical exploration, we opted to use emergency mechanical lithotriptor (Olympus emergency lithotripter handle: BML-110A-1). The emergency lithotripter handle was used under fluoroscopic guidance. The stone was crushed along with impacted basket, which enabled the basket to be disimpacted and removed safely. Balloon sweep of the bile duct was performed to remove remnant stone fragments.

**Results:** Patient tolerated procedure well with normalization of liver enzymes. At a later stage periampullary adenoma was endoscopically removed and repeat cholangiogram was normal.
Conclusions: It is not uncommon to have an impacted basket with a mechanical lithotripter. Extending sphincterotomy and using extracorporeal shock wave lithotripsy or laser lithotripsy may be helpful in these situations. However, before referring the patient for surgical removal of impacted basket, less invasive methods using emergency mechanical lithotripter as described in our case could be attempted successfully. [figure1]

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“Belly Bag” Studies in the ER: The Use and Abuse of Routine Estimations of Serum Amylase and Lipase Levels
Adnun Muhammad, MD, Depali Prasad, MD, Srinivas Cheruvu, MD, MSPH, Lilian Deeb, MD, C.S. Pitchumoni, MD, M.A.C.G.∗
Gastroenterology, Hepatology and Clinical Nutrition, Saint Peter’s University Hospital, New Brunswick, NJ.

Purpose: The healthcare system in the United States has been constantly grappling with the growing demand for appropriate and effective medical care while utilizing minimal resources. With an increasing demand to provide cost effective care in a timely manner, it is imperative to order tests appropriately. In ER across the country abdominal pain is one of the most frequent presenting complaints that requires evaluation with laboratory testing. Many tests are bagged together as “routine tests” and estimations of amylase and lipase levels are amongst the most as “belly bag” tests obtained as markers for Acute Pancreatitis (AP). There is a “gut feeling” among physicians that tests are bagged together as “routine tests” and estimations of amylase and lipase rank high.

Aim: To evaluate the utility of current practice of “routine estimations” of serum amylase and lipase in the ER for the evaluation of abdominal pain/discomfort by verifying the final diagnosis.

Methods: In this prospective study data is collected from 487 consecutive patients who presented to a teaching hospital ER over a 4 month period with the complaint of abdominal pain and had serum amylase/lipase done. Then the test results are correlated with the final diagnosis of AP.

Results: Total number of patients with amylase/lipase estimations done in ER: 487 cases Final diagnosis Acute Pancreatitis (AP): 8 out of 487 cases (1.64%)

Patients were divided into 2 categories:
1) Patients with no abdominal pain on presentation: 100 cases.

(Indications not clear but include nausea, vomiting, and abdominal discomfort)

Final diagnosis of AP: 0 out of 100 cases.

2) Patients with abdominal pain: 387 cases.

Final diagnosis of Acute Pancreatitis: 8 out of 387 cases.

Conclusions: 1) In the ER estimations of serum amylase/lipase are “routine” in evaluating any abdominal discomfort.

2) The frequency of misuse of estimations of serum amylase/lipase levels is quite high (98.4%).

3) If this pattern of misuse of amylase and lipase estimations is widely prevalent, there is a window of opportunity for physician education and cost containment.

More than 3 times elevation of Amylase and Lipase (cases of AP) in relation to location of abdominal pain

RUQ (3 out of 69) Epigastiric (5 out of 141) LUQ (0 out of 12)

R Lumbar (0 out of 15) Periumbilical (0 out of 15) L Lumbar (0 out of 8)

RLQ (0 out of 38) Suprapubic (0 out of 12) LLQ (0 out of 33)

Diffuse Abdominal pain (0 out of 44).

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What Happens to Serum Carbohydrate Antigen 19-9 after Biliary Stent Placement in Pancreaticobiliary Malignancy?
Brian R. Weston, MD, William A. Ross, MD, E. Lin, Xueimei Wang, Jeffrey H. Lee, MD.* Gastroenterology, MD Anderson Cancer Center, Houston, TX and Biostatistics and Applied Mathematics, MD Anderson Cancer Center, Houston, TX.

Purpose: CA19-9 is frequently followed to monitor disease progression. Bile duct obstruction has been associated with increased CA19-9. The purpose was to evaluate the correlation of CA 19-9 with the regression of bilirubin after stent placement for malignant biliary obstruction. The hypothesis was that biliary decompensation would result in a downward trend of CA19-9.

Methods: The records at MD Anderson Cancer Center were reviewed for patients who underwent first time ERCP with biliary stent placement for malignant obstructive jaundice from Oct. 2002 to Sept. 2005. Patients who achieved serum bilirubin ≤ 2 mg/dL and those with adequate CA19-9 data were identified and analyzed to determine association. CA19-9 levels needed to have been recorded within 15 days prior to stent placement and then post stent when bilirubin ≤ 2. Other examined variables included type of cancer, presence of metastasis, and level of pre-stent bilirubin.

Statistics: Spearman rank correlation methods were used to assess the correlation between variables. Fisher’s exact test was performed.

Results: A total of 52 patients with adequate serum CA 19-9 data who achieved bilirubin ≤ 2 after biliary stent placement were identified (pre-stent bilirubin range 2.8-21.9 mg/dL; mean 10.23; median 9.4). Forty (77%) had pancreatic cancer, 12 (23%) other biliary malignancies, and 23 (44%) with liver metastasis. 27/52 (52%) demonstrated a downward trend of CA19-9 post stent, 16/52 (31%) an upward trend, and 9/52 (17%) an equivocal change (defined arbitrarily as a change less than 20 U/mL). Although a change of CA19-9 was significantly correlated with bilirubin regression (Spearman correlation coefficient 0.36 and p = 0.009), the direction of change in CA19-9 was variable. Patients whose CA19-9 decreased had significantly higher baseline bilirubin as compared with patients whose CA19-9 level increased (p = 0.02). The change of CA19-9 was not significantly associated with cancer diagnosis (pancreatic vs other) (p = 0.16) or the presence of liver metastasis (p = 0.22).

Conclusions: Unlike the regression of CA 19-9 post stent placement in benign biliary obstruction, the change in CA 19-9 is unpredictable in cases of malignant biliary obstruction despite adequate biliary decompression and bilirubin regression. Further studies are necessary to find other confounding variables affecting CA 19-9 i.e. tumor burden.

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An Uncommon Presentation of Multiple Myeloma
Stacy Prall, DO,* David Schaefer, MD, Chad Potteiger, DO, Srini Dubagunta, MD. Gastroenterology and Hepatology, Geisinger Medical Center, Danville, PA.

Purpose: Pancreatic involvement in multiple myeloma (MM) is rare, but when occurs usually presents as jaundice from common bile duct obstruction. We report a case of multiple myeloma presenting as orbital and soft tissue masses with a non-obstructing pancreatic plasmacytoma. Most pancreatic involvement in multiple myeloma is identified post mortem with an estimated incidence of 2.3%. MM is a hematologic malignancy originating in the bone marrow. The neoplastic proliferation of clonal plasma cells typically results in osteolytic lesions which may result in pathological fracture. The most common presenting symptoms include back, hypercalcemia, renal insufficiency, anemia and infection. A 75-year-old man presented to his primary care provider with complaints of new onset right eye swelling worsening over the past 3 weeks. The patient had a past medical history significant for polycythemia vera with thrombocytosis, reflex esophagitis and a remote smoking history. No known occupational chemical exposure. No history of back pain, myalgias, fatigue, weight loss, fevers, or change in urinary pattern. Physical exam revealed ptosis of the right eye and a palpable firm non-tender mass above the right clavicle. Cardiac, respiratory, neurological and abdominal exam were unremarkable. Laboratory studies revealed hemoglobin of 9.9 with an otherwise normal CBC. Renal and liver function was normal. Fine needle aspirate of the supraclavicular mass was performed demonstrating plasmacytoid large cell lymphoma or multiple myeloma. CT scan identified a pancreatic head mass, splenomegaly, and bilateral pulmonary nodules.
Endoscopic drainage of pancreatic fluid collections (PFC) is increasingly being performed. A variety of techniques have been described to perform transmural entry, however, there is a lack of data on the technical success and safety of transmural entry using a single technique. We describe the largest experience in transmural entry of PFC’s without EUS-guidance using a dedicated aspiration needle (BAN-18, Cook Medical, Winston-Salem, NC). The transmural tract into the PFC was dilated using dilating balloons ranging from 6-20mm in diameter followed by subsequent placement of one-two 10-Fr double pigtail stents with or without nasoaoxic irrigation tubes. Successful entry was defined as entry allowing for placement of stents.

Conclusions: Endoscopic transmural drainage of pancreatic fluid collections can be performed safely and effectively via the seldinger technique without endoscopic ultrasound guidance. This data will allow sample size calculations to be made if direct comparisons to this technique and others are undertaken.

Surgical Outcomes in Patients with T4 Pancreatic Cancer

Prabheen Chahal, MD, Georgios I. Papachristou, MD, Todd H. Baron, MD,* Bret T. Petersen, MD, Christopher J. Gostout, MD, Mark D. Topazian, MD. Gastroenterology and Hepatology, Mayo Clinic, Rochester, MN.

Purpose: Pancreatic ductal cancer with vascular invasion or/and invasion into adjacent organs, T4 pancreatic cancer, is very poor prognosis. Herein, we analyzed outcomes in patients with T4 pancreatic cancer.

Methods: Medical records of 84 patients with pancreatic cancer admitted on between 1999 and 2004 at our department were reviewed retrospectively. 42 patients of them had pancreatic cancer with vascular invasion or/and invasion into adjacent organs in this sample.

Results: Twenty-one patients performed pancreatectomy (twelve patients with macroscopic curative resection, nine patients without macroscopic curative resection), fifteen patients performed palliative surgery due to local advance and distant metastasis. Six patients with T4 pancreatic cancer had no operation because of local advance and liver metastasis, but received chemotherapy (gemcitabine or 5-FU + CDDP). The 1, 2 and 3-year survival rate of all patients were 30.8, 21.7 and 10.9%. The 1, 2 and 3-year survival rate of no surgery patients were 30, 30 and 0%, that of the patients with palliative operation were 6.7, 6.7 and 0% and the patients with pancreatectomy were 49.5, 31.4 and 23.6% (p = 0.0039). In patients with pancreatectomy, The 1, 2 and 3-year survival rate of the patients performed macroscopic curative resection were 74.1, 43.2 and 43.2%, that of the patients without curative resection were 13.3, 13.3 and 0% (p = 0.0138).

Conclusions: Surgeons should perform curative resection if decide the surgery for the patients with pancreatic cancer. Moreover, surgeons should evaluate the stage of pancreatic cancer patients accurately.

Transmural Entry into Pancreatic Fluid Collections Using a Dedicated Aspiration Needle without Endoscopic Ultrasound Guidance: Success and Complication Rates

Prabheen Chahal, MD, Georgios I. Papachristou, MD, Todd H. Baron, MD,* Bret T. Petersen, MD, Christopher J. Gostout, MD, Mark D. Topazian, MD. Gastroenterology and Hepatology, Mayo Clinic, Rochester, MN.

Purpose: Endoscopic drainage of pancreatic fluid collections (PFC) is increasingly being performed. A variety of techniques have been described to perform transmural entry, however, there is a lack of data on the technical success and safety of transmural entry using a single technique. We describe the largest experience in transmural entry of PFC’s without EUS-guidance using a dedicated aspiration needle.

Methods: All patients who underwent endoscopic transmural drainage of PFC from October 1998-May 2006 were identified from the endoscopy database. Data were abstracted from the endoscopic procedure report and the patient records and placed in a JMP drive. All drainages were performed without EUS guidance after visualization of an obvious intraluminal bulge using a dedicated large-bore aspiration needle (BAN-18, Cook Medical, Rochester, MN).

Results

<table>
<thead>
<tr>
<th>Total Number of Patients</th>
<th>94</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (Male, Female)</td>
<td>50, 44</td>
</tr>
<tr>
<td>Age, Median (range) years</td>
<td>49 (12-78)</td>
</tr>
<tr>
<td>Types of PFC *</td>
<td>Organized pancreatic necrosis ●</td>
</tr>
<tr>
<td>Pseudocyst (acute pancreatitis) ●</td>
<td>45 (25 ● 19 ● 5)</td>
</tr>
<tr>
<td>Pseudocyst (chronic pancreatitis) ●</td>
<td>45 (25 ● 19 ● 5)</td>
</tr>
<tr>
<td>Pancreatic Abscess Size of PFC, Median (range) cm</td>
<td>11 (3-23)</td>
</tr>
<tr>
<td>Transmural drainage approach ● Transgastric ●</td>
<td>60 (31 ● 2 ● 1)</td>
</tr>
<tr>
<td>Transduodenal ● Transgastric and transduodenal ● Transpalpy</td>
<td>60 (31 ● 2 ● 1)</td>
</tr>
<tr>
<td>Successful entry (%)</td>
<td>91 (97%)</td>
</tr>
<tr>
<td>**Complications (%) ● Clinically significant bleeding ● Perforation (gall bladder)</td>
<td>4 (4.2) ● 3 ● 1</td>
</tr>
</tbody>
</table>

*0 patients had mild intraprocedure bleeding at puncture site managed with local epinephrine injection.

Characteristics of KINDREDS at High Risk for Pancreatic Cancer

James Disario, MD,* Nicole Omer, MBA, Richard Kerber, PhD, Kenneth Boucher, PhD, Randall Bart, MD. High Risk Cancer Clinics, Huntsman Cancer Institute, Salt Lake City, UT.

Purpose: Determine characteristics of familial pancreatic cancer (PC) from a population-based database.

Methods: Survey of the Utah Population Database (UPDB), which is a unique population-based database with complete ascertainment. It contains data on >10 million individuals. Familial standardized incidence ratios (FSIR) were calculated to determine risk. All cancer cases were pathologically verified by the Utah Cancer Registry (SEER). Some medical and family history data were collected by the Utah Familial Pancreatic Cancer Registry. Expected rates were calculated using controls from the UPDB.

Results: There were 58 kindreds each of 1,400-32,000 individuals at high-risk for PC and Each kindred had ≥ 5 PC cases. There was a 200-400% increased risk (3% lifetime risk) for individuals in these kindreds. Overall, there were 5208 cases of sporadic and 258 (4.72%) familial PC. Mean age at diagnosis was 69.5 ± 12.5 and 69.1 ± 12.3 for sporadic and familial PC, respectively. Men (2413 sporadic, 126 familial) and women (2795, 132) were equally affected (chi-square p = .43). By Kaplan-Meier analysis, median survival was 3 (IQR 11-8) months and 3 (IQR 1-8.5) months, respectively. There was no statistically significant difference when stratified by diagnosis year, diagnosis age, sex, or tumor location. Significant relative risk increases for other cancers in PC families included: Females ≥ 70 y.o. breast1.19, lung 1.64. Males ≥ 70 y.o. prostate 1.59, lung 1.39, melanoma 1.53; ≥ 90 y.o. colon, 1.33 (two tailed p < 0.05). Acute pancreatitis occurred in 101 persons in 17 kindreds and chronic in 9 persons in 3 families. Diabetes occurred in 1619 persons in 57 kindreds. The relative risk of acute (0.62) and chronic (0.53) pancreatitis, and diabetes (0.51) in these kindreds was not statistically significant.
Cases of Cystic Fibrosis (CF) in older adults

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Age/sex</th>
<th>Age when CF first diagnosed</th>
<th>Why CF was suspected</th>
<th>Genetic mutations</th>
<th>GI complications</th>
<th>Non GI complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>67/Male</td>
<td>29 yrs</td>
<td>Recurrent episodes of pneumonia and upper respiratory tract infections</td>
<td>D F 508</td>
<td>Distal intestinal obstruction of small bowel (DIOS) and acute cholecystitis</td>
<td>Obstructive lung disease, nasal polyp and complications related to diabetes</td>
</tr>
<tr>
<td>2</td>
<td>69/Female</td>
<td>52 yrs</td>
<td>Positive family history (2 daughters with CF)</td>
<td>R 117 H and G 542 X</td>
<td>None</td>
<td>Sinusitis and recurrent bronchitis</td>
</tr>
<tr>
<td>3</td>
<td>80/Female</td>
<td>74 yrs</td>
<td>Positive family history (2 nieces with CF)</td>
<td>R 117 H and G 542 X</td>
<td>Acute cholecystitis</td>
<td></td>
</tr>
</tbody>
</table>

Conclusions: From a population-based registry with complete ascertainment; 1) Familial PC accounts for 4.72% of cases and imparts a 3% lifetime risk, 2) The phenotype of familial and sporadic PC is similar, 3) Overall survival is similar for sporadic and familial PC, 4) PC kindreds have a predisposition to other cancers, 5) Risks of pancreatitis and diabetes are not increased in PC kindreds. 6) Surveillance may be warranted for PC and other cancers in affected kindreds.

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Biliary Complications Following Hepatic Trauma: The Importance of ERCP
David L. Lichtenstein, MD,* Elliot Servais, MD, Suresh Agarwal, MD, Peter Burke, MD, Erwin Hirsch, MD. Department of Gastroenterology and Surgery, Boston Medical Center, Boston, MA.

Purpose: The purpose of the study was to describe our experience with traumatic biliary complications and in particular define the efficacy, safety and outcomes of ERCP in the management of bile leaks following liver injury.

Methods: A retrospective analysis of liver injuries from October, 2001 to April, 2006 was performed. Information recorded included demographic, radiologic and operative interventions. A bile leak was diagnosed if there was bile noted in a surgical wound, bile leakage from an intra-abdominal drain, or a leak noted on hepatobiliary scintigraphy (HIDA). ERCPs were performed in all patients with bile leaks. Characteristics of the leak and endoscopic treatment of the injury were assessed. Clinical outcomes measured included healing of the leak, post-treatment biliary anatomy, and associated complications.

Results: 225 patients experienced major hepatic trauma (145 blunt and 80 penetrating). Twenty-eight patients (12.4%; 13 blunt, 15 penetrating) underwent ERCP for biliary injury diagnosed by HIDA (26 pts.) and/or by clinical suspicion from previously noted surgical findings or percutaneous biliary drainage (10 pts.). The average AAST liver injury grade was 3.25. The mean time to diagnosis of biliary injury was hospital day 7 (range 3-18). Laparotomy was performed in 18 (64%) and surgical or CT drainage of bilomas in 10 pts. (36%). All leaks identified on nuclear scintigraphy were confirmed at ERCP. However, HIDA scanning underestimated the extent of the injury in 8 patients where the leak was characterized as “contained” but found to be freely extravasating on ERCP. ERCP was performed at a mean of hospital day 7.5 (range 2-28). The total number of ERCPs performed was 50. Endoscopic therapy included biliary sphincterotomy (N = 6), stent placement (N = 16) or combined therapy (N = 6). All bile leaks resolved after ERCP. Cholangiography was normal in all 16 patients who received a follow-up ERCP. The average hospital length of stay was 25.8 days (range 3-70). There was one (3.5%) ERCP-related complication which was moderate pancreatitis. There were no deaths noted.

Conclusions: Bile leaks commonly occur in individuals with liver trauma (12.4%). ERCP is a safe and effective strategy for diagnosing and managing biliary complications following blunt and penetrating hepatic trauma. Although biliary scintigraphy has a high positive predictive value for diagnosing biliary leaks, ERCP better distinguishes the extent of injury and eliminates the need for more invasive surgical treatment.

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Cystic Fibrosis in Older Adults
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Purpose: Cystic Fibrosis generally regarded as a disease of childhood characterized by chronic sino-pulmonary disease, pancreatic insufficiency and elevated sweat chloride test has been frequently recognized in adults these days. Also it is recognized that cystic fibrosis includes a wide spectrum of disease severity that can present in adulthood with atypical or mild clinical features. The defective Cystic Fibrosis Transmembrane Conductance Regulator gene (CFTR) with > 1000 mutations can cause the classic type in children or with atypical features in adults. The life expectancy of patients with CF has greatly improved over past decades because of advances in management of CF including lung transplant (J Clin Gastroenterol. 2005; 39:307-17) Pancreatic insufficiency is present in about 85-90% of patients with CF. Recurrent idiopathic acute/chronic pancreatitis occurs in 1-2% of patients with pancreatic sufficiency (NEJM 1998; 339:645-52). Abnormalities of liver function test, fatty infiltration of liver, biliary cirrhosis, gall stones, portal hypertension and liver failure can be present as Gastrointestinal related complications. Also patients with cystic fibrosis can develop abdominal pain secondary to gastritis, peptic ulcer disease, malabsorption, intussusception and distal intestinal obstruction of small bowel (DIOS).

Aim: The aim of this report is to share some experience and knowledge with the cases of Cystic Fibrosis diagnosed over the past 3 years at our Institute in the age group of 18 years and above and to bring to the attention of physicians and gastroenterologists that in geriatric population one should be aware of the possibility of cystic fibrosis.

Conclusions: During the evaluation of adult patients with the symptoms mentioned above, Cystic Fibrosis should also be included in the differential diagnosis.

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Effect of Early Oral or Nasogastric Feeding on the Outcome of Cases with Acute Pancreatitis
Ari Wiesen, MD, Kostas Sideridis, DO, Prasun K. Jalal, MD, Simmy Bank, MD,* Division of Gastroenterology, Long Island Jewish Medical Center - Albert Einstein College of Medicine, New Hyde Park, NY.

Purpose: Acute pancreatitis is associated with significant morbidity and mortality. The mortality of acute pancreatitis has been reported in literature as 10-30%, but it may have improved recently with early recognition of its severity and institution of appropriate management. Recent studies showed a reduction in adverse outcomes with early enteral feeding. The purpose of the study was to evaluate the outcome of cases admitted with acute pancreatitis in a single center over the past 2 years and the effect of oral or nasogastric feeding on the prognosis.
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Role of ERCP in Acute Calculus Cholecystitis
Rizwan Safdar, MD, Wesam Bolkhir, MD, Giuseppe Aliperti, MD.∗
Internal Medicine, St. Louis University School of Medicine, St. Louis, MO and St. Louis, MO.

Purpose: Patients with Acute Calculus Cholecystitis (ACC) and high suspicion for main bile duct stones often undergo preoperative ERCP. Drainage of the gallbladder via selective cystic duct cannulation during ERCP is described but underreported, while percutaneous cholecystostomy is a widely accepted approach. We herein report our experience with gallbladder drainage during ERCP.

Methods: ERCP was performed with standard equipment and technique. After main duct cannulation and clearance, selective cystic duct cannulation was achieved with 0.025 or smaller hydrophilic guide wire. A balloon extraction catheter or smaller catheter was then advanced into the gallbladder over the guidewire, and small amounts of contrast were injected. Dislodging with the guide wire/catheter when feasible or simply bypassing with a nasobiliary drain. Gallbladder contents were aspirated and submitted for gram stain and cultures.

Results: 22/25 symptomatic patients (mean age 63.5 years; 15 F) with ACC underwent successful gallbladder drainage. Main duct stones were extracted in 13/22. Cystic duct stones were clearly identified in 18/22. Selective cystic duct cannulation was achieved with 0.025 or smaller hydrophilic guide wire. A balloon extraction catheter or smaller catheter was then advanced into the gallbladder over the guidewire, and small amounts of contrast were injected. Dislodging with the guide wire/catheter when feasible or simply bypassing with a nasobiliary drain. Gallbladder contents were aspirated and submitted for gram stain and cultures.

Conclusions: Selective cannulation of the cystic duct and gallbladder drainage during ERCP can be performed with high success rates.

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Endoscopic Management of Intra- and Extra-Hepatic Biliary Leak Following Hepato-Biliary Surgery, Does Location Make a Difference?∗
Christopher Miller, MD, Joel Bossoff, MD, Claudio Tomazzini, MD.∗
Division of Gastroenterology and Hepatology, University of Tennessee Health Science Center, Memphis, TN.

Purpose: To investigate the response to endoscopic management of biliary leaks identified in patients status post hepato-biliary surgery. Specifically, outcomes following ERCP (∗sphincterotomy) and stent placement were investigated.

Methods: A retrospective review of 360 consecutive ERCPs performed at our institution between October 2001 and May 2006 was performed. Ten cases of extra-hepatic and six cases of intra-hepatic biliary leak were identified. Outcomes following ERCP (∗sphincterotomy) and stent placement were then studied in these sixteen cases which were identified in nine males and seven females ranging from 19 to 60 years of age.

Results: Of the ten cases of extra-hepatic biliary leak, nine occurred after laparoscopic cholecystectomy and one was identified at the biliary anastomotic site in a patient status-post orthotopic liver transplantation. Of the six patients found to have intra-hepatic biliary leaks, three were status-post motor vehicle accidents with subsequent surgical management of hepatic lacerations, two had undergone resection of metastatic colon cancer lesions, and one was status-post liver transplantation. Nine of the sixteen patients underwent sphincterotomy at the time of their procedure, and all were treated endoscopically with placement of a biliary stent. All of the patients with extra-hepatic biliary leaks responded to endoscopic treatment without complication and with note of complete resolution of the leak. Two of the six patients with intra-hepatic leaks died despite endoscopic management (one due to an infected intra-abdominal collection following resection of metastatic liver disease and the other due to liver failure not felt to be related to the biliary leak). The remaining four patients with endoscopic leaks responded completely to stent placement.

Outcome Following Endoscopic Management of Biliary Leaks

<table>
<thead>
<tr>
<th>Type of Leak</th>
<th>Complete Resolution</th>
<th>Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intra-hepatic</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Extra-hepatic</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>TOTAL</td>
<td>16</td>
<td>14</td>
</tr>
</tbody>
</table>

p = 0.183.

Conclusions: In this series, ERCP with stent placement, with or without sphincterotomy, was highly effective in the management of biliary leaks. Although the small number of patients entered into this study limits the conclusion, it appears that intra-hepatic biliary leak is associated with a worse prognosis.

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Selective, Wire Guided Cannulation of the Common Bile Duct Reduces the Risk of Post-ERCP Pancreatitis by Initially Accessing the Bile Duct with a Soft-Tipped Guidewire, without Contrast Injection
R. Martin Bashir, MD.∗ Gastroenterology, Washington Hospital Center, Washington, DC.

Purpose: Pancreatitis is the most common and serious complication of diagnostic and therapeutic ERCP, occurring in 3-30% of cases overall. Patient factors such as age, prior history of post-ERCP pancreatitis, and technical
Prevention of Post-ERCP Pancreatitis by Using Protease Inhibitor
Tomoya Kawase, Koji Yoshida*, Yoshikatsu Nomura, Yuki Nagata, Shinichiro Yamamoto. Hepatobiliarypancreatology, Kawasaki Medical School, Kurashiki, Okayama, Japan; Gastroenterology, Aizu Central Hospital, Aizuwakamatsu, Fukushima, Japan and Gastroenterology, Hoshi General Hospital, Koriyama, Fukushima, Japan.

Purpose: Pancreatitis is one of complication of ERCP. In Japan we usually use protease inhibitor to prevent pancreatitis associated with ERCP; Urinastatin, Mesilate-Gabexate (FOY) and Mesilate-Famostat (FUT). Although efficacy of Urinastatin was reported in recent paper, other agents have not been reported yet also compare with other. This time we compare efficacy of prevention for post-ERCP pancreatitis about each agents. Further study is needed.

Methods: Retrospective assessment of all patients who underwent ERCP for selective CBD cannulation by a single endoscopist from July 2002 to June 2005 was performed. All patients included had initial, selective CBD cannulation using a soft-tipped guidewire and a sphincterotomy. The CBD was freely cannulated with the wire, after which time the cannulation was advanced into the mid CBD, prior to injecting any contrast. Cases involving minor ampullary cannulation were excluded.

Results: ERCP was successful in cannulation of the CBD in 99.1% of patients. A total of 716 ERCPs were performed for selective CBD cannulation over a 36 month period by single endoscopist. All procedures utilized initial wire-guided cannulation with a 0.025" or 0.035" soft-tipped guidewire. Fourteen patients (2%) developed clinically identifiable post-ERCP pancreatitis; only 6 (0.9%) required admission for 24-72 hrs. None had developed pseudocysts or sequelae of chronic pancreatitis up to 6 months after evaluation. There were no cases of severe pancreatitis (0%) or ICU admissions as a result of Post-ERCP pancreatitis.

Conclusions: Accessing the bile duct with a soft-tipped guidewire likely significantly reduces the risk of developing post-ERCP pancreatitis in adults. Further study is needed.

Near-Fatal Hepatic Artery Hemorrhage: A Rare Complication Following Covered Self-Expanding Metal Stent Migration
Burr J. Loew, MD, Kirk P Bernardino, MD, Talia Hoffstein, MD, Steve Amberson, MD, Andreas Stefan, MD. Division of Gastroenterology, Pancreaticobiliary Center, Maine Medical Center, Portland, ME.

Purpose: Covered self-expanding metallic stents (SEMS) appear more prone to migration than uncovered SEMS. Only one case of hemorrhage has been reported. Delayed migration of a silicone-covered self-expandable nitinol stent (Wallstent, Microvasive) resulting in severe hepatic artery hemorrhage is presented here. A 60 year-old man presenting with melena 14 months after placement of a covered Wallstent for a malignant distal common bile duct stricture secondary to pancreatic cancer developed migration of
the stent into the duodenum and bleeding from the ampulla. After stent removal, immediate torrential bleeding from the common bile duct ensued. The patient was stabilized with a 48Fr balloon, inflated in the distal biliary duct, and blood transfusion. Immediate angiography demonstrated erosion of the right hepatic artery from contact with the migrated Wallstent (Figure 1). The close apposition of the Wallstent to the artery was evident in retrospect on a pre-ERCP CT scan (Figure 2). The damaged artery was embolized with multiple coils. Abdominal CT scan revealed necrosis of the inferior third of the right lobe. The patient was managed conservatively. No evidence of bleeding or recurrent biliary obstruction was observed at 6 month follow-up. Reported covered SEMS migration rates range from 0-25%. Most covered SEMS migration involve biliary occlusion and duodenal ulceration at the site of stent impaction in the opposite duodenal wall. In this case, the non-conforming nature of the Wallstent coupled with its migration may have lead to a straightening tendency causing increased pressure exertion and subsequent duct erosion or perforation by the proximal stent end. Migration of covered SEMS is an emerging problem, with complications possibly more serious than initially reported. [figure1][figure2]

Small Intestine/Unclassified

The Clinical and Radiological Manifestations That Are Potentially Associated with Duodenal Diverticula
Faisal A. Bukeirat, MD,* Stephany S. Swart, MD. Medicine, WVU School of Medicine, Morgantown, WV and Radiology, WVU School of Medicine, Morgantown, WV

Purpose: Small bowel diverticula are less frequent than the large bowel diverticula, but when they do occur, they occur most frequently in the duodenum where they are usually asymptomatic. The aim of this study is to retrospectively evaluate the potential clinical manifestations and the radiological changes that are associated with duodenal diverticulosis in symptomatic patients.

Methods: From March 2003 to March 2006, the Electronic charts of 27 patients with symptomatic duodenal diverticulosis seen at one medical center were reviewed. The mean age of the patients was 64 years (range 43-86 years of age). There were 10 males and 17 females. The clinical and radiological data of those patients were reviewed.

Results: Of the 27 patients who were included in this study, 25 patients had upper abdominal pain (93%), 7 patients had acute diverticulitis (26%), 6 patients had acute cholangitis (22%), 5 patients had acute pancreatitis (18%) with no other etiology or explanation for their pancreatitis, 7 patients had sludge and or stones within the biliary system (26%), and 16 patients (59%) had a radiologic abnormality directly related to the duodenal diverticulum such as: pressure effect on the CBD, debris within the diverticulum, air-fluid level within the diverticulum, and or radiological evidence of acute diverticulitis (on MRI there is abnormal enhancement of the duodenal wall with stranding in the adjacent soft tissues on T1 weighted images, and on T2 weighted images we see increased signal intensity relating to edematous changes and diverticular wall thickening, Figures 1 & 2).

Conclusions: Although diverticulosis of the duodenum is usually asymptomatic, it should be recognized as a potential risk factor for various upper digestive health problems including unexplained upper abdominal pain, and possibly acute pancreatitis. [figure1][figure2]
Celiac Sprue—An Acquired Disease?
Elihu Shemesh, MD.* Gastroenterology Department, Rabin Medical Center, Golda Campus, Petah Tikva, Sackler Medical School, Tel Aviv University, Petach Tikva, Israel.

Purpose: Celiac sprue is a disease of small bowel mucosa caused by sensitivity to gluten. Diagnosis is based on positive serologic tests and typical abnormal small bowel mucosa. In latent celiac sprue, usually serologic tests are positive earlier than the small bowel mucosa abnormality.

Aim: We present 2 patients with anemia in whom endomysial antibodies were negative twice, small bowel biopsy were negative for celiac, who were diagnosed & 12 years later by positive serology and small bowel biopsy as typical celiac sprue.

Methods: Patients & materials: Two patients presented with transient anemia Hb 10 & 11 g/dL

Outcome Following Endoscopic Management of Biliary Leaks

<table>
<thead>
<tr>
<th>Pt. No</th>
<th>gender</th>
<th>age</th>
<th>presentation</th>
<th>Abnormal small bowel series</th>
<th>Interval since 1st -EMA (Yrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Male</td>
<td>37</td>
<td>Anemia</td>
<td>Yes</td>
<td>Normal</td>
</tr>
<tr>
<td>2</td>
<td>Male</td>
<td>63</td>
<td>Anemia</td>
<td>No</td>
<td>Normal</td>
</tr>
</tbody>
</table>

Upper GI series revealed a diffuse abnormality throughout the small bowel with strictures and dilatations suspicious for crohn’s disease. The other patients had a deformity of the duodenal bulb. Both patients remained symptom free for 8 & 12 years, when anemia returned and repeat studies showed typical histology in small bowel and high positive EMA > 1:160.

Discussion: We are not aware of previous reports of Celiac sprue patients with normal serology becoming highly positive.

Conclusions: These patients clinical course may indicate that a negative serology and small bowel biopsy in the routine investigation of anemia does not rule out celiac.

Eosinophilic Gastroenteritis and Celiac Sprue in the Same Patient: Two Diseases or Two Ends of a Spectrum?
Constantinos P. Anastassiades, MD, Dawn D. Ferguson, MD.* Division of Gastroenterology & Hepatology, Mayo Clinic College of Medicine, Rochester, MN.

Purpose: An 83-year-old farmer of Norwegian ancestry was hospitalized multiple times within one year for nausea, vomiting, diarrhea and weight loss. He was found to have peripheral eosinophilia with a count ranging from 0.79 to 6.74 x 10^9/L (normal reference range: 0.05 to 0.50 x 10^9/L). An extensive work-up for eosinophilia was performed and all tests for parasitic infection were negative. Bone marrow biopsy was non-diagnostic, but suspicious for smoldering lymphoma. An esophagogastroduodenoscopy (EGD) and colonoscopy were performed and gastric, small bowel and colonic biopsies were obtained. Duodenal biopsies showed partial villous atrophy, crypt hyperplasia and intraepithelial lymphocytosis suggestive of sprue, but they also revealed increased mucosal eosinophils. Increased mucosal eosinophils were also seen on gastric and colonic biopsies. The patient was vitamin D deficient, but not anemic or iron-deficient. Bone density scan was normal. Anti-gliadin IgA antibodies were positive and tissue transglutaminase IgA antibodies were negative. Based on these findings and the uncertain etiology of peripheral eosinophilia, the patient was treated with oral prednisone and his symptoms dramatically improved. A gluten-free diet was not recommended because of the patient’s advanced age and lack of sprue-associated comorbidities. Two cases of simultaneous eosinophilic gastroenteritis and celiac disease have been reported in the literature. Both patients were much younger than the one in this report. Interestingly, studies have shown that the eosinophil, through toxic cationic proteins such as major basic protein (MBP), plays a role in the pathogenesis of both diseases.
Methods: Caco-2 cell line cultures were divided into three groups: 1) inducer cells were exposed to oxidant (H2O2); 2) detector cells were not exposed to oxidant and were placed in a chemically isolated container in the proximity of inducer cells; 3) Control cells were also not exposed to H2O2 and were kept in a separate room. Parts of the experiment were done using a newly designed container (Farhadi’s cell container, patent pending) composed of isolated chambers for inducer and detector cells that are positioned side-by-side and share a thin, glass wall that precludes the passage of any chemical or electrical signals between the two containers. We assessed cytoskeletal morphology and tight junction protein abnormalities using immunofluorescent staining, Laser confocal microscopy, and SDS-PAGE fractionation.

Results: Exposing inducer cells to H2O2 resulted in substantial disruption of the cytoskeleton (actin) and of tight junctions in 56% of cells. In parallel, there was substantial cytoskeletal and tight junctional damage (25%) in detector cells compared to controls ($p < 0.0001$).

Conclusions: Our data provide evidence for the existence of a NCNE signaling system among intestinal cells. This novel signaling system can cause cytoskeletal damage in distant cells. The mechanism underlying this unique signaling phenomenon is unknown, although electromagnetic signaling due to oscillating ions is a possible candidate. Intercellular NCNE signaling could play a pivotal role in the pathogenesis and possible therapeutic intervention of gastrointestinal disorders related to oxidative induced barrier injury such as IBD.

## Amyand’s Hernia: A Report of 15 Years of Experience

Hemant Sharma, MRCS, Ashwini Gupta, MS, Narayan S. Shekhawat, MS, Mohammed A. Memon, FRCS.* Department of Surgery, Whiston Hospital, Rainhill, Merseyside, United Kingdom and Department of Surgery, Sawai Mansingh Medical College, Jaipur, Rajasthan, India.

Purpose: The presence of a vermiform appendix in an inguinal hernial sac is termed as Amyand’s Hernia. It may presents as a tender inguinal or inguino-scrotal swelling and is often misdiagnosed as an incarcerated or strangulated hernia. The purpose of this study was to review the management Amyand’s hernia at a single institution since 1991.

Methods: A retrospective analysis of 18 consecutive patients operated upon at our institution, between 1991 to 2005, with an Amyand’s hernia was undertaken. Patient’s demographics, treatment performed and postoperative outcome were analysed.

Results: There were 17 men and 1 woman. The median age was 42 years. None of the patients were diagnosed preoperatively. The commonest presenting symptom was painful inguinal or inguino-scrotal swelling (83%). All patients therefore underwent emergency surgery with a presumptive diagnosis of either incarcerated or strangulated inguinal hernia. Operative findings include eleven normal appendix, four inflamed appendix and three perforated appendix in the inguinal hernial sac. Patients with normal appendix (N = 11) had mesh hernia repair without an appendectomy. The rest of the patients (N = 7) with abnormal appendix underwent emergency open appendectomy followed by Bassini’s sutured hernia repair. One patient died in the postoperative period of pneumonia. Only one recurrent hernia has been detected to date.

Conclusions: Inflammatory status of appendix determines the type of hernia repair and surgical approach. Incidental appendectomy in case of a normal appendix is not favored.

## Is Routine Duodenal Biopsies (DBx) Necessary during Upper Gastrointestinal Endoscopies (EGD)?

Peiying Xiao, MD, Vijaya Boyella, MD, Hulya Levendoglu, MD.* Division of Gastroenterology, Brookdale University Hospital Medical Center, Brooklyn, NY and Division of Gastroenterology, SUNY Downstate Medical Center, Brooklyn, NY.

Purpose: Controversies exist whether DBx should be an integral part of EGD. Unsuspected celiac disease (CeDi), parasites when diarrhea is absent and stool yield is low can be found by routine Bxs. Polymorphs (PMNs) have been proposed as a reliable marker for acute duodenitis (AD) and chronic active duodenitis (CAD). The importance of chronic duodenitis (CD) who do not show PMNs remains unclear.

Methods: DBxs were done on 435 pts during EGD. Classification of duodenitis is based on Whitehead et al. criteria. Findings were correlated with age, sex, race, H pylori (HP) on gastric Bxs and histology. We had 136 males (M) and 299 females (F) age from 14-102, mean age of 57; 354 African American (AA), 57 Caucasian (CAU), 17 Hispanic (HI), 5 Asian (AS). 2 pts were less than 20 yrs old.

Results: AD was present in 1 pt, CAD in 12 (2.8%). CD in 386 (88.7%); 365 had mild CD (83.9%). 21 moderate CD (4.8%). 26 Bxs were normal (N, 6%). 10 pts (2.3%) had findings of congestion in 2, lymphangiectasia 2, villous atrophy 4, pseudolipomatous 1, adenomatous change 1. When mild CD and N Bxs were excluded significant duodenal inflammation (SDI) were present in 10.1% of pts (11% of M, 9.7% F, 17.3% AA 8.7%, CAU and 20% AS, none, in 17 HI). SDI is increased with increasing age (7.6% from 20-39, 9.4% 40-49, 11.7% over 60 yr of age). Although overall SDI was not different in H P + and -pts (9.8% vs. 10.4%), HP− pts showed age related increased SDI and HP+ did not. Lymphoid aggregate and follicles are seen in 13 pts, 10 was HP+, only 1 had N gastric histology ($p < 0.05$). 0.9% of Bxs were compatible with CeDi: 3 had chronic active gastritis. Out of 199 pts with significant gastric inflammation (SGI), 23 had SDI (12.1%) as opposed to 21/246 with mild or no gastritis. (8.5%, $p = 0.33$). Out of 48 pts with intestinal metaplasia (IM) 7 (14.6%) had SDI; while 27/387 (9.5%) with no IM ($p = 0.08$).

Conclusions: SDI occurred in 10.1% of pts; equally in M and F who are not suspected to have duodenal disease. CeDi was uncommon in our population (9.9%). SDI increased with increasing age and showed same age relation in HP− pts. SDI occurred with similar incidence with HP + and - pts. Severity of GI did not correlate with DI however more pt with IM had SDI when
compared with no IM. Summary: DBx should be considered during EGD in view of SDI in 10% of pts especially in AAs, ASs, in pts older than 60 and who is also known to have IM.

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Hemoglobin and Red Cell Indices as Predictors of Gastrointestinal Malignancy
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Gastroenterology. Queen Elizabeth Hospital, Gateshead, Tyne and Wear, United Kingdom.

Purpose: Recent studies showed that in patients with iron deficiency anemia (IDA) predictive factors of malignancy are male sex, age ≥50 years and presentation’s hemoglobin (Hb) of ≤ 9.0 g/dL. The National Institute for Health & Clinical Excellence (NICE) published guidelines suggesting urgent colonoscopy for males & females with unexplained IDA if Hb ≤11gr/dL & ≤10gr/dL respectively, while urgent gastroscopy is advised for any level of unexplained IDA. We aimed to check whether the degree of anemia and the RBC indices differ amongst patients with upper GI (UGI) and lower GI (LGI) cancers; furthermore, to assess the safety of the “alarm level” of Hb (NICE-LGI cancer guidance) and if a similar level can be used in the UGI cancer guidance.

Methods: Retrospective study; patients investigated for “anemia” between April 2002 and 2005 were identified using the electronic endoscopy register. All patients with confirmed malignancy (histopathology reports) were included in the study. The lowest values for Hb, Mean Corpuscular Volume (MCV) and Red Cell Distribution Width (RDW) -up to six months prior to endoscopy- were analysed using Stata 8.2.

Results: Ninety-three (N = 93) patients included; 32 had UGI and 61 LGI cancers. Mean ages were 73.2 years (54–92) vs. 76.5 years (53–95), with male predominance in both groups (M:F; UGI 1:1 vs. LGI 1:1.4:1). In the UGI group, 24 were gastric, 4 gastro-esophageal junction’s and 3 esophageal adenocarcinomas • one MALToma was found. In the LGI group, all were adenocarcinomas. Thirty-two were right sided, 22 left-sided while, 4 patients had synchronous lesions and 3 presented with hepatic metastases. The mean [UGI] Hb vs. [LGI] Hb level was: 8.9g/dL (SD = 1.5) vs. 9.1g/dL (SD = 1.4), mean MCV 79.2fL (SD = 9.4) vs. 78.7fL (SD = 10) & mean RDW 17.2% (SD = 3.5) vs. 17.7% (SD = 4.1). The difference of the parameters was statistically non-significant (p values: 0.2, 0.8 and 0.3 respectively).

Conclusions: The degree of anemia and the RBC indices are similar in patients with UGI and LGI cancers and therefore, poor predictor of its site. The suggested Hb level seems safe for our population; furthermore, potential use of the same Hb level in the suspected UGI cancer guidance seems reasonable.

Hematology Parameters in Patients with GI Cancers

<table>
<thead>
<tr>
<th>Parameters</th>
<th>UGI cancers (SD)</th>
<th>LGI cancers (SD)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hb (11.5–16.5 g/dL)</td>
<td>8.9 (1.5)</td>
<td>9.1 (1.5)</td>
<td>0.2</td>
</tr>
<tr>
<td>MCV (80–102 fL)</td>
<td>79.2 (9.4)</td>
<td>78.7 (10.0)</td>
<td>0.8</td>
</tr>
<tr>
<td>RDW (11.5–15.5%)</td>
<td>17.2 (3.5)</td>
<td>17.7 (4.1)</td>
<td>0.3</td>
</tr>
</tbody>
</table>

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An Open Label, High Dose Prospective Trial of the Safety of the Probiotic E. coli Strain M-17 in Healthy Volunteers
Samuel N. Adler, MD, Harold Jacob, MD,* Lesy Levine.
Gastroenterology. Bikur Holim Hospital, Jerusalem, Israel.

Purpose: The study assessed the safety of the probiotic E. coli strain M-17.

Methods: Healthy volunteers ages 18 to 60 participated in the study. Subjects completed a two-week run-in period. They maintained a diary to record bowel habits and abdominal symptoms. Thereafter subjects consumed E. coli M-17 (ProBactrix, BioBalance Corp.) in two divided doses of 60 ml each for 8 weeks (total 12 × 10⁹ CFU, dose10 times higher than used in clinical practice). Safety measures assessed at study entry and at 8 weeks were liver enzymes, renal function and hematology (complete blood count, differential WBC and platelets). Subjects also completed diaries that recorded stool frequency, consistency, presence of abdominal pain, discomfort, urgency, bloating or gas. Special endpoints were fever, infection, reactive arthritis, bronchospasm and allergic symptoms. The mean age was 27.1 years (range 18 to 60). 71 (51.4%) were males and 67 (48.6%) were females.

Results: 138 subjects were enrolled. 14 subjects were disqualified, 4 due to protocol violation; 5 for taking non-permitted medications, and 5 experienced adverse events. 9 subjects (6.5%) reported 13 adverse events judged by the investigator to have been related to study treatment. Drug-related adverse events were classified as possible for 7 subjects (5.1%) with 11 reports and probable for 2 subjects (1.5%) with 2 reports. Only 1 of these adverse events was moderate in severity; the others were classified as mild. Among these adverse events considered related to study product, 2 involved vomiting and 1 nausea. No bacteremia, allergic reaction, reactive arthritis, diarrhea or fever considered related to study product occurred. Laboratory assays performed at baseline and after 8 weeks of treatment showed statistically significant changes in mean white blood cell counts, including slight increases for segmented neutrophils and decreases for lymphocytes, monocytes and eosinophils; none of these values fell outside normal ranges. There was a statistically significant increase in creatinine, but this fell within the normal range. Assessments of bowel symptoms after 8 weeks of study participation showed no significant changes from baseline with respect to all parameters.

Conclusions: E.coli M17 in 10 times higher the recommended dose, was well-tolerated in 93.5% of subjects. 9 (6.5%) subjects experienced mild to moderate adverse events. Laboratory studies remained within the normal range. This first carefully conducted safety trial of E. Coli M17 indicates that it is safe.

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Evaluation of Patients with Hereditary Hemorrhagic Telangiectasia with Video Capsule Endoscopy: A Single Center Prospective Study
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Purpose: Hereditary hemorrhagic telangiectasia (HHT) is a rare autosomal dominant disorder causing telangiectasia formation throughout the body. There may be other associated small bowel findings related to HHT, given the association of MADH4 mutations with HHT. Video capsule endoscopy (VCE) was used to compare the small bowel findings observed in HHT and non-HHT patients.

Methods: VCE was performed consecutively on 84 patients (29 HHT and 55 non-HHT patients, 76 complete VCE studies) from Nov. 2004 to Feb. 2006. All patients underwent VCE and results were analyzed by a single endoscopist (S.C.).

Results: VCE detected telangiectasias evenly distributed throughout the small bowel in 24 (86%) HHT patients versus 14 (29%) non-HHT patients. Active bleeding was observed in 4 HHT patients, all of which had bleeding within reach of small bowel push enteroscopy. Unexpected findings were seen in both HHT (7.1%) and non-HHT patients (2.1%).

Conclusions: HHT small bowel telangiectasias were found evenly distributed throughout the small bowel by VCE. In HHT patients, small bowel telangiectasias found to be actively bleeding were in the proximal and mid-small bowel, all within reach of an enteroscope. In non-HHT patients, multiple (>10) angiectasias were only observed in post-menopausal females.

VCE identified unexpected small bowel polyps and mass-like lesions in both
HHT and non-HHT patients. VCE may be useful in confirming the diagnosis of HHT in patients who do not meet the diagnosis by Curacao criteria.

Results of Video Capsule Endoscopy

<table>
<thead>
<tr>
<th></th>
<th>HHT (N = 28)</th>
<th>Non-HHT (N = 48)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Mean ± SD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>11 (39%)</td>
<td>26 (54%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>GI Telangiectasias</td>
<td>24 (86%)</td>
<td>14 (29%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Proximal Bowel</td>
<td>18 (64%)</td>
<td>8 (17%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Mid Bowel</td>
<td>17 (61%)</td>
<td>7 (15%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Distal Bowel</td>
<td>17 (61%)</td>
<td>5 (10%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>&gt;10 GI Telangiectasias</td>
<td>18 (64%)</td>
<td>3 (6.3%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>&gt;5 GI Telangiectasias</td>
<td>22 (79%)</td>
<td>4 (8.3%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Gastric Telangiectasias</td>
<td>6 (21%)</td>
<td>0 (0%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Cutaneous Telangiectasias</td>
<td>25 (89%)</td>
<td>0 (0%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Actively Bleeding GI</td>
<td>4 (14%)</td>
<td>2 (4.2%)</td>
<td>NS</td>
</tr>
<tr>
<td>Telangiectasia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small bowel polypl</td>
<td>1 (3.6%)</td>
<td>1 (2.1%)</td>
<td>NS</td>
</tr>
<tr>
<td>Cecal mass like lesion</td>
<td>1 (3.6%)</td>
<td>0 (0%)</td>
<td>NS</td>
</tr>
</tbody>
</table>

Case Report: Primary Mucosa Associated Lymphoid Tissue Lymphoma (MALT L) of the Gallbladder
Margaret Gorman, MD, Gustavo Bello, MD, Pavlos K. Papasavas, MD. Daniel A. Leffler, MD, Melinda Dennis, RD, Brian Hyett, MD, Detlef Schuppan, MD, Ciaran P. Kelly, MD.* Surgery, The Western Pennsylvania Hospital, Pittsburgh, PA.

Purpose: Case Report

Methods: Patient is an 88-year-old female with history of two gallbladder attacks that happened in the last 1.5 years. The patient presented to The Western Pennsylvania Hospital from Ohio where she had a right upper quadrant ultrasound that showed multiple gallstones and gallbladder “membrane.” There were no signs of acute cholecystitis, but she was still having persistent ultrasound that showed multiple gallstones and gallbladder “membrane.” After explaining the risks and benefits of the procedure, the patient agreed to undergo laparoscopic cholecystectomy. Surgical pathology revealed a bilirubin of 1.8, AST 38 and an ALT 103. Ultrasound images of liver, gallbladder and pancreas were obtained. The gallbladder was normal in shape and size with multiple small stones within the lumen of the gallbladder. There was no pericholecystic fluid collection or gallbladder wall thickening. Final impression was cholelithiasis, no evidence of acute cholecystitis.

Results: Liver function tests (LFT’S) and an ultrasound to clarify the finding of “membrane” in the gallbladder was completed. Laboratory findings revealed a bilirubin of 1.8, AST 38 and an ALT 103. Ultrasound images of liver, gallbladder and pancreas were obtained. The gallbladder was normal in shape and size with multiple small stones within the lumen of the gallbladder. There was no pericholecystic fluid collection or gallbladder wall thickening. Final impression was cholelithiasis, no evidence of acute cholecystitis. The patient was scheduled for laparoscopic cholecystectomy. In addition, she had a HIDA scan with no acute cholecystitis and ejection fraction of 7%. There was no pericholecystic fluid collection or gallbladder wall thickening. Final impression was cholelithiasis, no evidence of acute cholecystitis.

Conclusions: MALT’s of gallbladder are very rare. However there are several cases reported and described in English literature.

Etiologies and Predictors of Diagnosis in Non-Responsive Celiac Disease
Daniel A. Leffler, MD, Melinda Dennis, RD, Brian Hyett, MD, Detlef Schuppan, MD, Ciaran P. Kelly, MD.* Gastroenterology, Beth Israel Deaconess Medical Center, Boston, MA.

Purpose: Nonresponsive celiac disease (NRCD), defined as a failure to respond to gluten free diet, is a common problem affecting 7 to 30% of celiac disease (CD) patients. The aim of this study was to determine the etiologies of NRCD and clinical factors predictive of final diagnosis.

Methods: All cases of biopsy proven CD seen over the preceding 5 years were included. NRCD was defined as; 1. referral for evaluation of lack of response to a GFD, 2. failure of clinical symptoms or laboratory abnormalities of CD to improve within 6 months of strict GFD, 3. or recurrence of symptoms or abnormalities while on a strict GFD. Statistical significance was determined using two sample t-test, chi squared and Fisher’s exact tests.

Results: 113 individuals out of a total of 603 (18.7%) with CD were found to have NRCD. 39 of the 392 patients (9.9%) with CD who received their primary care at our institution developed NRCD compared to 19% of referrals (p < 0.001). Of the 99 cases diagnosed at time of review, the most common etiology of NRCD was gluten exposure, accounting for 36%. Other common etiologies of NRCD included irritable bowel syndrome (22%), refractory sprue (10%), lactose deficiency (8%) small intestinal bacterial overgrowth (SIBO) (6%), and microscopic colitis (6%). The remaining 13% consisted of eating disorders, peptic ulcer disease, gastroparesis, Crohn’s disease, food allergies, common variable immune deficiency and duodenal adenocarcinoma. A limited number of factors were predictive of final diagnosis in NRCD. Weight loss was predictive of refractory sprue with an odds ratio of 31.1 (95% CI 5.9 to 163.1). An IgA anti-tTG titer above the upper limit of normal was predictive of gluten exposure at an odds ratio of 11.3 (95% CI 3.7 to 34.4) and a mean of 67 U/ml (range 2-135 U/ml) as was the absence of abdominal pain (p < 0.01). Irritable bowel syndrome (IBS) was associated with the presence of abdominal pain and absence of diarrhea (p < 0.01). Microscopic colitis and SIBO were also associated with diarrhea (p < 0.05). Female patients had a greater risk of being diagnosed with IBS (p = 0.04), but a decreased risk of refractory sprue (p = 0.006).

Conclusions: NRCD is a common phenomenon affecting > 10% of celiac patients. Most cases of NRCD result from one of a relatively limited group of disorders. High IgT, gender, and symptoms at presentation are predictive of final diagnosis. Eating disorders are a previously undescribed cause of NRCD which should be considered in appropriate clinical scenarios.

Antibiotic Therapy Reverses Thiamine Deficiency in Patients Following Roux-en-Y Gastric Bypass Surgery
Shilen V. Lahiani, MD, Hiral N. Shah, MD. Kenneth Alexander, RN, Frederick C. Finelli, MD, John R. Kirkpatrick, MD, Timothy R. Koch, MD.* Gastroenterology, Washington Hospital Center, Washington, DC and Surgery, Washington Hospital Center, Washington, DC.

Purpose: As standard-of-care, all patients receive daily vitamin/mineral supplements following gastric bypass surgery. Present dogma states that thiamine deficiency after gastric bypass surgery is caused by prolonged nausea and emesis. We previously reported that a majority of patients following Roux-en-Y gastric bypass surgery have thiamine deficiency and it is associated with high serum folate levels and abnormal glucose-hydrogen breath tests. We hypothesize that small bowel bacterial overgrowth is a mechanism for thiamine deficiency following gastric bypass surgery.

Methods: This is a retrospective chart review of patients who had Roux-en-Y gastric bypass surgery in 1999-2005. This study included: 1) postoperative patients who had whole blood thiamine levels below the lower limit of normal; 2) who then underwent a glucose-hydrogen breath test. Patients’ sex, age, blood thiamine levels after oral thiamine supplementation, and blood thiamine levels after antibiotic therapy were recorded. Abnormal glucose-hydrogen breath test was defined by increased breath hydrogen of >20 ppm within 45 minutes after 50 grams oral glucose. This study involved 17 females and 4 males; age range was 22-64 years (Mean age: 52 years).

Results: 21 patients (100%) with low blood thiamine had an abnormal glucose-hydrogen breath test. Of these patients, 15 received oral thiamine (100 mg twice daily); repeat thiamine levels remained low in all 15 (100%). Of these patients, 8 then received oral metronidazole while 1 received oral amoxicillin in addition to thiamine (100 mg twice daily); repeat blood thiamine levels were normal in all 9 (100%). While taking daily oral thiamine
Cytomegalovirus-Induced Ileocolitis in an Immunocompetent Host
Sameer Barkatullah, MD, Garth Swanson, MD, Shriram Jakate, MD, Srinadh Komanduri, MD.* Gastroenterology & Nutrition, Rush University Medical Center, Chicago, IL.

Purpose: We present a rare and unusual case of CMV ileocolitis in an immunocompetent host.

Methods: A 28 year-old woman with no past medical history presented to our institution for evaluation of diarrhea. She reported 6-8 loose, watery, non-bloody stools daily for 3 days prior to admission, associated with nausea, emesis and diffuse crampy abdominal pain. She denied fevers, sick contacts, or recent travel, and had no known history of immunodeficiencies or childhood infections. On exam the patient had normal vital signs and revealed only mild diffuse abdominal tenderness. Labs showed elevated AST 113 U/L and albumin of 2.7 g/L. Serum electrolytes and complete blood count were within normal limits. Stool culture, ova and parasites exam, and viral hepatitis serologies were negative. Abdominal plain films and ultrasound were also unremarkable. Her diarrhea persisted despite supportive measures and empiric treatment with levofloxacin and metronidazole.

Results: She ultimately underwent colonoscopy, which revealed severe erythema and friability of the terminal ileum (Fig. 1), and colonic mucosal edema. Biopsies showed severe active ileitis and moderate colitis of the right colon, both with viral inclusion bodies, consistent with CMV. Serologies demonstrated a detectable CMV IgM, but negative IgG. Immunodeficiency workup revealed negative HIV antibody, HIV RNA PCR, and autoimmune panel, and quantitative immunoglobulin levels were all normal. Clostridium difficile toxin was concurrently detected on stool samples sent prior to initiation of antibiotic therapy. Her antibiotics were changed to valganciclovir for CMV and vancomycin for Clostridium difficile infection, with rapid improvement of her symptoms.

Conclusions: CMV enterocolitis should be considered in any patient who presents with diarrhea with negative stool cultures who is refractory to conservative therapy. It is intriguing to consider whether local changes due to either initial CMV or Clostridium infection may have increased her risk for the other infection. To our knowledge this is the first reported case of CMV ileocolitis and concurrent Clostridium difficile colitis in an immunocompetent host.

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Giant Duodenal Diverticulum Causing Duodenal Obstruction and Obstructive Uropathy
Bogdan Cristescu, MD, Hulya Levendoglu, MD,* Digestive Diseases, SUNY Downstate Medical Center, Brooklyn, NY and Gastroenterology, Brookdale University Hospital Center; Brooklyn, NY.

Purpose: Although true duodenal diverticula (DD) may be seen in up to 20% of the upper gastrointestinal X-ray series (UGI), symptomatic DD are rare. Most DD measures 1–5 cm in diameter. Giant DD (10 cm or more) is rarely encountered. We report a patient with giant DD presenting with symptoms of duodenal obstruction (DO) and right obstructive uropathy (ROU) that has not been reported before.

Case report: 92 years old man with history of mild dementia, cerebrovascular disease, coronary artery disease, hypertension and diabetes mellitus was admitted with difficulty in swallowing, decreased food intake, nausea and vomiting for one week duration. Physical examination revealed a cachectic man with distended nontender abdomen, and active bowel sounds. Laboratory findings revealed normal electrolytes, mild renal insufficiency (BUN 25 mg/dL, Cr 1.6 mg/dL) and mild leukocytosis (WBC 14 520/cmm). × ray of the abdomen revealed distended fluid filled stomach. Patient refused nasoabdominal tube placement and he did not cooperate for the UGI. Esophagogastroduodenoscopy (EGD) showed markedly distended and fluid filled stomach, bulb and 2nd portion; 2000 cc of bilious fluid was aspirated. A giant 10 cm diverticulum full of vegetable and food debris was noted in the 2nd portion compressing the entrance to the 3rd portion. After the irrigation and suctioning of the content of the DD, pediatric colonoscope could be entered to the 3rd, 4th part of the duodenum and proximal jejunum, which were normal. Computed tomography scan of the abdomen confirmed the giant DD and the DO with ROU at the ureteropelvic junction. Ureteral stent was placed. Patient and his family refused any further interventions in his case.

Conclusions: Obstructive symptoms are described in the literature only in intraluminal DD. Since EGD alone does not allow a distinction between extra and intaluminal DD we consider that our patient had an intaluminal DD which can be confirmed by UGI. We also believe that because of the
anatomical proximity of the DD to the ureteropelvic junction, obstruction at this level was caused by the distended, debris filled DD. [figure1]

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**Yield of Wireless Capsule in the Evaluation of Patients with Obscure Gastrointestinal Bleeding**

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**Purpose:** The purpose of this study was to explore the yield of wireless capsule endoscopy (CE) in Hispanic Veterans with obscure gastrointestinal bleeding (OGIB). OGIB represents 5-10% of all gastrointestinal bleeds and the small bowel is the presumed source in many cases. CE is the latest diagnostic modality for small bowel evaluation but has never been studied in Hispanic veterans from Puerto Rico.

**Methods:** From May 2003 to December 2004, 41 endoscopic capsules were performed for the evaluation of obscure gastrointestinal bleeding. We retrospectively reviewed the records and CE findings of these patients.

**Results:** The medical records and endoscopic capsule findings of 38 men and 2 females veterans were reviewed. 98% of the population was Hispanic and 2% Caucasian, with a mean age of 71 years of age (range 48-88). The indications for wireless capsule endoscopy were anemia (85%), positive fecal occult blood testing (FOBT) (10%) and overt gastrointestinal bleeding (10%). Significant findings were found in 83% of the CE (34/41). Angiectasia was the most common finding and was present in 71% (29/41) of the patients. The proportion of angiectasias increased by more than 2/3 after age 58 and was significantly higher in patients above 71 years of age (p < 0.018). Distal ileum ulcerations were found in 8% of patients (3/40). Patients with anemia were more likely to have angiectasias, ulcers, polyps and mucosal changes, these associations were statistically significant (p < 0.001). The sole presence of positive FOBT did not correlate with any capsule endoscopic finding.

**Conclusions:** CE yielded significant small bowel findings that were useful for reassurance and directing course of management. A marked increase in telangectasias after age of 58 years of age was noted in this population. A similar population could not be found in the literature for comparison of results. Thus, CE should be considered in US Veterans from Puerto Rico with persistent OGIB particularly in the presence of anemia.

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**Familial Prevalence among First Degree Relatives of Celiac Disease in North India**

Rajiv Grover, DM, Amrinder Singh Puri, DM, *Naresh Aggarwal, DM, Puja Sakhuja, MD. Department of Gastroenterology, G B Pant Hospital, New Delhi, Delhi, India and Department of Pathology, G B Pant Hospital, New Delhi, Delhi, India.

**Purpose:** Celiac disease (CD) is more common in certain high risk groups. Family members of known celiac patients represent the most important group with reported prevalence of 4.7% to 10% among first degree relatives. There is paucity of such data from Asia and the Indian subcontinent: our aim was to analyze the prevalence of celiac disease (CD) in first-degree relatives of patients diagnosed with this disorder in Northern India.

**Methods:** 169 first-degree relatives (66 parents, 71 siblings and 32 children) of 53 index celiac disease patients were screened by using anti tissue transglutaminase antibodies (IgA TTG). In all seropositive relatives duodenal biopsy was performed. biopsy specimens were graded histologically as per Marsh classification. Patients with positive serology and biopsy suggestive of CD were counseled prior to starting Gluten free diet.

**Results:** The prevalence of seropositivity in first degree relatives was 13.6% (23/169). Of 23 seropositive relatives 22 consented for duodenal biopsy; fourteen of whom had biopsy changes suggestive of celiac disease. The prevalence of celiac disease among first degree relatives was 8.2% (14/169). The prevalence of celiac disease among siblings (15.6%) was much higher as compared to that in parents (3.5%) and children (3%) (p < 0.05). In 23% families (12/53) studied more than one family member was affected; two and three members in ten and two families respectively. Of 14 new cases detected by targeted screening, eleven (78%) were overtly symptomatic with chronic diarrhea (8) and easy fatiguability (3). Three children (22%) although not symptomatic, had short stature. Nine members detected to be seropositive had normal duodenal biopsy suggesting that they were potential celiacs.

**Conclusions:** The prevalence of CD among first-degree relatives (8.2%) is much higher than the prevalence of the disease in the general population. 78% (11/14) of the cases detected by targeted screening were overtly symptomatic, with majority patients had chronic diarrhea. Nine (5.2%) cases were diagnosed as potential celiac disease. Our data strongly supports the targeted screening of all first-degree relatives of CD patients.

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**Does Obesity Effect the Gastric Emptying or Small Bowel Transit Times of Capsule Endoscopy**

David Ramsay, MD, Michael Frist, MD, Christopher Entwisle, MD, David Jager, MD, Steven Zeddun, MD, Marie Borum, MD, FACG. *Division of Gastroenterology and Liver Diseases, George Washington University Medical Center, Washington, DC.

**Purpose:** Capsule endoscopy is increasingly used for the evaluation of the small bowel. However, there are no reported studies evaluating the impact of body mass index (BMI) on capsule transit times. This study evaluated the gastric emptying time (GET) and small bowel transit time (SBTT) of capsule endoscopy in overweight and obese patients.

**Methods:** This retrospective study evaluated the medical records and capsule endoscopy reports of consecutive patients who underwent small bowel capsule endoscopy at a university gastroenterology practice. The medical records were reviewed to determine the Body Mass Index (BMI) of each patient. Patients with a BMI <25 were considered to be at a desired weight, between 25 and 29.9 were considered to be overweight, and ≥30 were considered to be obese. All patients in whom a BMI could be determined were included in the study. The capsule endoscopy reports of patients in whom a BMI was determined were evaluated for GET and SBTT. A database was created using Microsoft Excel. Statistical analysis was performed using t-test. The study was approved by the university IRB.

**Results:** Medical records and capsule endoscopy reports of 186 patients were reviewed. Patients who were of desired weight (BMI<25) had an average GET of 59.88 minutes and SBTT of 289.37 minutes. Patients who were overweight (BMI 25-29.9) had an average GET of 60.65 minutes and SBTT of 248.97 minutes. Patients who were obese (BMI ≥30) had an average GET of 69.77 minutes and SBTT of 226.73 minutes. There was no statistically significant difference in the GET between the desired weight group compared to the overweight (p = 0.96) and obese groups (p = 0.66). There was also no statistically significant difference in the SBTT between the desired weight group and overweight group (p = 0.11). There was a statistically significant difference in the SBTT between the desired weight group and obese group (p = 0.02).

**Conclusions:** There are no published reports on BMI and capsule endoscopy determined transit times. This study revealed that BMI has no impact on GET. However, BMI had a significant effect on the SBTT. The results suggest a patient’s BMI influences small bowel transit, with obese patients having a more rapid SBTT. However, it is unclear if the increased transit time in obese patients impacts upon small bowel mucosal visualization. Additional investigations should be performed to determine if BMI influences capsule endoscopy results.

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**Malabsorption Following a Brief Fast**

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Purpose: Diarrheal diseases are considered an important inducers of malnutrition because they affect nutrition through a number of mechanisms; (1) reduced food intake, (2) altered digestion and absorption, (3) impaired utilization of nutrients, (4) other metabolic alterations. During the initial treatment for acute diarrhea, patients are fasted for 24 to 72 hours to provide rest for the gastrointestinal tract. A routine progressive diet, beginning with a clear-liquid diet, is a frequent diet order. However, there are no scientific data to support the use of clear-liquid diets following a brief fast. We investigated malabsorption in patients with acute infectious entero-colitis who were fasted for a few days.

Methods: Studies were performed in 22 patients (mean age 38 years, male/female = 13/9). Their diseases diagnosed were acute enterocolitis in 16 patients, colonic diverticulitis in 5, and osteoarthritis in 1. Patients are fasted during the initial treatment. The mean duration of fasting was 2.7 days (1-6). Diets began with mechanical soft diets in 18 patients, full-liquid diets in 3, solid foods in 1 (osteoarthritis). They all were asked to inflate a breath-collecting bag before taking breakfast, lunch, and dinner. Breath hydrogen concentrations were measured by using breath analyzer and compared to the fasting values.

Results: Breath hydrogen concentrations before meals varied from 0 to 12ppm. An increase in breath hydrogen concentration after the beginning of serving meals was found in 20 of 22 patients (91%), with a mean value of 17.4ppm (1-53). Ten patients (46%) had an increase of more than 10ppm, 24 to 36 hours after meals. No abdominal symptom was developed despite of a frequent increase in breath hydrogen concentration. Although diets progressed gradually to a common solid foods as tolerated, breath hydrogen concentrations were decreased to the baseline a several days after serving meals. There were no significant differences among three kinds of diets.

Conclusions: Malabsorption following a brief fast was detected more frequently than expected in the present study. Apart from the undesirable metabolic effects of even a brief fast, withholding oral intake may alter intestinal absorption.

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Duodenal Carcinoid: A Rare Cause of Lower Gastrointestinal Bleeding

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Purpose: Primary carcinoid tumors in the duodenum are extremely rare. We present a case of a young woman with a large duodenal carcinoid tumor that involved rare location in the fourth portion of duodenum with no further evidence of disease who presented with acute and chronic gastrointestinal bleeding.

Case report: 44 year old woman with history of chronic hypertension, hyperensive encephalopathy, end-stage renal disease on outpatient hemodialysis and diagnosis of severe refractory anemia presented from dialysis center with fever. Next day she had blood clots in the stool. She denied abdominal pain, flushing, nausea, vomiting, chest pain, cough, dyspnea, arthralgia, diarrehea or similar bleeding episodes in the past. On examination she was febrile, orthostatic and pale. Her abdomen was soft and nontender with no palpable masses or enlarged organs. Blood was present on digital rectal exam. Her hemoglobin dropped from 10.8 mg/dL to 7.9 gm/dL in one day and she was transfused blood. Her BUN level was 57 mg/dL, creatinine 10.4 mg/dL. She had an emergent colonoscopy which showed internal hemorrhoids. On esophagastroduodenoscopy (EGD) esophagus, stomach, duodenal bulb, descending duodenum appeared healthy. Fresh blood was seen distal to the ampulla of Vater and a large 5 cm raised, ulcerated mass lesion was seen in the fourth portion of the duodenum suspicious of malignancy. The lesion occupied almost half of the lumen but was nonobstructing. The biopsy showed carcinoid tumor positive for Neuron-specific Enolase, Chromogranin and Synaptophysin. She had CT scan of the abdomen, pelvis and chest, and bone scan which did not show metastasis. Her Chromogranin A level was 613 ng/ml.

Discussion: Duodenal carcinoids are rare tumors and incidence varies from 1–3% of all duodenal tumors and 2.6% of carcinoid tumors in US. These tumors are generally 0.5-2 cms in size, occur mostly in the proximal part of the duodenum or periampullary region and are occasionally associated with carcinoid syndrome. Erosion of duodenal carcinoid producing hemorrhage is a rare occurrence. This case is a unique presentation of erosion of a 5 cm duodenal carcinoid present in distal duodenum leading to an acute gastrointestinal blood loss superimposed on chronic low grade blood loss misconstrued as ‘refractory anemia’. Despite the large size of the tumor there was no metastasis to the liver.

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Characterization Genetic Diversity of 16S-23SrRNA Gene in Salmonella Isolates from Food and Animal Samples by PCR-Ribotyping

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Purpose: Salmonella is the most important diarrheagenic pathogens, which can cause to food borne disease. For it's importance, it is essential to identify and characterize it's genetic diversity in stool and food samples quickly and accurately. PCR-Ribotyping method has the highest sensitivity for these purposes. The aim of this study was comparing genetic diversity of 16S-23SrRNA genes in Salmonella isolates between food and stool samples.

Methods: In this study we had two different sampling from meat and stool of children with diarrhea less than 15 years old during 6 months. At the time of sampling we did microbial culture and serotyping, after that extracted DNA by phenol/chloroform and by using P1, P2 primers we did PCR-Ribotyping. PCR-products run on 1.8% agarose gel in 120V for 90 min and stained by Ethidium Bromide. At last we considered specific bands.

Results: 200 samples of stool and meat were positive for 16S-23SrRNA and all of them had 4-5 bands with the range from 700 to 1100 bp. [figure1][figure2]

Conclusions: According to the results we can say that all of the serotypes which isolated from stool and meat samples have the same source and genetic diversity and PCR-Ribotyping is a less expensive, sufficient, and rapid with high sensitivity method for identification Salmonella serotypes in food and stool samples.
Celiac Disease, Liver Cirrhosis and the Small Bowel: What Is the Link? A Prospective Study
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Purpose: The most reliable marker for celiac disease CD is the presence of abnormal small bowel SB mucosa defined by Marsh criteria. CD may be associated with liver disease and cirrhosis. Studies have shown that cirrhosis may cause lymphocytic infiltration of SB mucosa, decreased villous/crypt ratio, and reduced total absorptive surface. None of the studies described SB mucosal changes according to Marsh criteria. Verification that cirrhosis does not cause SB mucosal changes that fit Marsh criteria for CD is required if biopsy findings are to be used to establish a diagnosis of CD in cirrhotic patients. We aim to study the SB mucosa on biopsy in cirrhotics and non-cirrhotics and grade findings according to Marsh criteria.

Methods: We obtained multiple SB biopsies from 25 cirrhotics undergoing upper endoscopy EGD to screen for esophageal varices, and from 26 non-cirrhotics receiving EGD for reasons other than weight loss, malabsorption or iron deficiency. At enrollment, none of the subjects had a history of CD and all had normal celiac serology for EMA, hTTG and AGA. Pathologist was unaware of diagnosis and graded findings according to Marsh criteria. We tested a null hypothesis stating that the Marsh grade between both groups was NOT equivalent using a Mann-Whitney test for equivalence.

Results: There was no significant difference in age or gender between the two groups (p > 0.10) (table). There was no statistical difference in the SB mucosa between cirrhotics and non-cirrhotics. Mucosa was normal (Marsh grade 0) in 96% of each group, and (Marsh grade 1) in one subject in each group (figure). Thus, SB architecture was equivalent between cirrhotics and non-cirrhotics (p < 0.001, H0: groups are NOT equivalent).

Conclusions: Liver cirrhosis does not cause small bowel mucosal changes of celiac disease. This implies that small bowel biopsy should be as accurate in patients with liver disease as in patients without liver disease in the diagnosis of celiac disease.

<table>
<thead>
<tr>
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<th>Cirrhotics</th>
<th>Non-cirrhotics</th>
<th>p value</th>
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<tr>
<td>Age: Number (mean)</td>
<td>25 (57.5)</td>
<td>26 (51.9)</td>
<td>0.12</td>
</tr>
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<td>Gender: Number (%)</td>
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<tr>
<td>Male</td>
<td>13 (52%)</td>
<td>11 (42.3%)</td>
<td>0.49</td>
</tr>
<tr>
<td>Female</td>
<td>12 (48%)</td>
<td>15 (57.7%)</td>
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[figure1]
vessel after vagotomy by operation, bypass we study effect of vagus on lymphatic vessel and relationship between this effect and gastrointestinal function.

Methods: Mesenteric lymphatics in Wistar rat were observed under vital microscope with TV recorder. Record and measure lymphatic contraction frequency (a), lymphatic diameter in static state (d) and overall lymphatic contractile activity in mesentery. Maximal diastole calibre, maximal contract calibre and valva were also measured. Cut off the post shaft of vagus at esophageal hiatus of diaphragm. Record and measure the aforementioned indices 10min, 30min and 60min after operation.

Results: After denervation, lymphatic contraction frequency, lymphatic diameter in static state and overall lymphatic contractile activity decreased significantly. The rhythm of lymphatic contraction and the movement of valves became irregular and inconsistent with each other.

Conclusions: All those experiment show the integrality of vagus is indispensable to keep the pump function of lymphatic vessel in lymph circulation. Once this integrality encounter destroy, the starting, spreading and harmony of automaticity retractive will appear abnormal, dynamics of lymphatic vessel change thereby result in hedges of intestine lymph circulation.

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Metabolic Bone Disease: A Common Extra-Intestinal Manifestation in Indian Patients with Celiac Disease
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Purpose: Most data on metabolic bone disease (MBD) associated with celiac disease (CD) are from the West. There is no corresponding data from Asia where CD is now increasingly being recognized.

Methods: Consecutive patients of CD, both diarrheal and non-diarrheal, were studied from May 2003 to April 2006. Diagnosis was established by IgA anti-gliadin, anti tissue-transglutaminase antibodies along with suggestive duodenal histology. Biochemical and hematological investigations, serum intact-parathyroid hormone (iPTH) levels and bone mineral density (BMD) (hologic 4500 DEXA, expressed as ‘Z’ and ‘T’ score) were measured at baseline and then 6-12 months after starting gluten-free-diet (GFD). Prevalence of SHP and defective bone mineralization was determined. Response to GFD was also analyzed.

Results: Total 101 patients [ (42 children, 26 males, mean age 9.2 ± 4.8 yr) (59 adults, 22 males, mean age 32.3 ± 8.4)] were studied. Twenty eight children and 43 adults presented with diarrhea. Growth retardation in children (59 adults, 22 males, mean age 32.3 ± 8.4) and iron deficiency anemia in adults were most common atypical presentations. Time to reach correct diagnosis of CD was more than 3 years. Eleven children and 25 adults had history of bone pain. Only two of these 36 patients (both child) had history of low-trauma fracture. Duodenal biopsy was abnormal in all patients and serology was positive in 99 patients (2 patients had IgA deficiency). Mean iPTH levels in children and adults were 94.7 ± 29.2 pg/ml and 124.4 ± 39.3 pg/ml (reference values 7-54 pg/ml) respectively. Corresponding mean follow up iPTH values were 40.2 ± 23.6 pg/ml and 73.1 ± 22.8 pg/ml respectively. Eleven of 18 children (61.1%) and 27 of 33 (81.8%) adults had evidence of SHP before treatment. BMD was abnormal (T or Z score less than -1.0) in 83.3% children and 73.6% adults. Three children had radiological features of rickets. On follow-up, 2 of 9 children (22.2%) and 10 of 14 adults (71.1%) still had evidence of SHP on follow-up after GFD. BMD was abnormal 2 of 7 (28.5%) children and 7 of 15 (46%) adults on follow-up. Radiological evidence of healing rickets was seen in children who showed evidence of rickets initially.

Conclusions: Compared to Western literature, MBD is extremely common in Indian patients with CD and is usually sub-clinical. Delay in diagnosis and poor baseline bone mineralization may contribute to this problem in India.

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Diffuse White Spots of the Duodenum May Suggest Glucose Malabsorption
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Purpose: It has been unclear what endoscopic finding reflects small intestinal malabsorption. At panendoscopy, the second part of the duodenum was usually observed, and diffuse white spots were found in some patients. This endoscopic finding is considered to reflect abnormal lipid transport from the villi of the small intestine. The aim of this study is to evaluate the relationship between white spots observed in the duodenum and malabsorption of nutrient.

Methods: Consecutive 165 subjects who underwent upper gastrointestinal endoscopy were recruited in this study. At endoscopy, a tip of endoscope was placed to the second part of the duodenum and 20 ml of water containing 100 mg of 13C-glycine (N = 65), 13C-acetate (N = 65), and 13C-glucose (N = 35) was infused into the duodenum. Breath samples were taken at baseline and at 10-min interval for 30 min, 60 min, and 90 min after administration in 13C-acetate, 13C-glycine, and 13C-glucose breath test, respectively. The 13C/12C ratio of each sample was analysed and were expressed as delta over baseline. Absorptive function was determined as cumulative% dose at the endpoint of sampling.

Results: Patients were divided into three groups according to the grade of duodenal white spot as follows: “absent,” “patchy,” and “diffuse.” The mean values of cumulative% dose at 30 min of acetate were 7.3 ± 2.5%, 6.8 ± 2.8%, and 7.1 ± 1.3% in the “absent,” “patchy,” and “diffuse” group, respectively. For absorptive function of glycine, the mean values of cumulative% dose at 60 min were 11.4 ± 4.0%, 11.7 ± 4.0%, and 12.8 ± 3.0%, respectively. For glucose, these values at 90 min were 7.1 ± 1.3%, 5.9 ± 2.2%, 5.7 ± 1.5%, respectively.

Conclusions: Differences in absorptive function of acetate and glycine were not found between patients with and without duodenal white spots, whereas absorptive function of glucose tended to be lower in patients with duodenal white spots. White spots observed in the duodenum may be one of endoscopic findings, reflecting malabsorption of glucose.
small-bowel loops. Breath H2 level was 1 to 3 ppm. He was treated with intravenous administration of erythromycin. Four days after the treatment, X-ray demonstrated a decrease of small-bowel gas and a clear-liquid meal was served. Next morning fasting breath H2 level increased rapidly to 22 ppm and gradually decreased to 9 ppm after 5 days. Two days after diet progression, fasting breath H2 level increased to 44 ppm. Even when a diet order progress to solid foods, he did not complain of abdominal symptoms and intestinal gas on X-ray was not worsened.

Conclusions: A rapid increase of breath H2 level may reflect the movement of small-bowel contents to the colon in patients with small-bowel pseudo-obstruction. Change in breath H2 level had a close association with movement of intestinal gas.

Celiac Disease in Brazilian Patients: Associated Diseases, Complications and Causes of Death
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Purpose: The aims of the study were to know the associated diseases, complications and causes of death of Brazilian patients with celiac disease (CD).

Methods: According to current age the 157 studied patients were divided in 4 groups: I- Adolescents 11 to 20 years (23 = 14.6%), II-Young adults 21 to 40 years (71 = 45.2%), III-Adults 41 to 60 years (52 = 33.1%) and IV-Elderly > 61 years (11 = 7.0%). Gender: 125 female (79.6%) and 32 male (20.3%). At diagnosis 119 (72.8%) and 38 on a gluten-free diet (GFD) (24.2%). Follow up 1 to 36 years.

The diagnosis of CD was based on clinical data, on histological findings and by the presence of serologic autoantibodies. All the patients were submitted to routine blood tests and specific tests according to the suspicion of associated diseases. Bone mineral density were determined by DEXA in 53 patients at diagnosis. The data about associated disorders, complications and causes of death were obtained from the charts of the patients.

Results: The studied findings showed no differences in patients at diagnosis or in a GFD. Collectively, main associated disease were atopy (22.3%), depression (17.2%), thyroid disorders (15.9%), dermatitis herpetiformis (10.8%), diabetes type 1 (1.9%) and type 2 (2.5%), lymphoma (1.27%) and other tumors (3.18%). Anemia was present at diagnosis in all the groups: 65.2%, 76.5%, 73.9% and 55.5% respectively. Osteopenia/osteoporosis was detected in all the groups increasing with age. Spontaneous abortion was reported in group II 27.0%, group III 13.9% and group IV 26.3%. Four patients (4.5%) died: lymphoma 1, type 1 diabetes complications 1, acute meningitis 1 and suicide 1.

Conclusions: This experience is similar to those described in the world literature. We recommend a strict adherence to a GFD and periodic evaluations of associated disorders and complications, independent of the age at diagnosis or the duration of the diet. The optimal interval between evaluations still needs to be defined.

Is Rifaximin Effective Treatment for Small Intestinal Bacterial Overgrowth?
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Purpose: Rifaximin is orally administrated, non-absorbed, antibiotic whose utility in eradication of small intestinal bacterial overgrowth (SIBO) is currently being evaluated. The aim of this study was to investigate efficacy and safety of rifaximin 500 mg/day for 4 weeks in relieving symptoms and normalizing the glucose breath test (GBT) in patients with SIBO.

Methods: 20 consecutive symptomatic patients (16 females and 4 males, mean age of 47.8, range 19-85) were prospectively studied in an open-labeled fashion. Etiologies of SIBO included patients with irritable bowel syndrome, diabetic neuropathy, postgastric surgery and connective tissue disorder. Symptom score assessment, and the GBT were performed before and after treatment. 4 patients (70.0%) presented with diarrhea, 3 (15.0%) with bloating and gas and 1 (15.0%) with constipation as the dominant symptom. All patients had a positive GBT for hydrogen (11), methane (8), and 1 produced both gases.

Results: Among patients with diarrhea 12 of 14 (85.7%) reported a symptom improvement of more then 50%; 1 between 25-50%, 1 had no response after 4 weeks of rifamixin. Among patients with bloating and gas or constipation as the main symptom: 2 of 6 (33.3%) had improvement between 50-75% ; 3 (50%) had 25-50% improvement, and 1 (16.7%) had no response. Repeat GBT at the end of the 4 weeks normalized in 54.5% of hydrogen formers and 50.0% of methane producers, and there was a significant reduction (p < 0.05) in the area under the concentration-time curve as well as peak values. No adverse effects were observed.

Conclusions: Rifaximin in a dose of 800 mg per day for 4 weeks was safe and effective treatment in reducing symptoms especially diarrhea in patients with SIBO of multiple etiologies as well as normalizing the GBT in 50%. These data suggest a future therapeutic role for rifaximin in SIBO although controlled trials will be the next step.

Endoscopic Screening for Ileal Carcinoids during Colonoscopy
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Purpose: Carcinoids are rare tumors, with an annual incidence of approximately 3 per 100,000 population per year the majority of which arise from the gastrointestinal tract. Small intestinal carcinoid tumors are most commonly located in the ileum within 60 cm of ileocecal valve. Patients usually present in their 60s or 70s with abdominal pain or small bowel obstruction, and often have metastases to lymph nodes or the liver, even if the primary tumor is small. Carcinoids are often asymptomatic. Accepted guidelines for colorectal cancer screening recommend that adults undergo screening colonoscopy beginning at age 50. Intubation of the terminal ileum is a simple maneuver easily achieved during routine colonoscopy. We believe that intubation of the terminal ileum to screen for ileal carcinoids may be an appropriate addition to the standard screening colonoscopy examination. Discussion: Intubation of the terminal ileum was accomplished in the majority of endoscopies without added difficulty. During the 213 colonoscopies performed, the terminal ileum was intubated in 185 cases. A total of 3 ileal carcinoid tumors of the ileum were detected.

Methods: We retrospectively studied all of the screening colonoscopies performed by a single endoscopist who routinely intubates the terminal ileum. We collected data on the number of endoscopies performed, how often the terminal ileum was intubated, and any difficulties encountered in intubating the terminal ileum.

Results: Between October 2004 and October 2005, 213 colonoscopies were performed. The terminal ileum was intubated 185 times.

Conclusions: Intubation of the terminal ileum during routine colonoscopy can be useful to detect carcinoids of the terminal ileum. Larger prospective studies are needed to determine if intubation of the terminal ileum to screen for carcinoids should be incorporated into routine colorectal cancer screening.

Predictors of Intestinal Villous Atrophy in Patients with Chronic Diarrhea: A Clinicopathological Study of 92 Patients
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Purpose: Traditionally, the diagnosis of intestinal villous atrophy (IA) relies on the histological study of an intestinal biopsy taken by upper GI
endoscopy. The aim of this study was to evaluate potential non-histological markers of IA.

Methods: Adult patients with chronic diarrhea, three or more criteria of an organic disorder, who underwent an upper GI endoscopy with duodenal biopsies and culture, were recruited during a two-year period. According to histological findings, patients were classified as IA (cases) or non-IA (controls). Clinical records of patients and controls were examined for presenting symptoms and laboratory tests, in order to establish the final diagnosis. Frequencies and odds ratios (ORs) with 95% confidence intervals (CI) were computed. The Fisher’s exact and Mann–Whitney U tests were used for analysis.

Results: Fifty patients with IA and 42 controls were included. The mean age was 53.1 ± 16.2 yr and 52.3 ± 15.6 yr, respectively. Most symptoms and laboratory data were similar in both groups. However, clinical steatorrhea and serum β-carotene levels below 60 mg/dL were more frequent in IA (31 vs 15, p < 0.01 and 23 vs 8, p < 0.001, respectively). A tendency to positive culture in duodenal fluid aspirate was found in controls (20 vs 14, p < 0.08).

OR’s for these differentially distributed variables were: for clinical steatorrhea 2.94 (95% CI = 1.16–7.53), for β-carotene levels below 60 mg/dL 3.62 (95% CI = 1.29–10.77) and, for positive culture in duodenal fluid aspirate 0.43 (95% CI = 0.16–1.11). The number of intraepithelial lymphocytes per 100 epithelial cells was higher in cases as compared with controls (51 ± 14.3 vs 23 ± 12.2, p < 0.001).

Tropical sprue (12 vs 0) and celiac disease (8 vs 1) were more frequent in the IA group. In controls, small-bowel bacterial overgrowth (20 vs 14) was more frequent. (p < 0.001).

Conclusions: Clinical steatorrhea and low serum levels of β-carotene appear to be associated with IA. These data could be useful for the differential diagnosis in patients with malabsorption syndromes. However, further studies are required to confirm these findings.

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Mcl-1 Depletion Enhances Anti-Cancer Drug-Induced Apoptosis in Gastroenteric Cancer Cells

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Purpose: Apoptosis contributes to the regulation of the cell growth and regeneration and to the development of neoplasm. Mcl-1 (Myeloid cell leukemia-1) is an anti-apoptotic protein that regulates apoptosis sensitivity particularly in hematological and hepatobiliary malignancies. We have reported that Mcl-1 is uniquely overexpressed by cholangiocarcinoma cell lines, and mediates Tumor Necrosis Factor-related Apoptosis Inducing Ligand (TRAIL) resistance in those cells. Here we extend this study to evaluate if Mcl-1 contributes to apoptosis resistance in gastroenteric carcinoma cells, i.e., gastric cancer and colorectal cancer. The purpose of this study was: i) to examine Mcl-1 expression profiling among gastroenteric carcinoma cell lines, and ii) to evaluate if Mcl-1 depletion sensitizes apoptosis by anti-cancer drugs.

Methods: Thirteen digestive organ cancer derived cell lines, 4 gastric, 3 pancreatic, 4 colorectal and 2 cholangiocarcinoma, were used. Expression of Mcl-1 was assessed by SDS-polyacrylamide gel electrophoresis and Western blot analysis. Cells were exposed to anti-cancer drugs such as 5-fluorouracil and cisplatin. Apoptosis was quantitated by a morphological observation (DAPI) and caspase activity measurement. Adenovirus-mediated RNA interference (RNAi) technology was used to knock down expression of Mcl-1. Releasing cytochrome C was evaluated by subcellular fractionation and immunoblot analysis.

Results: Mcl-1 expression levels were valuable in the cell lines. In gastric cancer cell lines as well as colorectal cancer cell lines, depletion of Mcl-1 protein by RNAi technology effectively sensitizes the cells to anti-cancer drug-induced apoptosis. Mcl-1-knockdowned apoptosis was associated with mitochondrial depolarization, cytochrome c release from mitochondria and caspase activation. In contrast, Mcl-1 knockdown failed to sensitize apoptosis in pancreatic cancer cell lines.

Conclusions: These studies demonstrate that Mcl-1 mediates the resistance of apoptosis in gastroenteric cells by blocking the mitochondrial pathway of cell death. The results also identify some strategies for circumventing this resistance to the anti-cancer drugs.

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Enteroscopic Characteristics of Gastrointestinal Stromal Tumors Using Double-Balloon Endoscopy

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Purpose: Double-balloon endoscopy (DBE) enables scrutiny of the entire small intestine, plays many roles in diagnosis for various small intestinal diseases. We analysed that enteroscopic characteristics of GISTs using double-balloon endoscopy and clinical benefits of DBE for the patients of GISTs.

Methods: Nine consecutive patients were diagnosed with GIST by DBE. Patients characteristics, indications of DBE, capability of the diagnosis with biopsy specimen, relationship between two categorised group by enteroscopic size (Group A: volume of the tumor in intestinal lumen was 1/2 or more, Group B: less than 1/2) and measured size of the surgical sample, relationship between erosion size observed by DBE (Group C: tumor with tiny erosion, Group D: erosion in 1/3 or more area of the tumor surface) and mitosis of the tumor cells, were evaluated.

Results: Patients were 5 females and 4 males. Mean age was 66.3 (42-82) years old. Indications of DBE were obscure gastrointestinal bleedings and suspicion of the small intestinal tumor by previous radiography in 7 and 2 cases, respectively. In 6 of nine patients, biopsy specimens led to the pathological diagnosis of GIST: Positive relationship was observed between enteroscopic size of the tumors and measured size of the surgical samples. Mean sizes of Group A (N = 5) and Group B (N = 4) were 40mm and 27mm (p = 0.027). Erosion size of the tumor observed by DBE was related to the mitosis of the tumor cells in pathological specimens. Group C (N = 5) vs D (N = 4) was 1.6cells/50 high power fields vs 19cells/50HPFs.

Conclusions: GISTs of the small intestine were often diagnosed in the wake of obscure gastrointestinal bleedings. Relationship between enteroscopic findings and pathological findings may help with assessment of the tumor behaviour before surgery and marking at the tumor site with tattoo by DBE may lead to less invasion therapy like a laparoscopic surgery. Double-balloon endoscopy was useful for diagnosis of the GISTs which was not detected by previous evaluation with various radiological examinations.

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Incidence of Undiagnosed Celiac Disease in Patients with Short Bowel Syndrome

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Purpose: Short bowel syndrome (SBS) is characterized by malabsorption due to resection of small intestine. A subset of patients is dependent on parenteral nutrition and/or vitamin supplementation. Celiac disease (CD) is an immune-mediated disorder that results in gastrointestinal symptoms of malabsorption and diarrhea. Undiagnosed CD in patients with SBS might be expected to worsen the degree of malabsorption. The aim of this study was to determine the incidence of undiagnosed CD in a population of patients with the SBS.

Methods: We reviewed the records of all patients seen in the gastroenterology/nutrition clinic between 2004–2006. Patients with a clinical diagnosis of SBS, defined as prior resection of the small intestine and the need for...
parenteral nutrition or oral/parenteral vitamin supplementation, were asked to participate in the study. Patients with a history of CD were excluded. The medical records of the enrolled patients were analyzed to determine etiology of SBS and current medical treatment. Patient’s serum was analyzed for total IgA level and IgA tissue transglutaminase (TTG). If a patient had an elevated IgA TTG or a low total IgA, upper endoscopy with biopsies was performed. The study was approved by the institutional review board.

Results: Sixteen subjects consented to be in the study. Eleven (69%) patients were female and 13 (81%) were Caucasian. The average age of the patients was 59 years old. The most common etiologies of SBS were inflammatory bowel disease (8 patients) and ischemic bowel (6 patients). Fifteen (94%) subjects had either a total proctocolectomy, partial colectomy, or had an intact colon out of continuity with their small intestine. Thirteen (81%) patients were on parenteral nutrition. No subjects were IgA deficient. One of sixteen subjects had an elevated TTG IgA level (61 U/mL). Upper endoscopy was performed on this subject and demonstrated active gastroduodenal Crohn’s disease and no duodenal biopsy findings characteristic of CD.

Conclusions: In our population of patients with SBS predominantly due to inflammatory bowel disease, no patients were found to have CD using IgA TTG as a screening test. Larger studies need to be performed to determine if undiagnosed CD contributes to malabsorption in those with SBS. (Fund ed in part by the Gastrointestinal Research Foundation).

Free Intraperitoneal Air Does Not Always Represent a Surgical Emergency
Jery W. Bielecki, MD, Christian Vetter, MD, Ulrich Scheurer, Prof*, Juergen M. Gschossmann, PhD, GI Unit, Inselspital, University of Berne, Berne, Switzerland and Department of Internal Medicine, Kantonsspital Olten, Olten, Solothurn, Switzerland.

Purpose: Pneumoperitoneum with diffuse abdominal pain and elevated inflammatory serum markers generally results from free perforation of an hollow organ requiring emergency surgical exploration. In contrast, we present the case of a patient with diffuse abdominal pain and free intraperitoneal air as manifestation of pneumonia colii which could be treated conservatively.

Results: Case: A 50 year old female patient with a history of chronic obstructive pulmonary disease and recurrent pulmonary embolism requiring oral anticoagulation presented to the emergency department with melena and diffuse abdominal pain. On admission, she had a distended abdomen without muscular rigidity and Blumberg’s sign. Hemoglobin was 60 g/l (normal 121–154), white-cell count was 18 G/l (normal 3.5–10.5), and C-reactive protein level was 157 mg/l (normal < 5). CT scan of the abdomen revealed free subdiaphragmal air and hepatic portal venous gas as well as multiple intramural cystic gas collections in the wall of the terminal ileum and colon. The endoscopic examinations of the upper and lower GI tract were normal. Following reversal of anticoagulation and blood transfusion, the patient was treated conservatively with antibiotics (metronidazole/ceftriaxone). Additionally, we applied oxygen and a lactulose free diet. Seven days after admission, we repeated the CT examination of the abdomen, which revealed complete disappearance of the pneumatic cystic lesions of the gut wall and disappearance of free subdiaphragmal air as well as portal venous gas. The recovery of the patient was uneventful.

Conclusions: In the case of free intraperitoneal air, subserosal pneumatoasis coli has to be taken into consideration as differential diagnosis before the decision in favour of exploratory surgery is taken.

Factors Affecting the Success Rate of Retrograde Double-Balloon Enteroscopy (rDBE): A Multicenter U.S. Study
Shahab Meh dizadch, MD, Carol E. Sennard, MD, Lauren B. Gerson, MD, Jonathan A. Leighton, MD, Ann Chen, MD, Drew B. Scheombre, MD, Andrew Ross, MD, Derek Cheng, MD, Nancy Han, MD, A. Kamal, MD, Edwyn M. Harrison, MD, Kenneth F. Binnoeher, MD, Irving Wazman, MD, Richard A. Kozarek, MD, Simon K. Lo, MD.* Gl, Cedars-Sinai, Los Angeles, CA; GI, Univ of Chicago, Chicago, IL; GI, Stanford Univ, Palo Alto, CA; GI, Mayo Clinic, Scottsdale, AZ; GI, California Pacific, San Francisco, CA and GI, Virginia Mason, Seattle, WA.

Purpose: Obscure GI bleeding is often challenging but with new and improved diagnostic testing the source of blood loss is determined in most patients. Although Meckel’s Diverticulum is common in patients younger than 40 years of age, in this patient source of bleeding was most likely NSAID induced ulcerated lesion and Meckel’s Diverticulum was a “innocent bystander.” With more patients undergoing Capsule Endoscopy, this kind of scenarios will become more common.

A Case of Obscure GI Bleeding: Role of Capsule Endoscopy
Vijaypal Arya, MD,* Subhra Banerjee, MD, Krishnaiah Kalanuka, MD, Kalpana A. Gupta, MD, Siddharth Mogn, MS. Division of Gastroenterology, Wyckoff Heights Medical Center, Brooklyn, NY.

Purpose: Obscure gastrointestinal bleeding (OGB) is generally defined as recurrent acute or chronic bleeding for which no source has been identified by routine radiologic and endoscopic examination. OGB represents 5 to 10% of all episodes of gastrointestinal bleeding. The diagnosis is difficult to make because in most cases it originates in the small bowel. The most common causes are vascular ectasias, tumors, ulcerative diseases, and Meckel’s diverticula. We report a case of NSAID Induced small bowel ulcer bleeding diagnosed by Capsule Endoscopy.

Methods: Case Report:
A 19 year old white male presented with the complaints of bright red bleeding per rectum. He had no significant past medical or surgical history. His only medication was ibuprofen for muscle ache as needed, which he started 4 to 6 weeks prior to this episode. On examination his vital signs were stable and there were no postural changes. His Hemoglobin was 10.1 gm/dL and Hct was 28.4%. Upper endoscopy and Colonoscopy with ileoscopy did not reveal site of bleeding. Subsequently radionuclide (Te-99m) scintigraphy/Meckel’s Scan also failed to identify any source of bleeding. CAT scan of the abdomen and pelvis with IV and PO contrast was essentially normal except for incidental finding of a single left renal cyst. Patient was discharged with a presumptive diagnosis of GI bleed from internal hemorrhoids; on iron pills and a follow up appointment in GI clinic. Seven days after discharge from the Hospital patient came back with dizziness and weakness. He denied any bloody diarrhoea or passing black/tarry stools. H/H 7.3/20.2. A repeat upper endoscopy/Colonoscopy/bleeding scan/small bowel series were negative. A Capsule Endoscopy was then performed which revealed an ulcerated polypoid lesion in distal small bowel with active oozing. Intraoperatively a 1 cm fibroid polyp with superficial ulceration and Meckel’s Diverticulum without ulceration was found which were resected. Patient was discharged home in stable condition.

Conclusions: Obscure GI bleeding is often challenging but with new and improved diagnostic testing the source of blood loss is determined in most patients. Although Meckel’s Diverticulum is common in patients younger than 40 years of age, in this patient source of bleeding was most likely NSAID induced ulcerated lesion and Meckel’s Diverticulum was an “innocent bystander.” With more patients undergoing Capsule Endoscopy, this kind of scenarios will become more common.
and was probably explained by a reduction in time of advancement within the small-bowel ($p = 0.03$). The length of small-bowel examined increased with additional procedures and a total intestinal examination was possible in only one patient. Failure to pass beyond the TI occurred in 12 cases (20%), although the ileocecal valve could be entered in all but one case. An obstructing carcinoid mass within the TI prevented scope passage beyond the TI in 3 patients. Paradoxical withdrawal due to colonic looping was felt to be the reason prohibiting advancement. Failure was more common among patients with a prior abdominal/pelvic surgery compared to those without such history (11 of 35 vs. 1 of 24, $p = 0.019$). Time to achieve stable ileal intubation was also prolonged in patients with prior abdominal surgery (13.9 min. vs. 38.1 min. $p = 0.0006$).

Conclusions: rDBE is effective in evaluating and treating lower small intestinal lesions. Paradoxical endoscope retraction beyond the ileocecal valve contributes to a high percentage of rDBE failures. Prior surgery seems to be the most important factor associated with rDBE failure.

### 302

**A New Paradigm in Chemotherapy and Radiotherapy-Associated Gastrointestinal Toxicity: Emerging Evidence for Small Intestinal Bacterial Overgrowth as a Contributing Entity**

*Christopher D. Jahraus, MD,* *Doog Bettenhausen, PharmD.* Department of Radiation Oncology, University of Alabama at Birmingham, Birmingham, AL and Department of Medical Affairs, Salix Pharmaceuticals, Inc., Morrisville, NC.

**Purpose:** Gastrointestinal side-effects of cancer therapy are among the most widely recognized and feared toxicity for patients undergoing chemotherapy and radiotherapy. While agents such as 5HT3 antagonists have notably decreased the nausea associated with these treatments, diarrhea remains a troublesome and extraordinarily common problem in this patient population. Emerging data in GI literature support the notion of small intestinal bacterial overgrowth (SIBO) as central to the cause of numerous diarrheal disorders. Recognizing this, it has become our local practice to evaluate patients for SIBO when they develop a degree of diarrhea out of proportion to what we deem typical.

**Methods:** After obtaining IRB consent, we have retrospectively reviewed the records of all patients in the UAB Department of Radiation Oncology who have been sent for SIBO testing as described above, and will report our findings herein. Of note, methane testing was not available for this study. All patients with positive or equivocal results were treated with a course of rifaximin 400 mg orally, twice daily. The duration of the rifaximin was determined by the planned course of chemotherapy and/or RT.

**Results:** Hydrogen breath testing obtained on the first twenty patients so evaluated demonstrated 10 patients (50%) to have definitively positive breath tests, 3 patients (15%) with borderline or equivocal breath tests, and 7 patients (35%) with clearly negative tests. Patient age was widely distributed, from 26 to 75 years. Breath test positivity correlated most strongly with a symptom description including diarrhea.

**Conclusions:** SIBO is an entity commonly associated with diarrhea of numerous causes, however, this is to our knowledge, the first published report of its association with chemotherapy and/or abdominopelvic radiotherapy. We advocate early testing and treatment of patients experiencing diarrhea while on either type of cancer therapy, and are in the process of creating a prospective study to evaluate this matter with greater precision.

### 303

**Lumen Finding Steerable Guide Wire: A Novel Concept Facilitating Deep Enteral Access**

*Vinod K. Parashar, MD,* *Gastrointestinal, Gastrointestinal Associates, Washington, DC.*

**Purpose:** Consistent deep intubation of the small bowel remains problematic despite the availability of various methods. Current methods require fluoroscopy or long endoscopes. A method is needed which not only will allow safe placement of guide wires consistently beyond the ligament of trietz or deeper during endoscopy without fluoroscopy, but also is convenient and is not time consuming. Such method may assist in the placement of feeding tubes, modified wireless capsule endoscopes, double balloon endoscopes and/or standard endoscopes. Aim of this study was to evaluate the placement of a steerable lumen finding guide wire in an ex vivo sample of porcine small bowel.

**Methods:** A mechanical device is invented which allows 360 degree rotation of a flexible guide wire at varying speeds. Simultaneous incremental feeding of the rotating guide wire is also possible. A 260 cm. 0.35 inch guide wire (Jagwire, Boston Scientific, Nettick, MA) was attached to the device. A similar length of porcine small bowel was placed and fixed in a water bath for experimentation.

**Results:** The small bowel was transversed by the guide wire in it’s entirety by this method. Continuous deflection of the rotating guide wire tip against the small bowel mucosa coupled with incremental feeding allowed the lumen finding and, thus, the deep entral access.

**Conclusions:** A method is described which allows deep entral access by a mechanically steerable rotating lumen finding guide wire. Acute and survival studies are planned.

### 304

**Does Gender, Age or Body Mass Index Have Any Correlation with Transit Times within Upper and Lower Gastrointestinal Tract in Healthy Subjects?**

*Irene Sarofiek, MD, Marek Majewski, MD,* *The SmartPill Trial Group, Richard W. McCallum, MD.* Internal Medicine, *The University of Kansas Medical, Kansas City, KS and SmartPill Trial Group, Buffalo, NY.*

**Purpose:** Although there are recognized physiological differences within the GI tract between males and females, little is known regarding the relationship between gender, age, and BMI and transit times of the gut. This question could be effectively addressed utilizing non-digestible capsule (SmartPill) that is capable to assess the duration of the gastric residence time (GRT), small bowel transit time (SBTT), colon transit time (C TT), and total transit time (T TT) in humans.

**Methods:** 55 asymptomatic subjects, 21F, mean age of 32, (19-57 range), participated in this multicenter study. After an overnight fast all subjects swallowed the capsule equipped with sensors measuring pressure, pH and temperature with data being collected by a portable recording device. The time between ingestion of capsule and the rapid, sustained rise of pH by 3 pH units and exceeding the pH value of 4.0, was defined as GRT. Later on, a sudden drop of more than 1 pH unit for longer than 5 min. was regarded as an ileo-cecal (I-C) arrival. By subtracting GRT from I-C junction arrival time, SBTT was calculated, and in turn CTT was then determined. Spearman Rank Order Correlation, Mann-Whitney and t-test were used for statistical analyses. Times were expressed in minutes.

**Results:** Results are presented in Table 1 and 2.

**Conclusions:** 1. Healthy females have prolonged TTT, which could be explained by differences of CTT between genders. 2. There is no significant relationship between GI transit times and age (population under 60 years old). 3. BMI is significantly correlated with SBTT, GRT, and CTT. 4. SmartPill brings a new research and diagnostic potential for further assessment of GI tract function.

<table>
<thead>
<tr>
<th></th>
<th>Females (N = 21)</th>
<th>Males (N = 34)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>TTT (min)</td>
<td>2026 ± 1021</td>
<td>1557 ± 683</td>
<td>.046 (t-test)</td>
</tr>
<tr>
<td>GRT (min)</td>
<td>224 (192–261)</td>
<td>222 (195–244)</td>
<td>.807 (M-W test)</td>
</tr>
<tr>
<td>SBTT (min)</td>
<td>291 (250–356)</td>
<td>255 (237–381)</td>
<td>.451 (M-W test)</td>
</tr>
<tr>
<td>CTT (min)</td>
<td>1291 (708–2330)</td>
<td>887 (704–1291)</td>
<td>.096 (M-W test)</td>
</tr>
</tbody>
</table>

Data expressed as mean ± SD or median (25%-75%).

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*Abstracts*
Being, in the Multidimensional Affect and Pain Survey (101-MAPS). Pain is a subjective experience that has profound impact on the quality of life. The 101-MAPS is the only currently available instrument that takes into account all recognized pain dimensions. It classifies 101 items into three dimensions or “super clusters”: Sensory (57 items), Suffering (26 items) and Well-Being (18 items). The 101-MAPS questionnaire has been validated for cancer and postoperative pain.

Methods: Fourteen gastroenterologists, 11 internists and 11 medicine residents at Mount Sinai School of Medicine rated the items on the 101-MAPS based on their perception of the items’ relevance to pain in GI diseases, on a scale of zero to five.

Results: Of the hundred and one items in the 101-MAPS rated by the gastroenterologists, 25 items received a median rating of four or above. Of those 25 items, 23 were from the Sensory super cluster (total 57) and only one item each was from the Suffering (total 26) and Well-Being (total 18) super clusters. Compared to the composition of the 101-MAPS, these proportions indicate relative inattention to Suffering ($p < 0.01$) and Well Being items ($p < 0.05$). When the same task was performed by the internists and medicine residents, their mean super cluster scores did not differ from those of the gastroenterologists ($p > 0.1$).

Conclusions: These findings suggest a bias among physicians towards the sensory qualities and against the affective qualities when eliciting patients’ pain experiences. The results also suggest that this bias is found amongst sub-specialists and manifests during physician training.

### Table 2.

<table>
<thead>
<tr>
<th>BMI</th>
<th>Age</th>
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<tbody>
<tr>
<td></td>
<td>correlation coefficient (r)</td>
</tr>
<tr>
<td>TTT</td>
<td>−0.282</td>
</tr>
<tr>
<td>GRT</td>
<td>−0.399</td>
</tr>
<tr>
<td>SBTT</td>
<td>−0.281</td>
</tr>
<tr>
<td>CT</td>
<td>−0.149</td>
</tr>
</tbody>
</table>

### Abstracts S145

#### 305 Outcome and Efficacy of a Nurse Led Iron Deficiency Anaemia Clinic

Vikramjit Mitra, MBBS, MRCP, Savadip Chatterjee, MBBS, MD, Jayesh Vasisan, MBBS, FRCP, Carol Berthou, Krishnadas Bhattacharya, MBBS, MD, FRCP, Basant K. Chaudhury, MBBS, MD, FRCP.<sup>a</sup> Department of Gastroenterology, University Hospital of Hartlepool, Holdforth Road, Hartlepool, United Kingdom.

**Purpose:** The British Society of Gastroenterology (BSG) recommend that 90% of patients with iron deficiency anaemia (IDA) without obvious cause should have both upper GI endoscopy (OGD) and either colonoscopy or double contrast barium (DCB) enema (unless a firm cause is found with the first investigation) & be screened for coeliac disease and 100% of patients should have documented evidence of IDA. In this clinic a Specialist Nurse interviews the patients according to a standard proforma and arranges estimation of Hb, MCV, ferritin, anti-endomysial antibody, TSH, folate, VitB12 and urine for blood. Patients of IDA without obvious cause are identified and endoscopies and/or DCB enema are arranged accordingly. We carried out this audit to find out whether we are compliant with the BSG guidelines at our hospital.

**Methods:** Retrospective analysis of case notes of referrals to the clinic from November 2004 to July 2005 were reviewed according to a standard audit proforma.

**Results:** Out of 65 patients referred to the clinic, 51 (78.5%) had IDA of which 41 (80%) were females and 10 (20%) were males. All but one was seen within 3 months of referral (range 5 to 97 days; mean 28 days). Hb, MCV, ferritin, folate, calcium and magnesium were checked in all patients. 48 (94.11%) were screened for coeliac disease while TSH was done in all but one. 6 out of 51 IDA patients did not attend for endoscopy. Of the remaining 45 patients, 39 (87%) had both OGD and colonoscopy/DCB enema, 5 (11%) had only OGD and 1 (already diagnosed with carcinoma colon and angiodysplasia colon) did not undergo any procedure. 6 (13%) patients had GORD/benign gastric ulcer gastritis/large hiatus hernia, 3 (6.66%) coeliac disease, 4 (8.88%) oesophageal varices/oesophagitis, 2 (4.44%) colonic carcinoma, 6 (13.33%) diverticulitis, 1 (2.22%) colonic poly, 1 haemorrhoids and 1 had angiodysplasia. No cause was found in 19 (42%) patients of whom 6 were on NSAIDS, 3 had menorrhagia, and 1 had pernicious anaemia.

**Conclusions:** The nurse led clinic for IDA proves an effective way of investigating these patients, reducing waiting time and thereby picking up sinister lesions at the earliest (4.44% diagnosed with Ca colon). The mean waiting time from GP referral to first clinic appointment was 28 days and 94.11% & 95.5% of patients respectively were screened for coeliac disease and underwent both OGD and colonoscopy in line with BSG guidelines.

#### 306 Is There Physician Bias Against Eliciting Affective Qualities of Pain?

Savitha R. Tudi, MD, Deepthi Deconda, MD, Sitia Chokhavatia, MD, FICPC<sup>b</sup> David B. Sachar, MD, MACP, Susanne B. Clark, PhD, Crawford W. Clark, PhD. Medicine/Gastroenterology, Mount Sinai School of Medicine, New York, NY and Psychiatry, College of Physicians and Surgeons, Columbia University, New York, NY.

**Purpose:** To determine the weight given by physicians who assess patients’ pain experiences to each of the three dimensions, Sensory, Suffering and Well

Being, in the Multidimensional Affect and Pain Survey (101-MAPS). Pain is a subjective experience that has profound impact on the quality of life. The 101-MAPS is the only currently available instrument that takes into account all recognized pain dimensions. It classifies 101 items into three dimensions or “super clusters”: Sensory (57 items), Suffering (26 items) and Well-Being (18 items). The 101-MAPS questionnaire has been validated for cancer and postoperative pain.

**Methods:** Fourteen gastroenterologists, 11 internists and 11 medicine residents at Mount Sinai School of Medicine rated the items on the 101-MAPS based on their perception of the items’ relevance to pain in GI diseases, on a scale of zero to five.

**Results:** Of the hundred and one items in the 101-MAPS rated by the gastroenterologists, 25 items received a median rating of four or above. Of those 25 items, 23 were from the Sensory super cluster (total 57) and only one item each was from the Suffering (total 26) and Well-Being (total 18) super clusters. Compared to the composition of the 101-MAPS, these proportions indicate relative inattention to Suffering ($p < 0.01$) and Well Being items ($p < 0.05$). When the same task was performed by the internists and medicine residents, their mean super cluster scores did not differ from those of the gastroenterologists ($p > 0.1$).

**Conclusions:** These findings suggest a bias among physicians towards the sensory qualities and against the affective qualities when eliciting patients’ pain experiences. The results also suggest that this bias is found amongst sub-specialists and manifests during physician training.

#### 307 Intestinal Transplantation: Current Status and Future Considerations

Kareem Abu-Elmagd, MD, George Mazzaferro, MD, Geoffrey Bond, MD, Guilherme Costa, MD, Rakesh Sindhhi, MD, Kyle Soltry, MD, Hassam Kandil, MD, Robert Squires, MD, Stephen O‘Keefe, MD.<sup>c</sup> Surgery, University of Pittsburgh Medical Center, Pittsburgh, PA.

**Purpose:** Intestinal transplantation has been utilized only as a rescue therapy for patients with gut and TPN failure. Such limited indications were implemented during the developing phase of the procedure and continued to be the current practical guidelines. The substantial recent improvement in survival, however, may justify lifting the existing restriction criteria with increased utilization of the procedure.

**Methods:** Over a period of 16 years, a total of 385 transplants were performed in 198 adults and 157 children. Allografts were 42% intestine, 34% liver-intestine and 24% multivisceral. Main causes of intestinal failure were SBS in 74%, dysmotility in 13%, neonatal necrotizing enterocolitis in 5%, Common etiology of SBS was gastrochisis (33%), volvulus (32%), NEC (15%) and intestinal atresia (15%) in children and vascular thrombosis (38%), Cronkh’s disease (18%) and neoplasms (11%) in adults with similar frequency of dysmotility and trauma in both groups. Indication for hepatic replacement was TPN induced liver failure. Rejection prophylaxis was with tacrolimus and prednisone with use of cyclosporidine in 24 and daclizumab in 62 patients. Since 2001, 201 recipients were pretreated with anti-lymphocyte preparations and tacrolimus monotherapy.

**Results:** The overall cumulative patient survival was 82% (1yr), 58% (5yr), 34% (10yrs) and 31% (15yrs). Survival was better with dysmotility syndromes and micovillus inclusion disease. With recipient pretreatment and minimization of immunosuppression, survival outcome has significantly ($p = 0.0001$) improved with 1 and 5 yr survival rates of 92% and 77%, respectively. Despite use of the procedure as a rescue therapy, the current
survival of intestinal recipients is favorably comparable to that of previously reported for HPN patients. More impressive, is achievement of full nutritional autonomy in 95% of intestinal transplant recipients with discontinuation of TPN and restoration of unrestricted oral diet. Interestingly, most allograft survivors are currently on spaced doses of immunosuppression with improvement in quality of life and cost effectiveness.

**Conclusions:** With the currently achievable high therapeutic benefits, intestinal transplantation should be considered for irreversible intestinal failure patients and before development of TPN failure. Accordingly, the procedure must be included as an essential component of the management algorithm for this unique population.

### 308 Dental Enamel Defects in Celiac Disease: A Case Control Study

**Pardeep S. Brar, MD, Ted Malahias, DDS, Peter H.R. Green, MD.**

Medicine, Columbia University Medical Center, New York, NY and CT.

**Purpose:** Dental enamel defects reflect disease processes occurring during the period of enamel formation. European studies have demonstrated that defects are seen in patients with celiac disease (CD). We conducted a case control study in children and adults to assess this association in the US.

**Methods:** Biopsy proven CD patients and controls were recruited from a private dental practice and CD support groups. The cohort was divided into two groups (adults (≥ 16 years) and children (≤ 16 years) because there are very few restorations and enamel defects can be picked up easily in virgin teeth. A single dentist examined the oral cavity for dental enamel defects, aphthous ulcers and decayed missing and filled teeth (DMFT). Significant Caries Index (SCI), signifying prevalence of caries, was calculated. Enamel defects were graded as 0 (absent) through 4 according to Aine’s classification. All grades were combined for this study. Chi-square test was used to compare dichotomous variables. Linear regression was used for DMFT correlation.

**Results:** The cohort consisted of 67 CD patients (67% adults, 33% children; 79% females, 21% males) and 37 controls (46% adults, 54% children; 65% females, 35% males). Mean age in years for CD patients (adults 47.2 ± 14.4, children 9.18 ± 3.11) and controls (adults 38.5 ± 14.5, children 10.5 ± 2.56). Dental defects were identified in 26 children and 18 adults. Only grade 1 and 2 defects were seen, no grade 3 or 4 defects. The prevalence of dental defects was higher in CD 51% compared to controls, 27% p = 0.033. However, only children with CD had statistically significant higher prevalence of enamel defects (73% compared to 27% in controls, p = 0.0012). Among adults the prevalence was 83% in CD and 68% in controls (p = 0.35). There was a statistically significant correlation of dental defects and aphthous ulcers with CD, when combined (p < 0.0001) or presence of either one (p = 0.045). There was no significant correlation of aphthous ulcers with dental defects (p = 0.37). There was positive correlation of DMFT with age (p < 0.001) and negative correlation with dental defects (p < 0.001). Association of SCI with CD was not significant.

**Conclusions:** Celiac disease is associated with dental enamel defects in childhood, most likely due to the onset of CD during enamel formation. In adults, dental defects are common and celiac disease does not exert an influence. Dentists need to be aware of these associations.

### 309 A Novel “Twilight Protocol” To Optimize the Use of Small Bowel Capsule Endoscopy in the Ambulatory Office Setting: Report of Ten Cases

**Sruthu S. Vasireddi, MD, FACP.** Gastroenterology, JFK Medical Center, Edison, NJ. Gastroenterology, Bayshore Hospital, Holmdel, NJ and Director, Advanced Digestive Center, Inc., Metuchen, NJ.

**Purpose:** The conventional morning administration of small bowel capsule study in the office setting can be inconvenient for the patients and the physicians, since most specialist office practices open later in the day, and most gastroenterologists tend to have afternoon or evening hours following the morning procedure schedule, either at hospitals or ambulatory surgical centers. To enhance the convenience and to optimize the capsule utilization in the office setting, we devised a novel evening protocol for the small bowel capsule study and report the preliminary findings on ten patients.

**Methods:** Ten patients (5 male and 5 female) had the small bowel capsule administered in the office at 4 PM. They were advised to have a regular breakfast at 7:30 AM and were allowed to consume either water or Sprite Soda (which is translucent) for the rest of the day. They were allowed to consume water and medications after 2 hours of capsule ingestion and a light regular dinner after 4 hours. They were also instructed to remove the equipment at 12 PM if still awake, or early next AM upon waking. The data recorder was returned to the office in the morning.

**Results:** Eight of the ten studies performed were deemed adequate by the reading physician, taking into consideration the quality parameters including luminal preparation, image acquisition and visualization and complete small bowel transit. Two female patients did not have a good quality study utilizing the above parameters, due to slow transit and luminal debris. One patient was on narcotics for chronic back and pelvic pain issues and had an unremarkable subsequent small bowel series. The other patient had a repeat conventional morning capsule study, which again showed a delayed gastric emptying time of over 4 hours and an incomplete small bowel transit.

**Conclusions:** The “Twilight Protocol” for the small bowel capsule study provides for a good alternative to enhance the patient and physician convenience and use in the ambulatory private office setting. Eight of the ten patients had an optimal capsule study and two other patients had variables, which might have lead to a sub-optimal study with the conventional protocol as well. Further randomized double blind studies on a larger pool of patients, to eliminate the selection and operator bias, will be needed to validate this novel protocol.

### 310 Primary Burkitt’s Lymphoma of the Appendix Presenting as Acute Appendicitis

**Sathya Jagannohan, MD, Ryan Chauvin, MD, Gary Burton, MD.**

Internal Medicine and Hematology/Oncology, LSU Health Sciences Center, Shreveport, LA.

**Purpose:** Primary malignant small-bowel neoplasms are rare, constituting about 2% of primary gastrointestinal malignancies. Primary appendiceal lymphomas constitute only about 0.015% of all GI lymphomas. Burkitt’s lymphoma of the appendix has been reported to occur in children. We present an index case of Burkitt’s lymphoma of the appendix in an adult male who presented with acute appendicitis.

**Methods:** A 60 year old Caucasian male presented with one day history of right lower quadrant pain and nausea. Physical exam was unremarkable except for localized tenderness over the right lower quadrant. Laboratory exam was unrevealing. CT scan of the abdomen showed a 6.5 × 4.5 cm retroperitoneal enlargement that was consistent with appendicitis with no organomegaly. Emergent surgical exploration revealed a ruptured appendix with minimal peritonitis. The appendix appeared highly vascular and edematous but was not typical of acute inflammatory appendicitis. Histopathological analysis of the appendix revealed high grade lymphoma with serosal involvement. Tumor cells expressed a high mitotic rate with numerous tingible body macrophages creating the starry sky pattern, highly suggestive of Burkitt’s lymphoma. Cytogenetic analysis for t (8,14), IgH/c-myc translocation, FISH for c-myc rearrangement and PCR for IgH/JH gene rearrangement were positive. Immunohistochemistry revealed CD20 and CD10 positive cells which are specific for the diagnosis. Patient underwent staging workup and was found to have localized stage IE Burkitt’s lymphoma. He was initiated on aggressive chemotherapy with three cycles of (cyclophosphamide, vincristine, doxorubicin, high-dose metho-trexate, and intrathecal therapy).

**Conclusions:** Malignant small-intestine lymphoma has an estimated annual incidence of 0.12 per 100,000 persons, and represents approximately 20% of
primary malignancies of the small intestine. Histopathological characteristics include the tangible macrophages and the starry sky pattern. C-myc/IgH translocation has a specificity of 80% for the diagnosis. A high index of suspicion and meticulous histopathological examination were vital in diagnosis and therapy of this rare and aggressive tumor. [figure1]

Methods: In this prospective study, patients presented for evaluation of CD underwent WCE according to standard protocols.

Results: Total number of CD cases: 13, Older adults (Age above 60): 7 cases. (Males 2, Females 5)

Common indications: Anemia, chronic diarrhea, abdominal pain and unexplained weight loss (More than one indication coexisted in some patients).

Common findings: Scalloping, mucosal atrophy, layering or stacking of mucosal folds, mosaic pattern and nodularity (Multiple findings coexisted).

Conclusions:
1) Anemia in the older adults (age > 60) may be the sole manifestation of CD and needs further evaluation to confirm the diagnosis.
2) WCE provides as valuable tool to visualize the entire small bowel mucosa and to identify the nature, location and extent of mucosal abnormalities seen in CD.
3) In CD the duodenum may be entirely normal by the EGD examination while the proximal and distal small intestine may show classic features of CD.

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Presentation of Celiac Disease and Biopsy Findings: Any Relationship?
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Purpose: Celiac disease is an autoimmune enteropathy due to a reaction against gluten and is characterized by villous atrophy and intraepithelial lymphocytosis. The clinical mode of presentation is classified as classic (diarrhea predominant) and silent or atypical with anemia, osteoporosis, dermatitis herpetiformis and other less common modes of presentation (including screening of high risk groups). There is also a pathologic spectrum from mild to severe villous atrophy. In view of conflicting information as to whether the mode of presentation correlates with the degree of villous atrophy we reviewed a large cohort of patients with celiac disease.

Methods: Data including age, sex, age of diagnosis, mode of presentation and degree of villous atrophy was obtained from a data base of patients with celiac disease. The degree of villous atrophy was characterized as either partial villous atrophy (PVA) with a villous to crypt ratio of 3:1 or less but equal to or more than 1:1 and total villous atrophy (TVA) with villous to crypt ratio of less than 1:1, TVA also included cases of subtotal villous atrophy. The significance of association of the extent of villous atrophy with the presenting symptom of diarrhea was studied by a chi-square test.

Results: The cohort consisted of 499 adults, mean age 44.1 years, 68% females. The majority had silent celiac disease (56%) and total villous atrophy (65%). There was no correlation of mode of presentation with the degree of villous atrophy (p = 0.25). 68% of females and 58% of males had a severe villous atrophy (p = 0.052). There was a significant trend over time for a greater proportion of patients presenting as silent celiac disease and having partial villous atrophy, though the majority still had total villous atrophy.

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Celiac Disease in Older Adults: Evaluation by Wireless Capsule Endoscopy (WCE)
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Purpose: Celiac disease (CD) occurs in about 1% of US population (NIH Consensus Conference on CD 2004). It may be asymptomatic for many years or may present with diarrhea, abdominal pain, bloating, fatigue and weight loss. Common non-GI symptoms include anemia (iron deficiency and/or folate deficiency), arthritis and infertility. CD may remain latent for years and up to 20% of patients are older than 60 when CD is first diagnosed (Hankey GL. CD in elderly. Gut 1994; 35:65-67). CD is diagnosed by SB mucosal biopsy and serological testing of antibodies (IgA anti-tTG, IgA antiendomysial). WCE has provided us an opportunity to identify classical features of celiac disease and also to evaluate the nature, location and extent of mucosal abnormalities.

Aim:
The aim of this study is to identify various abnormalities in patients with CD with regard to their nature, location and extent of mucosal involvement in older adults.

Methods: Total number of CD cases: 13, Older adults (Age above 60): 7 cases. (Males 2, Females 5)

Common indications: Anemia, chronic diarrhea, abdominal pain and unexplained weight loss (More than one indication coexisted in some patients).

Common findings: Scalloping, mucosal atrophy, layering or stacking of mucosal folds, mosaic pattern and nodularity (Multiple findings coexisted).

Conclusions:
1) Anemia in the older adults (age > 60) may be the sole manifestation of CD and needs further evaluation to confirm the diagnosis.
2) WCE provides as valuable tool to visualize the entire small bowel mucosa and to identify the nature, location and extent of mucosal abnormalities seen in CD.
3) In CD the duodenum may be entirely normal by the EGD examination while the proximal and distal small intestine may show classic features of CD.
Conclusions: Among our patients the degree of villous atrophy in duodenal biopsies did not correlate with the mode of presentation. Diarrhea is probably related to other factors including the length of small intestine involvement in the inflammatory process, presence of pancreatic insufficiency, bacterial overgrowth, intestinal dysmotility and less well defined factors. Factors that predict the severity of the clinical manifestations of celiac disease need to be identified.

Methods: The subjects were 27 patients (19 men and 8 women, age range: 37–83 years, average age: 65.9 years) with 29 HCC nodules confirmed by contrast CT or abdominal angiography. In nodule size classification, no nodules were ≤1.0 cm in diameter, 7 were 1.1–2.0 cm, 18 were 2.1–3.0 cm, and 4 were 3.1–5.0 cm. A diagnostic ultrasound system (Aplio, Toshiba, Japan) and a micro-convex probe (PVT382BT, Toshiba) provided with the Aplio system were used for treatment. This probe permits puncture angles of 67° and 80° to be set and needles from 13G–22G to be used. A Cool-tip cluster needle was used in 3 patients and a 3.5-cm RTC needle was used in the other 24 patients. In this study, scanning with ApliPure™ (a new function of Aplio) and conventional B-mode scanning were also compared in 5 patients. The therapeutic effect was assessed using contrast CT and contrast echo images. The Advanced Dynamic Flow Imaging technique was employed for contrast echo studies.

Results: Puncture was performed successfully for all 29 nodules in all 27 patients for which RFA was performed. The blind area in which the needle is not visible in the image is minimal with the Aplio system. ApliPure™ is a technique combining spatial compounding and frequency compounding, and it is said to improve continuity of the edges of lesions. Although the number of cases in this study was small, we found that clearer images were obtained using this technique. Four nodules that were located 10 cm from the liver surface were not visualized in contrast echo studies performed before and after treatment. For the remaining 25 nodules, however, the therapeutic effect could be assessed. In addition, the micro-convex probe permitted treatment to be performed successfully without artificial pleural effusion for 3 nodules located immediately below the diaphragm that were not visualized using a conventional convex probe.

Conclusions: The use of a micro-convex probe helps to ensure more precise and more accurate percutaneous RFA of HCC.

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Usefulness of Radiofrequency Ablation with a Micro-Convex Ultrasound Probe for the Treatment of Hepatocellular Carcinoma

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Purpose: Radiofrequency ablation (RFA) has been clinically employed in Japan, and its usefulness in the treatment of hepatocellular carcinoma (HCC) has been reported by many researchers. RFA can be performed in various ways: percutaneously, laparoscopically, via a small incision, or intraoperatively. In our department, we generally perform echo-guided percutaneous RFA. The present study was conducted to assess the usefulness of RFA using a micro-convex probe.

Results: A total of 291 subjects, (F = 193, 66%, M = 98, 34%) mean age 46 ± 15SD years, were evaluated. In our cohort 18% were underweight (BMI < 18.5), 61% had normal weight (BMI 18.5–24.9), 14% were overweight (BMI 25–29.9) and 7% were obese (BMI more than 30). There was a statistically significant association between BMI and degree of villous atrophy (p < .0001), PVA (N = 96) with higher mean BMI of 23.2, compared to TVA (N = 195) with lower mean BMI of 21.4. There was no significant correlation with gender, age and mode of presentation. Compared to NHANES III data; the percentage of men and women with celiac disease, was relatively higher in the normal and low BMI range, but lower in the overweight and obese BMI range. There was a trend toward higher baseline BMI over time. Follow up BMI data were available for 225 patients and there was statistically significant increase of BMI by 0.9 (p < .0001). This change was negatively correlated with the baseline BMI, meaning lower the baseline BMI greater the change with diet.

Conclusions: Majority of the celiac disease patients had normal BMI, some were underweight and a few were obese. Baseline BMI correlated with degree of villous atrophy only. The change in BMI with diet was related to baseline value.

Liver

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Thyroid Dysfunction in Patients with Chronic Hepatitis C Treated with Pegylated Interferon alpha Therapy

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Purpose: Thyroid dysfunction has been reported in 1–3% of patients with chronic hepatitis C treated with interferon therapy. We prospectively studied this problem in our patients with an attempt to determine the role played by autoimmunity in thyroid dysfunction.

Methods: 39 patients (18 males and 21 females) aged 18–55 years with chronic hepatitis C were treated with pegylated interferon alpha in combination with ribavirin. Baseline thyroid stimulating hormone (TSH) and free thyroxine (free T4) levels were obtained on all patients prior to therapy. At baseline, every patient had an autoimmune panel sent which consists of antithyroid microsomal antibody, antithyroglobulin antibody and thyroid stimulating immunoglobulins and was euthyroid prior to beginning interferon therapy. Beginning at week twelve all patients had TSH and free T4 levels monitored on a monthly basis for the duration of the therapy. If there was any variation from the normal range a new set of thyroid autoantibodies were redrawn to evaluate for development of autoimmune thyroid dysfunction.

Results: 9 out of 39 patients (8 females and 1 male) or 23% showed changes in their thyroid functions between week 12 and the end of treatment. 7 of the 9 patients were genotype 3a. Of these group 8 patients became clinically hypothyroid and 1 patient developed transient hyperthyroidism requiring treatment and soon thereafter became hypothyroid requiring synthroid. From these 9 patients 2 developed new antithyroid microsomal antibodies and anti-thyroglobulin antibodies while 1 patient showed increase in levels of pre-existing microsomal and anti-thyroglobulin antibody titers. 3 of the 9 patients or 33% had thyroid autoantibodies as the mechanism of hypothyroidism. Only 2 of the 9 or 22% developed new thyroid autoantibodies.

Conclusions: In our cohort of mostly Pakistani genotype 3a patients there was a much higher incidence of hypothyroidism (23%) on Peg interferon and ribavirin treatment than 1-3%. This much higher rate of thyroid dysfunction could be due to a small sample size or it maybe due to a greater susceptibility...
of Pakistani women or genotype 3a patients to this complication. The large difference favors the latter. As the numbers show there is a 8 to 1 female predominance for this phenomenon. Finally only a minority of the cases are explained by thyroid autoantibodies (33%). This suggests that there are other unexplained mechanisms for the hypothyroidism perhaps including a direct effect of peg interferon on the thyroid gland.

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**Ultrasound Guide Liver Biopsy: Impact on Length of Stay and Complications**

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**Purpose:** The study assessed complications and length of stay with ultrasound guided liver biopsies.

**Methods:** Since December 2005 liver biopsies performed at the Orlando VA Medical Center utilized ultrasonography. Biopsies were done utilizing HDI 3000 Ultrasound System (ATL, Bothell, WA) and Coaxial TennoEvolution needle system (Cardinal Health, McGaw Park, IL). Patients were instructed prior to biopsy to stop taking aspirin, NSAIDS for 5 days and coumadin, Clopidogrel, and Ticlopidine for 4 days. They were instructed to be NPO for the procedure, have a driver on the day of the biopsy. The laboratory studies consisted of complete blood count: minimal hemoglobin >10 mg/dL, platelets >50,000/μL, prothrombin time <14 seconds, and international normalized ratio <1.5. Type and screen was done. The patient was scanned in both sagittal and longitudinal planes, the area was prepped in the usual manner and infiltrated with 2% xylocaine. Premedication was based on clinical exam, and underlying diagnosis. Biopsy was performed using the Coaxial Tenno Evolution system, 2 passes were made in the majority of patients, rarely 3. Post procedure, paatients in the PACU had vital signs every 15 minutes lying or sitting. Patients were assessed for pain (abdomen, chest and shoulder), shortness of breath or bleeding from the biopsy site. Prior to discharge repeat ultrasound of the liver was done for evidence of bleeding i.e the presence of hematoma or bile leak. Instructions to contact the GI nurse if they developed abdominal pain, blood in the stool or urine, fever, difficulty breathing or bleeding from the site. They were instructed to avoid heavy lifting and avoid being alone for 24 hours. A nurse called all patients 24 hours post procedure to assess and report to the physician (OLH).

**Results:** 44 biopsies were done by US guidance in a 4 month period. There were no hospitalizations, blood transfusions, fluid resuscitations or use of analgesia other than acetaminophen. One patient developed a localized abscess that responded to local measures, another had bile staining of the biopsy needle that required no intervention. Patients were discharged in 1 hour. Follow up phone interviews revealed no adverse events.

**Conclusions:** Ultrasound guided liver biopsy by a gastroenterologist in an outpatient setting is safe, reduces the length of stay and is more efficient than the standard approach.

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**The Effect of Processing on Liver Biopsy Core Size**

**Thomas R. Riley, III, MD,*, Frances Ruggerio, MD. Medicine, Penn State University - The Hershey Medical Center, Hershey, PA and Pathology, Penn State University - The Hershey Medical Center, Hershey, PA.**

**Purpose:** The liver biopsy is a valuable tool in the evaluation of acute and chronic liver disease. The size of a liver biopsy core that is viewed as adequate to allow for reliable interpretation varies by investigators with a wide range from 0.5 to 4.0 cm in length. The size of the biopsy core reported may change depending on what step in processing the measurement is made. The aim of this study was to assess the impact of processing on the liver biopsy core size.

**Methods:** 61 Liver biopsy cores were obtained in a standard fashion and measured prospectively and consecutively between November 2004 and April 2005. Biopsies were performed using a disposable automatic tru-cut 16 gauge needle. The empty cartridge measured 18 mm in size. With each core sample obtained 3 measurements were made: 1) the core while in the cartridge, 2) the core removed from the cartridge and layed on to the biopsy tray. 3) the core after formalin fixation. The student t-test was applied to assess for differences in size. Chi square was applied to look for associations.

**Results:** The average length of the liver biopsy core obtained when measured in the cartridge (CS) was 15 mm ± 2.0 mm with a range of 10–18 mm. The average length of the core when measured on the tray (TS) was 19.6 mm ± 3.5 mm with a range of 12–25 mm. Once fixed in formalin (FS) and measured the average core size was 18.3 mm ± 2.9 with a range of 12–25 mm. There was a statistical difference between all sizes. The p values between CS and TS, CS and FS, TS and FS were (<0.0001, <0.0001, <0.035) respectively. The cartridge has a pronounced compressive effect on average 4.6 mm (23%). The formalin fixation has a small but appreciable shrinkage effect on average of 1.3 mm (7%). Forty liver biopsy specimens showed both compression and shrinkage, 15 showed compression but no shrinkage, 1 had shrinkage but no compression, and only 5 showed neither. Age, diagnosis, fibrosis, and Knodell scores were not predictive of processing changes.

**Conclusions:** Liver biopsy core size changes during processing steps. Awareness of these changes is imperative for liver biopsy operators. The final size of the specimens when measured by the pathologist can be about 4–5 mm different then what the operator sees in the needle cartridge. In a broader context, clinical trials that require a minimum amount of tissue must account for these processing steps when setting the standard.

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**Hepatic Epithelioid Hemangioendothelioma 15 Years Later**

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**Purpose:** Epithelioid hemangioendothelioma (EHE) is an uncommon cause of increased alkaline phosphatase. Few cases have been described; none of them in Latin Americans or with a 15 year retrospective follow up. This vignette presents a 34 y/o Hispanic male who presented in 1991 with a one-month history of lightheadedness and weight loss. Physical exam was remarkable for coarse, non-tender hepatomegaly. Initial laboratory data revealed microcytic anemia, and an elevated alkaline phosphatase. Abdominal sonogram showed hepatomegaly with multiple calcifications. A liver biopsy demonstrated minute areas of fibrosis and microcalcifications. Endoscopy, colonoscopy and small bowel series were normal. Tumor markers including: AFP, CEA and HCG were normal. Repeat liver biopsy was positive for Factor VIII immunoperoxidase stains consistent with EHE. Chest CT showed evidence of bilateral lung metastasis. As of 2006 the patient shows no evidence of disease progression and is being followed with periodical CT scans. EHE is a vascular tumor of endothelial origin that preferentially arises in soft tissues of the extremities and in the lung. Liver involvement occurs as metastasis or as a primary tumor. Common presenting symptoms are upper abdominal pain, anorexia and weight loss. Jaundice, fever, and variceal bleeding are rarely seen. Liver function tests are usually normal, except for alkaline phosphatase. Imaging usually reveals peripheral multifocal hypervascular lesions, multiple calcifications, and fibrotic indentations of the liver capsule. Diagnosis is established by histology with a multifocal pattern of liver involvement, evidence of vascular differentiation, fibrotic centers, and involvement of adjacent sinusoids. This tumor is relatively avascular. Weibel-Palade bodies (cytoplasmic inclusions) may be seen. Immunohistochemistry, CD31, CD34, Factor VIII and anticytokeratins have been used for identification of this tumor. EHE has a low propensity to metastasize.
Therapeutic options include observation, chemotheraphy, radiotherapy or orthotopic liver transplantation (OLT). Surgical resection of amenable lesions should be considered. OLT has been shown to prolong survival even in the presence of metastatic disease. Prognosis is unpredictable. Most patients experience long survival. Important prognostic features include: younger age, disparity between the presence of multiple lesions and patients overall well-being, and presence of intramural calcifications.

Choice of Calcineurin Inhibitor and Development of New Malignancies in Liver Transplant Recipients

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**Purpose:** The goal was to examine whether the choice of calcineurin inhibitor is associated with the development of new malignancies in liver transplant patients. We also examined demographic and clinical variables associated with new malignancy development.

**Methods:** Data was obtained from The United Network for Organ Sharing (UNOS) on all liver transplants done from 1987-2005. To be included, patients must: 1) have been transplanted from 1995-2005, 2) be ≥ 18 years old at the time of transplant, 3) not have a history of malignancy or be found to have malignancy at the time of transplant, 4) not have received an organ from a donor with a history of malignancy, 5) have been discharged from the hospital on either cyclosporine (CSA) or tacrolimus, and 6) not have received a primary calcineurin inhibitor as their sole agent in the first 6 months post-transplant. Unadjusted hazard rates (HR) for each variable were obtained by entering them individually into a Cox proportional hazards (CPH) model. Statistically significant variables, as well as basic demographic variables, were then used to build a multivariate CPH model.

**Results:** 37,331 patients met criteria for inclusion. 24,433 (65%) were on CSA group. The most common non-cutaneous malignancies were non-Hodgkin’s lymphoma (614 cases), lung cancer (158 cases), and colorectal cancer (51 cases). After multivariate adjustment, there was no statistically significant difference in the hazard rate for developing a new malignancy for tacrolimus compared to CSA (HR 0.96, 95% CI: 0.84–1.09). Older age, male gender, and Caucasian race were independently associated with an increased hazard rate of malignancy. Clinical factors independently associated with a statistically significantly increased hazard rate for malignancy included alcohol-induced liver disease (HR 1.88, 95% CI: 1.59–2.20) or primary sclerosing cholangitis (HR 1.46, 95% CI: 1.18–1.78), and use of mycophenolate mofetil (HR 1.15, 95% CI: 1.02–1.29).

**Conclusions:** There is no significant difference in the hazard rate for developing a post-transplant malignancy among liver transplant patients receiving either a tacrolimus or CSA-based immunosuppressant regimen. After controlling for demographic variables, transplantation for alcohol-induced liver disease or primary sclerosing cholangitis and use of mycophenolate mofetil are associated with an increased hazard for new malignancy.

Molecular Epidemiology of Hepatitis C Infection in Liver Diseases in North India

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**Purpose:** Acute hepatitis C infection develops insidiously into chronic infection in 55% to 85% of cases. The present study aims to identify the risk factors for HCV infection; to measure HCV antibody prevalence in healthy blood donors; to identify Hepatitis C associated acute and chronic liver diseases by both HCV-RNA and anti-HCV antibody measurement; to assess for dual infections in the subsets of patients; and to characterize the HCV isolates.

**Methods:** A total of 711 consecutive acute and 1,186 chronic liver disease patients were studied over a period of 7 years. Sera samples from 3,504 voluntary blood donors were screened by anti-HCV antibody measurement. Demographic and clinical data including age, sex and risk factors for Hepatitis C infection were recorded. Patients with acute liver disease were divided into acute viral hepatitis (AVH) (N = 562) and Fulminant hepatic failure (FHF) (N = 149). Patients with chronic liver disease were subgrouped into cirrhosis (N = 876), chronic active hepatitis (CAH) (N = 288) and hepatocellular carcinoma (HCC) (N = 22). The sample were analyzed for HCV-RNA and anti-HCV antibody; HBsAg, anti-HBc, anti-HAV, and anti HEV antibody assay were done to assess coinfections. Genotyping of HCV RNA positive patients was done, wherever feasible.

**Results:** HCV infection was related to transfusion of blood products in 29% cases, intravenous drug abuse in 18% and tattooing in 8% cases. HCV antibody seropositivity was seen in 1.6% (56/3504) of blood donors. HCV-RNA was positive in 14.05% (79/562) of AVH cases. Anti-HCV antibody was positive in 33.3% (6/18) cases. In chronic liver disease, HCV was seen in 27.4% (240/876) cases of cirrhosis, 27.1% (78/288) cases of CAH and 18.2% (42/22) cases of HCC. The most common co-infection seen in 36.2% (87/240) cases of HCV related cirrhosis; in 37.2% (29/78) patients of HCV associated CAH and in 33.3% (2/6) cases of HCV related HCC. Genotype III was the most common genotype in studied population while 1b was the most common subtype seen.

**Conclusions:** The study highlights that hepatitis C infection is a significant problem in North India. The seroprevalence of 1.6% amongst voluntary blood donors represents a large overlooked reservoir of infection. HCV plays a definite role as sole agent in FHF cases. Genotype III is the most common genotype in the studied population.

Cost Effectiveness of Ultrasound Guided Liver Biopsy in the Management of Chronic Hepatitis C

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**Purpose:** Study was undertaken to determine if US guided liver biopsy is cost effective in the management CHC.

**Methods:** Forty-four patients, all HCV genotype 1 underwent US guided liver biopsy prior to being retreated with weight based Ribavirin and Pegylated Interferon. The Tenmo Coaxial Evolution System (Cardinal Health, McGaw, IL) and the HD 3000 Ultrasound (ATL, Bothell, WA) was used for all procedures. Patients with Grade 1 and 2 necroinflammation and Stage 1 and 2 fibrosis histologically were not to be retreated.

**Results:** The cost of therapy was calculated for the projected 48 weeks per patient based on published data of $1,294.99 per month for pegylated Interferon and $1632.98 for ribavirin. This cost is $35,136 per patient for 48 weeks. It does not include expenses that may be incurred for treating the side effects or complication of therapy. In our study population, projected total cost is on the order of $1,545,984.00 if all patients were retreated for 48 weeks. The projected cost of US guided biopsy was calculated as well based on actual ICD-9 generated reimbursement of $310.00 per patient. This calculated to be $13,640.00 in the absence of complications or side effects. The liver biopsy results showed that only four (4) patient, 9.9% had grade 3 or 4 inflammation and stage 3 or 4 fibrosis thereby requiring therapy. The projected cost of treating was calculated to be $14,054.00 for 48 weeks in the absence of complications or side effects. The projected theoretic saving for 48 weeks of retreatment in our study population without side effects or complication is on the order of $1,531,929.00 for drug cost.

**Conclusions:** The use of US guided liver biopsy is cost effective in the management of chronic hepatitis C patients who are being considered for retreatment.
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The Prevalence of Spur Cell Anemia in Hospitalized Cirrhotics and Its Relationship to Coagulation, Hemolysis and HDL Cholesterol

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Purpose: Spur Cell Anemia is often associated with severe liver disease and a poor prognosis. A two-step process involving acquisition of excess cholesterol within the red blood cell (RBC) membrane and subsequent splenic remodeling causing the characteristic acanthocyte shape has been proposed. Diminished hepatic production of high-density lipoprotein (HDL) in cirrhosis may lead to excess unesterified cholesterol available for RBC incorporation. The result is hemolysis producing anemia with an estimated prevalence of 5-10%. Few current studies characterize the prevalence, degree of hemolysis, effect on coagulation parameters and the level of HDL as an indicator of cholesterol esterification.

Methods: Thirty-three consecutive hospitalized patients underwent evaluation including hemoglobin, fasting lipid panel, liver chemistry, reticulocyte count, haptoglobin, lactate dehydrogenase and International Normalized Ratio. A blinded hematologist examined each patient’s peripheral smear. Comparison of the mean between those with and 2+ spur cells, defined as greater than 9 spur cells per high power oil emersion field was then performed.

Results: One-third of all patients had at least one spur cell, 15% had at least 2+. Mean hemoglobin and HDL was not significantly different. Those with 2+ spur cells had greater prolongation of INR, 2.26 vs. 1.83 (p < 0.05), lower Haptoglobin; 11.56 mg/dl vs. 74.56 mg/dl (p < 0.05), higher Reticulocyte percentage; 5.22 vs. 3.15 (p < 0.05) and higher unconjugated bilirubin level; 6.32 mg/dl vs. 3.13 mg/dl (p < 0.05). The Model for End Stage Liver Disease Score was higher in those with 2+ spur cells; 26.4 vs. 22.9 (p < 0.05).

Conclusions: Our findings suggest that Spur Cell Anemia is commonly under-diagnosed. There was no significant difference in HDL cholesterol in those with marked spur cell formation, suggesting that these two pathways are independent and that development of spur cells may reflect primarily splenic remodeling. Elevation of markers of hemolysis further supports a poor prognosis. A two-step process involving acquisition of excess cholesterol within the red blood cell (RBC) membrane and subsequent splenic remodeling causing the characteristic acanthocyte shape has been proposed.

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Fas and TNF-α Mediated Apoptosis and TNF-α Gene Polymorphism in Fulminant Hepatic Failure and Its Clinical Relevance

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Purpose: To elucidate relevance of Fas & TNF-α systems and TNF-α gene polymorphisms in fulminant hepatic failure (FH) and possible prognostic implications.

Methods: Study included 37 cases of FH, 45 cases of Acute Hepatitis (AH) and 60 healthy controls. In addition to routine investigations, soluble Fas Ligand (sFasL) and TNF-α values were determined by ELISA kits, at admission and at death or recovery in FH. Liver biopsy was obtained from 12 FH patients who died, after obtaining consent for: immunohistochemistry using Antibody to Human Fas and Human TNF Receptor 1 (TNF R1). TNF-α gene promoter polymorphisms at -238 (G/A), -308 (G/A), -857 (C/T) and -863 (C/A) positions were studied using PCR-RFLP.

Results: FH cases were divided into 2 groups: FH-E, expired (N = 23) and FH-S (N = 14), survivors. Mean sFasL and TNF-α levels at admission were higher in FH than AH but significant difference was not found between FH-E and FH-S, though FH-E group had higher values. FH-E cases, had higher than baseline sFasL and TNF-α levels at death; while FH-S cases showed either lower or similar levels as found at admission. Immunostaining revealed high expression of Fas and TNF R1, more in cytoplasm of apoptotic hepatocytes than viable swollen hepatocytes and the expression correlated with apoptosis as well as extent of hepatocyte destruction.

No association between the genotype and susceptibility to FH was evident, however carrier genotypes in relation to -308 & -857 positions were found to be associated with susceptibility to AH. The percentage of genotypes associated with high TNF-α production; either carrier genotypes -308 (GA/AA) and -857 (CT/TT) or wild genotype -863 (CC), was highest in AH group followed by FH group and were lowest in controls.

Conclusions: Serum TNF-α and sFasL levels are significantly higher in FH group than AH, but do not seem to predict mortality; rather serial measurements of these cytokines can be useful in this regard. High TNF-α producer genotypes definitely increase the risk of developing acute hepatitis; but out of these who have still higher TNF-α production rates than others limit the hepatic injury by sustaining the viral proliferation, while the others probably enter a vicious cycle leading to progressive hepatic injury. This could probably help in predicting FH in AH cases.

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Incidental Finding of Hepatic Hydatid Cyst

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Purpose: Cystic Echinococcosis is a rare disease in the United States and in endemic regions of the world, the incidence ranges from an incidence of 1 to 220 per 100,000. There is no consistent prodrmal symptomatology. Symptoms are most often related to the mass effect of the cysts in the liver, lung, or other tissue sites.

Methods: We present the case of a 55 year old Indian immigrant male with no significant past medical history except for a left inguinal hernia repair with mesh in 2004, a 60 pack year smoking history, and gastroesophageal reflux disease. A year after his hernia surgery, the patient had chronic post operative pain as well as erythema.

Results: During the workup of the groin area, a CT scan of the abdomen and pelvis was ordered and a cystic mass in the left lobe of the liver involving both the stomach and GE junction was incidentally noted. Serology was positive for echinococcal disease. The patient later received Albendazole and underwent liver resection. The patient tolerated the procedure and had an uneventful recovery.

Conclusions: Although extremely rare, hydatid liver cysts in the United States are increasing in frequency. Unlike our patient, the majority of cases reported in the literature present with symptoms, with less than 10% of patients asymptomatic on presentation.

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Does Hepatitis E Viral Load and Genotypes Influence the Final Outcome of Acute Liver Failure during Pregnancy

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Purpose: HEV is a small, non-enveloped, single–stranded positive sense RNA molecule approximately 7.5 Kb in length. The genome is organized into 3 separate but overlapping open reading frames ORF1, ORF2 & ORF3.
and is grouped into seven different genotypes. It is transmitted through fecal contaminated drinking water. The incidence and mortality rate in case of pregnant women with fulminant hepatic failure has been reported to be significantly higher specifically in Asian women. Indian pregnant women generally suffer from folate deficiency, which is known to cause reduced immunocompetence leading to increased risk of multiple viral infections and higher viral load.

To correlate and analyze the viral load and genotypes of Hepatitis E in acute liver failure patients during pregnancy.

**Methods:** A total of 100 FHF patients were included in the study, 50 were pregnant and 50 non pregnant. These cases were evaluated on the basis of history, clinical examination, liver function profile and serological test of HEV infection [IgM anti HEV (Genelabs Diagnostics, Singapore) using commercially available Elisa kits]. In all the HEV RNA positive cases viral load and genotyping was done by Real Time PCR and direct sequencing.

**Results:** Out of the 100 FHF patients, 28 (56%) pregnant and 8 (16%) non-pregnant women were HEV RNA positive. HEV viral load was higher in pregnant (5.87 × 10^7 ± 1.5 × 10^7 IU/ml) FHF patients as compared to the non–pregnant (199.2 ± 225.5 IU/ml) ones. Sequencing data showed that only one genotype, type 1 is prevalent throughout the country.

**Conclusions:** HEV infection was found to be significantly higher (p < 0.001) in pregnant FHF patients than that in non pregnant. Pregnancy appears to be a risk factor for viral replication since the viral was found to be more in pregnant FHF patients, which could be the reason for higher mortality in these patients. The genotype was found to be similar in both FHF pregnant and non-pregnant therefore strain variations can not be held responsible for vastly different clinical outcomes.

### Endoscopic Treatment of Biliary Strictures after Liver Transplantation. Location Makes a Difference

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**Purpose:** Biliary strictures after liver transplantation are frequent. The long-term and predictive factors of response to endoscopic treatment are not well known. The aim of this study was to demonstrate the role of endoscopic treatment, predictive factors of response, as well as long-term outcome in patients with biliary stricture after liver transplantation.

**Methods:** The study population included consecutive post-liver transplantation patients who underwent endoscopic retrograde cholangiography in our center during the period from October of 2001 to May 2006. Review of all reports from endoscopic procedures was performed. Clinical follow-up was obtained from the regular follow-up at post-liver transplant clinic.

**Results:** Twenty two from forty three patients referred for endoscopic retrograde cholangiography had biliary stricture. Sixteen patients (72%) had stricture at the area of the anastomosis and six had non-anastomotic biliary strictures. A total of 66 ERCP were performed with an average of three per patient. Balloon dilatation with or without 1-3 stent placement was performed in all cases. Overall 14 patients (64%) responded to endoscopic management. Two patient required surgery after initial response. Six patients lost the follow-up. One patient underwent unsuccessful ERCP and required percutaneous approach. Four patients (18%) died with persistent cholestasis despite endoscopic treatment. There was a significant difference in the response to endoscopic treatment in patient with anastomotic stricture versus patient with non-anastomotic stricture 13/16 (81.2%) vs 1/5 (20%) p: 0.024.

**Conclusions:** In our experience, endoscopic treatment of anastomotic biliary strictures is highly effective with a good long-term outcome. The presence of non-anastomotic strictures should be considered a factor for poor response to endoscopic management.

### Nutritional Effects of Transjugular Intrahepatic Portosystemic Shunt–An Often Neglected Benefit?

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**Purpose:** Transjugular Intrahepatic Portosystemic Shunt (TIPS) is a useful procedure offered to patients with advanced liver disease presenting with
Post-Infantile Giant Cell Hepatitis: Is It a Specific Disease?
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Purpose: Giant cell hepatitis (GCH), defined by the presence of multinucleated hepatocytes, is well known in children but rare in adults. The etiology and pathogenesis are still unclear, clinical course may be poor. Until today mainly case reports have been published, however. Aim: to analyse a cohort of patients with special attention to possible causative agents and outcome.

Methods: Retrospective analysis of patients with post-infantile GCH from the past 15 years. Included were biopsies from patients above 20 years with at least two synechial giant cells showing at least four nuclei in liver biopsy (each reviewed by two expert liver pathologists). Clinical records were reviewed. Patients with a follow-up of less than 6 months were excluded.

Results: We included 25 of 46 patients (mean 47 yrs, range 25–75), 11 men, 14 women. Most patients presented with a mixed cholestatic-cytolytic pattern: Bilirubin 15 × ALT 17 ×, GGT 6 × upper limit of normal. Serologic studies showed in 6 patients (24%) signs of acute viral infection (3 HAV, 1 HIV, 1 Rubeoviral, 1 HSV, 1 RSV + Paramyxovirus) and in 10 patients elevated autoantibodies (ANA 50%, SMA 30%, ANCA 28%, Anti-ds-DNA 6%, Anti-ASGP-R 6%, Anti-SLA 6%). One patient had a rheumatoid arthritis and 4 primary sclerosing cholangitis. In 7 possible causative drugs were identified. In 5 no cause was found. Histology showed in 12 patients acute, and chronic liver disease quality of life index symptoms score were measured at baseline and three-six months later.

Conclusions: Preliminary results of this study suggest potential nutritional benefits of TIPS. Multicenter randomized trials are warranted to further validate this clinical observation.

Free Leptin Index in a State of High Insulin Resistance and Advanced Fibrosis in NASH/Davis Medical Center, Sacramento, CA; Department of Surgery: Department of Pathology and Department of Endocrinology.

Purpose: Soluble leptin receptor (SLR) serves as a major leptin binding protein, but the SLR and the free leptin index (FLI) have not been studied yet in humans with nonalcoholic fatty liver disease (NAFLD) or nonalcoholic steatohepatitis (NASH). Since the measured leptin in the previous studies

Complications of portal hypertension namely recurrent ascites and variceal bleeding. Nutritional effects of TIPS have been described, but not prospectively studied to our knowledge.

Methods: We prospectively studied the nutritional effects of TIPS in cirrhotic patients. An institutional review board approved the study protocol. The indications for TIPS were diuretic resistant ascites or variceal bleeding. Patients with hepatocellular carcinoma, uncontrolled diabetes, chronic renal failure or malabsorption syndromes were excluded from the study. Informed consent was obtained. Nutritional parameters including body mass index (BMI), anthropometric measurements, laboratory parameters and chronic liver disease quality of life index symptoms score were measured at baseline and three-six months later.

Results: Twelve patients (6 male, 6 female; mean age 54) were enrolled between March 2002–June 2004. Mean baseline Model for End Stage Liver Disease (MELD) score was 13. Two patients (17%) died within 3 months of TIPS placement due to worsening liver function. One patient was lost to follow-up. Four patients had undergone an orthotopic liver transplant and therefore were unable to complete the study. Only six out of twelve patients were able to complete the study over three months. The results show an increase in BMI from 22 to 25. From anthropometric measurements the estimated muscle mass improved from 16.6 to 20.4, while the estimated percentage of fat diminished slightly from 14 to 13.85. Mean serum albumin improved from 2.5 to 2.65. Chronic liver disease quality of life index symptoms score from improved mean of 103 to 150. Only estimated muscle mass and chronic liver disease quality of life index symptoms reached statistical significance (p < 0.05).

Conclusions: All 4 patients with PSC had a chronic course, all 7 patients with medication induced GCH seem to be an unspecific reaction of the liver to different noxious stimuli (viruses, medication, autoimmune disorders). The stimulus seems to define the clinical course. PSC possibly predisposes to GCH. The prognosis of medication induced GCH seems to be good. Because of the heterogeneity of etiologies a specific therapeutic approach cannot be recommended. Efforts must be taken to identify a causative agent.

Effectiveness of Peginterferon and Ribavirin in Naive Patients with Chronic Hepatitis C in Clinical Practice
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Purpose: Data from clinical trials and from referral centers can not be translated into effectiveness in clinical practice. The aims of this study are to determine a) the rate of sustained virological response (SVR), b) co-morbidities, c) dose reduction and discontinuation of therapy in a cohort of naive chronic hepatitis C pts treated with peginterferon (PEG-IFN) and ribavirin (RIBA) in two non referral hospitals.

Methods: The clinical records of 183 consecutive chronic hepatitis C pts (113 men; mean age 49 ± 12) treated between 2002-2004 were reviewed. All pts had elevated ALT activity for at least 6 months and tested positive for anti HCV antibody and HCV RNA. A SVR was defined as clearance of circulating HCV RNA at 6-months post-treatment. All pts with HCV-1/4 (N = 84), HCV-2 (N = 64), or HCV-3 (N = 35) were treated with PEG-FN (alfa-2a 180 microgr/wk or alfa-2b 1.5 microgr/kg/wk) plus RIBA (800–1200 mg). All pts with genotype 1 or 4 were offered 12 months of therapy. Pts with genotype 2 or 3 were treated for 6 months. All pts were caucasions.

Results: Liver biopsy was done in 163/183 (90%) pts and cirrhosis (isshak stage 5–6) was present in 37/165 (22.4%). The non-biopsied pts did not show clinical, ultrasound and/or biochemical evidence of cirrhosis. SVR rates were 40.7% in HCV-1–4 pts, 90.6% in HCV-2 pts and 71.4% in HCV-3 pts, respectively. Comorbidities were found in 44/183 (24%) pts. The most common comorbidities were: diabetes in 15/44 (34%) pts and hypertension in 23/44 (52.2%) pts. Anemia was the major cause for dose reduction in 15/18 (83.3%) pts (all with a fall in haemoglobin level to < 10 g/dl attributable to hemolysis). Treatment was stopped in 16 pts: in 11/16 (68.8%) for adverse events (severe hypo-hyperthyroidism, severe anemia, depression or fatigue) and in 5/16 (31.2%) for refusal.

Conclusions: In clinical practice the combination of PEG-IFN and RIBA produces SVR rates, in naive chronic hepatitis C pts, comparable to those achieved in pts enrolled in RCTs, despite the presence of comorbidities and cirrhosis in 25% of treated. The outcome for genotype 2 HCV was higher (90.6%) than in pivotal registration and recent studies. The overall incidence of adverse events leading to withdrawal or dosage modification was lower in our patients than incidence reported from large international studies. Antiviral therapy is effective in a clinic setting outside of clinical trials and tertiary centers.

Free Leptin Index in a State of High Insulin Resistance and Advanced Fibrosis in NAFLD/NASH
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Purpose: Soluble leptin receptor (SLR) serves as a major leptin binding protein, but the SLR and the free leptin index (FLI) have not been studied yet in humans with nonalcoholic fatty liver disease (NAFLD) or nonalcoholic steatohepatitis (NASH). Since the measured leptin in the previous studies
Methods: Sixty-one patients who were listed for bariatric surgery were enrolled in this cohort study. Data including demographics and risk factors for the metabolic syndrome (BMI, diabetes mellitus type 2 (DM2), hypertension, and lipid profile) were obtained. Fasting blood was drawn at 1100h preoperatively, and the EDTA-plasma was analyzed for glucose, insulin, total leptin, and SLR. All patients had preoperative liver biopsies read by a hepatopathologist.

Results: Of 61 patients, 39 patients had sufficient liver specimens (size > 1.5 cm and > 10 portal tracts) and their serum was collected appropriately. Their demographics were: 10 male, 29 female and mean ages of 44.9 ± 1.5. Their mean BMI was 45.7 ± 0.9. Twenty patients had hypertension, 14 had DM2, and 20 had hyperlipidemia. Thirty-six of 39 had various degrees of steatosis: 5 had less than 10%, 15 had 10-29%, 13 had 30-60%, and 3 had greater than 60%. According to Brunt’s scoring system, 14 patients had grade 0, 20 had grade 1, and 2 had grade 2 NASH. Twenty-five had stage 0, 8 had stage 1 and 3 had stage 3 fibrosis. Spearman correlation with two-tailed test showed that FLI was negatively correlated with advanced fibrosis (stage > = 3) \((p = 0.007)\), Homeostasis Model Assessment (HOMA) score \((p < 0.001)\) and DM2 \((p = 0.003)\). In contrast, SLR was positively correlated with HOMA score \((p < 0.001)\). NASH grading was not significantly correlated with SLR or FLI. Serum total leptin was positively correlated with the BMI \((p = 0.006)\).

Conclusions: Serum total leptin is increased in obesity, but the state of insulin resistance may promote high levels of SLR thus decreasing the amount of serum free leptin. The low free leptin index seen in advanced fibrosis in NASH in this population is a novel finding and needs validation with larger studies.

Purpose: Clinical results regarding consensus interferon monotherapy are limited. The aim of this study was to evaluate the efficacy and safety of that treatment.

Methods: A total of 31 patients with chronic hepatitis C were enrolled. Of these, 28 had never been treated with interferon therapy, while 3 had received such treatment previously. The HCV genotype was 1b in 15 patients and 2a/2b in 16. A high viral load (more than 100 KIU/ml) was found in 26 patients in pretreatment examinations, while a low viral load (less than 100 KIU/ml) was found in 5. The patients were administered consensus interferon at 12 or 18 M IU once a day for 14 days in succession, then 12 or 18 M IU thereafter thrice a week for 22 weeks. At 24 weeks after the end of treatment, HCV-RNA was measured to determine the sustained virological response (SVR). Analysis was performed after categorizing patients with the 1b genotype and high viral load at the end of therapy into the 1b-High group and all others into the Others group.

Results: Among the 31 patients, 7 patients currently receiving treatment were excluded from evaluation, thus 24 were evaluated on an intention-to-treat (ITT) basis and 21 patients on a per-protocol-set (PPS) basis, after excluding 3 patients who did not finish the protocol. The SVR ratio in the ITT analysis was 70.1%, while it was 81.0% in the PPS analysis. The SVR ratios for the 1b-High group in the ITT and PPS analyses were 40.0% and 57.7%, respectively. All patients in the 1b-High group who accomplished SVR had a viral load of less than 300 KIU/ml at pretreatment. As for the Others group, the SVR ratios in the ITT and PPS analyses were 92.3% and 90.9%, respectively, and pretreatment viral load had no influence on SVR. No harmful effects of therapy were noted in any of the patients.

Conclusions: The efficacy of consensus interferon monotherapy for chronic hepatitis C was satisfactory, especially in patients with a pretreatment viral load lower than 300 KIU/ml. Further, no severe side effects were observed.

Hepatitis B Virus Genotypes in Saudi Arabia
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Purpose: Hepatitis B virus (HBV) infection has a wide spectrum of liver diseases, ranging from acute or fulminant hepatitis, chronic hepatitis, and cirrhosis to hepatocellular carcinoma. Recently, HBV genotypes have attracted increasing attention as they may affect the disease progression and outcomes of HBV related chronic liver disease, as well as to response to antiviral therapies. It has been reported that different hepatitis B virus (HBV) genotypes has distinct geographic distribution. Genotype A is prevalent in northern and central Europe, but it is also common in North America and sub Saharan Africa. Genotypes B and C are confined to Asia. Genotype D is widespread, but it is the predominant genotype in the Mediterranean region, while genotype E is found mainly in West Africa. Genotype F shows the highest divergence among the genotypes and is indigenous to aboriginal population of the America. The newly described genotype G has been found in USA and France. We aimed to study the prevalence of HBV genotypes in Saudi Arabia since there are no published data as well as to look for any association between different HBV genotypes with Alanine aminotransferases (ALT), Hepatitis B surface antigen (HBsAg), Hepatitis B e antigen (HBcAg) and HBV viral load.

Methods: Between January 2004 to December 2005, 912 HBV PCR positive sera were collected from Saudi patients and from this pool fifty-eight samples were selected randomly for HBV genotyping by INNO-LIPA (a line probe assay). Association between genotypes and HBsAg, HBcAg, ALT and viral load were tested using chi square test using SPSS version 11.

Results: Their mean age was 38.9 years (range 5-73 years) and 44 (76%) of them were male. Out of the 58 patients tested for HBV genotyping, 50 (86.2%) were HBV genotype D; three were genotype A (5.2%), three genotype E and two (3.4%) genotype A/D (mixed). There was no association between genotypes with ALT, HBsAg, HBcAg and viral load \((p > 0.05)\). Hepatitis B virus genotype D was found to be the commonest genotype prevalent in Kingdom of Saudi Arabia and there was no significant association between different HBV genotypes with ALT, HBsAg, HBcAg or viral load. HBV genotype E was detected in small percentage of cases.

Hepatic Infarct after Placement of a Transjugular Intrahepatic Portosystemic Shunt (TIPS)
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Purpose: Hepatic infarct is rare because of liver’s dual blood supply. It may occur due to a hypercoagulable state, hepatic artery aneurysms, tumor embolization, sickle cell crisis, vasculitis or inadvertent hepatic artery ligation. We describe a rare case of a TIPS-related hepatic infarct.
Methods: A 58-year-old woman with diabetes mellitus and cirrhosis related to NASH was admitted for recurrent GI bleeds from esophageal varices. Repeated treatments with endoscopic band ligation were unsuccessful and a TIPS was placed in the right hepatic vein with no immediate complications. On the day of TIPS, she had normal vital signs. Her abdomen was soft. Serum AST was 35, ALT 24, ALP 163 U/L, bilirubin 3 mg/dL, WBC 3,900/mm3, hemoglobin 7.1 gm/dL and hematocrit 25.4. Her platelets were 78,000 and PT 16 seconds. Porto-systemic gradient was 25 mm Hg. She was transfused with packed red cells and FFP.

Results: Few hours after discharge she presented to the ER with severe RUQ pain and fever. WBC was 16,000, AST 568 and ALT 789U/L. CT of abdomen revealed a wedge-shaped hepatic lucency (Figure 1) compatible with an infarct. The shunt was patent on Doppler Ultrasonography. She was observed closely in the ICU, given antibiotics, analgesics, and showed rapid clinical improvement. Her serum aminotransferases decreased to normal. She was discharged seven days later in stable condition. Follow up CT two months later (Figure 2) revealed almost complete resolution of the hepatic infarct.

Conclusions: Hepatic infarcts may complicate TIPS placement and may present with fever, leukocytosis, and elevation of serum aminotransferase levels. This case illustrates the presentation, natural history and potential reversibility of this rare complication and should be included in the differential diagnosis of abdominal pain, fever and abnormal hepatic biochemical tests following TIPS placement. [figure1] [figure2]

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Prevalence and Influence of Occult Hepatitis B Infection in Patients with Chronic Hepatitis C in Okinawa

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Purpose: Occult hepatitis B virus infection is defined by the presence of HBV-DNA in the patients’ serum without hepatitis B surface antigen (HBsAg). Recently, occult HBV infection is reported one of precipitating factors of chronic hepatitis C; however, the details is still remains unknown. We investigate the prevalence and the influence of occult HBV infection among patients with hepatitis C, especially patients who received interferon (IFN) treatment.

Methods: We retrospectively reviewed data on patients with hepatitis C who admitted to our hospital from 1993 to 1998. HBs surface antigen, anti HBs antibody, anti HBe antibody, and anti HCV antibody were measured by EIA and/or RIA assay. HBV-DNA was measured by PCR. Samples were stored at -16 C until assayed. As a IFN treatment for chronic hepatitis C, we performed Japanese standard protocol (IFN alpha 2b 300-600MU IM, every day for 2 weeks and 3 times/week for 22 weeks). Sustained viral response (SVR) is defined that HCV-RNA is negative more than 3 months after the end of treatment. The results were analyzed using χ2 test.

Results: During this period, there were 56 patients with chronic hepatitis C. Of them, 9 patients were HBV-DNA positive (16%). Among them, 1 patient was anti HBs antibody positive and remaining 8 patients were anti HBs antibody negative. There were no significant difference in sex (M/F, 24/24; 5/4), and age (mean ± DS, 57 ± 13, 58 ± 15) between HCV without HBV-DNA and HCV with HBV-DNA (occult HBV). Thirty one patients received IFN treatment used Japanese standard protocol. Of them, 24 patients were chronic hepatitis C without HBV-DNA and 7 patients were chronic hepatitis C with HBV-DNA positive (occult HBV infection). There were no significant difference in sex (M/F, 9/15; 4/3), and age (mean ± DS, 50.8 ± 10, 50.2 ± 7), and HCV genotype (1b: others, 16.8: 4.3) between HCV without HBV-DNA and HCV with HBV-DNA (occult HBV). After treatment, 6 (25%) patients of HCV without HBV-DNA and none of HCV with HBV-DNA (occult HBV) acquired SVR status, respectively. There was significant difference in the effect of IFN treatment between both groups (p <0.005).

Conclusions: Occult HBV infection was found 16% in patients with chronic hepatitis C in Okinawa. Effect of IFN treatment may be decreased in patients with occult HBV infection. Prevalence of HBV infection in general population was different in the world. So, in endemic area, occult HBV infection may be considered as one of precipitating factors for chronic hepatitis C.

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Prevalence of TT Virus Infection in Voluntary Blood Donors and Patients on Maintenance Hemodialysis in Tabriz, Iran


Purpose: Transfusion Transmitted virus (TTV) is a novel DNA virus that is associated with posttransfusion hepatitis. We investigated the prevalence of TTV and its role on liver disease in voluntary blood donors and patients on maintenance hemodialysis.

Methods: This cross-sectional study was conducted in March and April 2005. We tested 407 voluntary blood donors and 324 chronic hemodialysis (HD) patients in Tabriz, northwestern part of Iran, for the presence of TTV. Demographic and clinical data were registered. TTV DNA was detected using semi-nested polymerase chain reaction (PCR). Serum levels of alanine aminotransferase (ALT) and aspartate aminotransferase (AST) were also
measured. In addition, hepatitis B surface antigen (HbsAg), anti-hepatitis C virus (HCV), hepatitis E virus antibody, and anti-HIV were previously determined in all patients.

**Results:** The positive rate of TTV was 9.3% (95% CI: 6.1%-12.5%) in 324 patients on maintenance hemodialysis and 2.7% (95% CI: 1.1%-4.3%) in 407 cases of voluntary blood donors (p < 0.001). The prevalence rate of HBV, HCV and HEV infection were 4.6%, 20.4%, and 7.4%, respectively among HD patients. In voluntary blood donors the prevalence rate of HBV, HCV and HEV infection were 1.2%, 0.5% and 7.6%, respectively. All patients were negative for anti-HIV antibody. No relations were found between TTV infection and elevated levels of ALT or AST. Sex, mean duration of HD, history of transplantation, history of blood transfusion, and positive markers for either hepatitis B virus, hepatitis C virus or hepatitis E virus did not differ between TTV DNA positive and negative HD patients in both groups. In HD group, the presence of TTV DNA was found to be related to the age of the patients. TTV-positive patients were significantly younger than TTV-negative patients (p <0.018).

**Conclusions:** TTV infection was more prevalent in Iranian patients on regular HD than voluntary blood donors. No clinical significance of TTV virus could be elicited in both groups; neither it showed any clinical impact as a co-infection with other blood borne infections. Whether blood transfusions increase the risk of TTV infection was not revealed by this study. Our data did not show that when TTV alone is present it induces liver function tests alteration. However, in TTV-positive patients, long-term follow-up is necessary to clarify the effects of TTV on liver function.

**Hepatitis C, Metabolic Syndrome, and Inflammatory Markers: Results from the Third National Health and Nutrition Examination Survey [NHANES III]**

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**Purpose:** Studies have shown that hepatitis C (HCV) is associated with type 2 diabetes mellitus possibly due to insulin resistance and inflammation. Metabolic syndrome is a risk factor for type 2 diabetes mellitus. Our objectives were to assess the relationship between HCV and metabolic syndrome and inflammatory markers.

**Methods:** We used data from The Third National Health Nutrition and Examination Survey (NHANES-III). We excluded pregnant women, subjects with diabetes, those taking non-steroidal anti-inflammatory drugs, and those diagnosed with concomitant infection. We analyzed the data controlling for demographic variables, body mass index, use of contraceptives, had arthritis, and had gout.

**Results:** Among the 10,383 subjects, 2.3% had HCV and 16.7% had metabolic syndrome using the ATP III criteria. After controlling for the founders, HCV was not associated with metabolic syndrome but associated with HOMA insulin resistance and inflammatory marker ferritin. Among subjects with both HCV and metabolic syndrome, the adjusted HOMA insulin level was higher than those without HCV and metabolic syndrome. In addition, the serum ferritin level was a strong predictor of HOMA insulin resistance.

**Conclusions:** In clinical practice, serum ferritin can be obtained along with routine blood tests in any laboratory, and it has the potential to be a surrogate marker of insulin resistance in people with HCV and metabolic syndrome.

**Jaundice in African American and Hispanic Patients with Acquired Immunodeficiency Syndrome (AIDS)**

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**Purpose:** Although abnormalities in hepatic biochemical tests are common in patients with AIDS, overt jaundice is rather infrequent. The purpose of this study was to determine the etiology of jaundice in patients diagnosed with AIDS in our patient population.

**Methods:** Retrospective review of medical records of patients diagnosed with human immunodeficiency virus (HIV) infection and liver test abnormalities, over ten year period. Data were abstracted for demography, laboratory tests, abdominal ultrasonography (US), computerized tomography (CT), endoscopic retrograde cholangiopancreatography (ERCP), percutaneous transhepatic cholangiography (PTC), and liver biopsy results, and analyzed.

**Results:** Of 1,238 patients with abnormal liver chemistry and HIV infection, 1,040 (84%) had AIDS. Of 1,040 AIDS patients, 102 (10%) had jaundice (serum bilirubin > 3 mg/dL). Of 198 HIV positive patients (without AIDS) with abnormal liver chemistry none had jaundice. The common causes of jaundice were drugs (29%) and infections (28%). Liver biopsy was performed in 20 AIDS patients and the common findings were Mycobacterium avium complex (25%), Kaposi's sarcoma (25%), and drug induced hepatitis (20%). Of 102 patients with jaundice, 29 (28%) died during the hospital admission. Of the 29 deceased patients, 24 (83%) had CD4 count <50 cells/μL. Liver tests were not performed in this study. Liver associated enzymes abnormality was common amongst our patients with AIDS, however jaundice was infrequent and was associated with a high mortality in patients with CD4 count < 50 cells/μL. Drugs and infections are common culprits, and clinicians should have a high index of suspicion and low threshold for work-up and intervention to detect treatable conditions early with a hope to improve prognosis.

**Effect of Roux-en-Y Gastric Bypass (RYGB) on Clinical and Laboratory Data in Morbidly Obese Patients**

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**Purpose:** Roux-en-Y Gastric Bypass (RYGB) is the most common and effective procedure performed in the US for surgical treatment of obesity. The likelihood of having non-alcoholic fatty liver disease (NAFLD) is directly proportional to body weight[1]. NAFLD is being increasingly recognized as a major cause of liver-related morbidity and mortality. Given the increasing prevalence of obesity in North America, NAFLD is an important public health problem. The aim of this study is to determine the incidence of NAFLD in patients who underwent RYGB and to determine the effect of RYGB in a subgroup with abnormal liver tests (which include ALT, AST, alkaline phosphatase and bilirubin).

**Methods:** 400 consecutive patients who underwent RYBP were evaluated retrospectively. Only those who underwent random intra-operative liver biopsy were included. Patients with viral or autoimmune hepatitis, hemochromatosis or alcohol use (>20g/day) were excluded. Pathological analysis recorded the presence and degree of steatosis, portal and lobular inflammation, and ballooning. Preoperative and 6–8 month postoperative clinical and laboratory data was gathered which included age, BMI, AST, ALT, alkaline phosphatase (AP) and bilirubin. Paired t-test was used to compare these variables pre and post operatively.

**Results:** 205 patients were included in the study. 86.3% were female. The mean age was 36.8 ± 10.1 years. The mean BMI was 48.7 ± 7.4 kg/m², 90.7% had NAFLD as proven by liver biopsy. All the patients with normal liver biopsy had normal liver tests. 25.9% of patients with NAFLD had abnormal normal liver tests prior to RYGB. Of these patients with abnormal liver tests, 24.5% had abnormal AST, 38.9% had abnormal ALT, 71.7% had abnormal AP and 9.4% had abnormal bilirubin. There was significant improvement of ALT (p = <0.001), AP (p = <0.001) and bilirubin (p = 0.003) after adjusting for the decrease in BMI postoperatively.

**Conclusions:** Our study reiterates that NAFLD is highly prevalent in morbidly obese patients. About one-fourth of morbidly obese patients have
abnormal liver tests. Significant improvement of ALT, alkaline phosphatase and bilirubin was noted after bariatric surgery.

REFERENCE

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Does the Non-Alcoholic Fatty Liver Disease (NAFLD) Activity Score Correlate with Clinical and Laboratory Data in Morbidly Obese Patients?
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Purpose: Nonalcoholic fatty liver disease (NAFLD) is being increasingly recognized as a major cause of liver-related morbidity and mortality. The likelihood of having NAFLD is directly proportional to body weight. Many scoring systems have been applied for the grading and staging of NAFLD. The Pathology Subcommittee of National Institute of Diabetes and Digestive and Kidney Diseases designed and validated a histological scoring system that addresses the full spectrum of NAFLD and proposed a NAFLD activity score (NAS). NAS, which specifically includes features of active liver injury by Kleiner et al. is defined as the unweighted sum of scores for steatosis (0-3), lobular inflammation (0-3) and ballooning (0-2); thus ranging from 0 to 8. There have been no prior studies correlating NAS to clinical and laboratory data. The aim of this study is to correlate liver injury as assessed by NAS to clinical and laboratory data in patients who underwent RYGB as obesity treatment.

Methods: 400 consecutive patients who underwent RYGB were evaluated retrospectively. Only those who underwent random intra-operative liver biopsy were included. Patients with viral or autoimmune hepatitis, hemochromatosis or alcohol use (> 20g/day) were excluded. Pathological analysis recorded the presence and degree of steatosis, portal and lobular inflammation, and ballooning for NAS calculation. Preoperative clinical and laboratory data was gathered which included age, BMI, AST, ALT, alkaline phosphatase (AP), total cholesterol (TC) and fasting triglycerides (TG).
ANOVAs and Pearson correlation were used to correlate these variables to the NAS.

Results: 205 patients were included in the study. 86.3% were female. The mean age was 36.8 years. The mean BMI was 48.7 kg/m². 9.3% had NAS = 0, 69.8% had NAS = 1 – 2, 17.1% had NAS = 3-4 and 3.9% had NAS > 4. Steatosis was the greatest numerical contributor to the NAS. Men had a higher mean NAS after adjusting for BMI (p = 0.011). BMI (adjusted for sex), TG, AST and ALT correlated with the severity of NAS (p-values = 0.031, 0.007, 0.023, 0.003 respectively). However, NAS severity did not significantly correlate with age and TC.

Conclusions: NAFLD is highly prevalent in morbidly obese patients. There was close association of BMI, AST, ALT and TG with the severity of NAS.

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Correlation of MELD Scoring to Portal Hypertensive Changes among Patients Undergoing Orthotopic Liver Transplantation
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Purpose: MELD score is an established prognostic marker to follow the progression of liver failure among patients awaiting liver transplantation. MELD score includes parameters to assess synthetic and excretory functions of the liver, but does not reflect vascular changes induced by portal hypertension. To investigate a potential correlation between MELD score changes among cirrhotic patients and portal hypertensive changes noted during an upper endoscopic evaluation.

Methods: MELD scores of all transplanted cirrhotic patients between February 2002 and October 2005, were retrospectively analyzed. Pediatric patients and post TIPS patients were excluded. MELD scores were computed from initial presentation for transplant workup and final MELD at the time of transplant. The difference (delta MELD) was correlated to endoscopic features.

Results: Total of 146 patients with advanced cirrhosis were included. There were 74 females with age range 19-73 and 72 males with age range of 26– 68 years.
1. Grouping MELD scores into less than 15 and 15 or more, found no significant difference in varices or portal hypertension levels using t-tests.
2. Grouping varices and portal hypertension into present/absent categories versus MELD score and delta MELD found no statistical difference using t-tests.
3. Neither MELD score or delta MELD is correlated with portal hypertension and esophageal varices using Chi-square or Pearson product moment coefficient.

Conclusions: Retrospective analysis of MELD score or delta MELD versus presence of portal hypertension grade by endoscopy, indicated MELD has no predictive value in portal hypertensive changes. Our evidence also does not support using clinical MELD score or delta MELD to predict the extent of portal hypertensive mucosal and/or vascular abnormalities seen in end stage liver disease by endoscopic exam.
Since upper GI bleeding also contributes to mortality; an endoscopic scoring system is proposed to be developed for more accurate assessment and staging of liver cirrhosis prior to liver transplant listing, in addition to current MELD scoring system.

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Outcomes after Liver Transplant in Patients with Autoimmune Liver Disease: A Single Center Experience
Kaveh Sharzehi, Mary Ann H. Sherbondy. Gastroenterology, Henry Ford Hospital, Detroit, MI.

Purpose: Orthotopic liver transplantation (OLT) is an effective treatment for patients with advanced autoimmune liver disease, including autoimmune hepatitis (AIH), primary biliary cirrhosis (PBC), and primary sclerosing cholangitis (PSC). Recurrence of AIH, PBC, and PSC in the transplanted liver does occur, but the exact impact on outcomes is controversial. The aim of the study was to evaluate the rates of post-transplant rejection and recurrence of disease in patients with autoimmune liver disease.

Methods: A retrospective analysis of all patients undergoing first OLT for autoimmune liver disease at a single liver transplant center between 1993 and 2003. The patients with co-existing chronic liver disease and liver donor transplant recipients were excluded.

Results: A total of 42 patients were transplanted for AIH, PBC, and PSC. The mean age at transplant was 46.8 years and mean follow up was 5.53 years. The mean MELD score at the time of transplant was 16.8. An average of 1.3 biopsies per year was done in the follow up period. Episodes of acute rejection and recurrence of the primary disease were seen in 30 patients (70%) and 8 patients (18.6%) respectively. Chronic rejection was only observed in one patient. Mean time for recurrence was 3.3 years post-OLT. Recurrence was seen more frequently in PBC (26%) compared to AIH (6.7%). Loss of the graft occurred in 5 patients - two cases from recurrent disease, two cases from hepatic artery occlusion, and one case from miliary tuberculosis of the liver. Three of these patients were re-transplanted successfully. Death occurred in 4 patients (9.5%), and the causes of death were not related to rejection or recurrence. Changes in serum alkaline phosphatase and transaminases were predictive of rejection or recurrence only in 37% of cases. Recurrence was seen less frequently in the patients who received tacrolimus-based immunosuppression in comparison to cyclosporine (13% vs. 30%, NS). Rate of
recurrence was not affected by the use of mycophenolate or azathioprine as a secondary immunosuppressant.

Conclusions: AIII, PBC, and PSC remain good indications for liver transplant. Recurrence rates of the primary disease are low and it leads to the graft loss and re-transplantation in less than 5% of patients. Liver enzymes are not specific markers for rejection or recurrence. Tacrolimus may be more effective in preventing recurrence episodes than cyclosporine although controlled trials are required to fully investigate this finding.

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Sivelestat, a Neutrophil Elastase Inhibitor Prevents Endotoxin-Induced Liver Injury in Rats Following Partial Hepatectomy
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Purpose: During endotoxemia, neutrophils activated by inflammatory cytokines are known to release reactive oxygen species and neutrophil elastase, resulting in hepatic necrosis and dysfunction. We investigated the possible mechanism underlying the protective effect of a neutrophil elastase inhibitor (sivelestat) on endotoxin-induced liver injury following partial hepatectomy in rats.

Methods: Lipopolysaccharide (LPS) was administered intravenously to male Sprague-Dawley rats within 48 h of 70% hepatectomy. Prior to LPS administration, sivelestat or normal saline was given intravenously.

Results: The survival rate of the sivelestat-treated group was markedly improved compared to that of the controls. Sivelestat prevented increases in the concentrations of serum enzymes and total bilirubin related to liver injury. The levels of inflammatory cytokines in serum and liver tissue also were significantly lower in the sivelestat-treated group than in the control group. The degree of neutrophil infiltration, necrosis and apoptosis in the remnant liver was significantly decreased in the sivelestat-treated rats compared to the controls. Furthermore, sivelestat pretreatment greatly inhibited the activation of nuclear factor-kappa B (NF-kB), caspase 3 and 8 activities, cytochrome c release and the decrease of mitochondrial Bcl-xL content.

Conclusions: These results indicate that sivelestat prevents LPS-induced liver injury through the inhibition of the NF-kB activation and promotion of Bcl-xL expression.

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The Most Current Trends in Hepatocellular Carcinoma: a Retrospective Study of Associated Risk Factors in an Urban University Setting
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Purpose: The purpose of this study is to analyze the epidemiological data on HCC in an urban predominantly African-American population and to evaluate the prevalence of associated risk factors.

Methods: This is a retrospective study of two hundred adults with a diagnosis of HCC seen in an urban medical center between 1998 and 2005. The age, gender, race, serum alpha-feto protein (AFP) levels were ascertained. Associated risk factors such as hepatitis C virus antibody (anti-HCV), HIV and DM were determined and compared to accredited regional databases. Percentage of patients dying within one, three and five years of diagnosis was obtained.

Results: A total of 200 patients were evaluated, of whom 67% were African-American. The majority of patients (39%) were diagnosed between the ages of 51 and 60 (figure 1). A gender disparity was noted favoring males in a ratio of 7:3. HIV was present in 2.5% of tested patients in our study compared to an estimated 0.6% from statistics obtained from the Detroit Health Department. Anti-HCV was present in 83% of HCC patients. There was a high association between DM and HCC, with 72% of patients in our study having DM. Furthermore, there is a significant disparity noted in AFP levels in HCC patients with and without DM. Mean AFP levels in HCC patients with DM were 32,000 IU compared to levels of 100,000 IU in those without DM (p < .02). Fifty percent, 77% and 86% of HCC patients, died within 1 year, 3 years and 5 years respectively.

Conclusions: Our study of a predominantly African-American patient population, suggests that HCC is affecting a younger population. It is very commonly associated with DM, more so than in the general population. HCC is also commonly associated with anti-HCV positive status. Finally, a disparity in AFP levels in HCC patients with and without DM was noted, with diabetic patients tending to have lower AFP values. This finding could have implications in post-treatment screening for recurrence of HCC and warrants further investigation.

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Retransplantation for Recurrent Hepatitis C Virus Infection
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Purpose: To examine outcomes of retransplantation for recurrent hepatitis C compared to outcomes of retransplantation for non-HCV etiologies at our single center.

Methods: A prospective evaluation of all retransplantations done at our center between December 2002 and August 2005 was performed.

Results: Thirty-three retransplantation patients were identified. Seventeen were performed for recurrent hepatitis C (51.5%) and sixteen were performed for non-HCV indications (48.5%). The groups were found to be similar in gender, age, operative time, intraoperative transfusion requirements, length of stay, and length of follow-up. Statistically significant differences, with respect to average time to retransplantation (35 months vs. 68 months) and average MELD score at the time of retransplantation (22 vs. 30) were noted between the HCV and non-HCV groups respectively. Reoperations were required with similar frequencies (47% and 44%) amongst the HCV and non-HCV groups. 1 patient in each of the groups required additional re-transplantations during the follow up period. There were two deaths in each of the HCV and non-HCV groups. Survival was found to be 94%, 88%, 86%, and 85% for the HCV patients, and 88%, 88%, 87%, and 85% for the non-HCV patients at 1 month, 3 months, 6 months, and 12 months respectively.

Conclusions: Despite previously published studies, in our series of patients, excellent short-term outcomes after retransplantation were seen for hepatitis C patients compared to controls.

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Is the Lipid Reduction Seen with High-Dose Pravastatin (Prava) Associated with a Fall in ALT Values in HypercholesterolemicPts with NAFLD? Results from a Prospective, Randomized Double-Blind, Placebo (PBO)-Controlled Trial
Purpose: NAFLD is often seen as part of a metabolic syndrome with elevated total cholesterol (TC), LDL, and triglycerides (TG). Prior studies evaluating Prava and other statins in NAFLD have been equivocal, but were limited by their small size, low dose or short duration. As part of a larger trial seeking to demonstrate the efficacy and safety of high-dose Prava in hypercholesterolemic patients with various chronic liver diseases (CLD), we sought to correlate reductions in TC, LDL and TG levels in the subset of patients with NAFLD.

Methods: Well-compensated NAFLD pts with TC >160 mg/dL, LDL >100 mg/dL and TG <400 mg/dL, received Prava 80 mg/d or placebo in a 1:1 ratio at 69 sites. No other lipid lowering drugs were allowed. ALT and lipids were measured q1,2, and then q4 wks. A 2 sample t-test was used to correlate ALT with reductions in TC, LDL, and TG levels.

Results: Of 320 total pts enrolled, nearly 2/3 had NAFLD, with 90 randomized to Prava and 85 to PBO. They were well-matched: mean age 50y; M:F about 1:1; mostly caucasian; BMI 30kg/m2. Significant reductions in TC, LDL, and TG levels were seen at all time points for the Prava group (with no associated symptoms), but failed to reach statistical significance. When analyzed for changes in ALT from baseline, we still did not observe any difference in ALT reduction for Prava. Histological evaluation of the lipid changes was not studied, however, as no liver biopsies were performed as part of this trial.

Conclusions: While high-dose Prava was effective in lowering serum lipids in NAFLD pts, and while no hepatic or other concerns arose during this trial, we were unable to demonstrate a correlation between the lipid reductions and the lower # of ALT events seen over 36 wks.. Nevertheless, the use of a statin in these pts remains an attractive therapeutic prospect. The safety of Prava shown in this study suggests that further trials are warranted in hyperlipidemic subjects with NAFLD, perhaps of even longer duration, or combined with other agents such as ezetimibe, and with histological correlation.

The Model for End-Stage Liver Disease (MELD): An Overlooked Predictor of In Hospital Mortality and Resource Utilization in Patients with Variceal Bleeding

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Purpose: A major complication of end-stage liver disease is the development of variceal bleeding. Acute variceal hemorrhage accounts for about one-third of all deaths related to cirrhosis and places a major financial burden on the institution caring for those patients. Traditionally the Model for End-Stage Liver Disease (MELD) score has emerged as an excellent assessment of survival in patients awaiting liver transplantation and in those undergoing transjugular intrahepatic portosystemic shunt procedures. The aim of this present study was to examine the efficacy of the MELD score in predicting short-term mortality as well as resource utilization in hospitalized patients with end-stage liver disease, particularly those complicated by esophageal varices.

Methods: The hospital discharge database was queried for discharge ICD-9 codes 456.0–456.29 between July 1996 and March 2006. The hospital charts were then reviewed to verify the diagnosis of esophageal varices and enrollment in MELD score on admission, age, gender, length of stay and cause of death. Hospital charges were obtained using the Trenstar DSS patient database. Adjusted odds ratios were derived using XLSAT software to perform a backward stepwise logistic regression analysis. The most parsimonious model was chosen. Confidence intervals were derived using two sided tests of significance.

Results: A total of 160 patients were included in our study. Fifty-six patients (35%) had a MELD score ≥ 15 on admission, and 50% of those died within 30 days of admission (40% within 5 days of admission). This was compared to one-hundred and four patients (65%) with MELD score <15, of which only 10% died within 30 days of admission (18% within 5 days of admission). Patients with a MELD score of 15 or higher at presentation had a higher than 8 fold likelihood of dying within 30 days of presentation-adjusted odds ratio: 8.36 (3.78, 18.67 95% C.I.). There was no significant difference between both groups in overall length of stay however, patients with a MELD ≥ 15 had a three fold higher length of stay in the ICU compared to those with MELD < 15. This resulted in a significant difference between both groups- in patients with a MELD score > 15, total hospital charges were on average higher by $ 11,000.

Escitalopram for Prophylaxis of Major Depression during Peginterferon Alpha-2A and Ribavirin Therapy for Hepatitis C

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Purpose: While high-dose Prava was effective in lowering serum lipids in NAFLD pts, and while no hepatic or other concerns arose during this trial, we were unable to demonstrate a correlation between the lipid reductions and the lower # of ALT events seen over 36 wks.. Nevertheless, the use of a statin in these pts remains an attractive therapeutic prospect. The safety of Prava shown in this study suggests that further trials are warranted in hyperlipidemic subjects with NAFLD, perhaps of even longer duration, or combined with other agents such as ezetimibe, and with histological correlation.

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**Purpose:** Currently the most effective treatment for hepatitis C is the combination of PEG interferon alpha and ribavirin; unfortunately, interferon can induce depression and is a major reason for avoiding or discontinuing treatment. The purpose of this study was to: 1) determine whether patients with a history of major depression could complete a course of peginterferon alpha-2a and ribavirin for hepatitis C, if first treated with escitalopram, and 2) estimate the relapse rate of depression during treatment with peginterferon alpha-2a and ribavirin in subjects pre-treated with escitalopram.

**Methods:** Ten patients with major depression, in remission, were treated with escitalopram during peginterferon and ribavirin therapy. Escitalopram 10 mg/day was initiated 4 weeks prior to, and continued throughout interferon therapy. Dosage adjustments were made as needed. The Hamilton Depression Rating Scale (Ham-D), the Medical Outcomes Short Form and the Hopkins Symptom Checklist-90 were administered, along with other measures at pre-baseline, baseline, and 2,4,8,12,16,20,24,32,40,48 weeks.

**Results:** No statistically significant increases in mean Ham-D scores were observed. Depression relapse was defined as Ham-D score of 15 or greater. Mean Ham-D score prior to initiation of treatment was 3.90 (95% CI 2.17-5.63, p = 0.3874). Highest mean score during treatment was 8.22 (95% CI 4.33-12.12, p = 0.568), observed at week 16. Nine of 10 subjects (90%) completed their course of interferon alpha and ribavirin without significant psychiatric complications. One subject was terminated following substance abuse relapse at week 14. Two subjects had pathologic Ham-D scores of 15 and 17 at weeks 12 and 24, respectively. One of these subjects was the subject who was terminated for substance abuse relapse. Eight of 10 subjects maintained Ham-D scores <15, throughout the entire study. Mean escitalopram dosage at endpoint was 15.5 mg daily. Nine of the ten patients cleared their virus at the end of treatment.

**Conclusions:** Pre-treatment with escitalopram in subjects with major depression, in remission, may allow for completion of a course of interferon and ribavirin therapy for hepatitis C, without significant recurrence of depression symptoms.

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**A Novel Therapy for Non-Alcoholic Steatohepatitis: Essential Fatty Acids and Ursodiol**

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**Purpose:** The purpose of this case series is to evaluate the efficacy of essential fatty acid (EFA) supplementation in conjunction with Ursodiol in the treatment of non-alcoholic steatohepatitis (NASH).

**Methods: Clinical—**Nine patients were identified with chronic hepatitis and diagnosed with NASH (confirmed with needle core biopsies). The patients were prescribed EFAs 2000-3000 mg and Ursodiol 500 mg PO BID. AST, ALT, GGT, and BMI were measured at the time of diagnosis and at follow-up. The means of all parameters were calculated (±95% CI) and compared. Baseline and followup liver biopsies were obtained after a minimum of 3 years of treatment.

**Pathology—**All liver biopsies were fixed in 10% formalin, and processed in a standard fashion utilizing hematoxylin and eosin, Masson Trichrome, Prussian Blue, and PAS with diastase (PASD) histochemical stains. Biopsies were graded and staged according to the modified version of EM Brunt for NASH, and the percentage of parenchymal steatosis was estimated.

**Results: Clinical—**All patients, within 3 years, demonstrated normalization of AST and GGT, and 6/9 achieved normalization of ALT. The average AST, ALT, and ALT at presentation was 78 ± 25, 77 ± 53, and 130 ± 50, respectively. The average decreases observed for AST, ALT, and GGT were 50 ± 21, 93 ± 42, and 48 ± 47, respectively. The average BMI at presentation was 31 ± 3.0, and at last follow-up this was unchanged (see table 1).

**Pathology—**When comparing pre- and post-treatment liver biopsies, 4/9 patients showed decreased steatosis, 4/9 patients showed a decrease in grade, and 6/9 patients showed a decrease in stage. Overall, 8/9 patients showed improvement in ≥1 category and 1 patient showed improvement in all three. Importantly, no patients demonstrated progression of disease. Additionally, 3 patients demonstrated iron deposition, 6 patients showed hepatocellular multinucleation, and no patients had PASD positive hepatocellular inclusions.

**Conclusions:** Essential fatty acid supplementation in conjunction with Ursodiol successfully prevented progression and induced regression of NASH in this cohort. Further controlled clinical trials are needed to substantiate these results.

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**Table 1. Liver Enzyme and BMI means (±95% CI) at the time of diagnosis and follow-up biopsy.**

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Follow-up</th>
</tr>
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<tbody>
<tr>
<td>AST</td>
<td>78 ± 25</td>
</tr>
<tr>
<td>ALT</td>
<td>130 ± 50</td>
</tr>
<tr>
<td>GGT</td>
<td>77 ± 53</td>
</tr>
<tr>
<td>BMI</td>
<td>31 ± 3.0</td>
</tr>
</tbody>
</table>

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**Correlates of a Sustained Virologic Response in the Treatment of HCV**

John C. Hoefg, MD,∗ Tom Herron, Paul E. Lizzotte, MD, Wen-Pin Chen, MS, Christine E. McLaren, PhD. Medicine, University of California Irvine, Orange, CA; Family Comprehensive Cancer Center, University of California Irvine, Orange, CA and Radiology, University of California Irvine, Orange, CA.

**Purpose:** The quantitative liver spleen scan (QLSS) was assessed along with other markers of liver disease severity for correlates of an sustained virologic response (SVR) and relapse (R) compared to Non-response (NR). It is our hypothesis that the QLSS parameters will correlate with treatment response.

**Methods: Patients—**106 consecutive patients completing treatment for hepatitis C with pegylated interferon alpha 2a and ribavirin were retrospectively evaluated for treatment response. Routine laboratory tests (106 patients), histology (101), virologic tests, prior treatment and QLSS results at baseline (95) were recorded. The PHM, liver volume (LV/IBW) and spleen volume (SV/IBW) (ideal body weight = IBW in lb). Early virologic response (EVR) was <1/100 baseline RNA at 12 weeks treatment.

**Statistics:** Chi-square test compared treatment response and discrete variables. Analysis of variance tested for differences in treatment response for mean values of continuous predictors. Logistic regression determined the most parsimonious set of predictors of virologic response.

**Results:** The patients were Caucasian (80%), naïve (70%), 59% male, age (52 ± 9 yrs), and height (68 ± 4 inches), and weight (174 ± 39 lbs). The baseline blood tests and QLSS PHM, LV/IBW, and SV/IBW were in the table. Fibrosis stage was 0(10), 1(25), 2(16), 3(19) and 4(31) (where 4 indicated cirrhosis), Genotype 1,4,6 (81) and 2,3 (25) and RNA levels 3,639,022 ± 6,342,534 IU/ml. Treatment resulted in an SVR in 46, R in 27 and NR in 33. No differences in treatment response were noted for sex, race, ALT, Alb, INR. Significant differences (p < .01) to treatment from univariate analysis were found for EVR (p < .0001), prior treatment (p < .001), genotype (p = .004), cirrhosis (p = .02), platelets (p = .0029) and LV/IBW (p = .0089). By multivariate analysis, SVR compared to NR correlated with gender (p = .0128), prior treatment (p = .0006), IBW (p = .0079) and LV/IBW (p = .0219). By multivariate analysis, R compared to NR was associated with Caucasian race (p = .02), prior treatment (p = .0029) and LV/IBW (p = .042). For 74 naïve patients, significant differences by multivariate analysis

**Liver Tests**

<table>
<thead>
<tr>
<th>ALT</th>
<th>INR</th>
<th>Platelet</th>
<th>PHM</th>
<th>LV/IBW</th>
<th>SV/IBW</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>97</td>
<td>1.07</td>
<td>175</td>
<td>100</td>
<td>10.1</td>
</tr>
<tr>
<td>SD</td>
<td>112</td>
<td>.15</td>
<td>77</td>
<td>9</td>
<td>3.3</td>
</tr>
</tbody>
</table>
between groups were found for platelets ($p < 0.001$) and for LV/IBW ($p < 0.05$).

Conclusions: Prior treatment and LV/IBW were major determinants of the SVR and relapse compared to non-response.

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Applicability of Capsule Endoscopy in Screening for Portal Hypertension

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Purpose: Variceal hemorrhage remains a fatal complication of cirrhosis. Guidelines recommend screening for varices at 1-3 years. PillCam ESOTM is a novel, FDA approved device to evaluate the esophagus. It provides a means to minimize the cardiovascular risk of sedation with EGD. Aim: To determine applicability of this procedure to stage PHTN in patients with liver disease.

Methods: PillCam studies in our patients were performed using the manufacturer described procedure. Esophageal varices were graded as none, small (<25%of circumference of esophagus) and medium/large (>25% of circumference of esophagus). The reading was performed by three experienced endoscopists.

Results: Herein we report our results in our first 60 patients.

One patient could not swallow the capsule. The capsule did not pass through the LES during battery life in 2 patients. The gastric mucosa was not adequately visualized in 6 patients because of the presence of food. All our patients successfully studied found the procedure to be very tolerable. No AE's associated with PillCam ESOTM were found.

Conclusions: Capsule endoscopy is a simple and non-invasive procedure. Its use is well accepted by patients. There is optimal visualization of esophagus but limited visualization of the stomach. Capsule endoscopy is a reasonable, safe and comfortable alternative to EGD for screening for PHTN. While early in our experience, capsule endoscopy has the potential to become a powerful tool in the screening for portal hypertension.

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Efficacy of Combination Therapy with Peginterferon $\alpha$-2a (Pegasys) Plus Ribavirin in the Treatment of Chronic Hepatitis C in Saudi Population: A Retrospective Study

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Purpose: This is the first large scale retrospective study in Saudi population, planned to assess the efficacy and safety of Peginterferon $\alpha$-2a (Pegasys) and Ribavirin combination in the treatment of chronic hepatitis C. The primary objective was to evaluate the response rate of this combination therapy, and secondary objective was to analyze the effect of HCV genotype, histological staging, and history of previous treatment on sustained virological response (SVR).

Methods: 179 patients who completed 48 weeks of combination treatment and 6 months of post treatment follow up at KFSH & RC, Riyadh, were included in this retrospective study to assess the response of treatment. 93 were naive patients and 86 were previously treated patients with Interferon (IFN) alone or IFN with Ribavirin.

Results: Out of total 179 patients, SVR was reported in 91 (51%), Non-responders were 50 (28%) and Relapse was observed in 38 (21%) patients. However, among 93 naive patients the SVR was much higher (65%) with lower number of non-responder (21%), and much lower number of relapse rate (14%). In 86 previously treated patients, the SVR was low (36%), while relapse rate was higher (30%) and there were much higher number of (33%) non-responders. Genotype 4 was the commonest genotype (52%), followed by Genotype 1 (25%), Mixed genotype (11%), genotype 2 (5%), Genotype 3 (4%), and genotype 6 (<1%). When SVR was evaluated according to the genotype, the results were different, genotype 1 (53%), Genotype 4 (47%), genotype 2 (100%), genotype 3 (80%), and mixed genotype (28%). Genotype 4 patients were also evaluated independently: they showed 57% SVR in naive patients and 26% in previously treated patients. The overall sustained response rate in histopathological stage of 1 and 2 were 68%, in stage 3 and 4 were 32%. 16 patients (9%) received Erythropoietin to sustain hemoglobin above 10 gm% and 18 patients (10%) received Granulocyte Colony Stimulating Factor (Neupogen) during the course of treatment.

Conclusions: The overall SVR achieved in this study was 51%, but in predominantly genotype 4 Saudi populations SVR was 47%. Naive patients had significantly higher SVR, and lower rate of relapse and non responders, when compared with previously IFN treated patients. Histopathological staging 1 & 2 responded significantly better than Stage 3 & 4.

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Clinical Utility of Des-γ-Carboxy Prothrombin (DCP) as a Biomarker for Hepatocellular Carcinoma (HCC)

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Hepatology, UPHS, Philadelphia, PA and Transplant Surgery, Mount Sinai, New York, NY.

**Purpose:** HCC is a significant cause of morbidity in pts with chronic liver disease. Biomarkers such as alpha fetoprotein (AFP) are limited by their low sensitivity and specificity. DCP is a novel tumor marker for HCC. However, there are limited prospective data on its clinical utility.

**Methods:** This prospective study enrolled 494 pts from 7 sites with chronic HCV or HBV with either newly diagnosed HCC (N = 54) or at risk for HCC by virtue of having either liver cirrhosis (LC) or chronic hepatitis (CH), N = 440. Pts were monitored throughout the study with imaging and DCP measurements every 3 months and followed for at least 21 months. The primary endpoint was the development of HCC based on histology or accepted imaging criteria. Pts without HCC at entry were classified into 2 groups for analysis: (i) HCC developing during the study, and (ii) LC/CH without evidence of HCC. Pts with less than 21 months of follow up and an abnormal DCP were not included in this analysis (N = 124).

**Results:** 316 pts (mean age 52.2, 71.8% male, 76.3% LC, 69.0% from HCV, 8.9% had HBV and 22.2% had HCV and HBV) were analyzed. During the study, 39 pts developed HCC while 401 did not (annual incidence of 8.9%). A positive DCP was determined by the optimum cut off of 7.5 ng/mL obtained from ROC analysis. During the study, 14.2% had a positive DCP. The incidence of HCC in those with a positive DCP was 42.2% compared to 7.4% in those with DCP < 7.5 ng/mL. Thus, the relative risk of having HCC in pts with a positive DCP was 5.7. The sensitivity, specificity, positive predictive value, and negative predictive value (NPV) were 48.7%, 90.6%, 42.2%, and 92.6% respectively.

**Conclusions:** Those with an elevated DCP have a higher incidence of HCC compared to those who do not. The high specificity (90.6%) and NPV (92.6) suggest that DCP may have additional clinical utility in managing pts at risk for HCC. Future analyses are needed on the value of DCP alone or in combination with AFP and AFP-L3%.

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**356 Development of T-Cell Non Hodgkin’s Lymphoma in a Patient with Hepatitis C: A Case Report and Review of the Literature**

**Sindu Stephen, MD, Marie L. Borum, MD.** Division of Gastroenterology & Liver Diseases, The George Washington University, Washington, DC.

**Purpose:** Several studies have linked hepatitis C virus (HCV) with B-cell Non Hodgkin’s lymphoma (NHL). A meta-analysis revealed a 15% higher prevalence of HCV in NHL than in the general population. Yet, there is little mention of the association between HCV and T-cell NHL. We report a rare case of a 55-year-old male with chronic HCV presenting with T-cell NHL.

**Methods:** A 55-year-old male with a history of fatigue and a skin lesion on his back. His past medical history was significant for chronic HCV (genotype 1) and depression. Initially, he had abnormal liver-associated enzymes with moderate disease activity and mild fibrosis on biopsy. Since then, he completed a 48 week course of pegylated interferon and ribavirin, which resulted in an end-of-treatment response. No significant alcohol or drug use was reported and there were no malignancies in the family. On physical exam, he had no clinical evidence of chronic liver disease, but an oval, 4 cm indurated, fixed mass was palpable on his left upper back. His liver associated enzymes were normal with an undetectable HCV RNA. An HIV test was negative. Biopsies and radiographs of his lesion revealed metastatic anaplastic large T-cell NHL. Complete remission was obtained with chemotherapy, but six months later his HCV RNA was positive.

**Results:** Mechanisms responsible for development of lymphoproliferative diseases in HCV-positive patients remain unclear. The association between type II mixed cryoglobulinemia (MC) and HCV may predispose to development of B-cell lymphoproliferative diseases. The virus attaches to B-lymphocytes via CD81. The persistence of HCV may stimulate B-lymphocytes, resulting in B-cell lymphoproliferative diseases. The bel-2 proto-oncogene may also contribute to the development of NHL due to a t (14:18) which is more prevalent in HCV-infected patients. A second mechanism involves direct infection of target cells that undergo transformation. This was confirmed in one study by demonstrating the presence of HCV in lymph nodes of patients with NHL. Most studies have shown HCV RNA positivity at the time of diagnosis of lymphoproliferative diseases.

**Conclusions:** Our patient had an end-of-treatment response prior to the diagnosis of T-cell NHL. It is unclear how HCV might have played a causal role in his lymphomagenesis, but supports the speculation that there is an association. This case reinforces the importance of early awareness and recognition of these associations, which impacts management.

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**357 Race May Influence Patients’ Decision To Receive Hepatitis C Treatment**

**Mark Friedman, MD, David Jager, MD, Colleen Rodak, NP, Marie L. Borum, MD, FACG.** Division of Gastroenterology & Liver Diseases, The George Washington University, Washington, DC.

**Purpose:** Chronic hepatitis C infection (HCV) causes significant morbidity & mortality in the United States. Advances in therapy have improved viral eradication rates. However, a significant portion of HCV-infected individuals
who qualify for therapy decline treatment. This study evaluated if a patient's gender or race was associated with this decision.

Methods: Medical records of all patients evaluated for chronic HCV in a university practice between January 2004 and June 2006 were reviewed. No patients were excluded. Patients' gender, race, qualification for therapy and decision to receive treatment were obtained. A database was created. Statistical analysis was performed using chi-square with significance set at \( p < 0.05 \). The study was approved by the university IRB.

Results: Medical records of patients (170 men, 129 women; 50 white, 226 black, 23 other) were reviewed. 152 (51%) received treatment and 147 (49%) did not. Of the 147 patients who did not receive treatment, 56 (38%) did not qualify for therapy, and 91 (62%) were offered treatment but declined. In the 91 who were offered treatment and declined, there were 40 women and 51 men; 13 of the 91 were white, 74 were black and 4 of other ethnicities/races. Gender analysis revealed that 51 men and 40 women declined treatment, which was not significantly different \( (p = 0.97) \). Race analysis revealed that 13 of 20 whites and 74 of 118 blacks declined therapy. There was a significant difference \( (p = 0.038) \) in the rate at which whites and blacks declined treatment. The limited number of patients who were self-defined as an ethnicity other than white or black did not allow for statistical analysis. The primary reason that all patients declined therapy was concern about medication side effects. Black patients also stated that they received information from others that treatment was not effective because they were black.

Conclusions: Advances in HCV treatment have resulted in improved viral eradication rates. All patients who clinically qualify should be offered treatment. We found there was no significance in the rate at which women and men declined therapy. There was a significant difference in the rate at which whites and blacks declined treatment. Patients should not restrict their receipt of therapy based upon race. Focused patient educational interventions should address the issue of race & therapy. Specific interventions should therefore be developed to address patients’ concerns about medication side effects and the issue of race and therapy.

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The “A-2518G” Monocyte Chemotactic Protein-1 Gene Polymorphism Is Not Associated with Primary Biliary Cirrhosis

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Purpose: Monocyte chemotactic proteins (MCP's) are potent chemokines which, because of their effects on monocyte recruitment, are involved in the initiation and maintenance of inflammatory responses. MCP-1, -2 and -3 may play an important role in the formation of portal tract lesions, particularly bile duct lesions and granulomatous in primary biliary cirrhosis (PBC) as mononuclear cells from PBC patients have previously been shown to have increased expression of the MCP chemokine. Recently, an A/G polymorphism in the promoter region (−2518) of the MCP-1 gene has been identified which alters expression of MCP-1, with the G allele increasing MCP-1 production. This single nucleotide polymorphism has been implicated in the progression of a number of systemic inflammatory diseases, including hepatitis C, where the inheritance of the MCP-1-2518 G allele may predispose HCV patients to more severe hepatic inflammation and fibrosis. We wished to determine whether the MCP-1-2518 G allele is associated with susceptibility to PBC.

Methods: 70 patients with PBC and 121 healthy controls were analyzed. The diagnosis of PBC was made based on the presence of cholestatic liver enzymes, a positive AMA or M2 antibody and consistent liver histology. Genomic DNA was isolated and the A/G genotype was evaluated by PCR amplification and DNA sequencing. Genotype frequencies were analyzed using Armitage trend tests.

Results: Using the Armitage trend tests, there was no statistical significance between the two groups (SEE TABLE).

Conclusions: The MCP-1 -2518 A/G polymorphism is not a clinically significant susceptibility factor for PBC.

MCP-1 Genotyping Results

<table>
<thead>
<tr>
<th>Genotype</th>
<th>PBC (N = 70)</th>
<th>Control (N = 121)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A/A</td>
<td>44 (63%)</td>
<td>70 (58%)</td>
</tr>
<tr>
<td>A/G</td>
<td>19 (27%)</td>
<td>41 (34%)</td>
</tr>
<tr>
<td>G/G</td>
<td>7 (10%)</td>
<td>10 (8%)</td>
</tr>
</tbody>
</table>

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Comparison of Telomere Length in Chronic Hepatitis and Hepatocellular Carcinoma Cases with Cirrhosis and without Cirrhosis

Nitin Saini, MSc, Yogesh Chawla, DM,* Sanjeev Sharma, MSc, Ajay Duseja, DM, Ruhika Das, PhD, Arvind Rajvanshi, MD. Departments of Hepatology, PGIMER and Cytology, Post Graduate Institute of Medical Education & Research, Chandigarh, India.

Purpose: Telomeres are present at the ends of chromosomes and consist of hexameric DNA repeat sequences (TTAGGG)n. Telomeres shorten with each cell division because they cannot be replicated completely during normal DNA synthesis. They effectively ‘cap’ the ends of linear chromosomes and prevent end to end fusion. During the process of chronic liver cell death and regeneration, hepatocyte-specific telomere shortening and replicative senescence is linked to the development of cirrhosis and finally hepatocellular carcinoma (HCC), after expression of an enzyme called “telomerase” in the later.

Objective: To investigate telomere length and telomerase activity in patients with chronic hepatitis and HCC.

Methods: FNAC proven HCC patients were included in the study. Samples (FNAC) of 58 HCC [32 cirrhotics; 20 without cirrhosis & in 6 diagnosis of cirrhosis was not done] (Group I) and liver biopsy samples of 17 chronic hepatitis patients (Group II) were taken. Genomic DNA was isolated and “Mean Telomere Length” (MTL) was calculated by Roche Telomere length assay kit which uses Southern hybridization technique. Telomerase activity was also measured by using TRAP assay kit.

Results: There were 47 (81%) males and 11 (19%) females (57.63 ± 9.68 years; 29–82 years) in group I, 32 (56%) were positive for HBsAg [73% with genotype D and 26% with genotype A], 12 (21%) for anti-HCV, 13 patients (22%) negative for both HBsAg and anti-HCV. One patient was positive for both viral markers. In group II, 15 (80%) were males and 2 (12%) females (44.32 ± 7.16 years; 27-58 years), 10 patients (59%) were positive for anti-HCV and 7 (41%) for HBsAg. MTL in HCC cases with cirrhosis was 4.69 ± 2.09 kb (2–12.2 kb) and without cirrhosis 5.03 ± 2.31 kb (2–14.5 kb). Overall MTL in HCC was 4.81 ± 2.31 kb (2.0–14.5 kb). MTL in chronic hepatitis group was 7.04 ± 1.11 kb (5.5–10.4 kb). Telomerase was positive in 44 (76%) HCC cases. The MTL in telomerase positive HCC cases was 4.2 ± 0.26 kb (2.0–14.5 kb). Telomerase was also positive in 2 (12%) chronic hepatitis cases.

Conclusions: The difference between mean telomere length in HCC and chronic hepatitis group was not significant (although the length was shorter in HCC group), but the amount of mean telomeric DNA present in HCC cases was significantly higher. Telomerase was strongly expressed in HCC but not in chronic hepatitis liver biopsy samples.

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Sertaline for the Prevention of Depression with HCV Therapy

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Purpose: Current HCV treatment with peginterferon alfa and ribavirin is associated with severe side effects, including depression. The aim of this study was to evaluate if treatment with Sertaline prior to initiation of HCV therapy decreases the risk of depression during HCV treatment.
Methods: This was a randomized, double blind, placebo-controlled trial conducted at the Durham VAMC Liver Clinic. All patients had chronic HCV infection with no previous treatment and no symptoms of depression. Patients received peginterferon alfa-2b 1.5 mcg/kg weekly and ribavirin 13 ± 2 mg/kg divided twice daily. Patients received Sertraline 50 mg (or placebo) two weeks prior to the initiation of HCV treatment and then throughout treatment. Depression and anxiety were assessed using the Hamilton Depression Scale, Beck Depression Inventory, and the Hamilton Anxiety Scale.

Results: Forty patients were randomized, and the two groups had similar characteristics (Table 1). All patients in the Sertraline group completed at least 12 weeks of HCV therapy. Three of 20 patients in the placebo group did not complete 12 weeks of therapy. One patient withdrew prior to starting HCV therapy. Another relapsed to substance abuse, and the third had hyperglycemia. Clinical outcomes in the two groups were similar with early virologic response of 60% in each group, and sustained virologic response 50% in the placebo group and 45% in the Sertraline group. No severe episodes of depression occurred. Episodes of mild depression were significantly lower in the placebo group and 45% in the Sertraline group. No differences were seen in anxiety scores.

Conclusions: This pilot study found that Sertraline decreased the incidence of depression during HCV treatment. No benefit in virologic outcomes was noted, but larger studies are needed to further assess the role of prophylactic antidepressants during HCV therapy.

<table>
<thead>
<tr>
<th>Table 1. Patient Characteristics</th>
<th>Placebo (N = 20)</th>
<th>Sertraline (N = 20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (% men)</td>
<td>95%</td>
<td>95%</td>
</tr>
<tr>
<td>Race (% black)</td>
<td>50%</td>
<td>40%</td>
</tr>
<tr>
<td>Age, years (mean)</td>
<td>49.2 ± 5.8</td>
<td>47.3 ± 5.4</td>
</tr>
<tr>
<td>Genotype (% GT 1)</td>
<td>80%</td>
<td>90%</td>
</tr>
<tr>
<td>Advanced fibrosis (F3-F4)</td>
<td>40%</td>
<td>50%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 2. Results at 12 weeks</th>
<th>Placebo (N = 17)</th>
<th>Sertraline (N = 20)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beck (mild-mod depression)</td>
<td>35%</td>
<td>5%</td>
<td>0.03</td>
</tr>
<tr>
<td>HAM D (mild depression)</td>
<td>41%</td>
<td>10%</td>
<td>0.02</td>
</tr>
<tr>
<td>HAM A (anxiety)</td>
<td>5.9%</td>
<td>5%</td>
<td>NS</td>
</tr>
<tr>
<td>Early virologic response</td>
<td>60%</td>
<td>60%</td>
<td>NS</td>
</tr>
</tbody>
</table>

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Induction Therapy of Interferon alfa-2b in Combination with Ribavirin as Initial Treatment for Chronic Hepatitis C Genotype 1: A Pilot Study
Alma M. Palisoc, MD, Joseph Fayad, MD,* Ashok K. Singh, PhD, Irene M. Farnham, PhD. Internal Medicine, University of Nevada School of Medicine, Las Vegas, NV; Gastroenterology, Desert Gastroenterology Associates, Las Vegas, NV; Statistics/Hotel Management, UNLV Las Vegas, NV and Statistics, S.M. Stoller Corp., Las Vegas, NV.

Purpose: To evaluate the efficacy and effect of a daily dose induction therapy of interferon alfa-2b and ribavirin for previously untreated patients with chronic hepatitis C genotype 1.

Methods: Fifty-five treatment naive patients (age 18 and older) diagnosed with chronic hepatitis C (CHC) genotype 1 were given an induction therapy with a daily dose of interferon alfa-2b (IFN) at 3 MU for 16 weeks followed by 3MU three times a week for 32 weeks in combination with ribavirin (800–1000 mg, weight adjusted). All patients who remained in therapy continued the standard treatment from week 17 to 48. Efficacy of treatment was evaluated by determining sustained virological responses (SVR) and normalization of ALT. A comparison of selected parameters were made between patients who were responding to treatment vs. those not responding to treatment.

Results: Out of 55 CHC genotype 1 patients, 51 finished the study up to follow-up and 37 completed the treatment regimen. The SVR 42% for all patients in the study with 95% confidence interval (CI) of 28.7%–55.9%. The SVR was 45% (95% CI 31.1-5.9) for all patients who finished the study, and 62% (95% CI 44.8-77.5) for all patients who completed the treatment regimen (23 cured vs. 14 not cured). Principal component analysis was used to select parameters to better understand the mechanism of the combination therapy. Poor prognosis or treatment success statistically correlated with the following parameters: low WBC in early course of treatment, high WBC in late course of treatment, elevated basophils, low rbc, low eosinophils during week 1, high eosinophils in weeks 2-8, high CO2 level, hypercalcemia, elevated direct bilirubin, and elevated TSH.

Conclusions: Our study suggests that an induction therapy composed of a daily dose IFN for 16 weeks given in combination with ribavirin for patients with CHC genotype 1 increased the rate of SVR to 42%, a significant improvement on FDA approved regimen for the drug, and compared favorably to the newer regimen. Further research is needed to investigate the newly identified prognostic parameters so as to improve outcome.

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Impact of BMI on Post Liver Transplant Quality of Life (QOL)
Vijay Laxmi Misra, MD, Linda Munsch, LCSW, Richard Mangus, MD, Joseph Tector, MD, Jonathan Fridell, MD, Rodrigo Vianna, MD, Suthat Liangyunsakul, MD, Mazen Alsattie, MD, Siddharth Bhardwaj, MD, Beverly Musick, MS, Paul Kwo, MD,* Medicine, Indiana University/Clarian Health Partners, Indianapolis, IN; Transplant Surgery, Indiana University/Clarian Health Partners, Indianapolis, IN and Biostatistics, Indiana University, Indianapolis, IN.

Purpose: Obesity is a growing problem in the US and is associated with increased complication rates after surgery. There is significant variability in BMI requirements among transplant centers in the US. The AIM of our study was determine impact of BMI on QOL in post-OLT pts.

Methods: Single-center, prospective cohort study using an OLT database of pts who underwent OLT since 2002 & were at least one year post-OLT were consented and administered the SF-36 QOL Form to assess measure of well being. Demographic data, listing BMI, BMI at post-transplant were obtained from electronic medical records. Data were analyzed using SPSS. The QOL score means for different BMIs were compared using
3-way ANOVA and median values (data not shown) compared by Kruskal-Wallis Test.

Results: 186 pts (74% males) completed the QOL forms postOLT. 124 pts were married or living with a caregiver. There were significant differences in mean QOL scores in pts post transplant with higher BMIs (See table). QOL scores did not change significantly with change in BMI from pre to post transplant.

Conclusions: Higher BMI post transplant is associated with poorer QOL scores across multiple domains of SF-36.

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The Epidemiological Survey of Prevalence of Nonalcoholic Fatty Liver Disease in Iranian Metabolic Syndrome Adults

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Purpose: Nonalcoholic fatty liver disease (NAFLD) is a common clinical condition which is fast assuming importance as a possible precursor of more serious liver disorders including cirrhosis of liver and hepatocellular carcinoma. There is no published data on the prevalence of NAFLD in Iran. This study was down to determine the prevalence of nonalcoholic fatty liver in a metabolic syndrome population in Tehran by an epidemiological survey, and to analyze risk factors of fatty liver.

Methods: Total 430 metabolic syndrome persons who denied regular alcohol drinking participated in the survey, and underwent physical examination and laboratory tests. Questionnaire, physical examination, serum liver enzyme, and ultrasonographic examination of liver were undertaken. For all subjects with persistent liver enzyme elevation and ultrasonographic fatty deposition, additional studies were made, in order to exclude other causes of enzyme abnormality or fatty liver deposition. Analysis of data was performed through SPSS 13 for Windows statistical package.

Results: The overall prevalence of fatty liver as detected by ultrasonography was 45.5%, which 69.0% was female and 72.7% was more than 50years old. The prevalence of fatty liver was increased with age; this was markedly presented in females older than 50 years. Among persons with abnormal enzyme or sonography, 75.9% had NAFLD, 17.2% had autoimmune hepatitis and 6.9% had other cause such as viral or Wilson or hemochromatosis. In NAFLD persons 86.7% had liver enzyme abnormality, 85.6% had BMI greater than 30 and 89.35% had diabetes.

Conclusions: There is a high prevalence of nonalcoholic fatty liver among metabolic syndrome population in Tehran, to which overweight and diabetes are closely relevant. The estimated prevalence of NAFLD as detected is similar to the prevalence rate published from the West. NAFLD is perhaps as common in the developing world as in the developed countries despite lower prevalence of obesity.

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Mannose-Binding Lectin Gene Polymorphisms in Patients with Chronic Hepatitis B and Spontaneously Recovered among Iranian Population

Leila Alidoust Masouleh, MS, Leila Najafi, MS, Zahra Hajebrahimi, PhD Mohammad Hossein Somi, MD, Maryam Firoozi, BS, Mohammad Reza Zali, MD.* Liver, Research Center for Gastroenterology and Liver Disease (RCGLD)Shaheed Beheshti University of Medical Sciences, Tehran, Islamic Republic of Iran and Genetics, Tarbiat Modarres University, Tehran, Islamic Republic of Iran.

Purpose: Mannose-binding lectin (MBL) is a constituent of the human innate immune system which may play an important role in combating a variety of infectious diseases and thus may be important for determining hepatitis B virus (HBV) persistence. Since single-nucleotide polymorphisms (SNPs) in the gene encoding MBL alter the level functional, we hypothesized that mbl2 genotypes are a determinant of HBV persistence or recovery from viral infection. We determined MBL genotypes of two promoter (−550, −221) and SNPs of exon 1 (codon +52 and +54) in chronic hepatitis B subjects, spontaneously recovered and healthy control subjects.

Methods: In a case-control study, we examined 100 unrelated patients with Chronic hepatitis B and 100 spontaneously recovered patients were referred to RCGLD, Taleghani Hospital and 100 healthy controls which all had been matched by sex and age. MBL gene polymorphisms were determined by PCR-RFLP methods.

Results: The MBL genotype distributions in the three groups are shown in Table. There is no association between each polymorphism of the MBL gene with HBV infection in Iranian population excepting codon +52 (p = 0.00). Considering codon +52, frequencies of C/C genotype and T-allele carrier (C/T; T/T) were observed in 67% and 33% in chronic hepatitis B patients, 26% and 74% in spontaneous recovered subjects. Our finding have shown that the frequency of -550C, -221G, +52T and +54A alleles were 0.58, 0.76, 0.22 and 0.225 in chronic HBV patients and 0.57, 0.80, 0.38 and 0.3 in spontaneous recovered subjects, respectively.

Conclusions: Heterozygous for codon 52 mutant allele (C/T) may be associated with recovery from chronic hepatitis B.

Distribution of MBL genotypes in the studied population

<table>
<thead>
<tr>
<th>polymorphisms</th>
<th>Healthy Controls</th>
<th>Spontaneously recovered HBV</th>
<th>Chronic HBV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Position-550</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>G/G</td>
<td>23</td>
<td>15</td>
<td>18</td>
</tr>
<tr>
<td>G/C</td>
<td>37</td>
<td>54</td>
<td>50</td>
</tr>
<tr>
<td>C/C</td>
<td>40</td>
<td>31</td>
<td>32</td>
</tr>
<tr>
<td>Position-221</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C/C</td>
<td>12</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>C/G</td>
<td>27</td>
<td>29</td>
<td>40</td>
</tr>
<tr>
<td>G/G</td>
<td>61</td>
<td>66</td>
<td>56</td>
</tr>
<tr>
<td>Codon +52</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C/C</td>
<td>39</td>
<td>26</td>
<td>67</td>
</tr>
<tr>
<td>C/T</td>
<td>57</td>
<td>71</td>
<td>22</td>
</tr>
<tr>
<td>T/T</td>
<td>4</td>
<td>3</td>
<td>11</td>
</tr>
<tr>
<td>Codon +54</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>G/G</td>
<td>48</td>
<td>52</td>
<td>63</td>
</tr>
<tr>
<td>G/A</td>
<td>40</td>
<td>36</td>
<td>29</td>
</tr>
<tr>
<td>A/A</td>
<td>12</td>
<td>12</td>
<td>8</td>
</tr>
</tbody>
</table>

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The Frequency of IL-2, IL-6 and Interferon γ- Genes Polymorphisms in Hepatitis B Patients in Iran

Leila Najafi, MSc, Zahra Hajebrahimi, PhD, Leila Alidoust, MSc, Mohammad Hossein Somi, MD, Maryam Firoozi, BSc, Mohammad Reza Zali, FACG.* Liver, Research Center for Gastroenterology and Liver Diseases - Shaheed Beheshti University of Medical Sciences, Tehran, Islamic Republic of Iran and Genetics, Faculty of Science - Tarbiat Modarres University, Tehran, Islamic Republic of Iran.

Purpose: Cytokines play an important role in the defense against viral infection, both indirectly, through determination of the predominant pattern of the host response, and directly, through inhibition of viral replication. Several pro-inflammatory cytokines such as interleukin-2, interferon-gamma and tumor necrosis factor-alpha have been identified as participating in the viral clearance and the host immune response to HBV. The aim of the present study...
Conclusions: These findings are in contrast with other studied population of HBV in our subject. Maybe by enlarging our sample size, we will obtain more reliable results.

Distribution of polymorphisms and alleles frequency in our studied groups

<table>
<thead>
<tr>
<th>Polymorphisms</th>
<th>Healthy Controls</th>
<th>Spontaneous recovered HBV</th>
<th>Chronic HBV</th>
</tr>
</thead>
<tbody>
<tr>
<td>IL-2 (−330)</td>
<td>T/T 27.4%</td>
<td>27.1%</td>
<td>24%</td>
</tr>
<tr>
<td></td>
<td>Allele Frequency</td>
<td>G = 47.8%</td>
<td>G = 47.3%</td>
</tr>
<tr>
<td>IL-6 (−174)</td>
<td>G/G 47.4%</td>
<td>58.2%</td>
<td>53.6%</td>
</tr>
<tr>
<td></td>
<td>Allele Frequency</td>
<td>C = 52.6%</td>
<td>C = 46.4%</td>
</tr>
<tr>
<td>IFN-g (−874)</td>
<td>T/T 26.1%</td>
<td>35.3%</td>
<td>14.5%</td>
</tr>
<tr>
<td></td>
<td>Allele Frequency</td>
<td>A = 73.9%</td>
<td>A = 85.5%</td>
</tr>
</tbody>
</table>

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**The Role of Endothelin-1 in Cirrhotic Pulmonary Complication**

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**Purpose:** Increased level of endothelin-1 (ET-1) in hepatic cells and experimental liver cirrhosis had been detected. Animal studies have revealed that perfusion of end-1 can directly stimulate pulmonary nitric oxide production, causing pulmonary vasodilatation and hypoxemia emulate Hepatopulmonary syndrome (HPS). The main of this study was to determine the role of Endothelin-1 in cirrhotic patient with hepatopulmonary syndrome.

**Methods:** Fifty patients with biopsy proven cirrhosis and 50 normal healthy controls were selected for study. After getting informed consent, two dimensional echocardiography, chest x-ray and Pulmonary Function Test have been done for all cirrhotic patients; the patients who had intrapulmonary vascular dilatation in contrast echocardiogram were classified as the positive HPS. Among cirrhotic patients, 7 subjects with clinical and 13 subjects with sub clinical HPS were detected. Aspartate-Aminotransferase, Alanin aminotransferáz, Alkal phosphatase, Cell Blood Count, Bilirubin and ET-1 measured in both group. Plasma ET-1 concentrations were measured by ELISA assay. All data analysed by Spss Ver 13.

**Results:** There was no significant difference between patients with and without pulmonary hypertension in terms of sex, age, liver function, presence of collateral circulation, systemic hemodynamic, cardiac structure and left ventricle systolic and diastolic function or etiology of liver disease. ET-1 levels in cirrhotic patients (2.29 pg/ml) were significantly higher in cirrhotic patients in compare with normal healthy controls (0.85 pg/ml). There was no significant difference between plasma ET-1 level in both clinical and sub clinical HPS in compare with other cirrhotic patients. There was a significant difference between HPS and child classification. ($p = 0.007$)

**Conclusions:** The effect of HPS on cirrhotic patient’s survival in spite of high mortality is unclear. As the other study we found significant increase in plasma ET-1 levels in cirrhotic patients in compare with normal subjects, but in spite of previous study we found no relation between ET-1 levels and HPS only further studies with more cirrhotic patients with HPS will bridge the gap between scientific effort and credibility in this field.
Methods: In this cross-sectional analytical study 80 treatment naive chronic hepatitis c patients who were referred to Taleghani hospital, Tehran from 2004 to 2006 were included with non-probability convenient sampling. Patients’ liver biopsy samples were evaluated by two expert hepatopathologists. We divided patients into two groups based on pathology report: group A, without significant steatosis (steatosis in ≤5% of hepatocytes) and group B, with significant steatosis (steatosis in >5% of hepatocytes).

Age, gender, BMI, lipid profile, FBS, LFT, HCV-genotype, HCV-RNA viral load and liver fibrosis stage were determined and compared in two groups. HCV genotyping was analysed by PCR-RFLP method.

Results: Forty two (52.5%) out of 80 patients had steatosis. There was no significant difference between the mean age or sex distribution of patients with or without steatosis. BMI, mean viral load and serum levels of cholesterol, triglyceride, glucose, and gamma-glutamyl transpeptidase of steatosis group was significantly higher than non steatosis group (p < 0.05). Mean score of fibrosis was 2.17 ± 0.91 and 1.63 ± 1.02 in patient with and without steatosis, respectively (p = 0.015).

The frequency of patients with genotype 1 in the group without steatosis was significantly higher than the group with steatosis (p = 0.003), while the frequency of patients with genotype 3 in the group with steatosis was significantly higher than the group without steatosis (p < 0.0001).

The mean viral load in patients with genotype 3 infection with steatosis was significantly higher than patients with genotype 3 infection without steatosis (p = 0.009). The mean viral load in patients with genotype 1 infection with steatosis was not significantly different from patients with genotype 1 infection without steatosis (p = 0.565).

Conclusions: Infection with genotype 3 hepatitis c virus particularly if associated with high HCV-RNA level is associated with significant steatosis. But steatosis in patients infected with genotype 1 virus is associated with abnormal metabolic host factors than viral factors. Presence of steatosis is associated with more severe fibrosis in chronic hepatitis c.

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The Model for End-Stage Liver Disease Score to Serum Sodium Ratio Index as a Prognostic Predictor and Its Correlation with Portal Pressure in Patients with Liver Cirrhosis
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Purpose: The model for end-stage liver disease (MELD) and serum sodium (SNa) are both important prognostic markers in cirrhosis. A novel index, MELD to SNa ratio (MESO), was developed to amplify the opposing effect of MELD and SNa on outcome prediction. This study aimed to investigate the correlations between MELD, SNa, MESO index and hepatic venous pressure gradient (HVPG), and the prognostic ability of the MESO index.

Methods: A total of 213 cirrhotic patients undergoing hemodynamic measurement were retrospectively analyzed.

Results: The MESO index correlated with HVPG (r = 0.258, p < 0.001) and Child-Pugh score (r = 0.749, p < 0.001). Using mortality as the endpoint, the area under the receiver operating characteristic curve (AUC) was 0.860 for SNa, 0.795 for MESO index and 0.789 for MELD (p values all > 0.3) at 3 months. Among patients with Child-Pugh class A or B, the MESO index had a significantly higher AUC compared to MELD (0.80 vs 0.766, p < 0.001). A MESO index < 1.6 identified 97% of patients that survived at 3 months and the predicted survival rate was 96.5%. In survival analysis, MESO index > 1.6 independently predicted a higher mortality rate, with an adjusted risk ratio of 3.32 (95% confidence interval: 1.76-6.25, p < 0.001) in the Cox proportional hazard model.

Conclusions: The MESO index, which shows good correlation with portal pressure and takes into account the predictive power of both MELD and SNa, is a useful prognostic predictor for both short- and long-term survival. The MESO index may enhance the prognostic ability of MELD for cirrhotic patients.

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A Risk Score for Predicting Non Alcoholic Steatohepatitis in Patients with NonAlcoholic Fatty Liver Disease
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Purpose: Nonalcoholic fatty liver disease (NAFLD) has emerged as the most common chronic liver disease in the United States. 10-33% of these patients develop nonalcoholic steatohepatitis (NASH) which may result in fibrosis, cirrhosis and potential complications of portal hypertension. Currently, liver biopsy is the only means of assessing the severity of necroinflammatory changes. Firm recommendations in whom to perform liver biopsy have yet to be established. The aim of our study was to develop a risk scoring system to predict the probability of NASH in patients undergoing liver biopsy.

Methods: We retrospectively reviewed the medical records of 1083 consecutive patients undergoing liver biopsy between January 1999 and November 2005. Correlations were made with regards to race, age, sex, BMI, medications, diabetes, hypertension, bariatric surgery, triglycerides/cholesterol and AST/ALT. A correlation matrix was developed between the independent predictors so that a probability of NASH could be calculated.

Results: Of the 242 patients with NAFLD, 122 patients were found to have NASH based on clinical history and biopsy findings of moderate to gross macrovesicular fatty degeneration with inflammation. The significant predictors of NASH on univariate analysis were an age between 45 and 65 years, Non Caucasian race, female gender, presence of diabetes, hypertension, triglycerides ≥ 300 and cholesterol ≥ 200. On multiple logistic regression analysis, the following factors were found to be significant: Non Caucasian race (p = 0.03), an age between 45 and 65 years (p = 0.04), Diabetes (p = 0.0008), hypertension (p = 0.02), Triglycerides (TG) ≥ 300 (p = 0.006) and Cholesterol (Chol) ≥ 200 (p = 0.01). We then combined the significant predictors/factors to develop a risk scoring system for NASH. The probability of prediction of NASH was based on p = e^/1 + e and y = −1.78± 0.68 (Race) + 0.63 (Age) + 1.05 (Diabetes) + 0.71 (Hypertension) + 1.08 (TG) + 0.72 (Chol).

Conclusions: In conclusion, we predict this scoring system would be a useful tool in stratifying the risk of NASH for patients and enhancing the judicious selection of patients for liver biopsy. Prospective studies to confirm the utility of this scoring system are warranted.

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Psychiatric and Substance use Disorders Are Associated with Increased Mortality among US Veterans with Hepatitis C Infection
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Purpose: This longitudinal 4-year study was performed to examine the impact of co-morbid psychiatric (affective, anxiety and psychotic disorders) and substance use disorders on the clinical and virological outcomes of hepatitis C virus (HCV) infection.

Methods: Veterans with HCV infection admitted to the inpatient psychiatric and substance abuse treatment services at a Virginia VA Medical Center (N = 360) were identified between 1998-2002 and followed for clinical and virological parameters. A comparison sample of veterans with HCV (N = 310) from the same VA medical center but without psychiatric or substance use disorders was used as a control.

Results: HCV infection in veterans with psychiatric and substance use disorders was associated with a higher frequency of liver function abnormalities (32% vs. 21% p = 0.0027) and greater mortality (12% vs. 5% over 4 yr
period, \( p = 0.0003 \) as compared to veterans with HCV but without co-morbid psychiatric and substance use disorders. In multivariable logistic regression analysis adjusting for veterans' age and race, veterans with HCV but without psychiatric and substance use disorders had significantly lower odds of mortality than veterans with HCV and psychiatric and substance use disorders (OR = 0.29, 95% CI 0.16-0.56). The presence of psychiatric and substance use disorders was the strongest predictor of liver function abnormalities and increased mortality.

**Conclusions:** We conclude that co-morbid psychiatric and substance use disorders in veterans with HCV infection are associated with worsened liver disease and higher mortality. Further research is needed, however, to identify how the presence of psychiatric and substance use disorders contribute to increased mortality rates in veterans with HCV infection.

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**The Diagnostic Yield of a Comprehensive Metabolic Evaluation in Patients Diagnosed with Hepatitis C Infection**

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**Purpose:** To evaluate the diagnostic yield of an extensive search for co-existent liver pathology in patients being evaluated for hepatitis C treatment. Current recommendations suggest an extensive metabolic evaluation to exclude other co-existent causes of liver disease in patients diagnosed with chronic HCV prior to deciding on an antiviral therapy strategy. The diagnostic yield of this recommendation and how it impacts patient management is not clear.

**Methods:** Retrospective review of outpatient clinic records from 102 individuals with hepatitis C infection, undergoing evaluation for therapy between 8/1996 to 7/2004. Data was collected, including subject demographics and results for the following tests: TSH, iron studies, HCV genotype, HBsAg, HBsAb, HBeAg, anti-Hep A ab, alpha-1 antitrypsin level, and phenotype, ceruloplasmin level, and ANA. The data was compiled into an Excel chart and analyzed.

**Results:** Of the 102 patients studied, 50% were male and 50% female. The mean age was 51 ± 1 SEM. 90% were HCV genotype 1, 8% were genotype 2, and 2% were genotype 3. One biochemically hypothesized patient was identified with a TSH of 15.3. Hemochromatosis genetic testing was performed on 8 patients as a result of abnormal iron studies. One patient was homozygous for the C282Y mutation, 2 were heterozygous, and 3 patients were heterozygous for the H63D mutation. With regards to other viral co-morbidity, 2% were found to be HBsAg positive, 39% were HBeAg positive, and only 23% were HBsAb positive. No occult hepatitis B infection was diagnosed. Immunity to hepatitis A was present in 53%. HIV positive antibodies were found in 2%. No patients were found to have alpha-1 antitrypsin deficiency, however, 4% were heterozygous for the Z allele, and 7% were heterozygous for the S allele. 4% of the population was ANA positive. All patients had normal ceruloplasmin levels.

**Conclusions:** The results of our study support the screening for co-infection with viral hepatitis and HIV and for immunity against hepatitis A and hepatitis B to determine need for vaccination. While the diagnostic yield for hemochromatosis was low, screening for this treatable condition is recommended in patients with elevated liver tests. The yield of routine screening for alpha-1 antitrypsin deficiency, ANA and TSH was low. The economic impact of this routine testing in all patients with HCV, and the effects on individual treatment warrants further investigation.

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**Prevalence of Coinfection with HBV and HCV among HIV Patients in a General Hospital in Lima, Peru**

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**Purpose:** The introduction of highly active antiretroviral therapy (HAART) led to sharp drop of immunodeficiency related opportunistic infections, although short- and long-term liver toxicity of antiretroviral agents added to chronic HBV or HCV infection have resulted in a significant increase of liver-related complications amongst HIV-infected patients. Coinfection by hepatotropic viruses and the human immunodeficiency virus are frequent given the shared routes of transmission (sexual, mother-to-child and parenteral). The prevalence of HBV or HCV infection in HIV-infected population varies among different population, our aim is to determine our prevalence in a university general hospital in Peru.

**Methods:** We studied 349 new HIV-positive patients confirmed by ELISA and Western Blot, who were attended in our Tropical Medicine Institute in Hospital Nacional Cayetano Heredia (Lima-Peru) between January 2004 and December 2004. All serum patients were tested for HBsAg and HCV-antibodies with commercial assays according to the manufacturers’ instructions.

**Results:** During 2004, 349 HIV-positive patients were tested. 26 (7.45%) patients were HBsAg-positive. 11 (3.15%) patients were HCV antibody positive, and only 1 (0.29%) patient were both HBsAg-positive, HCV antibody positive. Sexual contact were the main way of HIV acquisition.

**Conclusions:** There are almost no available data on prevalence of coinfection HIV and HBV, HBV, HCV in Latin America. In our hospital, coinfection HIV-HBV was 7.45%, therefore there is no difference between this prevalence and EuroSIDA cohort prevalence (9%). Coinfection HIV-HCV in our hospital is only 3.15%, that is less than other cohorts as EuroSIDA cohort 33%, Spain cohort 23% and data in drug-users 75%. In the author’s resources-limited setting, the low prevalence of endogenous drugs users could be an explanation.

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**Spontaneous Bacterial Peritonitis Caused by Streptococcus Bovis**

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**Purpose:** SBP is one the life threatening complications of decompensated cirrhosis. Most frequently, it is caused by E.Coli, klebsiella and streptococci. Although streptococcus species have been isolated in 30% of cases of SBP, only few cases have been reported on SBP due to streptococcus bovis.

**Case report:** A 49 year old female with history of alcoholic liver cirrhosis admitted with complaint of abdominal pain with increased abdominal distention and fever for two days. She denied nausea, vomiting, diarrhea, hematemesis and melena. She had multiple admissions in last three months for therapeutic paracentesis, secondary to refractory ascites. On examination, she had fever of 101 °C, markedly distended belly with diffuse tenderness. The laboratory tests showed a WBC count of 29,000/μl and platelet count of 104,000/μl and hemoglobin of 9.1 g/dl. Blood chemistries were normal. Liver function test showed albumin of 1.4 g/dl, total protein of 5.4 g/dl, aspartate aminotransferase 72 U, alanine aminotransferase 197 U, total bilirubin 12.5 mg/dl, direct bilirubin 6.3 mg/dl, alkaline phosphatase 120 U and prothrombin time of 14.3 seconds. A diagnostic and therapeutic paracentesis was performed, which showed leukocytes of 1040/μl, 91% of which were neutrophils, lactic dehydrogenase 41 U/l, protein <1 g/dl and albumin <1g/dl. On culture of ascitic fluid streptococcus bovis was isolated. Blood and urine cultures were negative. The patient was treated with intravenous vancomycin. A paracentesis was repeated after 48 hours which showed 110 neutrophils/μl with negative cultures. Transthoracic echocardiography was done to rule out infective endocarditis which showed normal heart valves with no vegetation. Patient had undergone endoscopy and colonoscopy two months ago for workup of hematemesis. The endoscopy at that time revealed esophageal varices and colonoscopy revealed hemorrhoids. The repeated colonoscopy during this admission was not done because of high risk and low benefit. Patient improved clinically and discharged after 2 weeks.
Discussion: Streptococcus Bovis bacteremia and endocarditis has long been known to be associated with colon cancer but existence of similar association between S. bovis induced SBP and gastrointestinal malignancy is not well established yet. We recommend that more cases of S. bovis induced SBP should be reported with blood culture and colonoscopy, so that this association can be sorted out.

Drug Induced Liver Injury Network (DILIN) Prospective Study: Initial Results

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Purpose: The DILIN is a consortium of 5 clinical centers and a data coordinating center, and it initiated an ongoing “DILIN Prospective Study.” Its objective is to identify and recruit individuals with drug-induced liver injury (DILI) for conducting clinical, epidemiological, and mechanistic studies.

Aim: To report the etiology and clinical characteristics of DILI of patients enrolled into the “DILIN Prospective Study.”

Methods: Pre-defined biochemical criteria were used to recruit eligible patients with suspected DILI. Patients with with acetaminophen toxicity were ineligible. Extensive evaluation was performed to exclude competing etiologies. The causal relationship between implicated agent(s) and the episode of liver injury was systematically assessed. Samples of serum, urine, and DNA were collected and stored for future studies.

Results: 203 patients were recruited between 9/04 and 5/06, and data from 141 patients were available for this analysis. Selected characteristics are shown in Table 1. A single prescription medication was implicated in 75% and a single CAM product was implicated in 4%, whereas multiple drugs/CAM were implicated in 21% of cases. Antimicrobials (43%) and anticonvulsants (10%) were the most common classes of implicated agents. Causality assessment was conducted on 46 patients and it was definite in 26%, very likely in 41%, and probable in 13%. During 6-month f/u (N = 56), 7% died and 23% exhibited chronic DILI.

Conclusions: Antimicrobials and anticonvulsants are the most common classes of agents to cause DILI in this study. The incidence of chronic DILI (23%) is higher than many anticipated. Extensive clinical data and biosamples are available to conduct clinical and mechanistic studies including genetic analyses to identify risk factors and predictors of outcome.

Demographics and Selected Characteristics of Patients with DILI (N = 141)

<table>
<thead>
<tr>
<th>Metric</th>
<th>Percentage</th>
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<tbody>
<tr>
<td><strong>Demographics</strong></td>
<td></td>
</tr>
<tr>
<td>Age (mean ± s.d.)</td>
<td>49 ± 18 yrs</td>
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<tr>
<td>Sex:</td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td>60%</td>
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<tr>
<td>Male</td>
<td>40%</td>
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<tr>
<td>Hepatocellular pattern of liver injury</td>
<td></td>
</tr>
<tr>
<td>Cholestatic pattern of liver injury</td>
<td>56%</td>
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<tr>
<td>Mixed pattern of liver injury</td>
<td>20%</td>
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<tr>
<td>Peak AST (IU/L) (Mean ± sd)</td>
<td>995 ± 2212</td>
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<tr>
<td>Peak ALT (IU/L) (Mean ± sd)</td>
<td>903 ± 998</td>
</tr>
<tr>
<td>Peak Ak Phos (IU/L) (Mean ± sd)</td>
<td>374 ± 369</td>
</tr>
<tr>
<td>Peak Bilirubin (mg/dl) (Mean ± sd)</td>
<td>11 ± 10</td>
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</tbody>
</table>

Hepatitis C: Transmission Ways and Clinical Spectrum in Armenia


Purpose: In retrospective studies the frequency of anti-HCV revealing in population of Armenia was 2.4%, and with high percent (55.6%) among the patients with chronic liver diseases. If in the end of 1999 the part of HCV-infection in the structure of viral hepatitis was 5.4%, the current index is 17.3%. Our aim was to study HCV-infection transmission ways and clinical spectrum of the patients with Hepatitis C in Armenia.

Methods: Under observation there were 85 patients with Hepatitis C, admitted to the Infectious Hospital “Nork” during 2002-2004. Patients with HIV and HBV co-infection also were involved in research. The diagnosis of Hepatitis C confirmed, taking into account clinical course of disease, presence in blood anti-HCV and at a part of the patients RNA HCV as well. The patients were between 16 and 65 years old (67 males - 78.8% and 18 females - 21.2%).

Results: The HCV transmission via intravenous illicit drugs use was in 32 (37.6%) patients. 8 patients (9.4%) was infected with blood and blood products transfusion. Multiple sexual contacts specified 5 patients (5,7%). Various medical manipulations indicated 19 (22,4%) patients including one case via needle stick at a nurse. In 18 (21.2%) patients the source of infection was unknown.

Of 85 patients with HCV-infection in 4 (4.7%) was acute Hepatitis C and in 81 (95.3%) chronic Hepatitis C was diagnosed though none of them had no history of acute Hepatitis C. 18 (21%) HCV patients was co-infected with HBV and 5 (5.9%) with HIV. In 2 (2.4%) patients HCV-infection was combined with HIV and HBV. In 9 (10.6%) patients disease was at the stage of cirrhosis (to Child-Pugh). Abusing by alcohol during life pointed 10 (11.8%) patients. Extrahepatic manifestation developed in 3 (3.5%) patients and played a leading role in the clinical picture.

In 15 patients with a chronic Hepatitis C was determined HCV genotype. In 7 patients it was G3a, in 6 patients - G1b and in 2 patients - G2.

Conclusions: The results demonstrate domination of males with chronic HCV-infection in the age from 31 till 35 years (50.6%) and the active way of infection in intravenous drugs use. Risk factor HCV-infection through blood and blood products transfusion and medical manipulation is still actual for Armenia. HCV-infection manifestation usually occurs in the stage of disease chronic course and sometimes in the stage of cirrhosis. As the sources of HCV, HBV and HIV infections are similar, 23 (27%) patients had co-infection (with HBV-21.1% and HIV-5.9%).

Doppler Ultrasound Using Standardized Software Is Not Useful for Portal Pressure Measurement

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Purpose: Portal venous pressure (PVP) is measured for the understanding and management of portal hypertension. The “gold standard” for PVP measurement is a gradient of free and wedged hepatic venous pressures which is obtained by hepatic venous catheterization. This technique is invasive, inconvenient and is available only in specialized centers. The aim of this study is to estimate portal pressure through non-invasive measurements of portal venous flow using Doppler ultrasound and to compare with the PVP as assessed by the hepatic venous catheterization.

Methods: Patients undergoing hepatic venous catheterization for wedged hepatic venous pressure (WHVP) measurement for standard of care indications were prospectively enrolled. Ultrasound Doppler flow study of the portal vein was obtained prior to undergoing hepatic venous catheterization. Portal pressure was estimated by measuring the diameter of the portal vein, portal blood flow velocity and hepatic artery pulsatility index, as calculated by the standard ultrasound software. The estimated PVP was then compared with actual PVP as measured by hepatic venous catheterization. Patients with heart failure and portal vein thrombosis were excluded.

Results: The results on 13 patients are summarized in table 1.
Liver Ultrasound Is Not a Good Predictor of Hepatic Steatosis and Fibrosis

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Purpose: Transabdominal ultrasound imaging of the liver is widely used for the evaluation of liver disorders. Results of liver ultrasound imaging are used in clinical practice to guide therapy for the individual patients. The aim of this study was to compare and correlate hepatic ultrasound reports with liver biopsy findings. A second aim of the study was to evaluate inter-observer reliability of hepatic ultrasound reports.

Methods: A retrospective chart review was performed for all liver biopsies between September 1, 2004 and November 15, 2005 at our institution. Patients with a hepatic ultrasound study within three months of the liver biopsy were included. Liver biopsies were performed for standard of care clinical indications (83% HCV; 10% suspected NASH) by one of four hepatologists. Biopsies were interpreted by a single pathologist with an interest in liver pathology. Hepatic ultrasound was performed and interpreted by one of several radiologists in the radiology department prior to a liver biopsy. A total of 58 patients were identified. A sub-study to evaluate inter-observer reliability of hepatic ultrasound reports was performed by two radiologists who re-interpreted the same studies separately and were blinded to the indications, previous ultrasounds and liver biopsy findings. Thirty patients with variable ultrasound findings were included.

Results: The summary of ultrasound findings in predicting steatosis (>15%) and stage 3 and 4 fibrosis (Batts & Ludwig classification) by liver biopsy is shown in table 1.

The inter-observer reliability was analyzed by calculating Kappa value:
- Normal versus coarse echotexture - 0.4
- Normal versus fatty infiltration - 0.56

Conclusions: In this study, trans-abdominal hepatic ultrasound imaging in early liver disease appears to be a poor predictor of biopsy findings of steatosis and advanced fibrosis. In addition, among our radiologists, there is observer variability in the interpretation of ultrasound findings. We suggest that ultrasound alone is not an adequate tool for the clinical diagnosis of fatty liver disease or fibrosis.

Table 1. (N = 58)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>LR+</th>
<th>LR-</th>
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<tbody>
<tr>
<td>Steatosis</td>
<td>37%</td>
<td>68%</td>
<td>1.16</td>
<td>0.92</td>
</tr>
<tr>
<td>Fibrosis</td>
<td>50%</td>
<td>76%</td>
<td>2.08</td>
<td>0.65</td>
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</table>

LR+ = Likelihood ratio for a positive test
LR− = likelihood ratio of a negative test.

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Chemoembolization for Hepatocellular Carcinoma as a Bridge to Liver Transplantation—A Transplant Center Experience

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Purpose: Hepatocellular carcinoma (HCC) usually occurs in the setting of cirrhosis. Orthotopic liver transplantation (OLT) is potentially curative. A high percentage of patients drop off the transplant list while waiting due to progressive HCC. The aim of this study is to assess the benefit of transarterial chemoembolization (TACE) as a bridge to transplant at a single institution.

Methods: We conducted an Institutional Review Board approved retrospective medical record review of 30 subjects with HCC confined to the liver treated with TACE and subsequent OLT from 1993 to 2003. All subjects had biopsy proven or clinical diagnosis of HCC. Cisplatin, adriamycin and mitomycin were infused with ethiodol into the hepatic artery followed by embolizing agent. TACE was repeated as needed to treat all sites of disease.

Results: The study cohort included 25 males and 5 females; 21 with hepatits C cirrhosis, 1 with hepatitis B cirrhosis, 6 with alcoholic cirrhosis and one each with autoimmune hepatitis induced cirrhosis and primary biliary cirrhosis. At diagnosis 16 subjects had single and 14 had multiple nodules; the mean tumor size was 3.5 cm × 2.9 cm; the mean alpha fetoprotein (AFP) was 706 ng/ml (range 8.1-12,259). The median waiting time from diagnosis to transplant was 312 days (range 41-947). With a median follow up of 29 months, 14 subjects have died, 5 with recurrent HCC and 9 of other causes. The estimated survival probability is 97% at 12 months, 56% at 36 months and 44% at 48 months.

Conclusions: TACE controlled tumor growth to allow subsequent OLT. Mortality is influenced by recurrent HCC as well as transplant and immunosuppression related complications. Risk of mortality was not associated with pretreatment AFP; change in AFP with therapy, lesion size or presence of vascular invasion. Further evaluation is needed to identify patients likely to succumb to recurrent HCC or treatment related complications.

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A Retrospective Analysis of Prognostic Demographic Features of Hepatocellular Carcinoma

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Purpose: Hepatocellular (HCC) is a highly fatal cancer and has been on the rise in USA. The purpose of this study was to elucidate the exogenous factors that are determinants of prognosis for HCC.

Methods: The IMPAC Medical Registry Services Cancer Information Resource File was referenced for HCC cases diagnosed by clinical evaluation & biopsy between 6/1/1993 & 12/31/2003. A log-rank test of equality was used to identify significant individual predictors of mortality in these
patients. Odds ratios were calculated based on logistic regression model with binomial distribution.  

**Results:** 9349 patients, 6998 males & 2350 females, were followed for an average of 10 months. Age at diagnosis (<70 and ≥70) & gender were found to have significant differences in survival, p < 0.0001 & <0.017, respectively. Patients < 70 had a median survival (MS) of 7 months compared to a MS of 4 months in patients of 70 years & older. Caucasian patients also demonstrated longer MS than African American patients. (p < 0.0001) Tobacco or alcohol use, current & past, significantly decreased survival in HCC patients (p < 0.0001). MS periods for current tobacco use, past tobacco use & never used were 5, 6 & 7 months respectively. Mortality in HCC increased 1.6-fold in patients with current tobacco use vs tobacco abstinence (p < 0.0001, OR 1.6; 95% CI: 1.4-1.8) & 1.3-fold with past use vs tobacco abstinence (p = 0.0002, OR 1.3; 95% CI: 1.1-1.5). Mortality in HCC also increased 1.5-fold with current alcohol use vs alcohol abstinence (p < 0.0001, OR 1.5; 95% CI: 1.3-1.8) but past use was not found to be significant when compared to abstinence. Surgery is significantly associated with longer survival, 30 vs 4 months, respectively (p < 0.0001). Although in the short term (<36 months) chemotherapy was significantly associated with longer survival (p < 0.0001), in prolonged follow-up (>36 months), the effect disappears (p = 0.1456).

**Conclusions:** This is the first comprehensive demonstration that demographic factors (gender, race & age at presentation) are important clinical predictors for survival with HCC. Our data underscores the importance of tobacco use as an important determinant of survival from HCC. When limited by lack of information regarding etiology/extent of liver disease, the power of the large database size of IMPAC enables these novel insights regarding prognostic factors of HCC. If confirmed in other datasets, these parameters may be of value in predicting natural history & benefits of therapy from HCC.

### 381 Biomarkers (HCV FibroSURE®) Can Predict Significant Fibrosis in Patients with Chronic Hepatitis C (CHC) – The First Prospective Validation in a United States (US) Cohort

**Purpose:** In CHC, biopsy is the gold standard for assessment of liver fibrosis. HCV FibroSURE®, recently introduced in the US, has been proposed as an alternative to liver biopsy (LB). However, there are no prospective US data on its efficacy. We therefore, aimed to prospectively validate the concordance of HCV FibroSURE® and LB in CHC.

**Methods:** Forty-two consecutive patients undergoing both LB and FibroSURE® for evaluation of their CHC were included in this study. All patients were HCV treatment naïve and had routine hematologic, biochemical and serologic tests by standard laboratory techniques. A single pathologist unaware of FibroSURE® results staged and graded liver biopsies according to METAVIR and Knodell systems. We used MedCalc Software (V8.2.1.0, Belgium) for area under the receiver operating curve (AUROC) analysis, sensitivities, specificities, positive and negative likelihood ratios.

**Results:** The overwhelming majority of the 42 patients (Mean age ± SD = 45.8 ± 8.2 years) were Caucasians (88%) with male predominance (M = 71%, F = 29%). Important lab values (Mean ± SD) included platelets (218 ± 73 × 10^9/L), AST (63 ± 56 IU/L), ALT (89 ± 62 IU/L), and viral load (5.1 ± 8.6 million copies/ml). HCV genotypes 1 (52%) and 3 (28%) were more common. Staging and grading by histology and FibroSURE® are shown in the table. For significant fibrosis (F2-F4) defined by histology, the AUROC for FibroSURE® was 0.982 (95% CI 0.883 to 0.995, +LR of 9.5, p < 0.0001). Fibrose stage ≥ 2 was 100% sensitive and 89.5% specific in predicting significant fibrosis. When compared with METAVIR grade, AUROC for FibroSURE® activity ≥ 2 was 0.744 (95% CI 0.586 to 0.866, +LR of 4.03, p < 0.002). In contrast, this did not reach significance with Knodell activity (AUROC = 0.642, p = 0.11).

**Conclusions:** Surrogate biomarkers (HCV FibroSURE®) are highly predictive of significant liver fibrosis and activity in CHC. This could emerge as a non-invasive screening tool for hepatic fibrosis and diminish the need for liver biopsy in the management of CHC.

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### 382 The Distribution of Hepatitis C Virus Genotype in Southwest Native Americans and the Natural Progression of Infection

**Purpose:** Limited data exists regarding the epidemiology of hepatitis C virus (HCV) infection in Native Americans. Our hypothesis is the epidemiology and natural history of HCV infection in this underserved population differs from the mainstream U.S. culture.

**Methods:** Subjects in an Indian Health Service (IHS) hospital in the Southwest United States and a veterans population were studied in a retrospective cohort study. 562 IHS patients were identified by positive second generation Elisa anti-HCV antibody (anti-HCV EIA II) results obtained between 2000 and 2005 for standard clinical indications during outpatient visits at an Indian Health Service hospital and a veterans medical center. The diagnosis was confirmed by RIBA results in all subjects. Variables collected include age, and quantitative viral load in 260 subjects. Age of subjects stratified by genotype was compared to historical data obtained since 2000 at the VAMC. Statistics calculated with SPSS statistical software version 13.5 (SPSS, Inc. Chicago IL).

**Results:** 1. The total number of adult patients diagnosed with HCV infection during the last six years at the IHS hospital is 562. 2. Genotypes were identified in 105 patients, of which 39% were non-genotype 1, compared to 31% in the VA population. 3. Sixty-nine of 260 (26.5%) patients had undetectable HCV virus but persistently positive anti-HCV EIA II and RIBA. 4. Average age in the NA subjects varied significantly by genotype (ANOVA p < 0.005), and was significantly younger than the average age in the VA population (p < 0.001, Table1).

**Conclusions:** 1. The genotypic distribution is similar to findings in a veteran's population.

<table>
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<th>Age in Years by Genotype in Native Americans versus Veterans</th>
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2. The spontaneous viral clearance rate (26.5%), based on undetectable PCR in setting of persistently positive anti-HCV EIA II and RIBA, exceeds the historical range of 15-20%.

3. The younger age of infected Native Americans suggests different risk factors in this population.

The findings expressed in this abstract represent those of the authors and not those of the Federal Government.

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Development of a New Method for Hepatitis B Virus Genotype G and Its Prevalence among Japanese Acute Hepatitis B Patients

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Purpose: There are eight genotypes (A to H) in hepatitis B virus (HBV). Each of them has indigenous distribution among worldwide and unique clinical characters, but genotype G has not been understood the global distribution and clinical course in detail. HBV genotype G has unique 36bp insertions in core region. This insertion region was easy to make genotype specific primer of genotype G for PCR. However this region is too short to make a stable set of primers, so we decided to develop a new method of identifying genotype G utilizing restriction fragment length polymorphism (RFLP). Some reports found that genotype G was frequently co-infected with other HBV genotypes. We investigated the prevalence of genotype G among patients with acute hepatitis B (AHB) using this novel method.

Methods: One hundred-one AHB patients (72 men and 29 women, 16–72 years of age, mean 35.9 ± 13.6 years) admitted to our hospital from 1992 to 2005 were enrolled. HBV genotype was determined by RFLP and/or direct sequence of the S gene. We performed real-time fluorescent-probe PCR to quantify the level of HBV-DNA. Genotype G was detected by hemi-nested PCR method previously reported and a new method. We developed genotype specific PCR-RFLP for genotype G. 740bp products including unique insertion was amplified by hemi-nested PCR and RFLP targeting to this insertion.

Results: Most of these cases were self-limited illness, but 4 patients were fulminant hepatitis, and 4 cases developed to chronic hepatitis. HBV genotypes of AHB were A, 21; B, 4; C, 73; D, 1; F, 2. The mean HBV-DNA levels among these patients were A (N = 17), 9.07 ± 9.41 (mean ± S.D. log10copy/ml); B, (N = 1), 6.28; C, (N = 57), 7.79 ± 8.31; D, (N = 1), 7.92 (The levels of HBV-DNA could not be quantified among genotype F patients). Genotype G HBV was detected by neither hemi-nested PCR nor RFLP.

Conclusions: Some non-native genotypes (genotype A, D, F) were identified among Japanese AHB patients, however HBV genotype G was not detected by genotype specific PCR or RFLP. The incidence of genotype G infection was quite rare among Japanese AHB patients.

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Association of Metabolic Syndrome with Hepatic Inflammation and Fibrosis Stage in Nonalcoholic Fatty Liver Disease

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Purpose: Nonalcoholic steatohepatitis can develop from nonalcoholic fatty liver and progress to severe liver diseases such as cirrhosis. Recently, insulin resistance is proposed as a primary pathogenic mechanism in nonalcoholic fatty liver disease (NAFLD). NAFLD is thought to hepatic manifestation of the metabolic syndrome. The aims of this study were to evaluate the relationship of components of metabolic syndrome (waist circumference, fasting glucose, high density lipoprotein (HDL)-cholesterol, triglycerides, and arterial pressure) and indices of insulin resistance (fasting insulin level, homeostasis model assessment of insulin resistance; HOMA-R, C-peptide) with hepatic fibrosis or inflammation, and to assess whether component of metabolic syndrome is a risk factor of progression to liver injury each other.

Methods: The biochemical, clinical and histopathological data of thirty-nine patients with a NAFLD diagnosed by liver biopsy were analyzed. Liver biopsy findings were graded according to the method described by Brunt et al.

Results: 24 of 39 patients (62%) had the metabolic syndrome. Serum ferritin, body mass index, fasting glucose, triglycerides, and HDL-cholesterol were associated with hepatic inflammation (p = 0.001, p = 0.006, p = 0.034, p = 0.012, 0.048). Serum ferritin, body mass index, fasting glucose, and C-peptide were associated with fibrosis (p = 0.005, p = 0.013, p = 0.013, p = 0.041). Logistic regression analysis did not identify all components of metabolic syndrome as a risk factor of liver injury.

Conclusions: Component of metabolic syndrome except fasting glucose (waist circumference, HDL-cholesterol, triglycerides, and arterial pressure) shows no association with the degree of hepatic fibrosis. All components of metabolic syndrome may not be risk factors of hepatic injury in patients with NAFLD.

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The Spectrum and Response to Treatment of Chronic Hepatitis C Infection in African Americans and Hispanics at Harlem Hospital Center

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Purpose: To examine the variability in the pattern of chronic HCV infection and assess treatment outcomes in African Americans and Hispanics.

Methods: A retrospective analysis of 46 patients treated with Interferon alfa 2b and Ribavirin at Harlem Hospital Center between January 2003 and June 2005 was performed. Inclusion criteria were subjects with compensated liver disease and a positive HCV RNA. Primary end point was early virologic response and the secondary end point was end of treatment response.

Results: A total of 556 patients were referred to the Hepatology clinic. Ninety-nine of these patients had chronic hepatitis C, and 46 of these patients were treated (46%). The mean ages of treated African Americans (N = 28) and Hispanics (N = 13) were 51.64 and 51 respectively. Among these treated patients, there was a male preponderance in both the African American group (60.7% male) and the Hispanic group (61.5% male). The major causes for exclusion were active drug and alcohol abuse (7.4%), non compliance with initial clinic visits (27%) and psychiatric disorders (9.8%). Of the 46 patients treated, obesity and normal ALT were seen in 25% vs. 42% (Fisher Exact 1-tailed p-value = 0.2998) and 69% vs. 58% (Fisher Exact 1-tailed p-value = 0.4772) of African Americans and Hispanics respectively. Hispanics had significantly more advanced liver disease than African Americans (58% vs. 24% for cirrhosis; Fisher Exact 1-tailed p-value = 0.0287, 2-tailed p-value = 0.0376). Of the African Americans, 44% had steatosis compared to 12% of Hispanics (Fisher Exact 1-tailed p-value = 0.0823). African Americans had 85% of genotype 1 infection against 67% of Hispanics (Fisher Exact 1-tailed p-value = 0.2046). Early virologic response was substantially lower in African Americans (38% vs. 83%; Yates-corrected Chi-Squared = 5.63, p = 0.0177). The end of treatment response was 21% vs. 42% (Fisher Exact 1-tailed p-value = 0.2194) and SVR was 10 vs. 25% for African Americans vs. Hispanics respectively (Fisher Exact 1-tailed p-value = 0.2769).

Conclusions: African Americans appeared to be much less likely to have early virologic response than the Hispanics, although Hispanics had more advanced liver disease. Both groups had much lower sustained viral response than generally reported. Better therapeutic options for optimal response in both African Americans and Hispanics are needed.
Relation of Serum Resistin Concentration to Steatosis and Insulin Sensitivity in Patients with Chronic Hepatitis C Genotype 4

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Purpose: Hepatitis C virus (HCV) infection increases the risk of developing type 2 diabetes mellitus (T2DM) and insulin resistance. Resistin has been implicated in the pathogenesis of obesity-mediated insulin resistance and T2DM. Moreover, plasma resistin concentration is positively correlated with hepatic fat content in T2DM patients. The aim of the present study was to assess the relationship of resistin to insulin resistance and steatosis in HCV-infected patients.

Methods: 40 untreated patients with chronic hepatitis C (genotype 4) were studied. Insulin sensitivity was evaluated using the homeostatic model assessment (HOMA) system and serum resistin concentration was measured. Liver biopsy was performed. Fibrosis was evaluated using the modified HAI (Ishak) system. Steatosis was graded as absent or minimal (less than 1% of hepatocytes), mild (<30% hepatocytes involved), moderate (between 30 and 60% of hepatocytes involved) or severe (>60% of hepatocytes involved).

Results: Patients with steatosis (N=23) had higher body mass index (BMI) compared to patients without steatosis (N=17); 30.19 ± 3.96 kg/m² vs 24.69 ± 1.84 2.9 kg/m² (p < 0.001). The HOMA-insulin level positively correlated to BMI (r = 0.67; p = 0.001). There was no significant difference in serum resistin level between male subjects and female subjects (resistin = 10.73 ng/mL vs 11.64 ± 0.03 ng/mL; p = 0.22). No significant correlation was found between resistin and BMI (r = 0.24, p = 0.17) or HOMA level (r = - 0.37, p = 0.87). As regards the distribution of resistin level in relation to stage of hepatic fibrosis, it was not found to vary significantly among the different stages (Mild (Ishak 1-2): 11.33 ± 0.59 ng/mL; moderate (Ishak 3-4): 15.36 ± 9.26 ng/mL and advanced fibrosis (Ishak 5-6); 16.83 ± 14.66 (p = 0.34)). Resistin concentration was not significantly different in patients with steatosis compared to patients without steatosis (13.87 ± 9.56 vs 11.35 ± 7.58 ng/mL; p = 0.47). Resistin level did not show significant difference among patients with minimal, mild and moderate steatosis (p = 0.57).

Conclusions: The present study demonstrated that resistin level was not associated with insulin resistance in patients with chronic hepatitis C. Further studies are warranted.

Hepatitis B Virus DNA Levels, Genotypes and Histology in HBeAg Negative Chronic Hepatitis B Virus (CHBV) Infected Patients with Persistently Normal ALT, the ‘Inactive Carrier’

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Purpose: HBeAg negative chronic hepatitis B virus (CHBV) infected patients with persistently normal ALT (PNALT) for 12 mo. are generally diagnosed as inactive HBV carrier. In the NIH Workshop (2000) it was suggested that subjects with inactive disease could be differentiated from subjects with active disease by an HBV DNA of <10⁵ copies/ml. This cut-off value remains controversial. Also, there is paucity of histological data in HBeAg negative patients with PNALT. The aim was to correlate HBVDNA levels and liver histology in HBeAg subjects with chronic HBV infection with PNALT and compare with patients with intermittently normal ALT (INALT).

Methods: HBeAg - patients who had at least 1 year follow-up and had either PNALT (at least 3 ALT values in 1yr prior to liver biopsy) or INALT (at least 3 ALT values and at least one <40 IU/L in 1 yr. prior to biopsy). Biopsy specimens were scored by Knodell index.

Results: 116 HBeAg- CHBV patients with PNALT [Gr1, age: 34.6 ± 14.5y, 68.1% M] were compared with 172 patients with INALT [Gr2, age: 34.2 ± 13.9y, 84.3% M]. Liver biopsy was available in 58 patients in Gr1. Distribution of genotypes [A/D/A+D] was 30/60/10% in Gr1 & 14.3/57.1/28.6% in Gr2 [p = 0.349]. Mean ± SD (median (range)] baseline DNA was 4.50 ± 1.82 ± 4.29 (29.0-9.20) logcopies/mL in Gr1 & 5.77 ± 1.70 [5.45 (2.09-9.41)] logcopies/mL in Gr2 [p = <0.001]. 41 (35.3%) patients in Gr1 & 107 (62.2%) in Gr2 had baseline DNA >5 logcopies/mL [p = <0.001]. 29 (25%) patients in Gr1 & 8 (4.71%) in Gr2 had baseline DNA <3 logcopies/mL [p = <0.001]. Mean ± SD (median (range) HAI was 2.3 ± 2.73 (1-10) in Gr1 & 4.7 ± 2.54 (1-13) in Gr2 [p = 0.001]. 23 of 58 (39.7%) patients in Gr1 & 108 (62.8%) in Gr2 had HAI >3 [p = 0.003]. Mean ± SD (median (range)) fibrosis scores were 0.79 ± 0.81 (11-3) in Gr1 & 1.73 ± 0.97 (2-4) in Gr2 [p = <0.001]. Distribution of fibrosis stages [0/1/2/3/4/5] were 79.3/46.6/6.8/5.2/0.0% in Gr1 & 8.1/34.9/37.2/15.1/4.7% in Gr2 [p = <0.001]. Eight of 58 (13.8%) patients in Gr1 & 98 (57.0%) in Gr2 had ≥2 fibrosis [p = <0.001]. There was correlation between fibrosis stage & ALT (r = 0.176, p = 0.007) and HBVDNA (r = 0.21, p = 0.007). Similarly, there was correlation between HBV DNA and HAI (r = 0.348, p = <0.001).

Conclusions: 1) 35.5% of HBeAg-CHBV infected patients with PNALT have HBVDNA >5 log copies/mL. 2) 39.7% of such patients have HAI>3 and 13.8% have ≥2 fibrosis stage on biopsy. 3) The so-called ‘inactive carriers’ are not really inactive and hence the term should be abandoned.

Are U.S. Undergraduates in Danger of Acquiring Hepatitis C? Assessment of Students’ Risk Behaviors and Knowledge of the Disease

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Purpose: Transmission of hepatitis C (HCV) through sharing of pierced body jewelry has recently been reported. Given the frequency of piercing and tattooing, young adults may be at risk for acquiring HCV. The prevalence of HCV risk factors has not previously been studied in undergraduates. The aim of this study was to determine the prevalence of traditional and novel risk factors as well as HCV knowledge among a group of U.S. undergraduates.

Methods: A new validated survey that assesses traditional (intravenous drug use (IVDU), blood transfusion, etc.) and novel risk factors (sharing of body jewelry, injection steroid use, etc.), and knowledge of HCV was administered to students in 22 sections of a required health class at a large Midwestern university.

Results: 610/612 (99.7%) students participated. Demographics: 63% female, mean age = 20 ± 2 yrs, 72% Caucasian, and 18% African American. Student risk factors, 9% used intranasal cocaine, 1% IVDU and 1% received transfusion. 24% had tattoos. 69% have had at least one piercing in their lives, and 32% have a piercing in an area other than their earlobe. More than 60% of respondents with piercings report sharing pierced jewelry with at least one other person. 79% report undergoing a general medical exam in the last 3 years; however, almost 50% were not asked about any common HCV risk factors during that visit. 97% reported protecting themselves from HCV was important and 81% felt the disease had long-term consequences. 27% didn’t know HCV can be transmitted via IVDU, and 77% were unaware HCV could be transmitted by intranasal cocaine use. 26% felt they knew some/a lot (possible responses: nothing, a little, some, a lot) about HCV as compared to the 76% who felt they knew some/a lot about HIV. 45% were interested in being tested for HCV.

Conclusions: Nearly 12% of respondents report a history of at least one traditional HCV risk factor. When sharing of body jewelry (novel risk) and tattooing (possible risk) are included, more than 75% of students reported a HCV risk factor. Despite this level of risk, students are not being screened by health care providers and do not recognize the magnitude of their risk for acquiring HCV. Given the prevalence of these behaviors and identified opportunities for screening/education, further research should focus on this age group.
Multicentre Study with Recombinant Interferon α 2b for the Treatment of Chronic Hepatitis B & C Infection–An Indian Experience

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Purpose: Assess the efficacy and safety of indigenously developed Recombinant Interferon α 2b (IFN).

Methods: Open-label, non-randomized study. 31 patients of Chronic Hepatitis B (CHB) were enrolled to receive daily subcutaneous (s.c.) injections of IFN 5 MIU for 16 weeks. At baseline all patients were positive for HBsAg and HBV DNA, and mean serum ALT was 97.5 IU/L. 32 patients of Chronic Hepatitis C (CHC) were enrolled to receive thrice weekly s.c. injections of IFN 3 MIU and oral ribavirin 1000-1200 daily. All HCV RNA positive patients were tested for genotype. At the baseline mean the serum; RNA was > 3 million copies/ml and ALT was 141.1 IU/L. Both CHB and CHC patients had HAI > 5 in the last 6 months. Liver, kidney & thyroid function tests as well as presence of interferon antibodies were determined at baseline and repeated at end of therapy.

Results: After 16 weeks of therapy; 43% of CHB patients (33% of HBsAg positive & 50% of HBeAg negative) showed virological response (disappearance or ≥ 2 log decrease in serum HBV DNA). 58% patients seroconverted and 40% patients had normalization of serum ALT.

Out of 32 patients of CHC; 10, 1 and 21 patients had HCV genotypes 1, 2 & 3 respectively. Overall 70.9% patients showed virological response (undetectable HCV RNA by PCR) after treatment for 12 weeks. At 24 weeks; all patients (100%) of genotype 1 (N = 10) had shown undetectable HCV RNA while the response in genotype 2 (N = 1) and 3 (N = 21) was 100% and 85.7% respectively. Overall 74.2% patients showed normalization of serum ALT at 6 months. Biochemical response (normal ALT) in patients with genotype 1, genotype 2 and genotype 3 infections was 44.4%, 100% and 71.4% respectively. The adverse effects commonly reported during the study were fever, weakness, body ache, dyspepsia and anorexia. Biochemical alterations were within expected limits. No patient developed antibodies against interferon.

Conclusions: The treatment with IFN 5 MIU daily for 16 weeks in CHB and IFN 3 MIU thrice weekly in combination with daily ribavirin for 24 weeks in CHC showed significant virological and biochemical response. The drug was well tolerated by the patients.

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Lamivudine Treatment for Severe Acute Hepatitis B–A Controlled Trial

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Purpose: Role of antivirals in patients with acute viral hepatitis B (AVH-B) & especially severe cases has not been evaluated in controlled trials. The aim was to evaluate the efficacy of lamivudine in treating immunocompetent patients with severe AVH-B.

Methods: Patients with AVH-B & serum bilirubin ≥ 5 mg/dl at presentation were randomised into: Gr1: lamivudine 100 mg daily for 3 mo (N = 31), & Gr2: Placebo (N = 40). Severe AVH-B was diagnosed if patients fulfilled any 2 of the following criteria: (1) hepatic encephalopathy; (2) serum bilirubin ≥10.0 mg/dl; & (3) international normalized ratio (INR) ≥ 1.6.

Results: 22 (71%) patients in Gr1 & 25 (62.5%) in Gr2 had severe AVH-B. 2 patients in Gr1 & 1 in Gr2 presented with encephalopathy. Among the severe cases, median (range) log decline in HBV DNA from the baseline in Gr1 & 2 was 0.532 (0.0–3.06) & 0.123 (−0.72–0.88) at day 4 (p = 0.001); 0.690 (0.04–3.22) & 0.249 (−0.77–0.98) at wk 1 (p < 0.001); 0.836 (−0.21–3.45) & 0.436 (−0.24–1.33) at wk 2 (p = 0.002); 1.092 (0.34–3.49) & 0.509 (−0.24–1.44) at wk 3 (p = 0.001); & 1.214 (0.49–3.64) & 0.685 (−0.25–1.37) at wk 4 (p < 0.001), respectively. Median (range) percent decline in serum bilirubin levels from the baseline in Gr1&Gr2 was 24.8 (−29.4–62.2) & 24.7 (−38.8–73.3) [p = 0.94] at week 1; 58.4 (−56.6–80.7) & 47.5 (−29.6–77.9) [p = 0.51] at week 2; 72.2 (−105.4–89.6) & 61.8 (−30.7–88.6) [p = 0.93] at week 3; & 79.9 (−132.4–96.9) & 75.0 (−52.1–93.9) [p = 0.99] at week 4 respectively. Median (range) percent decline in serum ALT levels from the baseline in groups 1&2 was 61.8 (−143.6–88.7) & 34.1 (−34.3–94.0) [p = 0.50] at wk 1; 83.7 (0.82–96.0) & 64.1 (−52.1–97.4) [p = 0.05] at week 2; 91.2 (38.8–97.8) & 71.57 (−110.8–97.7) [p = 0.04] at week 3; & 94.1 (51.8–99.2) & 88.5 (−7.7–97.8) [p = 0.02] at week 4 respectively. Similarly there was no significant difference in trends of INR improvement in both groups of patients. There was no mortality in either group. At 1 year 20 of 31 (93.5%) patients in Gr1 & 37 of 40 (92.5%) in Gr2 lost HBsAg. At 1 year, 21 of 31 (67.7%) in Gr1 & 34 of 40 (85%) patients in Gr2 developed protective anti-HBs titer [p = 0.09]. All HBeAg positive patients in either group lost HBeAg. Anti- HBe developed in 71% & 87.5% patients in groups 1 & 2 [p = 0.13].

Conclusions: Although lamivudine causes greater fall in HBV DNA in patients with severe AVHB, the clinical benefit in terms of biochemical & clinical improvement is modest. There was a trend towards lower chance of developing protective antibodies to surface antigen when treated with lamivudine.

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34 Year Old Female Presents with Abdominal Pain

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Purpose: 34 year old female, gravida 4, para 0, at 16 weeks of gestation presented with abdominal pain for 3 days, epigastric/right upper quadrant, severe, with nausea and vomiting. Patient denied fever, arthralgias, visual disturbances or change in bowel habits. Her past medical history was significant for antiphospholipid antibody syndrome and systemic lupus erythematosus without active manifestations. She denied any history of smoking, alcohol
use, or illicit drug use. Her medications included aspirin, enoxaparin, hydroxychloroquine, and prenatal vitamins. She was allergic to sulfia and penicillin. Physical exam revealed elevated blood pressure (150/84 mmHg), tenderness in right hypochondrium with voluntary guarding, hepatomegaly and a gravid uterus. Lab studies revealed thrombocytopenia, elevated transaminases (7 times above the normal value), LDH and decreased haptoglobin. Urinalysis revealed proteinuria with trace blood. Ultrasound of the abdomen revealed thickened gallbladder wall without gallstones. CT scan and subsequent MRI of the abdomen revealed densities throughout the liver consistent with hepatic infarctions/necrosis. Our patient was diagnosed with HELLP syndrome with hepatic infarctions/necrosis. Hepatic infarction in pregnancy is a rare condition, with an estimated incidence of 1 in 40,000 to 250,000 pregnancies. The hepatic infarction although rare, usually occurs after the 20th week of pregnancy and usually involves the right lobe of the liver. The diagnosis is established by abdominal ultrasound, CT scanning, MRI or angiography. Hepatic rupture is a dangerous complication that can cause mortality rates as high as 85 percent. Treatment is generally limited to conservative management and delivery of the fetus. Our case is unique in that the patient presented with this clinical syndrome in the 16th week of her pregnancy and her hepatic infarctions included most of her liver. Our patient had an uncomplicated dilatation and evacuation procedure. [figure1]

Percutaneous Endoscopic Gastrostomy in Cirrhosis Patients: A Comparative Cohort Study
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Purpose: Cirrhosis is considered a relative contraindication for percutaneous endoscopic gastrostomy (PEG) with limited published data to support this position. The purpose of this study is to analyze outcomes of hospitalized cirrhotic patients who underwent PEG compared to cirrhosis patients without PEG and non-cirrhotic patients undergoing PEG.

Methods: Patients were found using ICD codes from the UVAHS clinical database (1993-2005) to identify cirrhotic patients undergoing PEG placement and comparative control cohorts. Systematic chart review validated the diagnoses and other clinical characteristics. The study population outcomes were analyzed compared to a hospitalized cohort with cirrhosis and a cohort undergoing PEG placement without cirrhosis.

Results: There were 26 patients with documented cirrhosis who underwent PEG placement. The most common etiology for cirrhosis was alcohol. The mean MELD score was 15.3 (95% CI, 12.4-18.2), INR was 1.4 (1.3-1.5), and platelet count was 161×1000/mL (115-207). Seven (26%) patients had esophageal varices and 16 (61%) had a history of ascites. Ten patients (39%) died within 30 days of the procedure; 2 deaths were related to the procedure and 3 were possibly related to the procedure. No patient who survived more than 30 days after PEG died within the next 60 days. Nine of the 10 patients that died within 30 days of the procedure had a history of ascites. Ascites was an independent risk factor for death (RR for death = 2.1, 95% CI 1.1-3.7, p = 0.04). When compared to a cohort of 554 inpatients with cirrhosis that did not receive a PEG tube and to a separate cohort of 341 inpatients without cirrhosis that did undergo PEG placement, mortality for the cirrhosis PEG patients at 30 days was not statistically different from the general cirrhosis cohort (38.5% vs 23.1%, p = 0.10); however, 30 day mortality for the cirrhosis PEG patients was higher than the general PEG cohort (38.5% vs 18.1%, p = 0.02). At 90 days after PEG, there were no statistical differences between any of the three cohorts in overall mortality (p>0.20).

Conclusions: Our findings suggest hospitalized cirrhotic patients undergoing PEG placement have 30 day mortality rates similar to a cohort of hospitalized cirrhotic patients without PEG placement. While PEG placement in cirrhosis should be considered carefully, its’ role in management of malnutrition in cirrhosis should be reconsidered. Prospective trials in the cirrhotic population are needed.

Demographics, Liver Function, and Source of Hepatitis C Virus Infection in Patients That Decline Interferon Treatment
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Purpose: Few data have been reported about patients who decline treatment for their CHC infection. We analysed the demographic information of a group of patients who made an informed choice not to receive interferon-based therapy, including the source and duration of their infections, and their biochemical liver function at the time of their decision.

Methods: The billing database of an open-access clinic was scanned using ICD-9 code 070.54. Patient charts were retrieved from protected medical records and retroactively analyzed. The following data were recorded: patient demographics, peak alanine aminotransferase (ALT) level, source of infection, and presumed duration of infection.

Results: Out of a total of 446 patients, 115 (26%) declined therapy and opted to be followed expectancy after a full discussion of the available therapeutic options and their side effects. Gender: Male 49 (42.6%) Female 66 (57.4%) Age (years): <25 3 (2.6%) 26–35 3 (2.6%) 36–45 13 (11.3%) 46–55 69 (60.0%) 56–65 16 (13.9%) >65 11 (9.6%) Peak ALT level (IU/L): 0–50 43 (37.4%) 51–100 46 (40.0%) 101–150 14 (12.2%) 151–200 4 (3.5%) 201–250 3 (2.6%) 251–300 3 (2.6%) 300+ 2 (1.7%). Documented source of infection: Transfusion 33 (28.7%) Intravenous drug use 49 (42.6%) Sexual 12 (10.4%) Unsterile sharp instruments 2 (1.7%) Unknown 19 (16.5%) Documented duration of infection (years): <10 14 (12.2%) 11–15 11 (9.6%) 16–20 34 (29.6%) 21–25 5 (4.3%) 26–30 36 (31.3%) >30 2 (1.7%) Unknown 13 (11.3%).

Conclusions: The decision not to be treated was primarily made by patients with the following characteristics: male, age 46–55 years, peak ALT level less than 100 IU/L, and duration of infection greater than 30 years. The main reasons cited for their decision were: absence of hepatitis-related symptoms, fear of side effects or efficacy, or social circumstances precluding effective treatment. Further observation of the natural history of CHC in these patients is recommended.

Liver Histology in Patients That Pursue Expectant Management of Chronic Hepatitis C: Correlating Genotype and Histology with Patients’ Decisions
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Purpose: The role of liver biopsy in treatment of chronic hepatitis C is currently under discussion. As yet, there is little data about extent of liver injury in patients that decline conventional interferon treatment. Our aim was to determine the degree of hepatic injury and the genotype of CHC infections among otherwise eligible patients who chose not to receive interferon-based therapy.

Methods: The billing database of an open-access clinic was scanned using ICD-9 code 070.54. Records of patients who declined interferon treatment were retrieved and retrospectively analyzed. The following data were analyzed: patient demographics, hepatitis C genotype, and liver biopsy results.

Results: A total of 446 charts were reviewed. Of these, 115 patients declined medical intervention. Of this subgroup, 103 patients had liver biopsy to assess liver injury. Male: 49 (42.6%) Female: 66 (57.4%) Grade 1, Stage 1: 38 (33.0%) Grade 2, Stage 1: 30 (26.1%) Grade 2, Stage 2: 17 (14.8%) Grade 2, Stage 3: 5 (4.3%) Grade 3, Stage 4: 3 (2.6%) Grade 3, Stage 3: 8 (7.0%) Grade 3, Stage 2: 1 (0.9%) Grade 3, Stage 0: 1 (0.9%) Total: 103 HCV Genotype 1A: 68 (59.1%) 1B: 37 (32.2%) 2A: 2 (1.7%) 2B: 1 (<0.1%) 3A: 3 (2.6%) 3B: 1 (<0.1%) 4: 3 (2.6%).
Conclusions: The majority of patients [N = 85 (74%)] that declined interferon treatment had minimal liver injury based on histologic results (rarely more than grade 1, stage 1). Consensus statements have recommended liver biopsy in patients with normal or near-normal ALT values since significant fibrosis can be seen in up to 25-30% of such patients. An informed decision not to receive interferon in genotype 1 patients with such mild disease appears justifiable while newer therapies are being developed.

Efficacy of Combination Weight-Based Therapy with Pegylated Interferon alfa-2b Plus Ribavirin for Treatment of Chronic Hepatitis C: Impact of Genotype and Race
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Purpose: Studies have investigated the efficacy of weight-based therapy with PEG-IFN alfa-2b plus ribavirin (RBV) in patients with chronic active hepatitis C (CAHC). We hypothesized that SVR rates associated with combination therapy for Caucasian and African American patients are higher than previously reported.

Methods: A retrospective study of patients with CAHC treated with PEG-IFN alfa-2b (1.5μg/kg/week) plus RBV (13 mg/kg/day) for 24 (genotypes 2/3 [G2/3]) or 48 weeks (G1, G4) was conducted from January 2001 to June 2006. Primary endpoint was SVR, defined as undetectable viral load 24 weeks after completion of therapy. SVR was calculated overall and by race, genotype, and race stratified by genotype. Results were compared with data from an extensive literature search, conducted to determine published overall SVR rates and SVR rates by race, genotype, and race by genotype associated with this combination therapy.

Results: 80 patients (63 Caucasian; 17 African American) were analyzed. Overall SVR rate was higher (61.3%; 49/80) than that in the registrational trial (54%; 274/511; p = NS). G1 patients in this study had significantly higher SVR rates than G1 patients in previous studies (53.7%[36/67] vs 42%[145/348], respectively; p = .04). SVR rates were higher among these G2/3 patients (100%; 11/11) and G4 patients (100%; 2/2) than those from previous studies (82%[121/147] for G2/3; p = NS; 50%-8[16] for G4; p = NS). SVR rates among African American G1 patients in this study were higher than SVR rates for those in previous studies (23.5%[4/17] vs 19%[19/100], respectively; p = NS). SVR rates among Caucasian G1 patients in this study were also higher than those in previous studies (64%-32/50) vs 52%-32/60; p = .06). Differences may not have reached statistical significance because of sample size.

Conclusions: Findings suggest that SVR rates associated with weight-based therapy with PEG-IFN alfa-2b plus RBV in patients with CAHC are higher for G1 patients than in previous studies. With a larger sample size, statistical significance may have been reached for the other groups examined (G2/3, G4, African American patients). We believe this level of response may be achieved with good patient compliance and education and by early detection and treatment of side effects.

Serum Sodium as a Prognostic Marker in Hospitalized Chronic Liver Disease Patients
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Purpose: Hyponatremia is a known complication of cirrhosis. Hyponatremia predicts survival in cirrhotic patients with ascites. Hyponatremia significantly increases the efficacy of Model for end stage liver disease (MELD score) to predict waitlist mortality (Ruf et al, liver transplantation 2005; 11:336-343). Hyponatremia also appears to be a risk factor for the development of spontaneous bacterial peritonitis (SBP), renal impairment and circulatory dysfunction in patients with cirrhosis. This study examined the relationship of low serum sodium and outcome in hospitalized patients admitted with the diagnosis of cirrhosis.

Methods: Retrospective chart review of 106 patients admitted with the diagnosis of cirrhosis at a university medical center was done. Data was collected on Child- Pugh and MELD score. Laboratory data (CBC, CMP, PT, PTT, INR) were collected on the first three days of admission and at discharge. CT/Ultrasound findings during hospital stay were recorded. Clinical data including ascites, gastrointestinal bleeding, hepatic encephalopathy, jaundice, hepatorenal syndrome and SBP were recorded. The data was analyzed by Student t-test, Chi- Square, and logistic regression analysis.

Results: We observed that patients with hyponatremia (Na<135) are 13-fold (1300%) more likely to have a diagnosis of alcoholic liver disease (p = .027), 2.8-fold (280%) more likely to complain of abdominal distension (p = .022), 4-fold (400%) more likely to have ascites (p = .009), 88% less likely to have variceal bleeding (p = .012), 85% less likely to have vomiting (p = .011) and 80% less likely to have GI bleeding (p = .007) than patients with normal sodium (>134). We also observed that patients with hyponatremia do not have an increased risk of death during hospitalization (p = .881). Improving hyponatremia significantly reduced the length of hospital stay (p = .024).

Conclusions: Our results indicate that hospitalized cirrhotic patients with hyponatremia have an increased risk of ascites, and are more likely to have diagnosis of alcoholic cirrhosis. These patients are less likely to develop variceal bleeding during hospital stay.Inpatient cirrhotics with hyponatremia do not have an increased risk of death, SBP, hepatic encephalopathy, or hepato renal syndrome. Improving serum sodium is associated with decreased length of stay.

Prospective Study Comparing Esophageal Capsule Endoscopy (ECE) vs. Upper Endoscopy (EGD) in the Detection and Grading of Esophageal Varices
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Purpose: To compare the diagnostic yield of ECE with conventional endoscopy (EGD) for detecting and grading esophageal varices as well as to determine patient tolerance for each procedure.

Methods: Prospective, pilot study. Twenty consecutive cirrhotic patients previously scheduled for EGD were enrolled in the study. After informed consent was obtained, patients underwent ECE via PillCam ESO, followed by conventional EGD. Demographic data including etiology of cirrhosis, Child Turcotte Pugh (CTP) score, and MELD score were obtained after informed consent. Results of the ECE were given to a physician who was blinded to the EGD results. Immediately after completing the ECE and after recovering from sedation from the EGD, the patients completed a visual analog scale assessing their level of anxiety, amount of pain, overall level of satisfaction and willingness to repeat each procedure in the future.

Results: After obtaining results of both studies (ECE and EGD), 18 patients were included for statistical analysis, while two patients were excluded due to inadequate data obtained from ECE. Population demographics: 12 males and 6 females; Avg. age = 50.11; Avg. CTP/MELD = 7.78±12.5. All patients had cirrhosis from either NASH, HCV, or ETOH. According to EGD, 17/18 patients noted to have presence of esophageal varices. ECE able to identify presence of esophageal varices in 13/17 (76% sensitivity). Of the 4 patients which ECE did not identify, all were found to have Grade I varices per EGD. ECE able to identify all varices rated Grade II or higher (9/9) per EGD. ECE and EGD noted to have exact correlation in size in 7/18 patients. All patients
tolerated both studies. Post study analog scale (1 least-10 most) showed larger level of anxiety during EGD (avg. 3.44) vs. ECE (avg. 1.6). Also overall satisfaction (1 most-10 least) after ECE (1.05) was slightly better than EGD (1.83). All patients stated they would undergo each study again if advised.

Conclusions: ECE is a tool which may be used reliably in the assessment of Grade II varices and higher. The technique appears to be less effective when evaluating smaller varices. The minimal discomfort, lack of sedation, decreased risk of complication, and patient level of satisfaction make this technique a method which may be used as an adjunct to conventional therapy.

Methods: This is a retrospective chart review study conducted at VA medical center, Oklahoma, OK. We reviewed electronic charts of newly diagnosed hepatitis B surface antigen positive (HBsAg+) patients (N = 93) over a 27 month period (2/104 to 5/06). The outcome measures were appropriate public health recommendations provided by gastroenterologists.

Results: Out of 93, 14 patient’s information could not be recovered from remote clinics. 79 charts were reviewed. Of the 30 patients referred to teaching gastroenterology clinics, only 19 (63%) had any documentation about public health: 10 (33%) were advised about evaluation for hepatitis B vaccine in household and sexual contacts; 7 (23%) were advised to receive hepatitis A vaccine and 2 (7%) were advised about needle transmission and safe sex practices. 30/30 (100%) patients were not of Asian origin, yet only 5/30 (16%) had Delta antibody and 17/30 (56%) had their HIV status investigated. 30/30 (100%) had hepatitis C antibody ordered, 26/30 (86%) had HBV DNA and 29/30 (96%) had E antigen status checked.

Conclusions: Documenting public health advice for newly diagnosed patients with acute or chronic hepatitis B infection is done poorly by our university affiliated VA gastroenterology clinic. Gastroenterologists need to be reminded that documenting such advice is the first step in managing HBV infection and protecting the health of the community. Gastroenterologists do well in the evaluation of viral status of hepatitis B and C in hepatitis B referrals, but are less complete in evaluating for the co-infections of HIV and Delta virus.

Evaluation of Public Health Recommendations for Hepatitis B in a University-Affiliated VA Hospital
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Purpose: Co-author TFB is aware of one malpractice case in hepatitis B that revolved around the failure of the physician to advise a prospective bride to have her husband vaccinated with the subsequent development of fulminant liver failure in the husband. The aim of this study is to evaluate appropriate public health advices and recommendations provided by gastroenterologists to hepatitis B surface antigen positive (HBsAg+) patients.

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Purpose: Whether MELD scores determined at the time of admission to the hospital can help to predict the duration of in-hospital survival.

Methods: We retrospectively studied consecutive cirrhotic patients who were admitted for the first time and died in the hospital during same hospitalization from June 2004 to November 2005. For each patient MELD was calculated within 24 hours of admission. Patients were classified in two groups based on the MELD score: Group A (MELD ≤ 18), Group B (MELD > 18). The profile, causes of death and mean in-hospital survival period was studied between the two MELD groups and compared with the Child’s class.

Results: During the study period, 122 cirrhotic patients died in our unit; mean age 46.35 ± 13.60 years; males 102 (84%) and females 20 (16%). The etiology of cirrhosis was: alcohol 51 (41.8%), HBV 33 (27%), HCV 13 (10.6%), alcohol + HBV 4 (3.3%), alcohol + HCV 2 (1.6%), auto-immune hepatitis 4 (3.3%), PBC 1 (0.8%), Budd-Chiari syndrome 2 (1.6%) and cryptogenic 12 (9.8%). Patients of both the groups were comparable in age, sex and etiologies. Twenty-eight (23%) patients had upper gastrointestinal bleed. The median survival of all 122 patients was 10 days (range 1-53 d). Mean duration of in-hospital survival of group A was 9.30 (±7.96) days and group B 10.29 (±9.68) days (p = 0.54). Hepatic encephalopathy (HE), upper

Abstracts
gastrointestinal bleed (UGIB), hepatorenal syndrome (HRS), and spontaneous bacterial peritonitis (SBP) were the main causes of death. Positive and predictive values of MELD and Child’s score in predicting death due to these complications was comparable (Table). In 22/28 (78.6%) patients with variceal bleed and 21/50 (42%) with hepatic encephalopathy, patients died despite a MELD of ≤ 18.

Conclusions: MELD score determined at the time of admission does not predict in-hospital survival. This is truer for patients with variceal bleed and hepatic encephalopathy.

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Recent Characteristics of Patients with Hepatocellular Carcinoma in Lower Manhattan
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Purpose: Hepatocellular carcinoma (HCC) is a common malignancy, affecting about half a million people worldwide. HCC occurs most commonly in the setting of hepatitis B (HBV) and hepatitis C (HCV) viruses. Our aim was to compare characteristics of patients with HCC occurring in the setting of chronic HBV and HCV infection at our center in Lower Manhattan.

Results: Of the 143 patients with HCC, 104 (74%) were men. 67 (47%) patients had + anti-HCV, 42 (29%) patients had + HBsAg, 6 (4%) had both and 28 (20%) patients had other diagnoses. HCC was diagnosed by histopathology in 93/143 (65%) patients and characteristic findings on imaging studies were detected by MRI (69) and/or CT (98). Of 42 HBV patients, 12 (29%) had + HBeAg. Portal vein thrombosis was present in 40/143 (28%) of the patients. 68 of 143 (48%) patients were alive, while 25 (17%) died from liver failure and/or tumor burdens from HCC. 50 (35%) patients were lost to follow-up. The mean survival after diagnosis was 370 days (range 5-1799 days).

Conclusions: More than 80% of HCC seen at our center was caused by HBV and HCV. Unlike patients with HBV-induced HCC, all patients with HCV-induced HCC were cirrhotic. Only one third of our HCC patients had significantly elevated AFP. A high proportion of patients were diagnosed at an advanced stage with poor prognosis.

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A Randomized Control Trial of Lactulose Versus Probiotics Versus Lactulose Plus Probiotics in the Treatment of Minimal Hepatic Encephalopathy of Cirrhosis
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Purpose: Minimal hepatic encephalopathy (MHE) is associated with poor quality of life and work disability. Treatment with lactulose and probiotics has shown some improvement. We compared lactulose, probiotics and a combination of lactulose plus probiotics in the treatment of MHE.

Methods: 190 cirrhotic patients without overt encephalopathy (Child’s A - 71 (37.4%), B - 72 (37.9%), C - 47 (24.7%)) were evaluated by psychometry (number connection test A, B and figure connection tests A,B) and P300 auditory evoked potential and critical flicker frequency (CFF). MHE was diagnosed by abnormal psychometry and/or P300 auditory evoked potential (P300AEP). Patients were randomized to receive lactulose (Group A, N = 35, dose 30–60 ml/day), probiotics (Group B, N = 35, dose 1 capsule t.i.d. each capsule containing streptococcus faecalis 60 million, clostridium butyricum 4 million, bacillus mesentricus 2 million, lactic acid bacillus 100 million) and a combination of lactulose and probiotics (Group C, N = 35) for one month. Response was defined by normalization of the abnormal test parameters and reduction in the venous ammonia level, and CFF values (> 40 Hz).

Results: MHE was diagnosed in 105 (55.2%) patients. Significant improvement (p < 0.05) was seen in abnormal psychometry tests, P300 AEP and venous ammonia level and CFF pre and post therapy (Table). Normalization of abnormal psychometry and P300 AEP were seen in 54.8%, 51.6% and 47% patients in groups A, B and C respectively (p = ns). The CFF improved > 40 Hz in 61%, 55% and 57% patients in groups A, B and C respectively.

Conclusions: Nearly 55% of cirrhotics have MHE. One month probiotic therapy was found to be as effective as lactulose. However, a combination of the two was not found to be more effective than either treatment given alone.

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Portal and Systemic Hemodynamics in Patients with Non-Cirrhotic Portal Fibrosis (NCPF)
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Purpose: Non-cirrhotic portal fibrosis (NCPF), also known as Idiopathic portal hypertension, is an important cause of portal hypertension (PHT) and varical bleeding, specially in the developing countries. The patho-anatomic defect in these patients is pre- and perisinusoidal in nature. While the portal
and systemic hemodynamic anomalies have been well studied in cirrhotic patients, there is no data in the NCPF patients.

**Aims and objective** To study the portal and systemic hemodynamic alterations in patients with NCPF and compare them with compensated cirrhotic patients.

**Methods:** Patients with NCPF (N = 16, mean age 27.7 ± 9.7 yr.) and matched Child’s A cirrhotic patients (N = 15, age 30.6 ± 7.9 yr.) who had bled in the past, were included. The last bleed was >4 weeks ago in each patient. The diagnosis of NCPF was based on presence of splenomegaly, varices, patent splenorenal axis and normal liver histology. The hemodynamics parameters were measured by introducing a balloon catheter introduce via the transfemoral route. The cardiac output was determined by Fick’s principle. A mean of 3 readings was taken in each patient.

**Results:** In the NCPF patients, the HVPG was significantly lower than in the cirrhotic patients (4.8 ± 1.36 mmHg vs. 16.6 ± 3.3 mmHg, p = 0.01). Patients with NCPF had hyperdynamic circulation and peripheral vasodilation comparable to cirrhotic patients. The cardiac output was (8.0/L/min vs 7.41 L/min p = 0.27), cardiac index (C.I.) (5.3 ± 0.87 L/min/m² vs. 4.9 ± 1.6 L/min/m², p = 0.46), the mean arterial pressure (MAP), (88 ± 15.7 mmHg vs. 90.8 ± 16.9 mmHg, p = 0.62), systemic vascular resistance (SVR) (858.6 ± 216.9 dynes × cm⁻¹ vs. 934.4 ± 238.1 dynes × cm⁻¹, p = 0.14) and pulmonary vascular resistance (PVR) (43.2 ± 19.2 dynes × cm⁻¹ vs. 52.4 ± 16.6 dynes × cm⁻¹, p = 0.16).

**Conclusions:** i) HVPG is normal in NCPF patients. ii) NCPF associated portal hypertension leads to a hyperdynamic state with high cardiac index and low systemic and pulmonary vascular resistance. iii) These changes are significant and comparable to patients with Child’s A cirrhosis. This suggests a predominant role of increased resistance per se rather than hepatocellular injury in the genesis of these hemodynamic alterations.

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**Endoscopic Variceal Ligation (EVL) Plus Propranolol (P) and Isosorbide Mononitrate (ISMN) Versus Endoscopic Variceal Ligation Alone in Secondary Prophylaxis of Variceal Bleeding: A Prospective Randomized Controlled Trial**

Anil Jain, MBBS, Ashish Kumar, MBBS, MD, DM, Pankaj Tyagi, MBBS, MD, DM, Barjesh C. Sharma, MBBS, MD, MD, Shiv K. Sarin, MBBS, MD, DM,* Gastroenterology, GB Pant Hospital, New Delhi, Delhi, India.

**Purpose:** Addition of ISMN to P synergistically decreases the portal pressure in cirrhotic portal hypertension (PHT) and reduces variceal rebleed. EVL is the standard therapy for prevention of rebleeding. Combination with P and ISMN in addition to EVL for secondary prophylaxis of variceal rebleed has not been evaluated. We compared EVL and P+ISMN versus EVL alone in the prevention of variceal rebleed.

**Methods:** One hundred and twenty-eight consecutive PHT patients with prior variceal bleed were randomly allocated to EVL plus P and ISMN (Gr 1, N = 61) or EVL alone (Gr 2, N = 67). EVL was done at 2 wk interval till variceal obliteration. Hepatic Vein Pressure Gradient (HVPG) was done at baseline (N = 90) and during follow up (N = 12). In Gr 1, incremental dosage of P (sufficient to reduce heart rate to 55 beats/min or 25% reduction from baseline) and ISMN in doses of 20–40 mg/day was administered and continued after obliteration of varices. The primary endpoint was bleeding and secondary endpoints were encephalopathy, SBP hospitalization and death.

**Results:** Baseline characteristics were comparable in two groups. Follow-up duration (Gr 1: 12.8 ± 19.1 mo, Gr 2: 10.5 ± 13.7 mo), cirrhotic and non-cirrhotic PHT patients (Gr 1: 50 [82%] and 11 [18%], Gr 2: 58 [87%] and 9 [13%]), and frequency of Child’s A (43% vs 36%), B (38% vs 55%), and C (19% vs 9%) were comparable. The mean baseline variceal grade (Gr 1: 3.2 ± 0.7 vs Gr 2: 3.2 ± 0.7) and HVPG (Gr 1: 16.2 ± 6.3 mmHg vs Gr 2: 15.6 ± 6.1 mmHg) were also comparable. In Gr 1 the mean daily P and ISMN dose administered were 114.3 ± 50 mg/day and 26.8 ± 10.2 mg/day respectively. Twenty-three (18%) patients bled, 8 (13.1%) in Gr 1 and 15 (22.3%) in Gr 2. All patients bled before variceal obliteration, the probability of variceal rebleed at 12 months was 12% in Gr I and 22% in Gr II (p = 0.13). The number of secondary endpoints were also similar in both the groups. Severe side effects of propranolol and/or isosorbide mononitrate were seen in 11% patients. There were no serious complications of EVL.

**Conclusions:** Both EVL plus propranolol and isosorbide mononitrate and EVL alone are effective in secondary prophylaxis of bleed in portal hypertension patients. Addition of propranolol and nitrate does not decrease the probability of variceal rebleed in patients on EVL. In addition, these drugs may be associated with intolerance and side effects warranting drug withdrawal.

### 405

**Trends of HBV, HCV Prevalence and Vaccination Status in Healthcare Workers in India**

Sukriti, Kamal Agarwal, Nirupma Pati, G.T. Kumar, A.T. Kannan, Shiv K. Sarin,* Gastroenterology, GB Pant Hospital, New Delhi, Delhi, India and Preventive and Social Medicine, GTB Hospital, New Delhi, Delhi, India.

**Purpose:** Health care workers (HCW’s) are exposed to blood and products and have high risk of acquiring HBV and HCV infection. HCWs also have a high risk of occult HBV infection (HBsAg negative, HBV DNA positive). Moreover, despite the awareness and potential risks, a proportion of HCWs globally never get vaccinated. This study investigated the prevalence of HBV and HCV infection and vaccination practices in HCWs in India.

**Methods:** 1394 HCWs including nurses (62.1%), doctors (23.5%), technicians (7.75%), fellows (0.7%), cleaners (6.9%) (Age - 33.8 ± 7.95 yr., M: F - 781: 613, body weight - 60.7 ± 10.6 kg) were screened for the presence of HBsAg, IgG anti-HBc, anti-HBs and anti-HCV by ELISA. In IgG anti-HBc positive HCWs, HBV DNA by nested PCR for surface and core region was done to detect occult HBV infection.

**Results:** Fifteen (1.07%) of 1394 HCWs were found to be positive for HBsAg; 40% were nurses, 26.6% doctors and others technicians and cleaners, 20% were HBsAg positive. The mean HBV DNA in HBsAg positive HCWs was 3675.05 ± 1279.239 pg/ml. However, the level were lesser than 0.5 pg/ml in 2/3rd cases. Evidence of past exposure to HBV (IgG anti-HBc positive) was seen in 25.2% and of occult HBV in 4.1%. Anti-HBs was positive (> 10 IU/ml) only in 68.1% either due prior exposure (16%) or vaccination (84%). Two hundred and ten (15.06%) HCWs never undertook vaccination, 60.3% of these were nurses, 22% doctors and 18.2% others. Vaccine non-response (Anti-HBs<10 IU/ml) was found in 4.7% of HCWs. Anti –HCV was positive in one doctor and one cleaner, (0.15%) and both were HCV RNA positive. No case of dual HBV and HCV infection was detected.

**Conclusions:** i) About 1% of HCWs in India have chronic HBV infection, 1/3rd of them with high HBV DNA levels ii) High prevalence of past exposure and occult HBV infection is present. iii) Prevalence of HCV infection in HCWs is low. (iv) Vaccine non-response is seen in 4.7% and one sixth of HCWs remain even today unvaccinated against HBV.

### 406

**Gastrointestinal Hemorrhage in Extra-Hepatic Portal Vein Obstruction: A Study of 553 Patients**

Ashish Kumar, MD, DM, Barjesh C. Sharma, MD, MD, Shiv K. Sarin, MD, DM,* Gastroenterology, GB Pant Hospital, New Delhi, Delhi, India.

**Purpose:** Extra-hepatic portal vein obstruction (EHPVO) is the commonest cause of portal hypertension (PHT) and variceal bleeding in children. It is associated with significant morbidty and mortality. We present the profile of gastrointestinal hemorrhage in a large series of patients of EHPVO.

**Methods:** A retrospective analysis of all consecutive patients of EHPVO since 1983 was done. The clinical records were retrieved and analyzed in terms of clinical presentation, especially GI hemorrhage.

**Results:** 553 patients of EHPVO were included in the study (66% males). The mean age at presentation was 19.4 ± 14 yr; 59% being ≤18 yr. 78% patients presented with GI hemorrhage (<18 yr: 82%, >18 yr: 71%; p < 0.01). Presentation with GI bleeding decreased as the age advanced (age group 1-12 yr 86%, 13-24 yr 77%, 25-36 yr 67%, 37-48 yr 66%, 49-60 yr 58%;
Percutaneous Liver Biopsy Performed during Inspiration: Is It Safe? Carlos R. Ponce, MD, Urias Cuartas, MD, Sherman M. Chamberlain, MD, Subbaramiah Srithar, MD. Internal Medicine/Gastroenterology, Medical College of Georgia, Augusta, GA.

Purpose: Percutaneous liver biopsies have been performed since the late 1800s with several technical modifications. Traditionally, the practice and teaching has been to perform percutaneous biopsies with the breath held at end-expiration to minimize morbidity. This biopsy technique is generally well tolerated when done by experienced operators, with mortality and morbidity rates reported at 0.015 to 0.11% and 2 to 3%, respectively. Contrary to methods described in the literature, we report a potentially safer technique by performing liver biopsies with the breath held at end-inspiration.

Methods: On retrospective analysis, a total of 2,670 percutaneous liver biopsies were performed by a single gastroenterologist (S.S.) between the years of 1986 and 2005. The indications were predominantly hepatitis B and C, autoimmune liver disease, alcoholic liver disease, primary biliary cirrhosis, hemochromatosis, and idiopathic liver disease. The age of patients ranged from 21 to 85. The needle insertion site was identified by locating the upper border of the liver using percussion with the breath held in both end-inspiration and end-expiration at the mid-axillary line. Biopsies were performed by using either a Menghini or Jamshidi needle under 2% local anesthesia. The biopsy needle was then inserted one or two intercostal spaces below the upper border of the liver at the mid-axillary line. End-inspiration was chosen at the time of biopsy to avoid a sudden inspiratory effort and potential liver displacement caused by pain. An adequate core liver sample was chosen at the time of biopsy to avoid a sudden inspiratory effort and consequent liver displacement caused by pain during the biopsy.

Results: Of 2,670 biopsies performed during this time period, our method encountered only two complications (0.07%), significantly lower than previously reported morbidity rates. One patient developed a pneumothorax and encountered only two complications (0.07%), significantly lower than previously reported morbidity rates. One patient developed a pneumothorax and encountered only two complications (0.07%), significantly lower than previously reported morbidity rates. One patient developed a pneumothorax and encountered only two complications (0.07%), significantly lower than previously reported morbidity rates. One patient developed a pneumothorax and encountered only two complications (0.07%), significantly lower than previously reported morbidity rates. One patient developed a pneumothorax and encountered only two complications (0.07%), significantly lower than previously reported morbidity rates. One patient developed a pneumothorax and encountered only two complications (0.07%), significantly lower than previously reported morbidity rates. One patient developed a pneumothorax and encountered only two complications (0.07%), significantly lower than previously reported morbidity rates.

Conclusions: Percutaneous liver biopsy is generally safe, with a low morbidity and mortality rate. In our experience, the above method of performing the biopsy during end-inspiration yielded a lower morbidity rate and no mortality when compared to biopsies done during end-expiration. We therefore conclude that the lower morbidity and mortality observed was a result of fixing the liver at end-inspiration, and consequent liver displacement caused by pain during the biopsy.
as well as patients with co-morbidities that can affect the hematological parameters were excluded from the study. Information was collected regarding demographics, medical and surgical history. Significant laboratory values and ultrasonography findings were recorded. All patients underwent EGD for evaluation for varices. All EGDs were performed by one of two endoscopists in the presence of a second endoscopist to confirm presence or absence of varices.

Results: We are reporting our preliminary data on the association of platelet number with the presence of varices. Age of patients varied from 48 to 80 years with mean of 59 years ± 1.8 (±SE). A total of 26 patients were studied of which, 8 (31%) had esophageal or gastric varices. The platelet count ranged from 66 to 290 with mean of 147 ± 11 (±SE). Analysis was done using bivariate correlation using Pearson correlation coefficients. There was a positive correlation coefficient of 0.520, between platelet count of <100K and presence of varices which was significant with p < .05. Subsequent analysis using platelet cutoff of 125K and 150 K did not show a significant correlation with presence of varices. The platlet count of ≤100, had positive predictive value of 71% for presence of varices.

Conclusions: Our preliminary data suggest that patients with platelet counts of less than 100 are more likely to have clinically significant varices on upper endoscopy. If this is further confirmed by larger sample size, we can avoid EGDs in a large proportion of patients by utilizing a simple laboratory value i.e. platelet count.

410
Management of Psychiatric Disorders in a Resident-Run Multi-Disciplinary Clinic Improves Adherence to Interferon Alpha Therapy in Patients with Chronic Hepatitis C
Nicole Agostino, DO, Vishal Patel, MD, Jody Yozviak, DO, Suzanne Templar, DO, Charles Brooks, MD,* Edward Norris, MD. Medicine, Lehigh Valley Hospital, Allentown, PA.

Purpose: Treatment of chronic hepatitis C (HCV) in patients with psychiatric illness is controversial secondary to depression and other neuropsychiatric side effects. The purpose of this study is to evaluate adherence to therapy with interferon-alpha in patients with chronic hepatitis C and established psychiatric diagnoses in a resident-run multidisciplinary HCV clinic.

Methods: Medicine residents in the HCV clinic are precepted by an attending gastroenterologist and psychiatrist and are supported by a registered nurse coordinator. Treatment for HCV with peg-interferon alpha 2a and ribavirin is guided by evidence-based protocols within the confines of managed care formularies. Baseline psychiatric diagnoses and course of psychiatric illness is followed.

Results: 16 patients had baseline psychiatric diagnoses. 7 had Major Depressive Disorder, 3 had Bipolar Disorder, 1 had Generalized Anxiety Disorder, 2 had Schizophrenia and 3 had Schizoaffective Disorder. 10 had co-morbid substance abuse disorders. 1 patient had a substance abuse disorder as the only diagnosis. Throughout treatment with interferon-alpha, all patients were maintained on their psychiatric medications, with rare adjustments. 2 patients needed increases in antidepressant dosage, 1 patient needed an antidepressant added to their regimen, and 13 had no changes in their antidepressant dose. No patient had a significant change in their mood stabilizing/antipsychotic doses. 3 patients had an increase while 13 had no change in dose of their anti-anxiety medication. 1 patient had a psychiatric hospitalization due to bizarre behavior after taking narcotics and benzodiazepines, but interferon treatment was not discontinued. No patients experienced suicidal ideation. None of the 16 patients had interferon therapy discontinued.

Conclusions: During treatment of under-insured and uninsured patients with HCV via a resident-initiated, multidisciplinary clinic, there were no significant changes in psychiatric symptoms of the 16 patients with prior psychiatric diagnosis who underwent treatment with interferon-alpha. Strict follow-up, with availability of a gastroenterologist, psychiatrist, residents and a nurse, led to 100% adherence to HCV therapy in psychiatric patients in our HCV clinic. This suggests that an integrative clinic can safely manage psychiatric co-morbidities and interferon-alpha treatment to expand access to care.

411
Perioperative Morbidity and Mortality Rates of Patients with Fulminant Hepatic Failure Being Evaluated for Orthotopic Liver Transplantation
John Youssef, MD, Kimberly Brown, MD, Dilip Mookna, MD, Mary Ann H. Sherbony, MD,* Gastroenterology, Henry Ford Hospital, Detroit, MI.

Purpose: Fulminant hepatic failure (FHF) is a rare cause of orthotopic liver transplantation (OLT), accounting for 6.4% of transplants per year in the United States. One and three year survivals (70.1% and 56.7% respectively) are lower than those reported for patients with chronic liver disease. Reasons for these differences are unclear. The aim of this study is to compare survival in listed and not listed patients with FHF at our institution and evaluate variables which may account for differences in survival between the two groups.

Methods: A retrospective analysis of all patients evaluated for liver transplant for FHF at a single transplant center from 2002 to 2004. Pre-transplant variables including age, gender, etiology of liver disease, insurance status, and MELD were recorded.

Results: From 2002 to 2004, thirty three patients with FHF were referred for OLT evaluation. 18 patients were listed for liver transplantation. Fifteen patients were not listed. Survival in patients not listed was 33% (5/15). Of the five survivors, 3 had acetaminophen toxicity. Of the eighteen patients listed, nine did not receive a transplant either due to death (7/9) or recovery (2/9). Of the nine who received transplant, survival at follow up was 87.5% (8/9). Age, gender, insurance status and MELD scores were not significantly different between the listed and not listed group. Acetaminophen accounted for a significantly higher number of patients in the non-listed versus listed groups (p = 0.03). Although overall mortality between the listed group (44%) and non-listed group (66%) was not significant, mortality in the patients listed and undergoing OLT was significantly lower as compared with patients listed but not transplanted (12.5% vs. 78%, p = 0.02) or not listed (12.5% vs. 66%, p = 0.03).

Conclusions: Patients with FHF continue to have significant mortality without transplant. The patients with FHF who eventually undergo OLT have a significantly higher survival rate than those patients not listed or listed and not transplanted. The majority of patients who recover from FHF without OLT have acetaminophen induced disease. No obvious differences existed between the listed and non-listed patients although further study with more patients is needed to verify this finding.

412
Comparison of Ribavirin with PEG-Interferon α-2a or with α-2b in Treatment-Naïve Patients
Amy Webb, MD, Isela Poy, MD, Rikin Patel, MD, Olga Ali, PA, Robert Page, PA, Maryam Kashi, DO, Ana Herrera, MD, John Schoolfield, MS, Paul Brock, PA, Anastacio Hoyumpa, MD,* Gastroenterology and Nutrition, UT Health Science Center at San Antonio, San Antonio, TX and Hepatology Clinic, South Texas Veterans Healthcare System, San Antonio, TX.

Purpose: The standard of care of hepatitis C (HCV) patients is peginterferon (PEG-IFN) in combination with ribavirin. There are competing claims as to which PEG-IFN is superior and better tolerated. One study indicates that PEG-IFN-α-2b is better in obese patients (Gastro 128: M953, 2005).

Methods: To compare outcomes of PEG-IFN α-2a or α-2b in combination with ribavirin in a retrospective study. 507 naïve HCV patients were identified from UTHSCSA and STVHCS between 2001-05. Excluded from the study were decompensated cirrhosis, liver transplant patients and those infected with HIV. Included in the multivariable logistic regression models were initial HCV viral load, genotype (GT), fibrosis stage, race, age, gender, BMI and PEG-IFN treatment. Intention-to-treat analysis was used. Outcomes for logistic regression were early treatment discontinuation (EDC) due to side effects, early viral response (EVR) (<2 log in HCV RNA in 12 wks), and sustained viral response (SVR) (HCV RNA<50 IU/ml 24 wks post treatment).
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N Acetylcysteine in the Management of Hepatorenal Syndrome (HRS): Our Experience with Four Patients
Navakanth Gorrepati, MD, MPH, Lath H. Jamil, MD, Mantha Balasubramaniam, MS, Tusar Desai, MD,∗ IM, William Beaumont Hospital, Royal Oak, MI; GI, William Beaumont Hospital, Royal Oak, MI and Research Institute, William Beaumont Hospital, Royal Oak, MI.

Purpose: N Acetylcysteine (NAC, Mucomyst), a precursor of cysteine, has been in clinical use for the management of acetaminophen overdose and prophylaxis of radiocontrast-induced nephropathy. However its role in the management of HRS has not been well characterized. To our knowledge only a single study was done on 12 patients (nine of whom had alcoholic cirrhosis) with HRS where NAC was given intravenously for five days. This treatment was well tolerated with no clinical side effects. The study showed benefit in HRS. Our goal was to study the temporal relationship of NAC treatment to Creatinine Clearance (CrCl) as well as glomerular filtration rate (GFR) in four patients.

Methods: We retrospectively reviewed the charts and lab values of four patients with HRS admitted between June 16th 2004 and Feb 6th, 2006. The underlying liver disease was Alcoholic Hepatitis (N = 2), Hereditary Hemochromatosis (N = 1) and Non-Alcoholic Steatohepatitis with Crypto-genic Cirrhosis (N = 1). NAC was administered intravenously at 150 mg/kg IV over 2 hours followed by a continuous infusion of 100 mg/kg daily for five days. One patient was received midodrine and octreotide prior to administering NAC. Renal function was estimated by studying CrCl (calculated by Cockroft Gault formula) and GFR (calculated by MDRD equation).

Results: The temporal relationship of these values was studied in relationship to the administration of the drug. Repeated measures analysis using random coefficients was performed to see if there is any difference. Treatment day was defined as day 0. Mean follow up was 9.5 days (range 8-10). CrCl increased from a mean of 27.72 ml/min to 39.68 ml/min in all the four patients (p value not significant). All four patients had a positive slope for both GFR as well as CrCl. None of them had any major side effects from the drug. [figure1]

Conclusions: NAC temporarily improved renal function in patients with HRS. However no conclusive evidence can be interpreted from our study due to its small sample size and due to widely present confounding factors. The p value is really of borderline significance likely due to small sample size. In view of the lack of effective treatment for HRS, NAC may be considered, as it is safe, inexpensive and well tolerated. Large multicenter randomized controlled trials are necessary to better manage these patients.

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Can N-Acetylcysteine Prevent Acute Renal Failure in Chronic Liver Disease Patients Undergoing Triple Phase CT Scan? (Abstract)
Andrew Albert, MD, MPH, Thomas Birris, MD, Sonu Dhillon, MD,∗ Stephen Sontag, MD, David VanThiel, MD, Jason Gonzalez, MD, Gastroenterology, Hepatology and Nutrition, Loyola University Medical Center, Maywood, IL.

Purpose: 1)To determine if beneficial effects of N-Acetylcysteine in cardiac catheterization patients could be seen in patients with chronic liver disease 2)To determine if N-Acetylcysteine may lower the incidence of acute renal failure in patients with chronic liver disease.

Methods: 400 patients with chronic liver disease were evaluated based on renal function before and after Triple Phase Abdominal CT Scan by a practicing hepatologist at Loyola. N-Acetylcysteine (NAC) was administered at a dose of 140 mg/kg, 4 hours before and 2 and 4 hours after the procedure. Renal function was assessed at baseline, 24, and 48 hours after completion of CT scan. The data were used to devise a retrospective study approved by the IRB to compare those who received NAC before and after administration of contrast material. Patients were categorized based on baseline renal function. Indications for CT Scan included those patients with chronic liver disease. Control patients received no NAC prior to or after CT scan. We accepted an increase in creatinine of .3 mg/dl as our definition of renal failure.

Results: Patients with baseline renal insufficiency responded much more favorably to administration of NAC than patients with normal renal function. Those with a baseline creatinine greater than 1.3 mg/dl demonstrated 10%
fewer cases of acute renal failure when receiving NAC. Results clearly show a statistical trend toward protective effect on kidney in patients with renal insufficiency at baseline (p = .0009).

Conclusions: Radiocontrast-Induced Nephropathy is a significant cause of acute renal failure in hospitalized patients. In cases of oxidative stress like that of acetaminophen toxicity, patients respond well to higher doses of NAC. Currently, there are no studies that document the effects of high dose NAC that of acetaminophen toxicity, patients respond well to higher doses of NAC. A larger study will be necessary to elucidate a stronger association between NAC and its protective effect on renal function in patients with chronic liver disease. This study demonstrates the beneficial effect of NAC on renal function in patients with chronic liver disease. A larger study will be necessary to elucidate a stronger association between NAC and its protective effect on renal function in patients with chronic liver disease. A larger study will be necessary to elucidate a stronger association between NAC and its protective effect on renal function in patients with chronic liver disease.

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Phlebotomy Improves Therapeutic Response to Interferon (INF) in Patients with Chronic Hepatitis C (CHC): A Meta-Analysis of Six Prospective Randomized Controlled Trials (RCT)

Laith H. Jamiil, MD, Tusar Desat, MD, Mamtha Balasubramaniam, MS, Raymond Koff, MD, Herbert Bonkovsky, MD.* GI, William Beaumont Hospital, Royal Oak, MI and IM, Univ of CT, Farmington, CT.

Purpose: Prospective RCTs comparing phlebotomy and INF treatment to IFN alone in patients with CHC have suggested a benefit for the phlebotomy group. However, statistical significance was achieved in only 1 of these trials. We performed a meta-analysis of RCTs comparing phlebotomy and IFN to IFN alone for the treatment of CHC.

Methods: The MEDLINE database and Cochrane registry of controlled trials were searched using the key words “phlebotomy” and “treatment of hepatitis C.” Reference lists of review articles discussing the interaction between iron and CHC and prospective RCTs comparing phlebotomy plus INF therapy to IFN alone were searched to identify additional RCTs that compared phlebotomy plus INF to IFN alone.

Results: Six prospective RCT were identified (table 1); all used sustained viral response (SVR) as an endpoint. Test of heterogeneity was applied. The 3 largest RCT excluded patients with cirrhosis. Two RCTs specifically included only patients with either high ferritin or high hepatic iron content. IFN treatment regimes varied. Length of treatment varied between 6-12 months. The phlebotomy plus INF group and the INF group did not differ with respect to the percentage of patients with cirrhosis or genotype 1. All 6 RCTs showed a benefit for the phlebotomy and INF group, and the results of the meta-analysis were not dependent on any single RCT, since excluding any single RCT did not change the results. Peto odds ratio for SVR in phlebotomy plus INF group 2.7; 95% CI 1.6 to 4.5 p < .0001.

Conclusions: Phlebotomy improves the SVR in response to IFN treatment in patients with CHC. Confirmation of this will require RCT with detailed pre-treatment iron studies and appropriately powered to demonstrate a statistically significant benefit.

Table 1. Clinical characteristics

<table>
<thead>
<tr>
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<th>PEG-INF 2a (N = 95)</th>
<th>PEG- INF 2b (N = 127)</th>
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<tr>
<td>Mean age</td>
<td>51.3</td>
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<tr>
<td>Race: %Caucasians</td>
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<tr>
<td>BMI</td>
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<tr>
<td>Genotype 1</td>
<td>54 (57%)</td>
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<tr>
<td>Non genotype 1</td>
<td>41 (43%)</td>
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</tr>
<tr>
<td>% with high viral load</td>
<td>71%</td>
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<tr>
<td>Mean dose PEG-INF (mcg)</td>
<td>180</td>
<td>140</td>
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<tr>
<td>Mean dose ribavirin</td>
<td>1020</td>
<td>1160</td>
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Table 2. SVR, Relapse and Non-response rates

<table>
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<tr>
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<td>44/95 (46.3%)</td>
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</tr>
<tr>
<td>SVR Genotype 1</td>
<td>17/54 (31.5%)</td>
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<td>SVR Non genotype 1</td>
<td>27/41 (65.9%)</td>
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<tr>
<td>Relapser</td>
<td>7/69 (10.1%)</td>
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<tr>
<td>Relapser Non</td>
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<tr>
<td>Non-responder</td>
<td>18/95 (18.9%)</td>
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<td>40</td>
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<tr>
<td>Non-responder</td>
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* p < 0.05

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Relapse and Non-Response Rates with Pegylated Interferon (PEG-INF) alfa 2a and 2b in the Treatment of Veterans with Chronic Hepatitis C

Sally Stitho, MD, Hector Rodriguez-Luna, MD, Erin Tharaldson, NP, Elizabeth Evanch, NP, Francisco C. Ramirez, MD, FAACG.* Gastroenterology, Carl T. Hayden VA Medical Center, Phoenix, AZ.

Purpose: Patients undergoing treatment for chronic HCV often endure side effects and complications to achieve the ultimate goal of sustained virologic response (SVR). Lack of therapeutic response (EOT) and relapse (positive HCV RNA 6-mo after EOT) rates are underreported.

Aim: To determine the non-response and relapse rates in patients with chronic HCV treated with ribavirin + PEG-INF 2a or 2b.

Methods: Clinical, demographic and virological data of naive patients with HCV undergoing treatment at a VAMC from November 2002 until now were included. ITT analysis was used.

Results: 222 naive patients received treatment (95 with PEG-INF 2a and 127 with 2b). Of these, 156 patients (69 in the PEG-INF 2a and 87 in the PEG-INF 2b) underwent treatment until either EOT was achieved or EVR was not achieved (non-responders). The initial demographics and virologic characteristics of patients in both groups is given in Table 1. The overall SVR in the PEG INF 2a was 46.3% and 32.3% for those receiving PEG INF 2b (p = 0.03) whereas the non-response rates were 18.9% and 33.1% (p = 0.02), respectively. The overall relapse rate was 7.1% (10.1% for PEG-INF 2a and 4.6% for PEG INF 2b). The clinical and virologic characteristics in these two groups of patients are depicted in Table 2.

Conclusions: 1) The overall SVR was 38.2%, significantly greater for those receiving PEG-INF 2a. 2) Conversely, the overall non-response rate was 27%, significantly greater for those receiving PEG-INF 2b. 3) The overall relapse rate (7.1%) was low and no different between both PEG-INF formulations.

Table 1. Clinical characteristics

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<tr>
<td>Relapser</td>
<td>7/69 (10.1%)</td>
<td>4/87 (4.6%)</td>
</tr>
<tr>
<td>Relapser Genotype 1</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Relapser Non</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Non-responder</td>
<td>18/95 (18.9%)</td>
<td>42/127 (33.1%)</td>
</tr>
<tr>
<td>Genotype 1 Non</td>
<td>16</td>
<td>40</td>
</tr>
<tr>
<td>Non-responder</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

* p < 0.05
High Dose Consensus Interferon and Ribavirin Should Be Considered for Treatment of Chronic Hepatitis C Patients Who Are Resistant to Peg-Interferon and Ribavirin

Kenneth D. Rothstein, MD, Ramesh Koka, MD, Holly Hargrove, Angel Fernandez, MD, Shailender Singh, MD, Victor Araya, MD, Santiago J. Munoz, MD. *Hepatology, Albert Einstein Medical Center, Philadelphia, PA.

Purpose: Consensus interferon (Interferon alfacon-1, CIFN) is a bio-optimized alfa interferon that exhibits increased in-vitro antiviral activity than the naturally occurring alfa interferons 2a and 2b. The majority of nonresponder and relaper patients with chronic hepatitis C are unable to achieve a sustained virologic response (SVR) with the combination of Peg-Interferon (PEG-IFN) and ribavirin (RBV), especially those who have genotype 1 and advanced disease. Improved response rates have been reported with high-dose CIFN therapy and RBV for patients who have failed to respond to PEG-IFN/RBV.

Methods: Patients who had been treated with PEG-IFN/RBV for HCV but did not obtain a SVR were eligible for treatment if they: 1) tolerated treatment with PEG-IFN/RBV, and 2) had advanced liver disease. Patients were given 27 ug of CIFN daily and RBV 400 mg BID during the first four weeks, followed by 18 ug daily and ribavirin 400 mg BID daily for the next eight weeks. At 12 weeks, CIFN was decreased to 15 ug daily while RBV was increased to 1,000-1,200 mg daily for 36 weeks.

Results: Fifty patients have been enrolled in the study, 72% male with a mean age of 50 years old. 96% had genotype 1. 72% had stage 3-4 fibrosis of which 52% of patients had cirrhosis. 81% of patients were nonresponders. 31 patients (66%) have achieved an early virologic response (EVR) at 12 weeks. 27 patients (66%) were undetectable at 24 weeks and 20 patients (52%) achieved an End-of-Treatment response (EOT). In an Intention to treat analysis, (ITT) of the 33 patients who have completed 72 weeks of treatment, 27 patients discontinued therapy, 7 of these patients (21%) have achieved a Sustained Virological Response (SVR). The obese group had low EVR, a negative predictor.

Conclusions: For HCV patients with advanced histologic disease who had previously failed therapy with PEG-IFN and RBV, the combination of high-dose CIFN and RBV is a well-tolerated and effective option. Although our numbers are small, 21% of patients achieved a SVR.

Parameters of response in HCV pts on PEG/RBV

<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>OBESE</th>
<th>LEAN</th>
</tr>
</thead>
<tbody>
<tr>
<td>t0 (hrs)*</td>
<td>5.5 (3.5, 8.9)</td>
<td>4.0 (0.1, 9.0)</td>
</tr>
<tr>
<td>ε (1/day)*</td>
<td>1.5 (0.8, 3.0)</td>
<td>1.3 (0.5,5.7)</td>
</tr>
<tr>
<td>δ (per day)*</td>
<td>83.9 (63.9, 98.9)</td>
<td>98.8 (70.2, 99)</td>
</tr>
<tr>
<td>HCV-RNA negativity (days)*</td>
<td>70.0 (44.0, 85.0)</td>
<td>36.0 (1.0, 70.0)</td>
</tr>
<tr>
<td>RVR (%)</td>
<td>22.2</td>
<td>40.0</td>
</tr>
<tr>
<td>EVR (%)</td>
<td>80.0</td>
<td>100</td>
</tr>
</tbody>
</table>

*Median (25th, 75th percentile)

Obesity Is Associated with Diminished Early Viral Kinetics, Rapid Virologic Response (RVR) and Early Virologic Response (EVR) in Patients with Chronic Hepatitis C Virus (HCV) Treated with Pegylated Interferon (PEG) and Ribavirin (RBV)

K. Cesario, MD.*, A. Wieckowska, MD, R. Lopez, MS, K. Edwards, NP, N. Zein, MD. Hepatology, Cleveland Clinic, Cleveland, OH.

Purpose: With inconsistent retrospective data, the role of obesity as a predictor of treatment outcome in chronic HCV remains controversial. Viral kinetics and mathematical modeling of kinetic parameters have formerly been validated to assess response rates and mechanisms of resistance. Our aim was to prospectively compare viral kinetics, RVR and EVR in obese and lean pts treated with PEG/RBV.

Methods: Naïve, Caucasian, Genotype 1 pts with body mass indices of ≥30kg/m² (obese) or ≤25kg/m² (lean) were recruited. Subjects were admitted to the GCRC to receive PEG alfa-2a/RBV and collect viral kinetic data. Viral load, delay (t0), free virion clearance (ε) and therapy efficacy (δ) were calculated from data obtained on days 0 to 2 (phase 1). Infected cell death rate (δ) was calculated from data obtained on days 0 to 14 (phase 2). Time to HCV-RNA negativity, RVR and EVR were determined at follow-up.

Results: 10 obese and 8 lean subjects were enrolled. There was no difference in initial HCV-RNA between groups. Obese subjects had diminished viral kinetics during both phase 1 and phase 2 (Figure). Specific parameters of response are shown in the Table. The lean group had ε>90% and high RVR, both positive predictors of sustained virologic response (SVR). The obese group had low EVR, a negative predictor.

Conclusions: Using mathematical modeling of viral kinetics, we prospectively showed that obesity is associated with decreased response to HCV therapy after controlling for genotype, race, viral load and type of therapy. These findings could be used to develop novel therapies in the future.

<table>
<thead>
<tr>
<th>HCV RNA</th>
<th>WK 12</th>
<th>WK 24</th>
<th>WK 48</th>
<th>SVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>VIRAL LOAD</td>
<td>(N = 47)</td>
<td>(N = 41)</td>
<td>(N = 39)</td>
<td>(N = 39)</td>
</tr>
<tr>
<td>≥2 LOG DECREASE</td>
<td>66%</td>
<td>66%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNDETECTABLE</td>
<td>47%</td>
<td>59%</td>
<td>52%</td>
<td>21%</td>
</tr>
</tbody>
</table>

Thrombotic Thrombocytopenic Purpura Associated with Interferon alpha for the Treatment of Chronic Hepatitis C

Pritesh Patel, MD, Ankur Sheth, MD, MPH, Dennis Sula, MD, John King, MD. *Internal Medicine, Louisiana State University Health Sciences Center, Shreveport, LA.

Purpose: Thrombotic thrombocytopenic purpura (TTP) is a rare entity characterized by microangiopathic hemolytic anemia, thrombocytopenia and symptoms consisting of fever, neurologic, or renal dysfunction. Development of TTP has been reported in relationship with many drugs. We report a rare case of TTP associated with use of interferon alpha (INF-alpha) for the treatment of chronic hepatitis C.
Methods: A 48-year-old female was diagnosed with hepatitis C eleven months ago. Liver biopsy revealed chronic hepatitis (grade 1 stage 0), and genotype of 1B. Treatment with INF and ribavirin was initiated six months ago. At the end of 24th week of treatment, she presented to the clinic with extensive bruising over both extremities. Laboratory data revealed hemoglobin of 8.9 g/dL, platelet count of 15 K/UL, blood urea nitrogen of 19 mg/dL, serum creatinine of 1.1 mg/dL, total bilirubin of 1.8 mg/dL, unconjugated bilirubin of 1.6 mg/dL, presence of > 1 schistocytes/hpf, negative Coombs, Lactate dehydrogenase (LDH) of 1050 U/dL, haptoglobin of < 8 U/dL, and negative anti nuclear antibody and cryoglobulins. A clinical diagnosis of TTP was made based on presence of microangiopathic hemolytic anemia and non-immune mediated thrombocytopenia. Interferon treatment was stopped and patient was started on plasmapheresis. At the end of 8th treatment with plasmapheresis, platelets increased to 184 K/UL and LDH decreased to 200 U/dL. ADAMTS13 assay revealed decreased activity to 5% in presence of an inhibitor. Thrombocytopenia was resolved without any clinical sequelae.

Results: Chronic acquired thrombocytopenia is seen in about 5-35% of patients with hepatitis C virus infection. The proposed mechanisms include direct infection by HCV of megakaryocyte lineage and/or dysregulation of the host immune system. However, thrombocytopenia may also be induced by INF-alpha therapy of chronic hepatitis C. In most cases, INF-alpha induced thrombocytopenia results from bone marrow suppression. A second rare cause of INF-induced thrombocytopenia is the development of autoimmune thrombocytopenia. Few case reports have associated TTP with INF-alpha use. Although the mechanism of this occurrence is unknown, it may involve a secondary release of cytokines, with perturbation of the immune system, or direct endothelial immunomodulating activities of INF.

Conclusions: TTP should be considered in differential diagnosis of thrombocytopenia in patients with hepatitis C treated with interferon.

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Racial Differences in Response to Pegylated Interferon Therapy in Patients with Chronic Hepatitis C Infection in a Community Hospital Center
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Purpose: The natural history of chronic hepatitis C and treatment response are different between African Americans and Caucasians, but little comparable data is available comparing Hispanics and African Americans. We retrospectively evaluated the ability to complete treatment and response to peginterferon alfa 2a or alfa 2b plus ribavirin in 103 (M: F, 68:35), treatment-naive, HCV-PCR-positive patients in 68 Hispanic and 35 African Americans.

Methods: Patients were treated with peginterferon alfa 2a 180 microg/week (N = 78) or pegylated IFN-alpha-2b 1.5 microg/kg per week (N = 25) and ribavirin 1000-1200 mg/day for 24 or 48 weeks at the investigators’ discretion based on the genotype of the patient. Treatment was discontinued if the patients failed to have a 2-log drop in viral load after 12 weeks of treatment. The primary endpoint was end of treatment virological response (ETR), defined as undetectable HCV RNA (< 50 IU/mL) after 24 or 48 weeks of therapy. The analysis was conducted by intention-to-treat.

Results: Of the 103 patients, 22% of the patients dropped out of the treatment before completing 12 weeks because of side effects of the drug or alternate reasons, and another 33% had treatment discontinued due to less than 2-log drop in HCV viremia at 12 weeks. There were no significant differences in the drop out rate in African Americans vs. Hispanics (20% vs. 23.5%, p = ns). HCV genotype-1 was the most prevalent genotype in both groups (88.6% vs. 75%, p = 0.107). Overall ETR was 26% (27/103) in this population. No significant differences were noted in the ETR between the African Americans and Hispanics (23% vs. 28%, p = 0.580). When data were analyzed by genotype, ETR rates were 18.3% (15/82) in genotype 1 vs. 57% (12/21) in genotype 2/3/4 (p < 0.0001). Both these ethnic groups had comparable response rates when only patients with genotype-1 were considered (19.4% vs. 17.6%, p = 0.847).

Conclusions: A significant proportion of the African Americans and Hispanics referred for HCV treatment dropped out early in the therapy, suggesting the need for evaluation of racial, socioeconomic and cultural barriers to successful treatment. Overall, both groups had similarly poor response rates. However, patients with non-genotype-1 infection had a significantly better ETR.

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Work-Up and Treatment of Chronic Hepatitis B in Clinical Practice: A 5-Year Retrospective Review
Paul Dambowy, MD, Bilal Hameed, MD, Coleman Smith, MD, Jerry Amundson, Lauren Crain, PhD, Kara Sullivan, MD, Paola Ricci, MD.* Gastroenterology, University of Minnesota, Minneapolis, MN; Digestive Care Center, HealthPartners - Regions Hospital, St. Paul, MN, Gastroenterology, Minnesota Gastroenterology, Plymouth, MN and Research Foundation, HealthPartners, Minneapolis, MN.

Purpose: To review work-up and treatment of chronic hepatitis B in community practice.

Methods: Retrospective records review of subjects with chronic hepatitis B (18 years or older, N = 334) identified by ICD-9 codes and a positive serum HBsAg at HealthPartners [HP] (HMO, Digestive Care Center) and Minnesota Gastroenterology [MNG] (Specialty Clinic) during 1999-2003. Data collected: age, gender, ethnicity, serum transaminases, serum eAg/eAb and HBV-DNA, liver biopsy, comorbidities (HCV/HIV coinfection, treatment drug(s), dates and length of treatment. Rates of eAg seroconversion and/or degree of suppression of HBV-DNA after treatment were obtained.

Results: 334 subjects (168-HP, 166-MNG) were 51%Male, 56% Asian, 25% African. 89% had documented serum eAg (60% neg, 40% pos) and HBV-DNA (< 10^4 copies/ml [c/ml] in 41%, 10^4 to 10^5 c/ml in 9%, >10^5 c/ml in 47%). 84% of HBsAg pos subjects had > 10^5 c/ml; 29% of HBsAg negative subjects had > 10^4 c/ml. 32% of patients had liver biopsy (106/334, 70% eAg pos, 30% eAg neg; indication: elevated transaminases and/or elevated DNA levels as > 10^4 copies/ml in 84/106). 63% (67/106) of biopsyed subjects were treated. 84 of 334 subjects (25%) were treated including 67 biopsyed (22 stage 3 or 4) and 17 non-biopsied subjects (2 with clinical cirrhosis, 2 on chemotherapy, 9 with elevated transaminases, 3 with DNA > 10^4, and 1 not documented). 69% (58/84) of treated patients were HBsAg pos and 26% (22/84) were HBsAg neg.

Serum HBV-DNA was < 10^5 c/ml in 76% (61/84). Treatment drugs: Interferon (14%), Lamivudine (36%), Adefovir (39%), Entecavir (2%). Rate of HBsAg seroconversion post-treatment was 37% (20/54). Serum HBV-DNA was suppressed to undetectable and/or < 10^4 c/ml after treatment in 51% (53/106) of treated subjects.

Conclusions: In our gastroenterology practices one third of subjects with chronic hepatitis B had indication to liver biopsy, 25% of all subjects with chronic hepatitis B underwent treatment, after significant fibrosis was found in one fourth of them.

Treatment was effective in a significant proportion of subjects. Protocolized post-treatment follow-up of HBV serologies will be necessary to assess long-term response and recurrence rates.

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Metabolome Analysis of Fatty Liver Treated with Cinnamon
Hong Luo, MD, PhD, Akiko Kashiwagi, Toshiyuki Shibahara, PhD, Yongchun Li, MD, Hisao Takayama, MD, PhD.* Faculty of Medicine and Research Center for Bioscience Technology, Tottori University, Tottori, Japan and Xianhuo Hospital, Capital University, Beijing, China.
**Purpose:** Fatty liver is being increasingly recognized as a common liver disorder that represents the hepatistic manifestation of the metabolic syndrome, a variably defined cluster of obesity, insulin resistance, hyperglycemia, hypertension and hyperlipidemia. The syndrome has become global health epidemics. Cinnamon, a traditional Chinese Medicine, has inhibited polyphagia in our previous study. The Otsuka Long-Evans Tokushima Fatty (OLETF) rat is a genetic metabolic syndrome animal model with fatty liver, exhibits an innate polyphagia, progressive overweight and hypercholesterolemia. The analysis of the metabolome is particularly challenging due to the diverse chemical nature of metabolites. To find effective control method for fatty liver, the effect of cinnamon on metabolome of OLETF was studied.

**Methods:** The animals were divided into 3 groups 1) cinnamon group in OLETF, 2) control of OLETF and 3) the counterpart Long-Evans Tokushima Otsuka rats as normal control. Cinnamon was dosed in diet (62.5 g/kg food) and animals could access to water and the food freely. Serum and liver sample were collected for metabolic analysis.

**Results:** Proteomics studies showed that the enzymes relative to lipid metabolism were different between the livers of OLETF and LETO, with PDQuest software analysis of 2-DE gels, MALDI-TOF mass spectrometry, and peptide fingerprints analysis as well as Swiss-Prot database searching. The wet weight and size of the OLETF liver were increased and lipid contained in the OLETF liver was higher than that in normal control. The serum cholesterol was higher in OLETF than that in normal control. With cinnamon treatment the wet weight and size of the fatty liver were limited and lipid in the fatty liver was decreased. The serum cholesterol in OLETF was decreased by cinnamon about 2/3, which was even lower than that in normal control. The water intake was inhibited along with polyphagia suppressed and abnormal proteome of the fatty liver in OLETF was corrected by cinnamon.

**Conclusions:** The metabolome could be improved by cinnamon in fatty liver rat. Cinnamon could be a useful Chinese Medicine for fatty liver treatment, especially in metabolic syndrome with fatty liver. Thanks the Supports form the Japan Society for the Promotion of Science (JSPS), Japan, President Foundation and VBL of Tottori University, Japan, Ministry of Education, China and CAMS, China. Email: luo_jsp@hotmail.com

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**Assessment of Adrenal Function in Patients with Chronic Hepatitis C and Severe Fatigue**

Irphan Gaslightwala, MD, Ann Danoff, MD, Jen Leong, MD, Edmund J. Bini, MD, MPH. Gastroenterology, NYU School of Medicine, New York, NY and Endocrinology, NYU School of Medicine, New York, NY.

**Purpose:** Fatigue is a disabling symptom of hepatitis C virus (HCV) infection. Since adrenal insufficiency is a known cause of fatigue and HCV is associated with several endocrinopathies, we hypothesized that adrenal dysfunction is a cause of fatigue in HCV+ patients.

**Methods:** Using the validated Fatigue Impact Scale (FIS) to assess fatigue (score 0 – 160; higher scores = more fatigue), we enrolled HCV+ patients with severe fatigue (FIS > 30) and HCV- controls without fatigue (FIS < 10). The Beck Depressive Inventory (BDI) was used to assess depression (score 0 – 63; higher scores = more depression). All patients had baseline adrenocorticotrophic hormone (ACTH), cortisol, and anti-adrenal antibodies measured, followed by administration of low-dose (1 mcg) ACTH; cortisol levels were measured at 30 and 60 minutes. After a washout period, this procedure was repeated using high-dose (250 mcg) ACTH. The primary outcome was the mean change in cortisol 30 minutes after low-dose ACTH.

**Results:** There were no differences in the age, gender, or race between the 26 HCV+ patients and 22 controls. HCV+ patients had higher FIS (82.4 ± 27.9 vs 1.3 ± 3.6, p < 0.001) and depression scores (20.0 ± 10.1 vs 1.3 ± 2.0, p < 0.001). There were no significant differences in the baseline ACTH levels (18.8 ± 10.3 vs 16.9 ± 8.7 pg/dL, p = 0.52), baseline cortisol levels (14.1 ± 4.2 vs 12.8 ± 3.0 mcg/dL, p = 0.24), mean rise in cortisol from baseline to 30 minutes (10.9 ± 6.0 vs 11.8 ± 5.0 mcg/dL, p = 0.061), or proportion without a rise in cortisol of ≥ 9 mcg/dL (42.3% vs 23.8%, p = 0.18) after low-dose ACTH. Similarly, there were no differences between the 2 groups at any time point after high-dose ACTH. As expected, FIS and BDI scores were strongly correlated in the HCV+ group (r = +0.62, p = 0.001), although we did not find any correlation between fatigue severity and either baseline cortisol levels (r = −0.18, p = 0.39) or the rise in cortisol 30 minutes after low-dose ACTH (r = −0.23, p = 0.27). BDI scores also did not correlate with either baseline cortisol levels (r = +0.22, p = 0.30) or the rise in cortisol 30 minutes after low-dose ACTH (r = −0.25, p = 0.23). None of the HCV+ patients had anti-adrenal antibodies detected.

**Conclusions:** Among HCV-infected patients with severe fatigue, we did not find an impairment of cortisol secretion or evidence of adrenal autoimmunity. Adrenal dysfunction does not appear to be a cause of fatigue or depression in patients with HCV infection.

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**TISSUE IS AN ISSUE. Intrahepatic Cholangiocarcinoma Mimicking Hepatocellular Carcinoma**

Yasser Jamal, MD,* Suftyan Hafeez Chaudhry, MD, Kerry Whitt, MD. Internal Medicine, University of Tennessee, Memphis, TN and Gastroenterology, University of Tennessee, Memphis, TN.

**Purpose:** To report an unusual and deceptive presentation of advanced cholangiocarcinoma.

**Methods:** Report: 60 years old white male presented with 3 months history of vague right upper quadrant pain and low grade fever. Pain was associated with 30 pounds weight loss and anorexia. On examination his liver was enlarged and tender with splenomegaly but no signs of cirrhosis. His lab work up showed high alkaline phosphatase 1096, LDL 737 and GGT 2280 but normal bilirubin. His AST was mildly elevated at1319 with normal ALT. His INR was normal with albumin of 2.4. His AFP was 406 and CA 19-9 was mildly elevated at 99 with normal CEA. Hepatitis panel, iron saturation, alpha 1 antitrypsin were normal. Ultra sound showed splenomegaly and large right liver mass with thrombosis of right portal vein. CT scan of abdomen showed necrotic mass 5X6cm in right lobe of liver with smaller satellite lesion in both lobes and right portal vein thrombosis likely due to invasion. EGD did not reveal any varices. His all tumor markers and radiological studies pointed towards hepatocellular carcinoma but with no previous liver disease, it made it doubtful. Ultimately CT guided liver biopsy was done which surprisingly showed moderately differentiated adenocarcinoma and immunostaining was positive with CK 7 and CA19-9 staining compatible with cholangiocarcinoma. With portal vein invasion he was not the candidate for surgery or palliative chemotherapy. Hospice was arranged and ultimately patient expired in one month.

**Conclusions:** Cholangiocarcinomas account for about 3 percent of all gastrointestinal cancers. Intrahepatic cholangiocarcinomas constitutes around 10 percent of all cholangiocarcinoma. Our case is unique as presumptive diagnosis of HCC was made due to very high AFP and liver mass and ultimately it was found out to be cholangiocarcinoma. Association of high AFP with cholangiocarcinoma is rarely reported in literature. Other tumor markers like CEA and CA 19-9 have been reported to be raised in cholangiocarcinoma. Portal vein invasion he was not the candidate for surgery or palliative chemotherapy. Hospice was arranged and ultimately patient expired in one month.

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**Hepatic Sarcoidosis: An Unusual Complication of Peginterferon alpha-2a Therapy in Patient with Hepatitis C**

Amir Mohammadal, MD, Khalid Aziz, MD.* Internal Medicine, University of Connecticut, Farmington, CT and Internal Medicine, Division of Gastroenterology, University of Connecticut, Farmington, CT.

**Purpose:** Hepatitis C virus infection (HCV) is a major public health concern. Current therapy includes subcutaneous administration of interferon and oral ribavirin. The adverse profile attributed to these agents includes...
Can Serum Albumin Predict the Future Development of Renal Insufficiency in Patients with Chronic Liver Disease?

George T. Hage-Nassar, MD,* Vijaya Boyella, MD, Bergasa Nora, MD. Gastroenterology, SUNY Downstate Medical Center, Brooklyn, NY; Hepatology, SUNY Downstate Medical Center, Brooklyn, NY and Gastroenterology & Hepatology, SUNY Downstate Medical Center, Brooklyn, NY.

Purpose: The aim of our study was to determine whether hypoalbuminemia can predict the future development of renal insufficiency in patients with chronic liver disease.

Methods: This is a retrospective study of patients with chronic liver disease. Renal insufficiency was defined by a creatinine level of 1.5 mg/dl or more. Patients with renal insufficiency were divided into three groups: In group I renal insufficiency existed before the diagnosis of chronic liver disease was made. In group II no chronicologic relation could be made to which disease existed first and in group III renal insufficiency developed after the diagnosis of chronic liver disease. In group III the serum albumin concentration was reviewed over the three months period prior to the documented onset of renal insufficiency, and an average serum albumin was calculated (ASA). Patients in group I and II patients, were not included in the analysis.

Results: 94 patients met the inclusion criteria for chronic liver disease. The number of patients with renal insufficiency in groups I, II and III were 3, 9 and 25, with a proportion of 8%, 24%, and 68% respectively. In group III serum albumin level was evaluated during the period extending up to 3 months prior to the onset of renal insufficiency, and average serum albumin (ASA) was calculated: 22 patients (88%) had an ASA of = < 2.7 g/dl, and only 3 patients (12%) had an ASA > 2.7 g/dl. (Fig. 2). In contrast 57 (61%) patients with chronic liver disease had no renal insufficiency at any point in time; most of these patients 42 (74%) had an ASA of > = 2.7 g/dl, while only 15 (26%) had an ASA of = < 2.7 g/dl. (Fig. 2).

Conclusions: Although albumin could be falsely low in inflammatory conditions, as well as in malnourished patients, an average serum albumin of less than 2.7 g/dl over a period of three months, appears to be a major predictive factor for the future development of renal insufficiency in patients with chronic liver disease. [figure1]
hemoglobin levels by the end of the follow-ups in groups A,B,C, and D were 11.5 g/dL, 10.5 g/dL, 9.9 g/dL, and 8.3 g/dL, respectively. The p values were < 0.001 between groups except groups B and C. Seven patients (50%) in group D were hospitalized or received blood transfusions. Three patients in group A died of sepsis and hepatorenal syndrome (HRS) and one due to lung cancer. Similarly four patients in group D and one in B died due to HRS and sepsis.

**Conclusions:** 1: Adding a PPI to propanolol may reduces the risk of GI bleeding and anemia in patients with PHG. 2: Prospective, randomized, controlled trials to evaluate propanolol versus propranolol plus a PPI in reducing risk of bleeding due to PHG in patients with obliterated esophageal varices are presently warranted. [figure1]

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**Liver “BUST UP”**

Sufyan H. Chaudhry, MD, Mankanwal S. Sachdev, MD,∗ Internal Medicine, University of Tennessee, Memphis, TN and Gastroenterology, University of Tennessee, Memphis, TN.

**Purpose:** To report a case of cirrhosis caused by occupational chemicals.

**Methods:** Case Report: A 26 year old white male was referred to hepatology clinic by his PCP with 3 year history of abnormal aminotransferases. After discovery of elevated aminotransferases he underwent a number of tests for diagnostic purposes. A liver biopsy was done about 6 months before his current presentation that showed early cirrhosis. On history, he reported that he had been healthy except occasional migraines for which he took acetaminophen (APAP). Three years ago he was found to have raised aminotransferases. He denied any family history of liver disease. He had been a regular alcohol user but had stopped since discovery of abnormal enzymes. He also decreased his APAP intake. He worked in a storage warehouse for a soft drink company. His exam was unremarkable and labs showed: AST 74, ALT 234, alkaline phosphatase 53, albumin 4.8, bilirubin 0.8, INR 1.0 and creatinine 0.8. Complete blood count was unremarkable. Chest x-ray was normal and on further work up, an abdominal ultrasound revealed fatty infiltration of the liver. Viral hepatitis panel was negative, serum ceruloplasmin and urine copper levels were normal. Alpha-1-antitrypsin level was also normal with MM phenotype. Anti-smooth muscle antibody was negative. Ferritin was marginally high with normal serum iron level and hemachromatosis phenotype showed heterozygote for C282Y. A repeat liver biopsy was done that showed moderate macrovesicular steatosis along with areas of chronic perportal hepatitis and one area with bridging fibrosis suggestive of evolving cirrhosis. There was minimal necroinflammatory activity accompanied by neutrophils and eosinophils. Minimal hemosiderin staining was noted while copper quantification was normal. On further questioning he recalled handling chemicals daily at his work including a degreaser called “Bust Up.” Its ingredients included Diethylene glycol and sodium xylene both of which has been shown to cause hepatotoxicity and liver biopsy was evident of steatohepatitis along with inflammatory process. Patient was asked to avoid contact with the chemicals and on follow up visits transaminases trended down.

**Conclusions:** NASH has been associated with exposure to xylene and benzene. Poisonous effects of diethylene glycol has been shown to cause centroporal necrosis in liver of rats. Our patient was exposed to these chemicals as part of his job and possibly due to underlying steatohepatitis caused pronounced fibrosis, liver damage and early fibrosis.

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**Body Mass Index Determines Response to Treatment in Patients with Chronic Hepatitis C Using Pegylated Interferon and Weight-Based Ribavirin**

Nikunj Shah, MD,* Peter Serughin, DO, Bernard Nemchausky, MD, Frank Iber, MD. Gastroenterology and Hepatology, Edward Hines Jr. VA Hospital, Hines, IL.

**Purpose:** To retrospectively review response to Pegylated Interferon (PEG) and weight-based ribavirin in patients with chronic hepatitis C and relationship to Body mass index (BMI).

**Methods:** Initially veterans were identified who were suitable candidates for treatment for hepatitis C. They were screened for their liver chemistry tests. In addition, they had HCV-RNA viral load and genotype determined. Liver biopsy was performed to determine their hepatitis activity index. Veterans were treated with either of pegylated interferons with weekly injections and weight based ribavirin (11–13 mg/kg) for 48 weeks. Sustained viral response (SVR) was determined based on HCV-RNA results 24 weeks after stopping treatment. BMI was calculated based on their pre-treatment weight and height.

**Results:** Between 7/2001 and 6/2004, 285 veterans started treatment for hepatitis C. 157 patients completed 48 weeks of treatment. 72 patients received peginterferon alfa 2b and 213 patients received pegylated interferon alfa 2a. Patients were classified into high BMI (> 30) or low BMI (< 30) group. Overall 33% (24/72) of patients had SVR in PEG alfa 2a group and 29% (62/213) in PEG alfa 2b group. In low BMI group patients receiving PEG alfa 2a had 37% (21/57) SVR and PEG alfa 2b group had 31.5% (33/105) SVR. In high BMI group patients receiving PEG alfa 2a had 20% (3/15) SVR and PEG alfa 2b group had 27% (29/107) SVR. There was no difference in demographics, genotypes, and stage of fibrosis amongst groups.

**Conclusions:** In patients with chronic hepatitis C, response to treatment using PEG interferon and weight-based ribavirin is determined by BMI. Patient with BMI greater than 30 PEG alfa 2b seems to be better than PEG alfa 2a. This may be due to dosing of PEG alfa 2b is weight based. Low BMI patients have higher SVR than high BMI group. Other factors related to high BMI and metabolic syndrome may play role in SVR.

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**Extended Re-Treatment for Chronic Hepatitis C Genotype 1 Patients Who Previously Relapsed Following 48 Week PEG/Ribavirin Therapy**

Jeffrey McMahon, PA-C, Stuart C. Gordon, MD,* Gastroenterology and Hepatology, Henry Ford Hospital, Detroit, MI.

**Purpose:** The appropriate management of PEG ribavirin relapsers remains undefined. A recent report demonstrated reduced relapse rates for certain HCV genotype 1 treatment naïve patients who received 72 vs. 48 weeks of therapy. The benefit of extending treatment to 72 weeks for previous PEG ribavirin relapsers, however, has not been reported. We assessed the efficacy of a repeat course of more protracted therapy for previous combination therapy relapsers.

**Methods:** We report three HCV genotype 1 patients who relapsed following their initial 48 week course of PEG/ribavirin. The three patients maintained >80/80/80 adherence during their initial treatment, and all relapsed within 12 weeks of their last dose. Each was re-treated with PEG-IFN alfa-2a 180 mcg once weekly plus ribavirin (>13.3 mg/kg/day, 1000–1200 mg). We assessed HCV RNA using Amplicor 2.0 quantitative and reflex TMA qualitative testing.

**Results:** All patients again maintained adherence at >80/80/80 throughout their 72 week course of repeat therapy. Each patient became HCV RNA negative by treatment week 12. Six months after completing re-treatment, each patient remained HCV RNA negative, thus now achieving a sustained virologic response.

**Conclusions:** Relapsers to PEG/ribavirin combination therapy may benefit from 1) a repeat course of therapy that exceeds 48 weeks, or 2) higher doses of ribavirin. Each patient remained adherent during both regimens, thus duration of viral negativity appears to represent a pivotal goal. Additional studies
are needed to determine the efficacy of extended therapy and/or higher ribavirin dosing for patients who previously relapsed following standard PEG ribavirin therapy.

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The Comorbid Conditions and Hemodynamics of Patients with Ischemic Hepatitis: A Clinical Evaluation
Mayur R. Trivedi, MD, Vijaya Boyella, MD, Cherif El Younis, MD, Nora V Bergasa, MD.* Hepatology, SUNY Downstate Medical Center; Brooklyn, NY.

Purpose: The aim of this study was to identify the clinical characteristics and risk factors of developing ischemic hepatitis in a large inner city hospital.

Methods: This was a retrospective study of 17 patients with the diagnosis of ischemic hepatitis based on consultations done by the Hepatology service since March 2004 at Kings County Medical Center and SUNY Downstate Medical Center in Brooklyn, NY. The diagnostic criteria included a reversible increase in serum aminotransferase activity reaching at least 20-fold the upper limit of normal, and excluding other causes of acute hepatitis in a clinical setting (Seeto RK et al, Am J Med. 2000). The charts of patients were reviewed for co-morbid conditions (e.g. DM, HTN, CAD, etc.), serum liver profiles were also recorded (e.g. activity of alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase, bilirubin, albumin, lactate dehydrogenase, PT, and INR), and ventilator settings, if available.

Results: The most common comorbidities were cardiovascular disease (82%), hypertension (82%), ESRD (82%), and diabetes (41%) in our patient population. Only 29% of the patients had a documented hypotensive episode prior to development of ischemic hepatitis. Three patients on ventilators were weaned off, and this had no impact on the development of ischemic hepatitis.

Serum Laboratory Values (N = 17)

<table>
<thead>
<tr>
<th>Test</th>
<th>Admission (Mean ± SD)</th>
<th>Peak Values (Mean ± SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AST (u/L)</td>
<td>55.7 ± 19</td>
<td>5871.5 ± 8383</td>
</tr>
<tr>
<td>ALT (u/L)</td>
<td>45.5 ± 25</td>
<td>2408.5 ± 1912</td>
</tr>
<tr>
<td>Total Protein (g/dl)</td>
<td>7.58 ± 0.90</td>
<td>6.44 ± 1.6</td>
</tr>
<tr>
<td>Albumin (g/dl)</td>
<td>3.65 ± 0.68</td>
<td>2.96 ± 0.76</td>
</tr>
<tr>
<td>Alk Phos (u/L)</td>
<td>157.1 ± 154</td>
<td>152.9 ± 102</td>
</tr>
<tr>
<td>Total Bilirubin (mg/dl)</td>
<td>0.88 ± 0.61</td>
<td>2.6 ± 2.2</td>
</tr>
<tr>
<td>PT (sec)</td>
<td>15.7 ± 3.2</td>
<td>21.4 ± 8.4</td>
</tr>
<tr>
<td>INR</td>
<td>1.51 ± 0.55</td>
<td>3.0 ± 1.96</td>
</tr>
</tbody>
</table>

Conclusions: Cardiac disease, hypertension, and ESRD were the three major risk factors for developing ischemic hepatitis. Weaning patients off of ventilators has no effect on the development of ischemic hepatitis. Laboratory findings revealed that there was at least a 50 fold increase in serum transaminases, and PT was prolonged by 5.7 sec. Albumin, total protein, and alkaline phosphatase remained relatively unchanged, which correlates with prior findings.

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The Role of Religiosity in the Outcome of Treatment for Chronic HCV Infection
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Purpose: To determine the influence of patient religiosity on the outcome of treatment of hepatitis C infection.

Methods: A prospective, blinded, cohort study was performed on hepatitis C infected-patients. Patients were categorized as higher religiosity and lower religiosity based on responses to questions derived from a modification of the Multidimensional Religiosity/Spirituality Questionnaire. Comparisons were made between high and low religiosity patients (total and treated population) on demographics, pre-treatment lab values, and response to treatment with sustained viral clearance. Analysis on comparisons consisted of Pearsons chi-squared (or Fishers exact test) for ordinal outcomes and both the two-sample t-test and the Mann-Whitney two-sample statistic for score outcomes (mean and rank, respectively).

Results: Eighty-seven of the 89 patients enrolled were recovered for analysis. The questionnaire results were used to place 38 (44%) in the higher religiosity cohort and 49 (56%) in the lower religiosity cohort. The patients (60% female) were ethnically diverse; African American 39%; Hispanic 31%; White 29%. African American race (59%) and female gender (74%) were associated with higher religiosity (p = 0.001, 0.026). Sixty-five (75%) patients were offered treatment with combination peginterferon and ribavirin therapy. Sixty-two agreed to begin treatment. Fifty-six patients (13 genotype 2 or 3; 42 genotype 1) completed the 24 or 48 week regimen. The frequency of being offered treatment, accepting treatment, and completing treatment were similar in both religiosity cohorts (p = 0.234, 0.809, 0.367). Thirty-one (55%) of those who completed treatment had negative HCV PCR 3-6 months after therapy. The sustained viral response was similar in the higher religiosity (50%) and lower religiosity (59%) cohorts (p = 0.517). Based on these sample sizes, post power analysis revealed only a 16% power to detect a difference between the proportions of 0.10.

Conclusion: We were unable to demonstrate that patient-reported religiosity was statistically associated with the outcome of treatment of chronic HCV infection. This study was funded in part by the Frank Lanza Research Fund and Public Health Service grant DK56338, which funds the Texas Gulf Coast Digestive Diseases Center.

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Racial Differences in Alpha-Fetoprotein Levels in Cirrhotic Patients with and without Hepatocellular Carcinoma
Niraj Gor, MD, Grace Guzman, PhD, Scott Cotler, MD.* Section of Hepatology, The University of Illinois at Chicago, Chicago, IL.

Purpose: The purpose of this study is to compare alpha-fetoprotein (AFP) levels between African American and non-African American patients with 1) cirrhosis and no evidence of hepatocellular carcinoma (HCC) and 2) cirrhosis with evidence of HCC.

Methods: 120 patients with cirrhosis on the liver transplant waiting list at the University of Illinois at Chicago (UIC) between 1999 and 2005 were evaluated. All patients had multiple imaging studies, including ultrasound and contrast-enhanced CT or MRI, showing no evidence of HCC. An additional 166 patients were studied who were entered into the UIC tumor registry with HCC between 1999 and 2005. Demographic data was collected including age, gender, race and cause of liver disease. MELD scores and UNOS criteria for transplantation were assessed for patients on the transplant waiting list and in the UIC tumor registry, respectively.

Results: Patients without HCC were younger (51 + 9 years) than those with HCC (60 + 12 years) [p < 0.001]. There were no significant differences in gender, racial distribution, or cause of liver disease between groups. There was no significant difference in MELD score among African American and non-African American patients without HCC. Among patients with HCC, there was no significant difference between groups in the proportion of patients that met the UNOS criteria for transplantation. Analysis of cirrhotic patients without HCC showed that African Americans had higher AFP levels (median 9.1, IQR 4.4-19.6) than non-African Americans (median 5.2, IQR 2.6-9.6) [p = 0.008]. A higher proportion of cirrhotic African American patients without HCC (11/28) had AFP levels greater than 10 compared to non-African Americans (20/92) [p = 0.063]. Among patients with HCC, there was a trend toward lower AFP levels in African Americans (median 13.5, IQR 6.25-116.5) compared to non-African Americans (median 23, IQR 5.25-126.8) [p = 0.057]. However, there was
no difference in the proportion of HCC patients with AFP levels greater than 10 by racial group \( (p = 0.39) \).

**Conclusions:** In our analysis, 1) AFP levels were higher in cirrhotic African American patients without HCC than in non-African American patients, however, 2) AFP levels were lower in cirrhotic African Americans with HCC than in non-African American patients. Our work highlights the need for further investigation of AFP levels in cirrhotic patients with and without HCC as a function of race.

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**Preliminary Results of Hepatocellular Carcinoma Patients Treated by Talaporfin Sodium and Intestinal Light Emitting Diodes – A Phase I Clinical Trial**

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**Purpose:** To report the preliminary results of a phase I clinical trial employing light activated talaporfin sodium (LS11) and interstitial light emitting diodes (LED) to treat inoperable hepatocellular carcinoma (HCC).

**Methods:** The patients with inoperable HCC which was limited within 3 lesions were enrolled in this study. LED light source was placed into the tumors percutaneously under CT or ultrasound guidance. Light activated talaporfin sodium, 1 mg/kg, was administrated intravenously 15 to 60 minutes before light energy was delivered. A total of 200 J/cm light energy was delivered. To sodium, 1 mg/kg, was administrated intravenously 15 to 60 minutes before the treatments were enrolled in this study. LED light source was placed into the tumors after the treatments (35.0 ± 2.63 mg/ml to 9.21 ± 3.56 mg/ml \( (p = 0.07) \). One patient showed a grade 1 erythematous change of the skin on hands under sunshine exposure. No major complications occurred.

**Conclusions:** Using light activated talaporfin sodium (LS11) and interstitial light emitting diodes (LED) to treat inoperable hepatocellular carcinoma is safe in this phase I clinical trial. Skin photosensitivity was minimal and the result of early exposure to sunshine. LS11 plus LED can also induce tumor kill. Conclusive treatment efficacy in HCC requires further evaluation in the future.

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**Characteristics and Outcome of Portopulmonary Hypertension**

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**Purpose:** Pulmonary artery (PA) hypertension developing in patients with portal hypertension (PH), also called portopulmonary hypertension (PPHTN), carries significant mortality in patients undergoing liver transplant (OLT). With OLT becoming the standard of care, implications of PPHTN are increasingly recognized. However, PPHTN remains rather poorly characterized.

**Aim:** To define the clinical, biochemical, hemodynamic and outcome characteristics of PPHTN.

**Methods:** PPHTN was defined as PA systolic pressure ≥ 40 mm Hg (PAs), PA mean pressure ≥ 25 mm Hg (PAm), Pulmonary capillary wedge pressure (PCW) <15 mm Hg. Pulmonary vascular resistance (PVR) ≥ 120 dynes.s.cm \(^{-5}\). During evaluation of candidates for OLT eleven patients identified to have PPHTN were followed for 19 to 48 months. Their clinical, biochemical, hemodynamic parameters, natural history and outcome were analyzed.

**Results:** There were 8 females and 3 males with age of 51.4 ± 2.1 years. Etiology of liver disease was alcoholism and autoimmune hepatitis in one each, cryptogenic in 2, Primary sclerosing cholangitis in 2 and chronic hepatitis C in 5. Shortness of breath was experienced by one, 9 had ascites, and 6 had significant splanchnic varices. Biochemical parameters revealed MELD score of 13.2 ± 1.0 (range 8-18), total s. bilirubin 2.0 ± 0.3 mg%, s. albumin 3.3 ± 0.2 Gm%, AST 109.4 ± 28.3 IU and ALT 72.4 ± 20.5 IU. Cardiac output was 7.4 ± 0.9 L/min (range 4.6-11.4), PAs was 57.5 ± 4.2 mm Hg, PAm was 33.8 ± 3.7 mm Hg, PCW was 15.3 ± 2.1 mm Hg. PVR was 299.5 dynes.s.cm \(^{-5}\), 2-D echocardiography showed tricuspid regurgitation (TR) in all. Treatment (calcium channel blockers, sildenafil, endothelin receptor antagonists, or intravenous prostacyclin analogue) for 19.4 ± 4.3 months (range 1- 48) dropped the PAs to 49.1 ± 4.6 mm Hg. Four patients were given OLT; seven denied OLT because of high PA pressure. From the time diagnosis of PPHTN was made, six are alive for 33.3 ± 4.1 months and 5 died after 17.6 ± 6.3 months.

**Conclusions:** PPHTN occurs in patients with cirrhosis of all etiologies with significant PH and is more frequent in females. PA hypertension remains asymptomatic in most patients. All of the patients have hyperdynamic cardiac hemodynamics and increased PVR. The finding of TR on 2 D echocardiography is a good screening indicator of PA hypertension. Response to treatment is variable and less than desirable. Significant PPHTN often prohibits OLT and those not transplanted have decreased survival.

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**Does the Grade of Inflammation on Liver Biopsy Predict the Response to Combination Treatment with Pegylated Interferon and Ribavirin in Hepatitis C Patients?**

Isam Daboul, MD,∗ Vikas Ghai, MD, Charles Filipiak. Department of Gastroenterology, Medical University of Ohio, Toledo, OH.

**Purpose:** Using the degree of fibrosis on liver biopsy as a component of the basis of therapy is proven to be helpful in predicting response, treatment is generally advised if the liver biopsy displays a Metavir score of less than or equal to 2 or an Ishak score of less than or equal to 3. No studies using the role of degree of inflammation to predict the response to treatment are available.

**Methods:** We conducted a retrospective chart review study on 29 naive patients with hepatitis C genotype 1 {age 59-62 years (mean 44)} who were treated with the standard approved doses of Pegylated interferon and Ribavirin (combination therapy) after having a liver biopsy. The rate of early response (defined as 2 log or more reduction in the viral count at 12 weeks of therapy) was calculated for the patients in each degree of inflammation group (1-4). Patient with more than or equal to 2 log reduction in the viral count at the end of 12 wks were considered as an initial responder to treatment. Patients with other hepatitis C genotypes were excluded because of the low number of patients.

**Results:** Five patient had grade 1 inflammation (three responded to the treatment and two failed the treatment) Fourteen of them had grade 2 inflammation (ten responded to the treatment and four failed to respond) Seven had grade 3 inflammation (four responded to treatment and 3 failed to respond) Three had grade 4 inflammation (two responded to the treatment and one failed to respond) 68% of the patients with grade 1 or 2 inflammation were initial responders to the therapy as compared to 60% in patient with Grade 3
or 4. The difference in the response rate was not statistically significant. (p = 0.478)

Conclusions: The early response rate to treatment of hepatitis C genotype 1 patients did not show a statistically significant difference between various degrees of inflammation on liver biopsy. Studies with larger number of patients and different hepatitis C genotypes are needed.

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Maternal HBV DNA Levels Correlate with Frequency of Vertical Transmission of Hepatitis B in Newborns
Chandana Pande, MBBS, Shanda Patra, MBBS, MS, Namita Mishra, MBBS, A.K. Dutta, MBBS, MD, Shubha S. Trivedi, MBBS, MS, Shiv K. Sarin, MBBS, MD, DM*; Gastroenterology, GB Pant Hospital, New Delhi, Delhi, India; Obstetrics and Gynecology, Lady Hardinge Medical College, New Delhi, Delhi, India and Pediatrics, Kalawati Saran Children’s Hospital, New Delhi, Delhi, India.

Purpose: Vertical transmission is a common mode of HBV transmission in endemic areas. HBeAg status is known to influence the transmission rate. There is scanty data whether HBV DNA levels influence the transmission rate. We studied the vertical transmission rate based on maternal HBV DNA levels and HBeAg status.

Methods: All pregnant women attending the antenatal clinic from September 2004 through March 2006 were screened for HBsAg, HBeAg, anti-HBe and HBV DNA was done in HBsAg positive women. All women were followed till delivery. At delivery, cord blood was tested for HBsAg and HBV DNA.

Results: A total of 9,440 pregnant women, (mean age ± 3.1 yr.) were screened; 99 (1%) tested positive for HBsAg; 23 (23%) for HBeAg and 34 (34%) for anti-HBe. HBV DNA was high (≥2.4x10^6) in 15 (15%), moderate (2.4x10^6–2.4x10^5) in 7 (7%); low (1.2x10^5–2.4x10^4) in 47 (47%); and undetectable (<1.2x10^5) in 31 (31%). Six (25%) HBeAg positive and 13 (39%) anti-HBe positive women had low or undetectable HBV DNA respectively. Of the 99 women, 52 (52%) have delivered so far. HBeAg, HBV DNA and HBeAg were positive in 27 (52%), 24 (46%) and 7 (13%) cord blood samples of infants respectively. HBV DNA transmission was significantly higher in HBeAg positive than HBeAg negative mothers (8/11 [73%] vs. 16/41 [39%]; p < 0.05). 100% and 42% of HBeAg negative women with moderate and low HBV DNA transmitted HBV infection to newborns. In 4 of 19 (21%) women with undetectable DNA, perinatal transmission was noted. Transplacental HBV transmission was highest in women with high HBV DNA load (Table 1).

Conclusions: (i) A linear correlation exists between maternal HBV DNA level and transplacental HBV DNA transmission (ii) HBeAg negativity per se has little correlation with transmission, (iii) Perinatal transmission occurs in about 20% newborns despite very low maternal DNA levels.

<table>
<thead>
<tr>
<th>HBV DNA in mother</th>
<th>High (&gt;1000 pg/dl)</th>
<th>Moderate (5–1000 pg/dl)</th>
<th>Low (0.5–5 pg/ml)</th>
<th>Undetectable (&lt;0.5 pg/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(N = 7)</td>
<td>(N = 5)</td>
<td>(N = 21)</td>
<td>(N = 19)</td>
<td></td>
</tr>
<tr>
<td>Cord blood HBV DNA</td>
<td>7 (100%)</td>
<td>4 (80%)</td>
<td>9 (43%)</td>
<td>4 (21%)</td>
</tr>
<tr>
<td>Mother’s HBeAg</td>
<td>Pos (N = 6)</td>
<td>Pos (N = 2)</td>
<td>Pos (N = 2)</td>
<td>Pos (N = 1)</td>
</tr>
<tr>
<td>Neg (N = 1)</td>
<td>Neg (N = 3)</td>
<td>Neg (N = 19)</td>
<td>Neg (N = 18)</td>
<td></td>
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<tr>
<td>Perinatal transmission rate</td>
<td>6 (100%)</td>
<td>1 (50%)</td>
<td>1 (50%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>1 (100%)</td>
<td>3 (100%)</td>
<td>8 (42%)</td>
<td>4 (22%)</td>
<td></td>
</tr>
</tbody>
</table>

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Clinical and Pharmacological Correlates of Non-Alcoholic Steatohepatitis in the Morbidly Obese
William A. Moorad, MD, Christopher D. Still, DO*, Peter Benotti, MD, Glenn S. Gerhard, MD, Michael J. Komar, MD. Gastroenterology and Nutrition, Geisinger Health System, Danville, PA; General Surgery, Geisinger Health System, Danville, PA and Weis Center for Research, Geisinger Health System, Danville, PA.

Purpose: Non-alcoholic steatohepatitis (NASH) is an increasingly prevalent problem associated with obesity. Among patients undergoing bariatric surgery, routine intraoperative liver biopsy can identify normal histology, steatosis, NASH, or fibrosis. The goal of this study was to prospectively examine the affect of medication use and co-morbidities on the different histological subtypes in morbidly obese patients undergoing bariatric surgery.

Methods: Two hundred and forty-nine patients scheduled for gastric bypass surgery were prospectively recruited. All patients underwent a six to eight month clinical assessment including a complete history and physical, anthropometric measurements, and laboratory tests. The medical record was used to identify medications and co-morbidities. For patients selected to undergo surgery, a liver biopsy was taken as a routine part of the operative procedure and was assessed for specific histological abnormalities. Data was entered into a research database. Histological subtypes, co-morbidities, and medication use were evaluated and compared.

Results: Preliminary data suggests differences in co-morbidities and medication use among the major histological subtypes.

Conclusions: In the morbidly obese patient undergoing bariatric surgery, preliminary data suggest preoperative clinical data can predict liver histology.

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Non-Cirrhotic Portal Fibrosis: A Clinical Profile of 366 Patients
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Purpose: Non-cirrhotic portal fibrosis (NCPF), or Idiopathic Portal Hypertension, is an important cause of non cirrhotic portal hypertension leading to significant morbidity and mortality. It constitutes nearly 10-15% of all causes of variceal bleed in developing countries. We present the clinical profile of a large series of well characterized patients of NCPF.

Methods: A retrospective analysis of all patients with NCPF consecutively seen since 1983 was done. The diagnosis of NCPF was based on the presence of varices, dilated, thickened and patent portal vein and normal liver histology. Their clinical records were retrieved and analyzed.

Results: 366 patients were included in the study. The male:female ratio was 1:1, and 98% were from low socio-economic strata of society. The mean age of presentation was 31.6 (±13.8) years. 262/366 (72%) patients had presented with GI bleed. The frequency of bleeders increased with age: ≤12 yrs 50%, 13-24 yrs 66%, 25-36 yrs 72%, 37-48 yrs 73%, 49-60 yrs 78% and >60 yrs 93%. The bleeders had presented with median 1 episode (range 1 to 20) of bleeding prior to presentation. Those who had bled more than once, tolerated the bleeds well and had a median of 3 bleeding episodes in a median span of 6 months (bleeding risk 0.5 episodes/month). The bleeders had required a median of 2 units of blood transfusion for their bleed. 97% patients had esophageal varices with a median grade of 3. 31% had gastric varices, 70% of them GOV1. Median HVPG (N = 53) was 7 mmHg (range 2–15 mmHg), diagnostic of pre-sinusoidal site of resistance in NCPF. History of pain abdomen was found in 27%, transient ascites in 25%, jaundice in 18%, pedal edema in 18%, and lump left abdomen in 12%. Splenomegaly was seen in 74%, the mean spleen size was 8 ±5 cm below costal margin. 41% had Hb ≤ 7 gm/dl, 22% had TLC ≤ 4 x 10^9/mm^3 and 27% had platelets ≤ 80 x 10^3/mm^3. Liver function tests were normal in 98%, with median bilirubin of 0.9 mg/dl, AST 39 IU/L, ALT 35 IU/L, alkaline phosphatase 193 IU/L, albumin 3.7 g/dl and prothrombin time within 3 seconds of control. HBsAg was positive in 5.7% and anti-HCV in 2.2%, predominantly due to transfusions. The histology of liver showed normal hepatic architecture, mild kupffer cell hyperplasia and no evidence of chronic hepatitis or cirrhosis.

Conclusions: Gastrointestinal hemorrhage is a serious complication of NCPF and it presents predominantly in the young adults. Though the re-bleeding risk is high, the bleeds are well tolerated. The liver functions, liver architecture and HVPG remain normal in these patients.
The Severity of Hepatitis C Recurrence Post Liver Transplantation Correlates with Poorly Controlled Diabetes Mellitus

Gordon Liss, MD, Muhammad Hafi, MD, Kirti Shetty, MD.* Division of Transplantation, Georgetown University Hospital, Washington, DC.

Purpose: Recurrence of hepatitis C virus (HCV) infection is a common occurrence following liver transplantation (LT). Epidemiological and case-controlled data suggests an association between HCV recurrence, and post-transplant diabetes mellitus (DM). We therefore undertook this study with the following aims: (1) To determine the risk factors for the development of post-transplant DM in HCV positive LT recipients (2) To assess the relationship between severity of DM (as determined by peak blood glucose level) and rate of HCV recurrence (3) To determine whether poorly controlled DM correlated with severity of HCV recurrence as assessed by peak bilirubin level.

Methods: We retrospectively examined the records of all patients with HCV who underwent an LT at our center between 2000 and 2005. Variables studied included age at transplant, immunosuppression protocol, time interval between LT and histological HCV recurrence, peak blood glucose within 2 weeks of HCV recurrence, episodes of acute cellular rejection (ACR), and number of days of steroid exposure. The Pearson correlation coefficient was used to analyze the data.

Results: A total of 45 patients were identified, of whom 68% were male, with a mean age of 51. Ten patients (22%) had pre-existing DM, an additional 2 patients developed DM post-OLT. HCV recurrence was preceded by acute cellular rejection (ACR) in 27% of patients. A significant correlation was noted between peak bilirubin and peak serum glucose levels at the time of HCV recurrence (p = 0.01). A trend was noted between rate of recurrent viral disease and mean peak serum glucose (p = 0.06), even though this did not reach statistical significance. DM post-OLT correlated with pre-OLT DM, duration of steroid therapy, and ACR.

Conclusions: 1. Post-OLT DM is associated with duration of steroid therapy, and episodes of ACR. 2. Poorly controlled DM correlates with the severity of HCV recurrence as measured by serum bilirubin levels. Further prospective studies are required to further define the relationship between these two important clinical entities.

A Survey of Practice Patterns in Physicians Treating Hepatitis B in New York and San Francisco

Calvin Q. Pan, MD, FACP,* Hepatology, Department of Medicine, Mount Sinai Services at Elmhurst Hospital, Queens, NY.

Purpose: Management of chronic hepatitis B (CHB) patients has become a great challenge for clinicians. Despite there are several published guidelines in evaluation and management of CHB, the inconsistency in different practice persists. We sought to determine self-reported practices in evaluation and management of CHB among physicians.

Methods: A survey for physicians who treat CHB was undertaken. A survey instrument was developed, and then distributed when physicians attended the hepatitis B educational programs or seminars in New York City and San Francisco.

Results: Seventy two responded (response rate 64%), including 55 primary care, 6 ID and 11 GI physicians. Most of them worked in community hospitals or private practices. 63% respondents treated more than 25 CHB patients per month. 22% reported offering genotype testing. 5% reported using fibrotest/fibroscan to evaluate fibrosis. For patients on oral anti-CHB agent, 25% reported testing genotypic mutation periodically and at the onset of viral breakthrough, 75% reported doing the mutation analysis only when both ALT and DNA breakthrough occurred. For non-cirrhotic HBeAg (+) patients achieved HBeAg lost or seroconversion as a treatment end point for HBeAg positive non-cirrhotic patients. Only a few physicians treated decompensated cirrhotic patient with combine therapy to prevent resistant. Most physicians would use AFP as screening tool. Nearly all physicians are interested in a revised national guideline for the management of hepatitis B. Since the above inconsistencies exist, a new guideline to address the above issues will improve the quality of care of hepatitis B patients.

Chronic Hepatitis C: Retreatment of Pegylated Interferon/Ribavirin Nonresponders

Helder Cardoso, MD, Ana Horta Vale, PhD,* Margarida Mendes, MD, Pedro Bastos, MD, Artur Machado, MD, Carlos Santos, MD. Serviço de Gastroenterologia, Hospital S. João, Porto, Portugal.

Purpose: To assess the efficiency of retreatment in chronic hepatitis C patients nonresponders to previous treatment with pegylated interferon and ribavirin (PEG/R). To characterize the response to retreatment.

Methods: Retreatment of 33 patients previously nonresponders to PEG/R (original group of 142 patients with chronic hepatitis C): male gender in 73%; mean age 51.2 ± 11.8 years; genotype 1 in 79%; 3 in 15% and 4 in 6%; mean viral load 962430 ± 1196572U/mL; fibrosis F0-F2 in 61% and F3-F4 in 39%; previous relapse in 61% and null response in 39%; full dose initial treatment in 61% and insufficient dose (intolerance or low adherence) in 39%. Patients were treated with pegylated interferon (α2a or α2b) different from the initial treatment and ribavirin (1000–1200 mg/day), for 48 (genotype 1A) or 24 weeks (genotype 3). Measures in order to correct modificable factors of non response: multidisciplinary team; nurse daily support; use of epopetin; early treatment of depression and other adverse events.

Results:

<table>
<thead>
<tr>
<th>n</th>
<th>SVR</th>
<th>RX</th>
<th>NR</th>
</tr>
</thead>
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<td>Total</td>
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<tr>
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</tr>
<tr>
<td>Previous ribavirin dose ≤800 mg/day</td>
<td>15</td>
<td>67%</td>
<td>27%</td>
</tr>
<tr>
<td>Previous ribavirin dose &gt;800 mg/day</td>
<td>18</td>
<td>11%</td>
<td>39%</td>
</tr>
</tbody>
</table>

Sustained virologic response (SVR), Relapse (RX), Null response (NR).

SVR was lower in genotype 1 (p = 0.03). Null response (NR) was higher in F3-F4 (p = 0.018). SVR was higher in relapers (p = 0.006). SVR was higher in previous inferior dose of ribavirin (p = 0.001).

Conclusions: Retreatment of our group of nonresponders to PEG/R achieved a SVR of 36%. The efficiency of the retreatment was higher in patients with previous inferior dose of ribavirin (67%), relapers (55%) and genotype #1 patients (71%), what resembles the results of naive patients. Those patients with insufficient dose in the initial treatment should be retreated with higher dose of ribavirin (>1000 g/day), if needed with the use of epopetin or other measures to treat adverse events or improve adherence. Those patients with full dose initial treatment had low SVR (11%), nevertheless the SVR was higher in relapers (29%). None of previous null responders with full dose initial treatment achieved SVR, in these patients new therapeutic regimens
should be considered: higher dose, prolonged treatment or combination of new drugs.

Prevalence of Diabetes Mellitus in Different Stages of Hepatitis C Virus Disease: A Pooled Data Analysis
Harshit S. Khara, MD, C.S. Pitchumoni, MD,* Dept. of Gastroenterology & Hepatology, St Peter’s University Hospital, New Brunswick, NJ.

Purpose: Among the various extra-hepatic manifestations of HCV disease, its association with DM has been confirmed (Allison et al. J Hepatol 2014; 21:1135-9) as well as disproved (Mangia et al. Am J Gastroenterol 1998). Among the various extra-hepatic manifestations of HCV disease, its association with DM has been confirmed (Allison et al. J Hepatol 2014; 21:1135-9) as well as disproved (Mangia et al. Am J Gastroenterol 1998; 93:2363-7) by many studies.

Methods: We conducted multiple searches of published medical literature from 1994, when the association was first reported, to present using keywords “Hepatitis C virus,” “Diabetes Mellitus” and related terms. The inclusion and exclusion criteria were irrespective of the outcome of a clinical study. All studies were analyzed according to the different stages of HCV disease.

Results: Table 1

Conclusions: 1. The prevalence of DM is higher in all stages of HCV disease compared to controls and gradually increases with the clinical progression of HCV disease.
2. There is an increased risk for DM in HCV than in HBV disease, as seen from individual studies, indicating that DM is a complication of HCV disease and not of chronic hepatitis.
3. The prevalence of DM in HCV induced cirrhosis is higher than in cirrhosis from other etiologies.
4. Whether early detection and treatment of HCV disease with ribavirin and peg-interferon dual therapy will have an impact on the prevalence of DM and insulin resistance in HCV patients is currently being studied by us.

A Double Blind Placebo Controlled Crossover Trial of Sertraline To Prevent Depression during Combination Therapy for Hepatitis C Infection
Esmat Z. Sadeddin, Christian Dang, Stuart Chen, Laura Alba, Wendell K. Clarkson.* Gastroenterology, UMKC, Kansas City, MO and Internal Medicine, Saint Luke’s Hospital, Kansas City, MO.

Purpose: to determine if prophylactic therapy with sertraline would reduce the risk of depression during therapy of patients with hep c undergoing treatment and achieve increased adherence to combination therapy. We hypothesized that sertraline would reduce the risk of interferon induced depression compared to placebo, and improve completion of therapy.

Methods: 30 patients were prospectively randomized to receive sertraline 50 mg daily or identical sertraline placebo initiated 4 weeks prior to initiation of combination therapy with weight based interferon alpha 2b and ribavirin. CES-D scores were obtained at baseline upon initiation of sertraline study drug, and every 4 wks. Patients were unblinded in the event of a CES-D score of 16 or greater, and those receiving placebo were crossed over to active drug. An increase in sertraline by 50 mg was provided at 4 week intervals up to a maximum dose of 150 mg, if the CES-D remained 16 or above.

Results: Baseline depression scores were similar between the two groups. After 4 wks of treatment with combination therapy, 8/15 (53%) of patients in placebo group were unblinded due to a score of more than 16, compared to 5/15 (33%) in the group receiving active drug. In placebo group, only 5/15 (33%) finished 4 wks of therapy. In the active treatment group, 10 patients out of the 15 (67%), were able to finish 4 weeks of treatment with a score less than 16 and were able to tolerate the sertraline well. only 3 patients scored more than 16 and had to be switched to a dose of 100 mg of sertraline (20%) from the peg. interferon treatment.However, by week 12 of treatment, only two patients out of the placebo group were able to stay on placebo (13%) and scored less than 16. And total of 11 patients (73%) scored more than 16 and were able to tolerate the sertraline well. only 3 patients scored more than 16.

Changes in Growth Factor and Cytokine Expression in Biliary Obstructed Rat Liver and Their Relationship with Delayed Liver Regeneration after Partial Hepatectomy
Hiroaki Shimizu, MD, PhD, Hironobu Makino, MD, PhD, Fumio Kimura, MD, PhD, Hiroyuki Yoshidome, MD, PhD, Masayuki Ohtsuka, MD, PhD, Masaru Miyazaki, MD, PhD.* Department of General Surgery, Chiba University Graduate School of Medicine, Chiba, Japan.
Purpose: Major hepatic syndrome associated with obstructive jaundice is often complicated by hepatic failure, suggesting that biliary obstruction (BO) may influence liver regeneration and cause hepatic failure after major hepatectomy. Although several previous studies regarding liver regeneration with obstructive jaundice have been reported, it is not clear how BO affects liver regeneration. In this study, to determine the effect of BO on liver regeneration, we investigated hepatic expression of growth/inhibitory factors, and also activation status of hepatic stellate cells (HSC's) before and after hepatectomy in BO and sham-control rats.

Methods: Hepatocyte growth factor (HGF), its receptor, c-Met, vascular endothelial growth factor (VEGF) and transforming growth factor-β1 (TGF-β1) mRNA expression in both liver tissue and isolated liver cells were investigated after BO by quantitative reverse-transcription polymerase chain reaction using a LightCycler. Immunohistochemical staining for desmin and α-smooth muscle actin (α-SMA) was also studied. Regenerating liver weight and proliferating cell nuclear antigen (PCNA) labeling index, and growth factor expression were then evaluated after 70% hepatectomy with concomitant internal biliary drainage in BO rats or sham-operated rats.

Results: Hepatic TGF-β1 mRNA levels increased significantly 14 days after BO, and further increased with length of cholestasis. Meanwhile, HGF and VEGF tended to increase, but was not significant. In cell isolates, TGF-β1 mRNA was found mainly in the hepatic stellate cell (HSC) fraction. Immunohistochemical studies revealed increased number of HSCs (desmin-positive cells) and activated HSCs (α-SMA-positive cells) in portal areas after BO. In a hepatocyte model, liver regeneration was delayed in BO rats, as compared to sham-operated rats. TGF-β1 mRNA was significantly up-regulated up to 48h after hepatectomy, and the earlier HGF mRNA peak was lost in BO rats.

Conclusions: BO induces proliferation and activation of HSCs, resulting in up-regulation of TGF-β1 and negative regulation of HGF expression. The altered expression patterns may be involved to a considerable degree in delayed liver regeneration after hepatectomy in rats with obstructive jaundice. These findings may provide clues for the treatment of impaired hepatic regeneration after major hepatectomy with obstructive jaundice.

Purpose: The metabolic syndrome has become global health epidemics. Fatty liver is a common liver disorder that represents the hepatic manifestation of the syndrome. Gymnemic acid, extract from traditional Chinese Medicine gymnema sylvestre, has improved the lipid lever in the serum of metabolic syndrome in our previous study. The Otsuka Long-Evans Tokushima Fatty (OLETF) rat is a genetic metabolic syndrome animal model. Proteomics and Pathologic Analyses of Fatty Liver in Otsuka Long-Evans Tokushima Fatty Rat Treated with Gymnemic Acid

Methods: Proteomics and Pathologic Analyses of Fatty Liver in Otsuka Long-Evans Tokushima Fatty Rat Treated with Gymnemic Acid

Results: Proteomics analyses showed that the enzymes relative to glucose and lipid metabolism were different in the livers between OLETF and LETO, with PDQuest software analysis of 2-DE gels, MALDI-TOF mass spectrometry, and peptide fingerprints analysis as well as Swiss-Prot database searching. The wet weight and size of the OLETF liver were increased in the OLETF. Pathologic study showed that the areas containing lipid were more than 50%. The wet weight and size of liver were decreased by gymnemic acid. With gymnemic acid treatment, the enzymes relative to glucose/lipid tended to normal and the areas containing lipid were decreased to less than 20% with wet weight and size down in the liver.

Conclusions: The metabolic syndrome could be improved by gymnemic acid in fatty liver rat by regulation of the enzymes relative to glucose and lipid metabolism in liver. Gymnemic acid could be a useful Chinese Medicine for fatty liver treatment, especially in metabolic syndrome with fatty liver.

Purpose: Gymnemic Storage Disease-Ia (GSD-Ia), an autosomal recessive genetic disorder, the result of defective expression of the glucose 6-phosphatase gene results in a block in glycogenolysis. Infants with GSD-1a present in the first few days of life with hypoglycemia, acidemia and seizures. As a result of improved medical management, GSD-Ia patients have an increased life expectancy and a resultant increase in the incidence of hepatic adenomatosis and hepatocellular carcinoma (HCC). GSD-Ia patients with large adenomas or with clinical evidence of malignant transformation have undergone partial hepatectomy; however, this represents only a temporary solution, as adenomas with malignant potential will develop in the remaining liver segments. There is no established criterion for the management of this patient population.

Methods: Retrospective case series of three consecutive patients with GSD-Ia managed by orthotopic liver transplantation.

Results: Orthotopic liver transplantation (OLT) is one potential therapeutic modality for the management of hepatic adenomatosis and HCC. In this setting OLT provides the added benefit of curing the underlying GSD-Ia and its potential complications. Here we report on 3 patients with GSD-Ia and hepatic adenomatosis who underwent successful OLT. Two of the three patients had a previous liver resection for treatment of large adenomas, even though they had adenomatosis involving both lobes. All patients underwent OLT utilizing the standard implantation technique. The total operative time was not significantly different between patients with and without prior liver resection; however, the time to complete the hepatectomy was significantly different 224 v. 155 mins. (p < 0.05). All patients were cured of GSD-Ia after transplant, with normal glucose and c-peptide levels. Moreover, there was a statistically significant alteration in metabolic parameters including normalization of lactate acidosis (7.34 v. 1.74 mmol/L) as well as cholesterol (439.8 v. 148.3 mg/dl) and triglyceride levels (1225 v. 193 mg/dl). All patients are working full time, and report improved energy levels, endurance and quality of life.

Conclusions: The improved outcomes in liver transplantation and the success of correcting GSD-Ia and its associated potentially fatal complications, warrant that OLT be considered a primary treatment option for GSD-Ia patients with hepatic adenomatosis.

Purpose: Major hepatic syndrome associated with obstructive jaundice is often complicated by hepatic failure, suggesting that biliary obstruction (BO) may influence liver regeneration and cause hepatic failure after major hepatectomy. Although several previous studies regarding liver regeneration with obstructive jaundice have been reported, it is not clear how BO affects liver regeneration. In this study, to determine the effect of BO on liver regeneration, we investigated hepatic expression of growth/inhibitory factors, and also activation status of hepatic stellate cells (HSC's) before and after hepatectomy in BO and sham-control rats.

Methods: Hepatocyte growth factor (HGF), its receptor, c-Met, vascular endothelial growth factor (VEGF) and transforming growth factor-β1 (TGF-β1) mRNA expression in both liver tissue and isolated liver cells were investigated after BO by quantitative reverse-transcription polymerase chain reaction using a LightCycler. Immunohistochemical staining for desmin and α-smooth muscle actin (α-SMA) was also studied. Regenerating liver weight and proliferating cell nuclear antigen (PCNA) labeling index, and growth factor expression were then evaluated after 70% hepatectomy with concomitant internal biliary drainage in BO rats or sham-operated rats.

Results: Hepatic TGF-β1 mRNA levels increased significantly 14 days after BO, and further increased with length of cholestasis. Meanwhile, HGF and VEGF tended to increase, but was not significant. In cell isolates, TGF-β1 mRNA was found mainly in the hepatic stellate cell (HSC) fraction. Immunohistochemical studies revealed increased number of HSCs (desmin-positive cells) and activated HSCs (α-SMA-positive cells) in portal areas after BO. In a hepatocyte model, liver regeneration was delayed in BO rats, as compared to sham-operated rats. TGF-β1 mRNA was significantly up-regulated up to 48h after hepatectomy, and the earlier HGF mRNA peak was lost in BO rats.

Conclusions: BO induces proliferation and activation of HSCs, resulting in up-regulation of TGF-β1 and negative regulation of HGF expression. The altered expression patterns may be involved to a considerable degree in delayed liver regeneration after hepatectomy in rats with obstructive jaundice. These findings may provide clues for the treatment of impaired hepatic regeneration after major hepatectomy with obstructive jaundice.
Purpose: To report a case of INH induced fulminant hepatitis given for Latent Tuberculosis.

Case Report: A 38 years old African American male presented with 3 weeks h/o epistaxis, hemoptysis and hematochezia. He recently moved to this city for a job and on pre employment examination found to have positive PPD and was on isoniazid for the last 2 months. On examination he had distended abdomen with bilateral leg edema and crepitations in both lungs. On labs he had leucocytosis with WBC of 18000, severely anemic with HCT of 18, platelets of 121, INR of 6.4 and albumin of 1.8. His lactate level was significantly elevated to 9.8. His transaminases were elevated with AST of 129 and ALT of 187 with marginally elevated bilirubin to 1.6 and normal alkaline phosphatase. His hepatitis panel, alpha 1 antitrypsin, copper, ceruloplasmin, iron saturation and acetaminophen levels came normal. He was eventually diagnosed with INH induced hepatic failure. He was started on supportive therapy with FFP, PRBC and Vitamin K but was not able to get a liver transplant and eventually expired.

Conclusions: So our case mainly signifies the importance of close follow up of the patients who are started on any hepatotoxic drug. Most of the studies showed that incidence of hepatotoxicity with INH is 0.5—2%. The overall case-fatality rate is approximately 10 percent in patients who develop clinically apparent hepatitis. Approximately 90% of INH hepatitis occur within the first three months after initiation of therapy. 10 to 20% of patients taking INH experience mild hepatic injury which is evidenced only by mildly elevated serum aminotransferases (usually <100 IU/L). The prognosis for mild INH hepatotoxicity is excellent, with an overall mortality rate of only 0.001 percent. Age is also important determinant for INH hepatitis with incidence increases from 1.2% (35—49yr) to 4.6% in over 65years. So we should be more watchful while placing any older age person on INH. The treatment of patients with INH hepatitis is largely supportive. The only effective preventive measure for INH hepatitis is screening for early detection of hepatitis especially during the first three months and discontinuation of INH during this time frame, which can prevent severe sequel.

Advanced Primary Biliary Cirrhosis with Multiple Myeloma. A Rare Association
Tomás Rodríguez, MD, Pikesh Kumar Patel, MD, Simeon Carvajal, MD. * Gastroenterology, Bronx Lebanon Hospital Center, Bronx, NY.

Purpose: A 68-year-old woman was admitted with diffuse ecchymotic skin lesions. She was found to have multiple subcutaneous nodules on the abdominal wall, hepatomegaly, and normocytic normochromic anemia.

Results: The transaminases and alkaline phosphatase (ALP) were normal but gammaglutamyl transpeptidase (GGT) was elevated at 205 U/L. The serum albumin was 2.9 mg/dL and the PT was 24 s. Viral hepatitis serology was negative, but AMA was 3+. Serum electrophoresis revealed a monoclonal band and B2 microglobulin elevated at 4.48 mg/L. IgG levels were 4750 mg/dL (normal 844—1912 mg/dL). A CT scan of the abdomen revealed a cirrhotic liver and splenomegaly. Bone marrow biopsy showed plasmacytosis of 28%. Liver biopsy revealed lymphocytic infiltration of the portal tracts with marked fibrosis, bile duct proliferation and piecemeal necrosis. A diagnosis of multiple myeloma and PBC was made.

Conclusions: AMA reacts against the dihydroxyoamide acetyltransferase component (E2 subunit) of pyruvate dehydrogenase complex (PDC-E2) and is the serologic hallmark of PBC. PBC is the only disease in which there are B- and T-cells that are autoreactive against PDC-E2. Hypergammaglobulinemia in PBC is thought to be due to polyclonal B cell activation, defective hepatic clearance of antigens from the gut and immunologic imbalance between lymphocyte suppressor and helper functions. A decreased suppressor T cell function in patients with PBC have been observed in vitro studies. It is generally recognized that B cell hyperactivity with enhanced production of immunoglobulins or autoantibodies is related to this T cell dysfunction. Monoclonal gammopathy occurring in the course of chronic liver disease is rare and in most cases benign. Only a few cases of PBC associated with multiple myeloma have been reported. The coexistence of both diseases may be due to alterations in both cellular and humoral immune functions, and transformation from polyclonal to monoclonal gammapathy. The factors leading to this transformation are unknown. Our case is unique in that the ALP was normal. The reason for the normal ALP is unclear. Also our patient presented with advanced cirrhosis as opposed to early cirrhosis reported in prior cases. The coexistence of PBC and multiple myeloma is rare but a pathogenic relationship cannot be excluded.

Hepatic Sarcoidosis in U.S. Veterans
Kerry N. Whitt, MD, Bradford Waters, MD,* Mohammad K. Ismail, MD. Department of Medicine, University of Tennessee, Memphis Medical Center, Memphis, TN and Department of Medicine, Memphis VA Medical Center, Memphis, TN.

Purpose: To describe the clinical presentation and outcome of hepatic sarcoidosis in a population of U.S. veterans.

Methods: Retrospective chart review of veterans with sarcoidosis involving the liver.

Results: 18 veterans with hepatic sarcoidosis have been followed at our center since 1980. Sixteen of these patients have undergone liver biopsy and have a compatible clinical history while two have biopsy-proven pulmonary sarcoidosis with longstanding cholestasis. Median duration of follow-up was 39 months (range 1-277 months). All but one patient were diagnosed at our institution. 3/18 were female, and 14/18 were African-American. The mean age at diagnosis was 40 years (range 22-59). Common clinical presentations involved the presence of abnormal liver chemistries in conjunction with: 1) No symptoms attributable to the liver (6/16) 2) Acute febrile illness (5/16) and 3) Abnormal imaging study suspicious for malignancy (3/16). The majority were cholestatic with variable transaminase levels. Alkaline phosphatase levels at diagnosis were a median of 359 IU/L (range 32-1387). Clinical jaundice was never detectable in the absence of hepatic decompensation. Angiotensin converting enzyme (ACE) levels were elevated in 87%. 13/18 veterans developed granulomatous liver disease either as part of an acute presentation of systemic sarcoidosis or in isolation prior to the onset of disease in any other organ system. 7/18 continue to have only liver involvement. 2/18 progressed to decompensated liver disease necessitating a liver transplant evaluation. The majority maintained preserved synthetic function without any complications from portal hypertension. 3/18 patients died in follow-up, and two deaths resulted from hepatic complications prior to transplant. The first was infected with hepatitis C and died at age 34, 12 years after his diagnosis of hepatic sarcoidosis. The second was a morbidly obese diabetic who died at age 58, 33 years developing sarcoidosis.

Conclusions: Hepatic sarcoidosis manifests itself in young patients and commonly results in asymptomatic, isolated cholestasis. Although the clinical course is typically benign, about 10% of our patients suffered decompensated liver disease. These occurred in the setting of concomitant hepatitis C and suspected nonalcoholic fatty liver disease. The role of sarcoidosis as a “second hit” to patients with chronic liver disease should be investigated in larger, multicenter studies.

Time Course of Intragraft Chemokine Expression and Immune Cell Infiltration in Acutely Rejecting Rat Livers
Hiroaki Shimizu, MD, PhD, Masayuki Ohitsuuka, MD, PhD, Fumio Kimura, MD, PhD, Hiroyuki Yoshidome, MD, PhD, Masaru Miyazaki, MD, PhD. * Department of General Surgery, Chiba University Graduate School of Medicine, Chiba, Japan.

Purpose: During acute rejection of allogeneic liver, an abundant infiltration of macrophages and T cells become apparent in the graft. The mechanisms that regulate this specific pattern of graft infiltration are not fully understood; however, it may be crucial in determining transplant outcome. The C-C chemokines are known to be primarily chemoattractant for macrophages
and T lymphocytes, and plays an important role in the process of trafficking of these cells to sites of tissue inflammation. IP-10, one of the members of the C-X-C chemokines, is also known to have greater chemotactic activity for activated T cells. In this study, we investigated the time course and relationship between intragraft chemokine expression, the type, and the number of infiltrated immune cells after rat liver transplantation.

**Methods:** We performed rat orthotopic liver transplant in both syngeneic (LEW-to-LEW) (SYN) and allogeneic rejection (ACI-to-LEW) (REJ) group. After the transplant, the kinetics of expression levels of MIP-1α, MIP-1β, RANTES, IP-10 mRNA in the graft liver were investigated by RT-PCR. The number of macrophages/macrophages of acutely rejected liver were examined by ED1 and ED2 immunohistochemistry.

**Results:** In the REJ group, the hepatic allografts survived 11.7 days. The mRNA expression of C-C chemokines, MIP-1α, MIP-1β and RANTES in the allografts significantly increased on days 3 to 5 after transplantation in REJ group, compared with the SYN group, however, decreased thereafter. These elevated C-C chemokine expression were associated with ED1+ cells infiltration. Meanwhile, C-X-C chemokine, IP-10 mRNA levels in the allografts were significantly higher than those in the isografts after day 5, and further increased thereafter. The number of infiltrating T cells into allograft was apparently increased after day 5, and correlated to the allograft tissue damage.

**Conclusions:** The chemokines may be involved in the immune cell infiltration into acutely rejecting liver allografts. The expression of C-C chemokines may play an important role in recruiting non-resident macrophages, as anti-gen presenting cells, prior to the T cell reactivity to alloantigen. Then, increased expression of IP-10 may promote activated T cells into the graft, resulting in amplifying acute rejection process. Therefore, manipulation of these chemokines may be of value in reducing immune cell infiltration in the grafts, and also prolong survival.

### Colon

**452**

**Decreased Levels of AIF Renders Resistance to Oxaliplatin Mediated Apoptosis in the Progression of Colon Cancer Carcinogenesis beyond Caspase-3 Activity**

*Sergio Huerta, MD,*† *Yu-mei Anguiano-Hernandez, MS, Emily J. Goulet, BS, Sara Huerta-Tepoz, PhD, Edward H. Livingston, MD, Surgery, UT Southwestern Medical Center, Dallas, TX; Surgery, VAMemorial Hospital, Dallas, TX and UNAM, Mexico City, Mexico.

**Purpose:** Activity of caspase-3 demonstrates that the stage II colon cancer cell line SW480 is more sensitive to apoptosis compared to its metastatic counterpart, colon cancer cell line SW620 (stage III), when induced with 500 mM oxaliplatin (36% vs. 15%, respectively). Dye exclusion studies demonstrated that the SW480 cells are more sensitive to cell death compared to SW620 cells (31% vs. 8%, respectively). The degree of DNA fragmentation by TUNEL is greater than the level of apoptosis observed by active caspase-3 in SW480 cells, which suggests mechanisms other than caspase-3 activity responsible for cytoxic-induced cell death. This study was undertaken to determine the modified apoptotic gene products, including factors beyond caspase-3, which render resistance to cytoxic-mediated apoptosis in the progression of colon carcinogenesis.

**Methods:** Pro-apoptotic Bax and Apoptosis Inducing Factor (AIF) as well as anti-apoptotic Bcl-2 and Bcl-xL mitochondrial mediators of apoptosis were studied by RT-PCR, Western blot analysis and immunohistochemistry. Apoptosis in untreated cells (control) and oxaliplatin-treated cells (50 mM, 100 mM, and 500 mM) was examined by flow cytometry for caspase-3 activity and TUNEL.

**Results:** TUNEL demonstrated that the SW620 cells were more resistant to oxaliplatin-mediated apoptosis compared to the SW480 cell line at base line (control) and following 24-h treatment with 500 mg treatment with oxaliplatin (20% vs. 49%, respectively). Caspase-3 activity showed 14% vs. 34% in parallel experiments. Expression of Bax, Bcl-2, Bcl-xL and AIF was similar in both cell lines by RT-PCR. However, immunohistochemistry showed a marked increase in staining in the SW480 cell line with anti-AIF antibody.

**Conclusions:** These findings suggest that oxaliplatin-mediated resistance to apoptosis in metastatic colon cancer may be mediated by AIF and that this regulation is unlikely affected by individual gene expressions of Bax, Bcl-2, or Bcl-xL. Translocation of AIF from the inter-mitochondrial membrane to the cytosol in metastatic colon cancer mandates further studies and may be a potential target for chemotherapeutic interventions.

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**Clostridium difficile Infection: Antibiotic Risk and Financial Impact**

*Ethan Weinberg, Eric Quianzon, MD, Kamalakumar Bangoria, MD, Robert P. Ferguson, MD.*† *Department of Medicine, Union Memorial Hospital, Baltimore, MD.*

**Purpose:** We retrospectively reviewed hospital records to investigate the relative risk of *Clostridium difficile* (C. diff) infection with specific antibiotics and to quantify the potential economic impact of nosocomial C. diff.

**Methods:** Records were reviewed for all patients admitted between September 1, 2003, and August 31, 2005, who had a discharge diagnosis that included C. diff infection. This group was compared with age and primary diagnosis matched control without C. diff infection from the general hospital database at the time. Controls and C. diff cases were also matched by initial pre-C. diff length of stay (LOS). To avoid cases with pre-hospitalization infection, patients were included in the C. diff group only if they had proven C. diff infections identified after hospital day three. Those identified before hospital day three were considered community acquired and were excluded. Antibiotic utilization was determined from the hospital pharmacy database reported in terms of antibiotic days.

**Results:** There were 241 positive assays for C. diff, 120 community acquired and 121 hospital acquired. We were able to match 103 of the hospital-acquired cases with controls. Average LOS was 8.7 days longer in the C. diff group compared to controls. Of the 121 hospital-acquired cases, 68 received ceftriaxone therapy, 46 vancomycin, 28 ceftazadine, 13 cefazolin, 13 ceftriaxone, and 7 ampicillin. Fifteen cases had no apparent hospital antibiotic treatment. Many patients received multiple or simultaneous courses with different antibiotics. Although ceftazolin and ceftriaxone had nearly equal utilization, five times more C. diff cases were reported with ceftriaxone than with cefazolin. With hospital costs averaging an estimated $1200 a day, the average C. diff-associated LOS prolongation of 8.7 days represented an average additional cost of approximately $10,000 per infected patient.

**Conclusions:** In studies outside the U.S., newer generation cephalosporins have been identified as frequently associated with the risk of C. diff infection. We found similar results that confirmed the dramatic impact on LOS and hospital costs caused by C. diff infection associated with third-generation cephalosporins. As has been done elsewhere with success, hospitals should consider antibiotic restrictions.

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**Significance of Incidental Finding of Colorectal Wall Thickening on Computed Tomography Scan in African-American and Hispanic Patients**

*Manmeet Padda, MD, Anil Dev, MD, Cyril Anyadike, MD, Jaydatt Vagdama, PhD, Ioannis Giannakopoulos, MD.*† *Int. Medicine, Charles R. Drew University, Los Angeles, CA.*

**Purpose:** To evaluate the significance of incidental finding of colorectal wall thickening (CWWT) on computed tomography (CT) scan in minority population.

**Methods:** We reviewed retrospectively medical records of patients from Jan 94 to Dec 05. Those patients were included in whom colonoscopy was done only due to the incidental finding of CRWT on CT scan. Patients with history of colorectal malignancy, IBD, colorectal surgery, liver disease, incomplete
colposcopic exam, age < 18 yrs and Non-African-Americans or Hispanics were excluded. The endoscopic and pathological findings were reviewed.

Results: 31 patients met the criteria. Mean age (±SD) of the patients was 48.8 ± 9.4 yrs. 13 (42%) were African-Americans and 18 (58%) were Hispanics. 12 (39%) were male and 19 (61%) were females. Colonoscopic examination was abnormal in 20 (65%) and normal in 11 (35%) patients. Positive predictive value of CRWT for abnormal colon exam was 65%. Mean age (±SD) was 44.9 ± 9 in normal and 51.0 ± 9 in the group with abnormal colon exam (2 sided p value 0.05). Abnormal colon exam revealed diverticulosis in 8 (40%), polyps in 6 (30%), diverticulitis in 1 (5%), erythematous mucosa in 8 (40%), mass in 2 (10%) and polyps in 6 (30%). Pathological findings were consistent with adenocarcinoma in 2 (10%) cases, tubular adenoma in 4 (20%), hyperplastic polyps in 4 (20%), colitis 7 (30%), lymphoid aggregates in 3 (15%), and melanosis coli in 1 (5%).

Conclusions: Abnormal colon exam was found in 65% of the patients. The prevalence of the abnormal exam was higher in the older patients. Prevalence of malignancy was 10% and adenomas was 20% in such patients; therefore, any abnormal CRWT should be further evaluated with endoscopic examination. Further studies with large sample size are needed to evaluate the role of the colonoscopic examination.

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Screening Colonoscopy in the Veteran Population: A Single Center Analysis
Ognian A. Pomakov, MD, Sandeep Bahadur, MD, Michael D. Sitrin, MD,* Division of Gastroenterology, University at Buffalo, SUNY, Buffalo, NY.

Purpose: Although colonoscopy is considered to be the most comprehensive screening test for colorectal cancer (CRC), there is a shortage of endoscopy resources to provide it to all eligible individuals. The goal of this study was to identify the population that would benefit most from screening colonoscopy and the population that might be adequately served by using the combination of fecal occult blood test (FOBT) and flexible sigmoidoscopy (FS).

Methods: We have studied retrospectively the results of screening colonoscopies of veterans at a single institution (Western NY VA Medical Center) performed between Jan. 2003 and December 2004. Patients who were average risk for CRC and having their first colonoscopy were divided in two groups: 1. Negative (or not tested for) FOBT (N = 489) and 2. Positive FOBT within last 6 months (N = 196). The results were also analyzed by age group: 50-60; 60-70; 71-80 and above 80 years old. FS theoretical “miss-rate” (the percentage of patients with proximal [above 60 cm]advanced adenomas and no distal adenomas that would have been missed if patient was screened with a FS instead of a colonoscopy) was calculated in each group.

Results: Number of patients in each group, percentage of patients with adenomas, advanced adenomas, proximal advanced adenomas and theoretical “miss-rate” of FS are shown on following table:

Prevalence of adenomas, advanced adenomas, proximal advanced adenomas and FS theoretical “miss-rate”

<table>
<thead>
<tr>
<th>Group</th>
<th>N of Patients</th>
<th>% Pt with adenomas</th>
<th>% Pt with advanced adenomas</th>
<th>FS “miss-rate”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average risk, (−)FOBT</td>
<td>489</td>
<td>26%</td>
<td>9%</td>
<td>4%</td>
</tr>
<tr>
<td>Average risk, (+)FOBT</td>
<td>196</td>
<td>39%</td>
<td>23%</td>
<td>9%</td>
</tr>
<tr>
<td>Average risk, (−)FOBT 50–60 years old</td>
<td>93</td>
<td>24%</td>
<td>4%</td>
<td>2%</td>
</tr>
<tr>
<td>Average risk, (+)FOBT 50–60 years old</td>
<td>76</td>
<td>29%</td>
<td>13%</td>
<td>7%</td>
</tr>
</tbody>
</table>

Conclusions: A (+) FOBT significantly increased the probability of finding adenomas and advanced adenomas despite the high use of ASA, NSAID’s and higher prevalence of hemorrhoids in the veteran population.

In this cohort, veterans 50 - 60 years old, and FOBT (−) had a lower prevalence of advanced lesions and lower FS “miss-rate” than those ≥ 60 years. FOBT testing plus flexible sigmoidoscopy for average risk patients 50 - 60 years old and reserving colonoscopy for all patients with adenomas on flexible sigmoidoscopy, FOBT (+) or those ≥ 60 years, might be an appropriate, cost-effective screening strategy.

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Ischemic Colitis: Female Bias and More Common Than You Think
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Purpose: The objectives of the study were to estimate the frequency of ischemic colitis (IC) occurrence in clinical practice and to examine the clinical associations.

Methods: We retrospectively reviewed the charts of patients who were admitted to the hospital service of a community based 6 physician gastroenterology (GI) practice located in western Pennsylvania over a five-year period beginning on October 1, 1999. We analyzed those patients with a final diagnosis of IC based upon clinical, endoscopic and, histological aspects. Co-morbid diseases, medications and outcomes were studied. Analysis utilized SAS statistical software.

Results: We identified 111 patients diagnosed with IC, 100 of whom were determined to be definitively diagnosed, and 11 were diagnostically possible where either the histology, clinical findings, or endoscopic findings were atypical. These IC patients represent 1.3% of the 9,378 total encounters in our GI hospital practice for the 5 year study period. The average age was 62 years (range: 21-92), 77% were older than 50 years, and 77% were female. Nine IC patients (8%) had a total of 14 relapses (1 to 4/patient), always at the same site. Abdominal pain occurred in 97% of the combined group and bleeding occurred in 92%. The most common sites of involvement were the splenic flexure (70%), the rectosigmoid (31%), transverse colon (17%), and ascending colon (9%). Co-morbidities included ASHD (25%), ASPVD (16%), IBS (20%), COPD (10%), diabetes (10%), and constipation (4%). Three previously well cases were each actually induced by one of three colonoscopy preparations: bisacodyl tablets, polyethylene glycol, or sodium phosphate tablets (Visicol). Common medications were aspirin (30%), NSAIDs (17%), estrogen (15%, 21% of the women), antplatelet drugs (7%), and warfarin (3%). One patient taking alosenor required a colectomy. One other patient who had 3 relapses was found to have mesenteric arterial stenosis and improved following angioplasty and stenting. The rest resolved spontaneously.

Conclusions: Our community-based experience over five-years shows that IC occurred in 1.3% of new hospital GI encounters. Seventy-seven percent were females, 77% were older than 50 years and 8% relapsed. Commonly IC developed in patients with no risk factors, but ASHD, IBS, COPD, and diabetes were minority associations. Rarely were colectomy or vascular intervention required. IC actually was induced by colonoscopy prepping in 3 cases.
**Purpose:** Examine preventive use of orally administered and poorly absorbed (<0.4%) rifaximin (R), an antibiotic marketed in the U.S. for treatment of uncomplicated travelers’ diarrhea, (TD).  

**Methods:** Rifaximin was given in a dose of 600 mg in a single dose or matching placebo (P) for 14 days to 210 U.S. students within 72 hours of arrival in Mexico the summer of 2005.  

**Results:** Seven subjects randomized to R and two to P experienced TD within 24 hours of the first dose and were excluded from analyses. Three R and 1 in the P group failed to return to the clinic and were counted as failures. 20/99 (20.2%) R-treated and 49/102 (48.0%) in P group (p < 0.001) developed TD, defined as ≥ 3 unformed stool per day plus an enteric symptom during the 14 days (protection rate 57.9%). Treated diarrhea or diarrhea requiring antimicrobial therapy occurred in 14 (14.1%) and 33 (32.4%) in the two respective groups (protection rate 56.3%). Diarrhea stool samples were positive for a pathogen in 4 R-treated and 17 P-treated subjects (p = 0.005). Pathogens identified in the R vs. P groups were: enterotoxigenic Escherichia coli (ETEC) 4 vs 15, and enteraggregative E. coli (EAEC) 2 vs 5. Median rifaximin minimal inhibitory concentration (MIC) of ETEC was 32 mg/ml in both treatment groups. Corresponding medians for EAEC were 48 and 32, respectively. Rifaximin was well tolerated with adverse events occurring in a similar percentage of both groups.  

**Conclusions:** This is the second study showing significant effectiveness of daily rifaximin in preventing TD in U.S. residents in Mexico. A third rifaximin prevention trial is underway with European travelers to Thailand. The use of rifaximin 600 mg QD is a promising agent to prevent TD in persons planning trips to high-risk regions who: are on a tight schedule; have become ill in past trips or have underlying comorbidity indicating possible increased susceptibility; or request preventive medication.

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**Severity of Clostridium difficile Associated Diarrhea in Solid-Organ Transplant Patients**  
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Internal Medicine, Gastroenterology, Duke University Medical Center, Durham, NC; Internal Medicine, Infectious Diseases and International Health, Duke University Medical Center; Durham, NC; Internal Medicine, Duke University Medical Center, Durham, NC; and Comprehensive Center Biostatistics, Duke University Medical Center, Durham, NC.

**Purpose:** Clostridium difficile associated diarrhea (CDAD) has a wide spectrum of disease severity. Studies have implicated immunosuppressants as a risk factor for severe disease. Solid-organ transplant recipients are exposed to long-term immunosuppression but few studies have compared the severity of CDAD in transplant patients to non-transplant patients.  

**Methods:** All adult solid-organ transplant patients with CDAD seen at Duke between 1999 and 2003 were studied. A control group was randomly selected in an age-stratified fashion from non-transplant patients with CDAD. The primary outcome was the development of fulminating colitis defined as death, ICU admission or urgent colectomy within 30 days of diagnosis. A secondary outcome was relapse within 60 days. Categorical variables, including antibiotic exposure, immunosuppressive therapy, chemotherapy use, and transplant status were analyzed using Fisher’s Exact Test.  

**Results:** Eighty transplant cases and 86 non-transplant cases were reviewed. The groups were similar in age, gender and CDAD treatment regimen. Primary and secondary outcomes are summarized below:  

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Non-transplant</th>
<th>Relative Risk (RR)</th>
<th>95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulminant Colitis</td>
<td>11 (13.8%)</td>
<td>6 (7.0%)</td>
<td>1.97</td>
<td>0.76,5.08</td>
</tr>
<tr>
<td>Relapse</td>
<td>5 (6.2%)</td>
<td>6 (7.0%)</td>
<td>0.90</td>
<td>0.28,2.82</td>
</tr>
</tbody>
</table>

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**Human Colon Cancer Cells Lack Mutations in RACK1, a Suppressor of Oncogenic Src Tyrosine Kinases**  
Barrett G. Levesque, MD, Kelly C. Lee, MS, Christine A. Cartwright, MD.  
Department of Medicine, Stanford University, Stanford, CA.

**Purpose:** Previously we showed that Src tyrosine kinases are activated early in the development of human colon cancer and are suppressed during intestinal cell differentiation. Activated Src is oncogenic. Thus, it is important to search for mechanisms that regulate Src activity in normal colon cells. In doing so, we will learn about how loss of that regulation results in uncontrolled growth and malignant transformation. We identified RACK1 as an endogenous substrate, binding partner and inhibitor of Src. We demonstrated that RACK1 regulates colonic cell growth by suppressing Src activity at the G1 checkpoint and by inducing apoptosis via the intrinsic and Akt pathways. These results suggested that RACK1 is a tumor suppressor because it inhibits cell growth and activates cell death. Here we hypothesized that RACK1 is mutated in colon cancer cells and thereby unable to inhibit Src activity and cell growth.  

**Methods:** To assess for mutations in RACK1 that might contribute to Src activation in colon cancer, we sequenced the coding region of RACK1 from 5 different human colon carcinoma cell lines: HT-29, WID; LS174T, COLO 205 (all have high Src activity) and SW480 (low Src activity).  

**Results:** We found no mutations in RACK1 from any of the cell lines or from HEK cells (non-tumorigenic human epithelial cells).  

**Conclusions:** Thus, genetic mutations in RACK1 do not appear to be a mechanism by which Src is activated in human colon cancer. We are now assessing whether altered subcellular localization, post-translational modifications or other protein-protein interactions of Src and/or RACK1 contribute to the activation of Src in colon cancer.

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**The Utility of Flexible Sigmoidoscopy after CT Colonography Revealing Only Rectosigmoid Findings**  
Patrick E. Young, MD, Andrew B. Gentry, MD, Brooks D. Cash, MD.  
Gastroenterology, National Naval Medical Center, Bethesda, MD.

**Purpose:** The VA Cooperative 380 and the CONCeRN Trial both demonstrated the superior yield of colonoscopy to sigmoidoscopy in average risk individuals undergoing colorectal cancer (CRC) screening. Current consortium guidelines indicate that colonoscopy is the preferred CRC screening test. However, resources are inadequate to provide population colonoscopy screening and alternative methods are needed. Computed tomographic colonography (CTC) is another total colonic examination that has been shown to be as accurate as colonoscopy for the detection of colonic neoplasia 6 mm or larger at our institution. The aim of this study was to determine the prevalence of advanced colonic neoplasia in patients in whom CTC revealed only rectosigmoid (RS) polyps and to determine the diagnostic yield of only polypectomy via flexible sigmoidoscopy (FS) examination in such patients.  

**Methods:** All subjects were participants in a trial in which they underwent both CTC and colonoscopy with segmental unblinding. Patients with only RS findings by CTC were retrospectively identified. Findings at FS were estimated by including only lesions that were identified and removed distal to the descending sigmoid junction during colonoscopy. This anatomic delineation was chosen because several studies have shown that the average
endoscopist in a primary care setting is able to reliably examine the colon to the sigmoid-descending colon junction with FS. Pathologic evaluations of any lesions proximal to this point were reviewed. Polyps were classified according to the following criteria: Adenocarcinoma, tubulovillous adenoma, tubular adenoma > 1 cm, and > 3 tubular adenomas were considered advanced findings. All other lesions were deemed non-advanced.

Results: 203 patients had only RS polyps identified on CTC. 64 (32%) of these patients were found to have right sided lesions during colonoscopy. Three (1.5%) of these lesions were advanced neoplastic lesions.

Conclusions: Miss rates for advanced lesions with FS after CTC showing only RS lesions are comparable to miss rates for colonoscopy. FS may be used to follow-up CTC which only reveal RS findings with little risk of missing proximal advanced colonic neoplasia. Employing this strategy would decrease the cost and risk of follow-up examinations after CTC. Further study to determine the cost effectiveness of this approach is warranted.

461 Laser Doppler Flowmeter Predicts Colonic Ischemia during Colonoscopy
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Purpose: Laser Doppler flowmetry can assess colonic tissue blood flow by measuring the number of erythrocytes flowing through the mucosal microcirculation in a defined spatial compartment. The use of endoscopic laser Doppler flowmeter to diagnose colonic ischemia has not been reported. We hypothesize that real-time laser Doppler flowmeter can be used to predict the likelihood of colonic ischemia during colonoscopy.

Methods: Patients scheduled to undergo routine colonoscopy and patients suspected to have ischemic colitis were asked to participate in the study. Those patients with normal colonoscopies were used to characterize the colonic blood flow in the various anatomic regions of the normal colon to establish a baseline reference for the healthy colon. Patients with ischemic colitis were assessed to determine if colonic ischemia can be distinguished from the normal colon using laser Doppler flowmeter. A laser Doppler flowmeter (BFL 21, Transonic Systems Inc., Ithaca, NY) was inserted through the accessory channel of the colonoscope to assess mucosal blood flow using gentle contact. Recordings were obtained with endoscopy light on.

Results: Four patients have been evaluated to date, 3 patients with normal colonoscopy and 1 patient with sigmoid volvulus. The tissue perfusion units (TPU) in the normal colon were as follows: cecum 35.1 ± 8.9, ascending 38.1 ± 4.8, transverse 48.3 ± 13.1, descending 37.7 ± 7.8, sigmoid 37.1 ± 3.9, and rectum 35.3 ± 3.0, respectively. One TPU corresponds to 1 ml/min/100 g tissue when the volume of tissue measured is 1 cubic millimeter. In the patient with the sigmoid volvulus, the viable areas of the rectosigmoid averaged 37.0 ± 0.6 TPU whereas the cyanotic point of the volvulus was 8.0 TPU, a nearly five-fold decrease (p < 0.01). During laparotomy, gangrenous sigmoid volvulus was identified. Histologic examination demonstrated transmural hemorrhagic infarct, confirming endoscopic suspicion and laser Doppler flowmeter diagnosis of severe colonic ischemia.

Conclusions: Laser Doppler flowmetry offers real time, non-invasive, continuous monitoring of mucosal blood flow in the gastrointestinal tract. When inserted through an endoscope, it offers a rapid, quantitative and thus, objective method for assessing tissue perfusion during colonoscopy. It remains to be determined whether there is a value threshold for colonic blood flow to diagnose transmural necrosis during endoscopic laser Doppler flowmetry.

463 Factors Associated with Differences between Colon and Rectal Cancer
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Purpose: Colorectal cancer has historically been epidemiologically viewed as the same disease entity. However, recent studies have highlighted that rectal and colon cancer may have a different natural history due to differences in their presentation, natural history, and management modalities. The following study was undertaken to investigate factors independently associated with each type of cancer with the hypothesis that rectal cancer has a more aggressive clinical behavior and it is associated with worse outcome.

Methods: A retrospective review was performed on all patients who had colon or rectal cancer diagnosed between January 1998 to December 2001 at the Veterans Affair North Texas Health Care System. Sixty-five clinical factors were assessed by univariate analysis in patients grouped into whether they had rectal cancer (N = 30) or colon cancer (N = 44). Factors assessed included demographics, medication history, tumor stage, and mortality. All values are presented as means ± SE, statistic significance was determined at a p ≤ 0.05.

Results: From Jan 1998 to December 2001, 74 patients with colorectal cancer were identified. Ninety-seven percent were men (mean age 64.2 ± 1.0 yo). Follow up was available in all 74 cases. The demographics of patients in both groups were similar. There was no difference in mortality between rectal and colon cancer. Univariate analysis demonstrated that patients with rectal cancer had: a history of hematohcezia (38% vs. 50%; p = 0.05), anemia (50% vs. 73%; p = 0.05), NSAIDs use (54% vs. 27%; p = 0.03), greater incidence of alcohol abuse (30% vs. 53%, p = 0.03), presence of a palpable mass (0% vs. 40%, p<0.001), and more advanced cancer stage (stage 1.5 vs. 1.8, p = 0.02).

Conclusions: Our small cohort of patients did not yield differences in mortality in patients with rectal vs. colon cancer. Patient with rectal cancer have a greater incidence of hematohcezia, anemia, NSAIDs use, alcohol abuse, presence of a palpable mass and more advanced stage. Studies with larger numbers are needed to delineate differences in the clinical behavior of colon and rectal cancer. Epidemiological studies show differentiate between rectal and colon cancers such that the accurate mortality of each type of cancer could be established.

464 Oral Rifaximin in Treatment of Clostridium difficile-Associated Diarrhea
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Purpose: The prevalence and severity of Clostridium difficile–associated diarrhea (CDAD) is increasing. Up to 25% of patients experience recurrence
after standard first-line therapy, and appropriate treatment for CDAD recurrence is not well defined. Failure rates of 22% with metronidazole have been reported, a substantial increase from historical failure rates of 2% to 10%. Rifaximin is an oral, nontoxic antibiotic with broad-spectrum activity. Preclinical data support a role for rifaximin in treatment of CDAD. This retrospective chart review evaluated the safety and efficacy of rifaximin in the treatment of CDAD.

Methods: Consecutive patients aged ≥18 years diagnosed with CDAD, based on time to last unformed stool, stool score, and C difficile–positive toxin assay) between March 2005 and April 2006 were treated with rifaximin 400 mg twice daily (b.i.d.) or 3 times daily (t.i.d.) for 10 to 14 days. Response was assessed by resolution of clinical symptoms, CDAD recurrence 30 days posttreatment, and incidence of adverse events (AEs).

Results: 19 patients (mean age, 60 y) with CDAD were identified; 14 (74%) with newly diagnosed disease and 5 (26%) with recurrent disease. Those with recurrent CDAD had previously received oral vancomycin (N = 4) or metronidazole (N = 1) as first-line therapy. All patients received rifaximin 400 mg b.i.d. (N = 1) or t.i.d. (N = 18), with a majority (89%) treated for 14 days. At the end of rifaximin treatment, 17 patients (89%) had complete resolution of symptoms, with an average time to symptom relief of 6.7 days. Only 2 (10%) of 19 patients treated with rifaximin experienced CDAD recurrence (days 12 and 15 posttreatment). Rifaximin was well tolerated with no discontinuations due to AEs. Overall, there were 3 reports each of headache and nausea.

Conclusions: Rifaximin 800 mg/d or 1200 mg/d was well tolerated and effectively resolved clinical symptoms of CDAD. In addition, rifaximin prevented CDAD recurrence in a majority of patients. Randomized, placebo-controlled studies are warranted to further investigate the role of rifaximin in CDAD treatment and prevention.

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Massive Lower Gastrointestinal Bleeding Caused by Dieulafoy’s Ulcers of the Rectum: A Case Series

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Purpose: Dieulafoy’s ulcers are a rare, but well-documented cause of upper gastrointestinal tract hemorrhage, typically occurring in the stomach. Although such ulcers have been infrequently found in the small bowel and colon as well, there are increasing reports of Dieulafoy’s ulcers in the rectum as a cause for lower GI bleeding.

Methods: Today, colonoscopy with endoscopic sclerotherapy, epinephrine injection, or laser coagulation is the most popular treatment method.

Results: Here, we present two similar patients with massive bleeding from Dieulafoy’s ulcers in the rectum – one was successfully treated endoscopically with epinephrine injection, while the other required over-sewing of the lesion for persistent rebleeding.

Conclusions: Colonoscopy with endoscopic sclerotherapy, epinephrine injection, or laser coagulation is the most popular treatment method.
Conclusions: In our study, drop in serum albumin level and abnormal blood leucocyte count were associated with prolonged hospitalization and mortality. The drop in serum albumin level is not only because of co-morbid conditions, CDAD itself associated with protein-losing enteropathy (2). Such patients may warrant more aggressive management of CDAD along with correction of underlying co-morbid conditions and nutritional requirements.

REFERENCES
1. McFarland; Nosocomial acquisition of CDAD; NEJM 1989 Jan 26;204- 10.
2. Dansinger; Protein-losing enteropathy is associated with CDAD but not with asymptomatic colonization; Clin Infect Dis 1996 Jun;932–7.

 Colon Cancer: How Can We Diagnose It?
Edson J. da Silva, MD, Colon Cancer: How Can We Diagnose It?

Conclusions: Eighty nine adults (60 males; aged 25 – 68 years) were studied. Thirty patients had pre and post SH, RP and MSP within normal range (RP range 71 – 96 mmHg; MSP range 124 – 192 mmHg). Nine patients had high pre SH, RP (range 114 – 160 mmHg) and MSP (range 204 – 216 mmHg) which returned to normal range post SH. There was no incidence of post SH fecal incontinence.

Conclusions: SH is a safe and effective procedure for haemorrhoids with no adverse effect on anorectal pressures and continence.

Rapidly Rising Prevalence of Microscopic Colitis
Douglas J. Sprung, MD,* Gregory M. Sprung, GI, The Gastroenterology Group, Maitland, FL.

Purpose: To study the changing prevalence of microscopic colitis over the past 16 years.

Methods: A retrospective computerized list of all patients with either lymphocytic colitis or collagenous colitis was obtained from our private community GI practice data base in Orlando, Fl from 1/90- 4/30/06. A breakdown was made of new diagnoses by year.

Results: 92 cases of microscopic colitis were identified, 31 (35%) with collagenous colitis, 54 (57%) with lymphocytic colitis, and 7 (8%) with both lymphocytic and collagenous colitis. 14 had remission, then recrudescent disease, an average of 4 years apart, with a range of 1- 8 years. There was a distinct change in the prevalence of microscopic colitis from 2004 onwards. Whereas 1-5 cases were found annually from 1990 - 2003, (a mean of 3.4cases/year), in 2004 there were 15, in 2005 there were 20 patients, and in the first third of 2006 there were 10 patients. Patients were predominantly female, comprising 78% of lymphocytic colitis, 90% of collagenous colitis and 83% of those that had both lymphocytic and collagenous colitis.

Conclusions: 1. There has been a marked increase in prevalence of microscopic colitis beginning in 2004 with a 200% increase, then a 25% rise in 2005 and a projected 50% rise in 2006. The reasons for this observation are as yet unknown.

2. Lymphocytic colitis is > 3 times as prevalent as collagenous colitis.

3. 15% (N = 14) of patients had remission and then recurrence of symptomatic colitis (8 patients with collagenous and 6 with lymphocytic colitis), an average of 4 years apart.

4. There is a marked female predominance in all forms of microscopic colitis.

New Paradigms/Patterns in the Presentation, Clinical Features, and Outcomes Associated with Ischemic Colitis
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Purpose: The study aim was to determine whether the presentation, clinical features, and outcomes of patients with ischemic colitis (IC) have changed compared to historical series.

Methods: ICD-9 codes (557.0, 557.1, 557.9) and the endoscopy database of a 580 bed hospital were used to identify all individuals during 1 year with IC. 44 patients with clinical, radiographic, endoscopic, and/or histological findings of IC are reported.
Results: The average age was 69.7 years and presenting symptoms included: abdominal pain/cramping (66.6%), hematochezia (53.3%), diarrhea (31.1%), and nausea/vomiting (26.7%). Unlike previous studies, 82.2% of IC patients were female, 16% of patients presented with CNS signs/symptoms (sycope (8.9%) and confusion (6.7)), and the classic triad of abdominal cramping, diarrhea, and hematochezia was present in only 18% of patients. Co-morbid associations included: HTN (80%) and HMG CoA reductase inhibitor therapy (40%). Unlike previous studies, no patients were receiving digoxin. 78% of patients had colonoscopy or limited colonoscopy, and similar to previous studies, left colon IC was most common (86%), followed by the transverse colon (9%), and right colon involvement was unusual (6%). Doppler interrogation of mesenteric vessels was performed in 49% of patients and hemodynamically significant stenoses were identified in 18%. Although the literature consistently reports at least 20% of IC patients require surgical intervention, conservative management was successful in 90% of patients. Of the 40 patients with primary colon ischemia (excluding 2 patients with diffuse large and small bowel necrosis and 2 patients with secondary IC – 1 with a sigmoid volvulus complicated by IC and 1 with iatrogenic IC, secondary to vascular ligation) none required surgical intervention. Hospital length-of-stay and mortality were increased in patients requiring surgical intervention (34.8 days vs 7.7 days and 40% vs 5.26%).

Conclusions: In this series, IC was much more common in females than in males. Hypertension was a common association in patients presenting with IC as well as “statin” therapy. Overwhelmingly, patients with primary IC did not require surgical intervention and patients infrequently presented with the classic triad of abdominal cramping, diarrhea, and hematochezia. Patients requiring surgical intervention had prolonged hospitalizations, increased mortality, and confounding disorders including mesenteric ischemia and volvulus.

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Endoscopic Mucosal Resection – Is It for Every One?
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Purpose: To analyse the feasibility and outcome of endoscopic resection of colorectal neoplastic lesions at a district general hospital in UK.

Methods: Retrospective review of case notes of all patients who underwent endoscopic mucosal resection of flat colorectal mucosal lesions over a period of four years from 2002 to 2005 under the care of one consultant gastroenterologist.

Results: 54 patients (age range 52-89 yrs) had removal of a total of 103 colorectal mucosal lesions (size range 3-90mm, median size 20mm). The largest of the lesion was well spread out with 26 (48%) patients having lesions on right side and 28 (52%) on left side. 50 patients (93%) had successful endoscopic resection. EMR was not attempted in two patients due to technical reasons and two patients needed surgery following diagnosis of malignant polyp on histology. There were no major procedure related morbidity or mortality. After a median follow up of 24 months 39 (72%) were disease free, 4 (7%) had recurrence at the site of resection and 5 (9%) had new polyps.

Conclusions: EMR is safe, effective and minimally invasive treatment for large benign colorectal polyps. It is feasible with in the confines of basic endoscopic infrastructure available in any endoscopy unit of a district general hospital.

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Expression of Heme Oxygenase-1 Is Associated with a Better Long Term Survival in Patients with Colorectal Cancer
Jan C. Becker, MD, Hirokazu Fukai, MD, Yasuo Imai, MD, Tokiko Kimura, MD, Thorsten Pohle, MD, Wolfram Domshcke, MD, FACG, Takahiro Fujimori, MD.* Department of Medicine B, University of Muenster, Muenster, Germany and Department of Surgical and Molecular Pathology, Dokkyo University School of Medicine, Mibu, Tochigi, Japan.

Purpose: Heme oxygenase-1 (HO-1) has emerged as a crucial mediator of mucosal defense in the GI tract. Its pathway products biliverdin/bilirubin and carbon monoxide reduce oxidative stress, inflammation, and promote resistance to apoptosis. The role of HO-1 in gastrointestinal malignancies, however, remains to be elucidated. In the present study we analyzed HO-1 expression in human colon cancer samples.

Methods: 55 paraffin-embedded surgical specimens of colon cancer and 19 adenoma samples were stained immunohistochemically for HO-1 expression using an anti HO-1 monoclonal antibody. HO-1 expression was evaluated independently by two different investigators and subsequently correlated with clinical data and outcome.

Results: Colorectal cancer samples of 55 Japanese patients were analyzed, 26 female, 29 male. Mean patient age was 62.46 ± 1.48 years. Cancer stages were as follows: Dukes A 27.3% (15/55), Dukes B 43.6% (24/55) and Dukes C 29.1% (16/55). 78.2% (43/55) had lymphatic invasion, 52.7% (29/55) venous invasion and 29.1% (16/55) lymph node metastases. Mean observation period was 65.87 ± 3.96 months. Focal HO-1 expression could be documented in 41.8% (23/55) of the cases. Kaplan-Meier analysis showed a significantly better survival of patients with HO-1 expression (p = 0.0184). The rate of venous and lymphatic tumor invasion was significantly lower in samples expressing HO-1 (p = 0.0340 and p = 0.0483 resp.). Fewer lymph node metastases were found in patients with HO-1 expression, but changes did not reach statistical significance. HO-1 expression in colon adenoma could be detected in 36.8% (7/19).

Conclusions: This study demonstrates a HO-1 expression rate of 41.8% in colon cancer and 36.8% in adenoma samples. HO-1 expression is associated with a lower rate of venous and lymphatic tumor invasion and a trend towards fewer lymph node metastases. Patients with colon cancers expressing HO-1 have a better long term survival. Further studies are needed to examine the impact of HO-1 in adenoma-carcinoma sequence.

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Where To Look & How To Treat Diverticular Hemorrhage
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Purpose: Definitive diverticulitis (TIC) hemorrhage is diagnosed on urgent colonoscopy when active bleeding, a non-bleeding visible vessel (NBVV), or an adherent clot is found in a single TIC. There are no reports about the usual location of the bleeding TIC’s, location of the stigmata in the TIC, nor specific guidelines for TIC treatments. Our purposes were to define these parameters by analysis of consecutive, prospectively treated patients with documented TIC hemorrhage.

Methods: By review of study records & endoscopic pictures, we analyzed colonic location of the TIC with major stigma, position in TIC (neck vs. base), treatments utilized & rebleed rates.

Results: For 37 recent patients with definitive TIC hemorrhage, locations of the bleeding TIC were distal colon (descending or sigmoid)-13/37 (35.1%), splenic flexure-4/37 (10.8%), hepatic flexure or right colon-20/37 (54.1%). In contrast, more than 70% of colonic TICs in these patients were in the left colon. For 35 patients with endoscopic images, 17/35 (48.6%) had the stigmata at the neck & 18/35 (51.4%) were at the TIC base. NBVV was most common at the neck (7/8-75.7%); active bleeding less often at neck (3/7-43%); & adherent clot most frequently at TIC base (13/20-65%). Previously, most hemostasis attendings treated neck stigmata with epinephrine (EPI) injection (1:20,000) & MPEC (low power, short pulses)-COMBO. However, for stigmata at the TIC base, EPI alone was more frequently used, because of concerns for transmural injury with coagulation. However, rebleeding rates with EPI alone (2/8-25%) were higher than COMBO therapies (1/8-5.5%).
Since EPI+Hemoclipping has replaced EPI &/or MPEC for all stigmata in the TIC base, there were no rebleeds (0/5).

Conclusions: 1. In contrast to a higher prevalence of non-bleeding diverticula in the left colon, 64.9% of major stigmata were at or proximal to the splenic flexure. 2. Major stigmata of TIC hemorrhage were found at the TIC neck in 48.6% & base 51.4%. 3. Locations differed by stigmata with NBV most often at the neck (87.5%) & clots more commonly at the TIC base (65%). 4. Based upon rebleeding, safety concerns, & improved efficacy of hemoclips, combination therapies are now recommended for all stigmata: EPI+MPEC at neck & EPI+Hemoclipping at the base. Supported by NIH K24, NIH Core Grant, & Boston Scientific Corp.

Fatal Cytomegaloviral Colitis after Infliximab in a Patient with Suspected Crohn’s Disease Exacerbation

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Purpose: Cytomegalovirus (CMV) is an omnipresent member of the herpes virus family found throughout the world. In the United States, approximately 50-85% of adults over the age of 40 are infected, but there are rarely long-term symptoms in the immunocompetent host. Remicade (infliximab, Centocor) is a chimeric IgG1 monoclonal antibody which targets the tumor necrosis factor-α receptor, thereby inhibiting the function of a cytokine that mediates host immune resistance, especially to intracellular microorganisms such as CMV. Within the past decade, this drug has been heralded as a powerful therapy for various chronic inflammatory disorders, including psoriasis, rheumatoid arthritis and IBD, especially refractory or fistulizing Crohn’s disease. However, an array of infectious complications following infliximab therapy has been reported.

Methods: This case report follows the course of a 62 year-old gentleman with suspected Crohn’s exacerbation on protracted high dose prednisone who received a single dose of infliximab hours before colonic biopsies unexpectedly revealed viral inclusions indicative of CMV colitis (Figure 1).

Results: Gancyclovir (5 mg/kg IV every 12 hours) was initiated immediately and the steroids tapered. Despite antiviral therapy the patient experienced worsening abdominal pain, bloody diarrhea, and fevers. Repeat flexible sigmoidoscopy demonstrating persistent CMV colitis. Gancyclovir was switched to Foscarnet (90 mg/kg every 12 hours) and broad spectrum antibiotics were added. Patient’s course continued to deteriorate finally developing a fatal bowel perforation 30 days into the hospitalization.

Conclusions: This is the first case report of fatal CMV colitis in the setting of infliximab therapy. It underscores the need for continued high index of suspicion for serious opportunistic infections that may complicate infliximab therapy whether pre-existing or after onset of therapy. CMV colitis should be suspected in inflammatory bowel disease flares not responsive to initial therapy. [figure1]

Analysis of Findings of Colonoscopies Performed in Patients above 65 Years of Age with the Predominant Symptom of Constipation

Srikrishna Nagri, MD, Yashpal Arya, MD.* Gastroenterology, Wyckoff Heights Medical Center, Brooklyn, NY and Gastroenterology, Brooklyn Hospital Center, Brooklyn, NY.

Purpose: To validate the need for urgent colonoscopy in patients above 65 years of age presenting with the predominant symptom of constipation.

Methods: Constipation is defined as persistent, difficult, infrequent, or seemingly incomplete defection for the purpose of this study. We included 678 consecutive colonoscopies performed in patients above 65 years of age referred for the predominant symptom of constipation in Wyckoff Heights Medical Center in the last 5 years.

Results: We analyzed 678 consecutive colonoscopies performed in patients above 65 years of age referred for the predominant symptom of constipation in Wyckoff Heights Medical Center in the last 5 years. 72% of the patients were female. 413 (61%) had diverticulosis, 439 (65%) had hemorrhoids, 197 (30%) had adenomatous polyps, 6 (1%) had large cancerous tumors and 177 (26%) had mucosal abnormality in some part of the colon. Reported general prevalence of diverticulosis is above 60%, hemorrhoids above 50%, polyps above 40% and cancer above 1% in this population. Other significant findings noted were melanosis in 51 (7.5%) patients, A VM in 5 patients, solitary rectal ulcer in 7 patients and colonic stenosis in 1 patient. The prevalence of the above pathologies in this study group is not significantly different as compared to the general prevalence of these pathologies in this age group reported in literature.

Conclusions: Constipation is a very common complaint among the geriatric population with prevalence as high as 40% among people above 65. Patients above 65 are three times more likely to consult a physician for constipation. Constipation leads to 2.5 million physical visits each year in the US. $800 million are spent on laxatives annually. Tertiary care evaluation of constipation is reported to cost $2752/patient. Risk factors for constipation include age (above 65 years) and a low fiber diet. Colonoscopy is still one of the first investigations considered by gastroenterologists for constipation in this patient population. Constipation is postulated to be the cause or effect of significant colon pathology which may be detected during colonoscopy. This study failed to validate the need for urgent colonoscopy because of the predominant symptom of constipation in this age group. Timing and need for colonoscopy should be determined based on the clinical presentation and the colon cancer risk of individual patient.

A Non-Selective Cannabinoid Agonist Relaxes the Colon and Reduces Post-Prandial Colonic Contraction in Humans

Tuba Esfandyari, MD, MSc, Irene Ferber, BS, Duane Burton, Alan Zinsmeister, PhD, Michael Camilleri, MD.* Clinical Enteric Neuroscience Translational and Epidemiological Research, Mayo Clinic, Rochester, MN.

Purpose: The aims of this study were to compare the effects of dronabinol (DRO) and placebo (PLA) on colonic motility and sensation in healthy volunteers.

Methods: In a double-blind, parallel-group study, 52 volunteers were randomly assigned to a single dose of DRO 7.5 mg or PLA p.o. with concealed allocation. Barostat manometric assembly was placed into descending colon with the aid of fluoroscopy. This allowed assessment of colonic compliance and sensation prior to ingestion of study medication orally. After one hour, the compliance, tone and sensory tests were repeated, and were followed by the ingestion of a 1000 kcal chocolate milkshake with colonic motility tested for one hour. Planned sample size had sufficient power to detect 38%
differences in primary motor endpoint (colonic tone) and 60-70% change in sensory ratings.

**Results:** There was a significant inhibition of postprandial colonic tone ($p = 0.048$), a borderline effect of relaxation in fasting colonic tone (fasting volume, $p = 0.096$) and an overall significant effect on compliance ($p = 0.045$) with DRO, though the effect on compliance was most pronounced in females. While DRO did not significantly alter any thresholds for sensation, there was an increase in sensory rating for pain during random phasic distensions at all pressures tested and in both genders ($p = 0.024$).

**Conclusions:** A non-selective cannabinoid agonist relaxes the colon and reduces post-prandial colonic contraction in humans; effects on compliance are gender related. Increase in pressure-mediated sensation does not reflect the relaxation of colonic function, and requires further study. The potential for cannabinoids to modulate colonic motor function in disease deserves further study.

### Results

<table>
<thead>
<tr>
<th>Data</th>
<th>Placebo (N = 28)</th>
<th>Dronabinol (N = 24)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age ($y$)</td>
<td>34.2 ± 2.5</td>
<td>36.8 ± 2.8</td>
</tr>
<tr>
<td>Gender F:M</td>
<td>16:12</td>
<td>14:10</td>
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<tr>
<td>BMI (kg/m²)</td>
<td>24.5 ± 0.7</td>
<td>25.3 ± 0.7</td>
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<tr>
<td>Colonic compliance (ml)</td>
<td>19.4 ± 0.6</td>
<td>17.3 ± 0.7</td>
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<tr>
<td>Colonic fasting tone (ml)</td>
<td>89.1 ± 6.0</td>
<td>96.2 ± 8.6</td>
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<tr>
<td>Sensory threshold GAS, mmHg</td>
<td>25.3 ± 3.7</td>
<td>29.5 ± 3.5</td>
</tr>
<tr>
<td>Sensory Rating PAIN 20 mmHg, mm VAS</td>
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<td>29.7 ± 4.5</td>
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<td>Sensory Rating PAIN 36 mmHg, mm VAS</td>
<td>43.6 ± 5.0</td>
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<td>$^*$p &lt; 0.05</td>
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**Incidental Positron Emission Tomographic (PET) Demonstration of Abnormal Focal 18-FDG (Fluoro-Deoxy-Glucose) Uptake within the Colon May Be Related to Benign, Precancerous, or Malignant Tumors:**

**Case Report and Review of the Literature**

Maninder Pabla, MD, Jaswinder Singh, MD,* Chakshu Gupta, MD, Ashok Malani, MD. Department of Medicine, HRMC, Saint Joseph, MO.

**Purpose:** Incidental positron emission tomographic (PET) demonstration of abnormal focal 18-FDG (fluoro-deoxy-glucose) uptake within the colon may be related to benign, precancerous, or malignant tumors. We report a case of an incidental hyperplastic polyp of the colon discovered due to increased uptake on PET scan during breast cancer evaluation.

**Case Report:** A 56-year-old woman with recently diagnosed breast cancer underwent an 18-FDG PET scan to further evaluate bilateral pulmonary nodules and two low attenuated liver masses detected on CT scan. The PET study showed no abnormal radiotracer uptake in either lung, essentially ruling out the possibility of lung metastasis from the breast carcinoma. There was, however, a focus of localized radiotracer accumulation within the proximal ascending colon (SUV of 8.38) and the liver (SUV of 4.7). Colonoscopy revealed a polyp in the area of increased uptake as well as two additional polyps in the cecum and transverse colon. These were hyperplastic polyps on pathological examination. A percutaneous biopsy of the liver mass contained a hemangioma.

**Discussion:** During initial or staging work up an unexpected abnormal focal uptake may be noted on 18-FDG PET scans. This patient population may also be at a high risk for primary colon cancer and further workup may be necessary to evaluate PET findings. Premalignant colon lesions such as villous and tubulovillous adenomas have been reported with increased uptake on PET scans. Their detection is related to their size (>1.3 cm) and preferential locations at the less mobile segments of the colon. Recently, hyperplastic polyps, usually considered as benign and nonneoplastic lesions of the colon, have been reported as additional causes of focal colonic 18-FDG uptake. Contrary to the diffuse pattern of FDG accumulation in the colon, which is mostly benign and physiologic, focal radiotracer colonic uptake on. In a study of 197 patients with lung cancer, 59 had diffuse colonic uptake and 17 had focal colonic uptake on PET scans. Of those, 5 were found to be malignant on biopsy.

**Conclusions:** Colonoscopy with biopsy may be recommended for evaluation of patients with localized colonic uptake on PET scans. Diffuse FDG uptake is usually associated with normal colonoscopy and may not need a colonoscopic evaluation in all patients.

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**Symptom Response to Standard Antibiotic Therapy in Patients with High Breath Methane**

Sheila Rodriguez-Stanley, PhD, Susan Riley, RN, Sattar Zubaidi, MD, Philip B. Miner, Jr., MD,* Clinical Research, The Oklahoma Foundation for Digestive Research, Oklahoma City, OK.

**Purpose:** Advances in breath testing have suggested that high breath methane is characterized by symptoms of constipation, flatulence, bloating, gas and abdominal pain due to methane-induced inhibition of colonic motility. It is unclear whether the bacteria producing methane reside in the small intestine or the colon and whether standard antibiotic therapy can improve symptoms by decreasing methane-producing bacteria. The aim of our study was to determine if a standard course of antibiotics for small intestinal bacterial overgrowth (SIBO) eliminates high breath methane upon re-test corresponding to improved gastrointestinal symptoms.

**Methods:** Fourteen patients (mean age 45.8 years; 5 M, 9 F) that were referred to the OFDR gastrointestinal physiology laboratory for chronic lower gastrointestinal complaints underwent LBT and were found to have high breath methane (mean 38.8 ppm; range 9-77 ppm). Patients were given a standard course of antibiotics, and were re-tested and re-treated if necessary. Symptom data pre and post treatment were tabulated.

**Results:** Primary presenting symptoms were constipation in 13 (93%), 3 of which also had occasional diarrhea. One patient presented with gas and bloating only. Twelve patients were treated with at least 1 course of metronidazole (10 days, 750 mg/d). Four patients were prescribed a subsequent course of xifaxin, and another 4 patients were given zelnorm. Symptoms were not improved in 7 patients (50%), with very little improvement in 5 (36%). 2 patients (14%) had 0 ppm methane upon re-test, 1 of which had corresponding symptom improvement. Seven of 9 (78%) patients that have been re-tested had continued high baseline methane, despite several treatment regimens, with no apparent increase in methane over the LBT, suggesting that the source of methane is colonic and not SIBO.

**Conclusions:** 1) High breath methane correlates with symptoms of constipation, 2) treatment with several courses of antibiotics that are effective therapy for SIBO did not improve symptoms nor did it eliminate methane-producing bacteria, 3) High breath methane at baseline probably indicates methane production by colonic flora which may explain why eradication of methane-producing bacteria is difficult and why antibiotics fail to resolve constipation.

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**Occurrence of Re-Procedure Following Hemorrhoidectomy: A Reflection of Learning Curve?**

Rajesh K. Choudhary, FRCS, Raghu K. Sridhar, MBBS, Debashis Debnath, FRCS, Samuel Debrah, FRCS.* General Surgery, Darlington Memorial
Purpose: Complications of hemorrhoidectomy may warrant further procedures including re-operations. Little is known about the associations between re-procedures following hemorrhoidectomy and severity of hemorrhoid, type of hemorrhoidectomy and grade of surgeon. We aimed to assess any such association between the occurrence of re-procedures following hemorrhoidectomy and other factors.

Methods: All hemorrhoidectomies that took place between September 1999 and August 2004 were included in the study. Severity of hemorrhoid was described as non-prolapsing, mild-prolapsing and severe-prolapsing. Hemorrhoidectomies were classified as stapled and open. Surgeons were grade as consultant and trainee.

Results: A total of 262 hemorrhoidectomies took place. Re-procedures rate was 14.9% (N = 39). Fifteen (38.5%) procedures were done as outpatients, the rest (N = 26; 66.7%) warranted re-operations as daypatients or inpatients. Banding (N = 10), phenol injection (N = 3) and cautereization (N = 2) were commonly performed outpatient procedures. Excision of anal skin tag (N = 13) was the commonest re-operation. Recto-vaginal fistula (N = 1) and Fournier’s gangrene (N = 1) were the two most serious conditions in the study that required re-operations. Occurrence of patients requiring re-procedure was not significantly related to the severity of hemorrhoid (N = 1, 6.7% of 15 for non-prolapsing; N = 24, 14.3% of 168 for mild-prolapsing and N = 14, 17.7% of 79 for severe-prolapsing hemorrhoid) [p = 0.5]. Frequency of re-procedure was significantly higher amongst the stapled hemorrhoidectomies (N = 25, 24.3% of 103), than open hemorrhoidectomies (N = 14, 8.8% of 159) [p = 0.001]. Occurrence of re-procedures was also lower amongst hemorrhoidectomies performed by trainees (N = 5, 7% of 71), compared to consultants (N = 34, 17.8% of 191) [p = 0.03]. However, majority of stapled hemorrhoidectomies were performed by the consultants (N = 100; 97.1% of 103), than trainees (N = 3; 2.9% of 103) [p < 0.00000001].

Conclusions: Re-procedure rate following hemorrhoidectomy was small. The study had shown a significant association between re-procedure rate and grade of surgeon as well as type of hemorrhoidectomy. This may represent the steep learning curve associated with mastering a new technique and have clinical governance as well as training implications. No association was noted with the severity of hemorrhoids.

Purpose: Post-hemorrhoidectomy hemorrhage is a well-documented complication. However, little is known about any association between post-operative hemorrhage and duration of stay in the hospital, readmission rate, type of hemorrhoidectomy, concomitant retention of urine and opioid analgesia requirement. We aimed to assess any such association between post-hemorrhoidectomy hemorrhage and other factors.

Methods: All hemorrhoidectomies that took place between September 1999 and August 2004 were considered for the study. Duration of stay was measured in terms of days. All readmissions that were relevant to original hemorrhoidectomy were included. Type of hemorrhoidectomy was classified as open and stapled. Opioid analgesia included morphine, pethidine and tramadol. Hemorrhage was categorized as mild (<100 ml), moderate (100–300 ml) and severe (>300 ml).

Results: A total of 262 hemorrhoidectomies took place. Occurrences of mild, moderate and severe post-operative hemorrhage were 28 (10.7%), 3 (1.1%) and 3 (1.1%) respectively. Three patients required blood transfusion. Those who developed post-operative hemorrhage stayed significantly longer (N = 4.5 ± 0.3 days), compared to those who did not (N = 2.5 ± 0.08 days) [p < 0.00000001]. Postoperative hemorrhage was significantly lower in stapled group (N = 7; 6.8% of 103), than open group (N = 27; 17% of 159) [p = 0.017]. The frequency of post-operative hemorrhage was not significantly different amongst those who developed post-operative retention of urine (N = 8; 20% of 40), than those who did not (N = 26; 11.7% of 222) [p = 0.15]. Opioid requirement was significantly more amongst those who developed post-operative hemorrhage (N = 22; 64.7% of 34), compared to those who did not (N = 82; 36% of 228) [p = 0.001].

Conclusions: The study had showed that post-operative hemorrhage following hemorrhoidectomy had significant association with duration of stay, type of hemorrhoidectomy and opioid analgesia. However, no significant association was noted with sex, readmission rate and concomitant urinary retention. These have important implications on counseling, choice of operation and management issues.

Purpose: Bowel thickening, albeit a nonspecific finding on CT, may be related to significant bowel pathologies, such as neoplasm, inflammatory diseases, and ischemia. Although it has been previously described, its accuracy and clinical relevance remains uncertain. The objective of our study is to determine the importance of endoscopic evaluation in patients with incidental findings of thickened bowel wall on CT.

Methods: This is a single institution retrospective study that analyzed patients who underwent colonoscopies for either abnormal small or large bowel CT findings. Patients with past medical histories that predisposed them to have bowel wall thickening, such as colon cancer, ischemic colitis, and inflammatory bowel disease, were excluded. Those with normal CT findings that were non-bowel related were also excluded. For patients who met the inclusion criteria of abnormal bowel wall thickening, any abnormal colonoscopic findings were biopsied and confirmed with histology.

Results: We reviewed patients at Albany Medical Center from November, 2004 to March, 2006. Eighty-three patients with abnormal CT findings who underwent colonoscopies were included. All abnormal endoscopic findings were biopsied and verified with pathology. Nine (18%) patients had ischemia, 7 (14%) had HBD, 5 (10%) had invasive carcinoma, 3 (6%) had diverticulitis, and 2 (4%) had nonspecific colitis. Normal colonoscopic findings comprised of 23 (47%).

Conclusions: Our review shows that more than half of the patients with thickened bowel wall on CT had significant pathology. Therefore, any incidental finding of bowel wall thickening on CT should warrant further endoscopic examination.
with bleeding or obstruction by causing intussusception (I) of the segment of the gut where it is located. Since it is rare, there is high chance to miss colonic I particularly when it is focal which may not have classical signs on imaging studies. I is in folding of one segments of the intestine within another this can be focal or partial. In adults it accounts for 5-10% of all cases, 90% of cases cause is associated with malignancy in 54-69% such as bowel carcinoma and lymphoma. We present a case of focal/noncircumferential colocolic I in sigmoid colon with a nonspecific symptoms with no classical radiological signs, to emphasize the importance of high degree of clinical suspicion to make a diagnosis and for early intervention.

**Methods:** A 37-year-old white female who presented with several week h/o of intermittent abdominal pain on the left side and rectal bleeding. Colonoscopy revealed large non obstructing sub mucosal lipoma without ulceration in descending colon. A month later patient presented with recurrent bleeding, constipation and abdominal cramps. At that time sigmoidoscopy revealed mucosal protrusion appearing like polypoidal growth occluding entire lumen with ulceration seen. Small Bowel Follow Through Study was with in normal limits. Barium Enema showed 3 × 4.5 cm filling defect in the region of the sigmoid colon with a smooth margin attached to one wall of the colon on the medial aspect of the descending colon. CT-scan demonstrated a large filling defect in the descending colon with a CT density of lipoma, without signs of I. Patient underwent Laparoscopic left colon resection for colonic obstruction revealed focal segmental I from a large sub mucosal lipoma. Pathology report showed sub mucosal lipoma with surface mucosal ulceration 3 cm in diameter and protruding 5 cm towards the lumen.  

**Conclusions:** 1. CT and Barium enema are generally useful in the diagnosis of complete colonic I but can miss the focal segmental I. 2. Most of the lipomas are sub mucosal, small, asymptomatic and incidentally found during colonoscopy. If the lipoma is large and when presents with rectal bleeding and abdominal pain high clinical suspicion is necessary for the early diagnosis of I. 3. Although malignant lesions are common cause of I in adults benign lesion such as lipomas should also be considered.

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**Prevalence of Urinary and Fecal Incontinence in Older Individuals**  
Carline R. Quander, MD, MS, Martha C. Morris, ScD, Miranda Ku, MD, Julia L. Bienias, ScD, Denis A. Evans, MD, * Internal Medicine, Rush University Medical Center, Chicago, IL; Rush Institute for Healthy Aging; Preventive Medicine; Rush Alzheimer’s Disease Center and Department of Neurological Sciences.

**Purpose:** In this analysis, we investigate the prevalence of fecal and urinary incontinence in community dwelling individuals.  
**Methods:** A total of 6,097 participated in in-home interviews and responded to questions on incontinence. Participants were asked questions about the presence of fecal incontinence, as well as the frequency and quantity of episodes of urinary incontinence.  
**Results:** The prevalence of fecal incontinence was substantially higher among persons with symptoms of urinary incontinence. For example, the prevalence of fecal incontinence was 5.1% among individuals without any symptoms of urinary incontinence and was 36% among persons with symptoms of urinary incontinence that occurred almost daily. The prevalence of fecal incontinence was 50% among individuals who leak enough urine to wet the floor. In logistic regression models adjusted for age, sex, and race, the odds of prevalent fecal incontinence increased with increased quantity and frequency of urinary incontinence. Compared to individuals without urinary incontinence, individuals with any occurrence (ranging from less than once a month to almost daily) had a 4 fold increased odds of fecal incontinence (OR = 4.5; 95% CI; 3.7, 5.4). Compared to individuals with a quantity of urinary incontinence ranging from never to a few drops, those with a higher quantity (ranging from enough to wet the underwear to enough to wet the floor) had a 5 fold increased odds (OR = 5.3; 95% CI; 4.4, 6.4).

**Conclusions:** Older persons with urinary incontinence may be at greater risk of fecal incontinence.

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**Objective Quality Control for Colonoscopy: Automated Extraction of Endoscopic Metrics from Video Files**  
Piet C. de Groen, MD,* JungHwan Oh, PhD, Wallapak Tavanapong, PhD, Johnny Wong, PhD. Division of Gastroenterology and Hepatology, Mayo Clinic, Rochester, MN; Department of Computer Science, Iowa State University, Ames, IA and Department of Computer Science and Engineering, University of North Texas, Denton, TX.

**Purpose:** Objective data to explain why a significant number of large polyps and cancers are not detected during colonoscopy do not exist. Here we present a novel, objective approach to automatically extract endoscopic metrics reflecting quality from digital video files created during colonoscopy.

**Methods:** Digital Video Signal Capture. A workstation was developed that digitally captures and stores the complete video file generated during colonoscopy.

**Quality Control Algorithms.** We developed software that automatically extracts 5 metrics from digitized video files created during colonoscopy. Metric 1 measures the overall duration of the insertion phase termed the *insertion time*. Metric 2 measures the duration of the withdrawal phase termed the *withdrawal time*. Metric 3 measures the clear withdrawal time defined as the duration of the withdrawal phase without out-of-focus frames. Metric 4 reflects the number of back and forth movements. Metric 5 includes fractions of Metric 3 that are spent on close inspections of the colon wall (off-axial or wall view) or global inspections (axial or lumen view).

**Results:** We created approximately 250 digital video files during colonoscopy. Several critical algorithms were developed that allowed discrimination between clear and out-of-focus frames, forward or backward movement, and presence or absence of the appendix. The image recognition algorithms that detect out-of-focus frames and movement direction have high sensitivity and specificity (>95%). Appendix recognition on a test dataset had a sensitivity of 90% and a specificity of 86%.

**Conclusions:** We have created a novel software that automatically extracts 5 objective quality control metrics from colonoscopy video files. Our method has the potential to provide large scale, continuous quality control for...
coloscopy in the day-to-day medical practice setting. Lastly, our method may be useful to assess progress during colonoscopy training, or as part of endoscopic skills assessment evaluations. [figure1]

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Serrated Adenoma Is a Risk Factor for Subsequent Adenomatous Polyps

Emily Glazer, MD, Vidushi Golla, MD, Robin Forman, DO, Henry C. Bodenheimer, Jr., MD.* Digestive Diseases, Beth Israel Medical Center, New York, NY.

Purpose: Serrated adenomas (SA) are defined by the presence of both hyperplastic and adenomatous features on histology. These uncommon polyps are thought to play an important role in the development of sporadic colorectal cancers (CRC) with MSI. There is paucity of data regarding the risk of progression of SA to CRC. This study was undertaken to define the relationship between SA and future development of adenomatous polyps.

Methods: Colonic biopsy specimens that contained a pathologic diagnosis of SA were identified from a pathology database of a major urban academic medical center. Those patients with absence of concomitant malignancy, complete colonoscopy, good or adequate prep and presence of at least one follow up procedures were identified. These were matched to controls (identified from colonoscopy database) by age, sex, indication for colonoscopy, polytype number and sex (excluding serrated polyps) and duration of follow up. Demographic data as well outcomes of follow up procedures were recorded and compared. Analysis of variance statistics was used for continuous variables.

Results: Between 1/1997 and 6/2005 17,226 colonoscopic biopsies and polypectomies were performed. Of those, 80 patients (0.5%) with SA were found. 80% of SA were found in the left colon. Average age of patients undergoing colonoscopy was 58.5, average age of patients with SA was 68 (p = .004). Of all patients with SA, 7 (9%) had concomitant CRC. Final groups contained 19 patients and 19 controls and were well matched. Mean follow up interval in the patient group was 29 months vs. 31 months in the control group (p = .82). On follow up examination 6 patients (31%) and no controls had adenomatous polyps (p = 0.01).

Conclusions: While serrated adenomas are uncommon, they are commonly associated with colorectal cancer. SAs appear to be found more commonly in the left colon and in older patients. This study found a significant association with colorectal cancer. SAs appear to be found more commonly in the left colon and in older patients. This study found a significant association with colorectal cancer.

Demographics and outcomes

<table>
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<th>Patients</th>
<th>Controls</th>
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<tr>
<td>Age (mean, SD)</td>
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<td>65 (10)</td>
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<td>% male</td>
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<td>Initial exam # of associated adenomas</td>
<td>9 (32%)</td>
<td>9 (32%)</td>
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<td>Months of f/u (mean, SD)</td>
<td>29 (25)</td>
<td>31 (19)</td>
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<td>Follow up exam # of associated adenomas</td>
<td>6 (31%)</td>
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</table>

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Prevalences & Outcomes of Different Stigmata of Definitive Diverticular Hemorrhage with Medical-Surgical Treatment or Colonoscopic Hemostasis

Dennis M. Jensen, MD,* Gustavo A. Machicado, MD, CURE Hemostasis Research Group. CURE, Dig. Dis. Res. Ctr., Los Angeles, CA; Division of Digestive Diseases, David Geffen School of Medicine at UCLA, Los Angeles, CA and GI, VA GLAHC, Los Angeles, CA.

Purpose: Our purposes were to describe: 1) prevalences of different stigmata of diverticular (TIC) hemorrhage & patient (pt) outcomes for medical-surgical treatment (MED-SURG) or colonoscopic hemostasis (COLO HEMOS), & 2) findings on removal of adherent clots on TICs & treatment recommendations.

Methods: From 3 consecutive, prospective cohort studies of lower GI bleeding by the same hemostasis team, all pts with definitive TIC bleeding were analyzed. All had focal active bleeding, a non-bleeding visible vessel-NBVV, or adherent clot-CLOT on urgent colonoscopy after purge. 58 consecutive pts were studied, classified by stigmata & treatment, & 30 day severe rebleeding & emergency surgery (SURG) rates were determined. Chi-squared tests were used for statistical comparisons.

Results: For all pts, the mean age was 69 yrs, 27% ingested NSAIDs or ASA prior to bleeding, 36% were females, & 100% had co-morbidities. There were no significant differences for background variables for treatment groups. Prevalences of TIC stigmata for all pts were active bleed 31%, NBVV 22%, & CLOT 47.1%. For 25 MED-SURG pts, rebleed rate was 44% & SURG rate was 36%. Rebleed rates increased from 33% for CLOT, to 50% for NBVV, to 67% for active bleeding TICs. In contrast, for 33 COLO HEMOS pts, significantly less rebleeds (9.1%) & SURG (6.1%) resulted. For 16 pts whose adherent clots were removed, 87.5% had underlying major stigmata (4 NBVV, 5 active bleed, 5 active bleed & VV) & 12.5% had no stigmata. Epinephrine (EPI) injection (1:20,000) prior to cold guillotining off clots significantly reduced active bleeding (to 14%) & facilitated MPEC or hemoclipping compared to our previous technique of forceful clot removal without EPI (active bleed in 67%).

Conclusions: Among 58 pts with definitive TIC hemorrhage: 1) Prevalences of TIC stigmata were active bleed 31%, NBVV 22%, & CLOT 47%. 2) EPI pre-injection, cold guillotining off clots, & MPEC or hemoclipping are recommended for CLOT since rebleeding rates were high on medical therapy (33%) & major stigmata were very frequent upon clot removal. 3) Rebleeding & emergency surgery rates @ 30 days were significantly higher for medically treated pts (44% & 36% respectively) than colonoscopic hemostasis (9.1% & 6.1%). Supported by NIH K24 & NIH CURE Human Studies CORE Grants.

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Compliance with Clostridium difficile Associated Diarrhea (CDAD) Treatment Guidelines in a Large Community-Based Health System

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Purpose: Clostridium difficile associated diarrhea (CDAD) is a common cause of morbidity/mortality and increased length of stay in hospitalized patients. Several recent publications have described increasingly virulent strains of Clostridium difficile (C-diff) colitis leading to worsened patient outcomes. Previous survey-based research has suggested suboptimal compliance with national guidelines for the treatment of CDAD. The aim of this study was to assess inpatient treatment practices in a large community-based health system, and to assess the compliance with the ACG practice guidelines for the management of C-diff colitis.

Methods: A retrospective chart review was performed for all inpatients from March 2002 through March 2004 who had a positive stool C-diff toxin assay. Data collection included analysis of patient demographics, medication treatment choices, alterations in treatment regimen and patient outcomes.

Results: DEMOGRAPHICS: 43% of the patients were male. The mean age was 70 ± 16 years. 87% of the patients were Caucasian, 11% were African American. 91% had received antibiotics in the three months prior to admission and 10% had received cancer chemotherapy in the preceding three months. 8% of patients were admitted with the diagnosis of C-diff colitis. 13% underwent endoscopic evaluation.

TREATMENT CHOICES: Oral metronidazole was prescribed as initial therapy for 78% of patients, while 5% were prescribed oral vancomycin. Of the patients treated with oral vancomycin as initial treatment, 27% were treated in compliance with the ACG practice guidelines.
Results: In addition, drug-related adverse events (AEs) were recorded. EIA for C. difficile toxin at day 10, and symptomatic relapse 2 weeks after resolution; secondary assessments were time to last unformed stool (TLUS), to maintain a symptom diary. The primary efficacy outcome was symptom

Methods: 400 mg PO TID as first-line therapy in patients with CDAD. A prospective, open-label trial to assess the efficacy and safety of rifaximin showing efficacy against C. difficile. We performed an investigator-initiated, based on previous reports of a rising incidence of C. difficile-associated diarrhea (CDAD) as well as more virulent strains of the organism. This information, in combination with the limitations of existing treatments (side effects, resistance, cost and recurrence), has prompted studies of new therapies. Rifaximin is a derivative of rifamycin newly available in the U.S. and is characterized by broad-spectrum anti-microbial activity, minimal systemic absorption (<0.4%), an excellent safety profile, and animal data showing efficacy against C. difficile. We performed an investigator-initiated, prospective, open-label trial to assess the efficacy and safety of rifaximin 400 mg PO TID as first-line therapy in patients with CDAD.

Methods: Eligible patients were those with >3 unformed stools/day, enzyme immunoassay (EIA)-positive for C. difficile toxin and who had not been treated with metronidazole or vancomycin for at least 2 days before the positive EIA (treatment-naive). Patients received study drug and were asked to maintain a symptom diary. The primary efficacy outcome was symptom resolution; secondary assessments were time to last unformed stool (TLUS), EIA for C. difficile toxin at day 10, and symptomatic relapse 2 weeks after treatment. In addition, drug-related adverse events (AEs) were recorded.

Results: 8 patients (mean age 55y, SD ±15y, 4M, 4F) with CDAD were recruited and received 10 days of rifaximin. All 8 patients reported symptom resolution with treatment and 7 reported a median TLUS of 127.5h (range 84-187h). The 8th patient (with a history of AML and prior CDAD) had 3 days without a bowel movement but then during treatment reported pasty stool and was treated for persistent CDAD after day 10. On day 10, 4 patients had a negative EIA for C. difficile toxin, 1 patient had persistent positive EIA but was asymptomatic, and 2 asymptomatic patients did not submit samples. So far, 5 of 7 patients (including the positive EIA patient) have completed 2 week follow-up and there have been no relapses. There were no drug-related AEs in this study.

Conclusions: This open-label study demonstrates that rifaximin 400 mg PO TID is an effective first-line therapy for the treatment of CDAD and has an excellent safety profile. In addition, these results suggest that this therapy may not have significant relapses. Further study of this promising agent in patients with CDAD is warranted.

Rifaximin Is Effective and Safe for the Treatment of Clostridium Difficile-Associated Diarrhea

David T. Rubin, MD,*, Sunana Sohi, MD, Mathew Glathar, MD, Tojo Thomas, MD, Nicole Yadron, BA, Bonnie L. Surma, RN. Department of Medicine, The University of Chicago, Chicago, IL.

Purpose: There have been recent reports of a rising incidence of C. difficile-associated diarrhea (CDAD) as well as more virulent strains of the organism. This information, in combination with the limitations of existing treatments (side effects, resistance, cost and recurrence), has prompted studies of new therapies. Rifaximin is a derivative of rifamycin newly available in the U.S. and is characterized by broad-spectrum anti-microbial activity, minimal systemic absorption (<0.4%), an excellent safety profile, and animal data showing efficacy against C. difficile. We performed an investigator-initiated, prospective, open-label trial to assess the efficacy and safety of rifaximin 400 mg PO TID as first-line therapy in patients with CDAD.

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Differences in the Prevalence and Distribution of Colorectal Polyps Based on Gender and Ethnicity: A Prospective Study

Shaily Jain, MD, William D. Johnson, PhD, Anil Minocha, MD.* Medicine, University of Mississippi Medical Center, Jackson, MS and Preventive Medicine, University of Mississippi Medical Center, Jackson, MS.

Purpose: Previous research suggests that gender and racial differences exist in the prevalence and distribution of polyps. Most of these studies had smaller number of patients, were done based on registries, or did not have enough African American (AA) representation. The objective of our study was to evaluate these variables prospectively in an AA predominant population.

Methods: Patients receiving colonoscopy at a tertiary care medical center were enrolled prospectively. The polyps were defined as rectal, left sided (sigmoid colon, descending colon and splenic flexure) or right sided (transverse colon, hepatic flexure, ascending colon and cecum). The pathology on the polyps was noted as hyperplastic or adenomas. Polyps >= 1 cm, tubulovillous and villous histology or high-grade dysplasia were defined as advance adenomas.

Results: 960 patients were enrolled from May 2005 to February 2006. 929 patients who were of Caucasian Americans (CA) or African American (AA) ethnicity were included for analysis. 59.5% (553) were AA and 40.5% (376) were CA. Overall, there was no difference in the prevalence of polyp between AA and CA (41.2% vs 45%; p = NS). However, CA had significantly more hyperplastic polyps than AA (18.4% vs 13.6%, p = 0.0478).

Prevalence of all adenomas by location in depicted in table 1. Males were more likely to have rectal adenomas than females. CA males were five times more likely than AA females to have rectal adenomas and 2.9 times more likely to have right-sided adenomas (OR 5.0, CI 1.9-12.1 and OR 2.9, CI 1.1-7.2).

Prevalence of all adenomas according to race is depicted in table 2. CA had significantly more adenomas in rectum as compared to AA. Out of the patients who had advance adenomas, CW were more likely to have adenoma in rectum as compared to AA (36% vs 11.9%, p = .01).

Prevalence of adenomas by location in depict on sex

<table>
<thead>
<tr>
<th>Location</th>
<th>Rectum</th>
<th>Left side</th>
<th>Right side</th>
</tr>
</thead>
<tbody>
<tr>
<td>Males</td>
<td>27</td>
<td>51</td>
<td>81</td>
</tr>
<tr>
<td>Females</td>
<td>16</td>
<td>70</td>
<td>94</td>
</tr>
<tr>
<td>p-value</td>
<td>0.008</td>
<td>NS</td>
<td>NS</td>
</tr>
</tbody>
</table>

Prevalence of adenomas by location in rac e

<table>
<thead>
<tr>
<th>Race</th>
<th>Rectum</th>
<th>Left side</th>
<th>Right side</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA</td>
<td>26</td>
<td>50</td>
<td>74</td>
</tr>
<tr>
<td>AA</td>
<td>19</td>
<td>71</td>
<td>103</td>
</tr>
<tr>
<td>p-value</td>
<td>0.01</td>
<td>NS</td>
<td>NS</td>
</tr>
</tbody>
</table>

Incidental CT Findings of Colonic Luminal Thickening, Luminal Mass or Stricture – How Much Should We Worry?

Sheela Channabasappa, MD, Melchor Demetria, MD,* Bashar M. Attar, MD, FACC, L. Sooraj, MD. Gastroenterology, John H. Stroger Jr. Hospital of Cook County – Rush Medical College, Chicago, IL.

Purpose: Patients with incidental abdominal computerized tomography (CT) scan findings of colonic thickening, stricture and mass are frequently referred for endoscopic evaluation. However, CT imaging is not very sensitive or specific for differentiating benign from malignant pathology. The aim of our study is to assess the yield of colonoscopy for different abnormal CT colon findings in a larger group of patients and to determine variations of this yield with age.

Methods: We analyzed all colonoscopic procedures performed for abnormal CT scan readings of the colon from 2003 to 2005 in a large public teaching
hospital. Patients with known colon cancer or metastatic disease, incomplete colonscopy and known IBD were excluded from this study. We defined diverticulosis, hemorrhoids and small left sided hyperplastic polyps as normal variants and did not include these as abnormal findings. The endoscopic and histopathological findings were reviewed.

Results: During the study period 174 colonoscopies were performed for abnormal CT readings of the colon. Of these 20 patients were excluded. Indications for colonoscopy in the remaining 154 patients were colonic thickening N = 91 (59%), (diffuse N = 12, right colon N = 29 and left colon N = 50), mass N = 49 (31.8%), and colonic narrowing/stricture N = 14 (9.1%). Age distribution was < 40yrs (18.2%), 40-60yrs (46.8%), 60-80yrs (30.5%) and >80yrs (3.9%). Abnormal colonoscopy was found in 24 of 49 (49%) patients with CT finding of mass and 6/14 (42.9%) patients with CT reading of stricture/narrowing. However, only 22 of 91 (24%) patients with thickening had abnormal colonoscopy. The prevalence of colon cancer was 13.1%. PPV of abnormal CT colon predicting abnormal colonoscopy was 33.8%.

Conclusions: Reading of thickening of colon on CT is a poor predictor of pathological findings on endoscopy. The yield of endoscopy dramatically increases when the CT reading is mass, stricture or narrowing. The study suggests a trend towards higher likelihood of abnormal colonic findings with increasing age over 60 yrs. We recommend colonoscopy for all CT findings of mass, polyloid lesion, stricture and narrowing. Due to the low yield of clinically significant findings in patients with thickening of colon on CT, routine colonoscopy is not recommended in all cases, clinical judgement should be used.

Correlation between Polyps Detected on Virtual Colonoscopy (VC) vs. Optical Colonoscopy (OC) for Colorectal Cancer Screening (CRC) in Newly Trained Radiologists

William E. Norris, MD, Richard Choi, MD, Franklin Goldwire, MD, Inku Hwang, MD, Jennifer Pak, BSN, Corrine Maydonovitch, BS, Michael P. Brazaitis, MD, Roy K.H. Wong, MD.* Gastroenterology, Walter Reed Army Medical Center, Washington, DC.

Purpose: We have reported that VC is a very sensitive modality in identifying colonic polyps when 2 expert radiologists interpret the studies (sensitivity 88.7%, Pickhardt et al, NEJM 2003; 349). We questioned whether radiologists could be trained utilizing a standard 1 week VC course to maintain a similar degree of accuracy in a non-protocol setting.

Methods: 9 staff radiologists underwent an intensive VC course (100 VC interpretations prior to independent reading). These radiologists then prospectively interpreted 1647 VC’s (7/2003-12/2005) performed primarily for CRC screening (97%), with instructor radiologists’ oversight of detection of polyps. Only patients with polyps ≥ 8 mm on VC were referred to (optical colonoscopy)OC for polypectomy, while polyps < 5 mm were ignored. VC prep consisted of Fleets phosphosoda, Dulcolax tablets, barium and Gas troview for solid stool and liquid tagging, with Viatronix software to generate VC images. The sensitivity and positive predictive values (PPV) of the VC and OC were calculated based on the recorded polyp findings.

Results: 119 (7.2%) patients (mean age = 61 years, 65.5% M) who underwent VC had polyps ≥ 8mm and were referred for OC. 143 polyps ≥ 8mm were seen on both VC and OC, while 13 polyps ≥ 8mm were seen only on OC (VC false-). 16 polyps ≥ 5mm were seen only on VC (VC false+). 110 advanced lesions were detected (4 adenocarcinomas), 28 TSA’s (2 with HGD), 72 TA’s and 2 lymphomas. The per polyp sensitivity of VC in detecting polyps ≥ 8 mm was 92% (143/156) with a PPV for VC of 90% (143/159). 38.5% (5/13) of missed polyps on VC were in the sigmoid with the other polyps equally distributed equally in the colon. Per patient analysis revealed 8 patients with polyps ≥ 8 mm on VC, who had a normal OC. No VC polyp ≥ 8 mm was missed by newly trained staff when reexamined by the expert VC interpreter, although 10% of polyps ≥ 8 mm were downgraded to no polyps status.

Conclusions: (1) VC performed at this institution remains a highly sensitive procedure for the detection of clinically significant colonic polyps and is an excellent modality for CRC screening. (2) With proper training and equipment (Viatronix software, solid and liquid tagging) most radiologists can achieve similar results. (3) An expert reader or approved program should exist to maintain high reader performance through QA & QC for VC interpretation.

Lifestyle or Resveratrol? Comparison of White and Red Wine Consumption and Colorectal Neoplasia

Joseph C. Anderson, MD,∗ Brendan J. Wiggins, MD, Zvi A. Alpern, MD, Carol A. Martin, ANP, Patricia M. Hubbard-Ells, ANP. Gastroenterology, Stony Brook University, Stony Brook, NY.

Purpose: Although alcohol consumption increases the risk for colorectal neoplasia, wine may have a protective effect (Anderson et al Am J Gastro 2005), possibly due to the high resveratrol content. We examined the prevalence of colorectal neoplasia (CRN) in red and white wine drinkers with similar lifestyles. Our hypothesis is that only the consumption of red wine, with higher levels of resveratrol, is associated with a reduction in CRN prevalence.

Methods: Age, gender, BMI, family history, smoking history, medications, alcohol consumption (including red and white wine), aspirin/NSAID use, exercise, fruit/vegetable, red meat, endoscopic findings and pathology from asymptomatic patients (>40 years old) having a screening colonoscopy were entered into a database. Subjects were divided: 1) Alcohol abstainers 2) Red wine drinkers (≥ 3 glasses/week) and 3) White wine drinkers (≥ 3 glasses/week). Significant colorectal neoplasia (SCRN): any villous tissue, High Grade Dysplasia, large tubular adenomas or ≥ 2 adenomas (any size).

Results: 1741 patients were screened (1381 abstainers; 245 red; 115 white (at least 1 drink/week)). No significant differences between the wine drinkers (≥ 3 drinks/week) were observed except that red wine drinkers were more likely to smoke less and be male. See Table 1. Table 2 shows that red wine dramatically reduced the risk of SCRN (68%) but white wine did not.

Conclusions: 1) Consumption of ≥ 3 glasses/week of red wine reduced the risk for SCRN. 2) We speculate that the high resveratrol content accounts for this effect.

<p>| Table 1. Demographics in Wine Drinkers Who Consumed At Least 3 Drinks/Week |</p>
<table>
<thead>
<tr>
<th>Abstainers (N = 1381)</th>
<th>Red Wine Drinkers (N = 176)</th>
<th>White Wine Drinkers (N = 68)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>57.2</td>
<td>59.0</td>
</tr>
<tr>
<td>Gender (%F)</td>
<td>51.1%</td>
<td>39.1%</td>
</tr>
<tr>
<td>Smoking</td>
<td>19.9%</td>
<td>11.1%</td>
</tr>
<tr>
<td>Fam Hx</td>
<td>15.3%</td>
<td>13.6%</td>
</tr>
<tr>
<td>BMI</td>
<td>28.69</td>
<td>26.89</td>
</tr>
<tr>
<td>NSAID use</td>
<td>30.7%</td>
<td>37.3%</td>
</tr>
<tr>
<td>DrinksWine/week</td>
<td>4.0</td>
<td>7.03</td>
</tr>
<tr>
<td>Fruit/Veg/day</td>
<td>2.67</td>
<td>3.21</td>
</tr>
<tr>
<td>Exercise</td>
<td>1.94</td>
<td>2.27</td>
</tr>
</tbody>
</table>

<p>| Table 2. Risk and Prevalence of Significant Neoplasia in White and Red Wine Drinkers |
|-------------------------------------------|-----------------------------|-----------------------------|</p>
<table>
<thead>
<tr>
<th>Abstainers (N = 1381)</th>
<th>White Wine (N = 68)</th>
<th>Red Wine (N = 176)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Significant Neoplasia</td>
<td>9.9% (137)</td>
<td>8.8% (6)</td>
</tr>
<tr>
<td>Odds Ratio (95% CI)</td>
<td>1.0 (0.37-2.07)</td>
<td>0.32 (0.14-0.74)</td>
</tr>
</tbody>
</table>

Multivariate analysis controlling for smoking and age
Mycophenolate Mofetil Induced Colitis
Raymond B. Bedgood, DO, Ayaz J. Chaudhary, MD, FACP,* Jeffrey R. Lee, MD, V. Goei, MD. Gastroenterology/Hepatology, Medical College of Georgia/VAMC-Augusta, Augusta, GA.

Purpose: We describe the clinical presentation, endoscopic appearance, and histology of two rare cases of diffuse colitis in patients being treated with Mycophenolate Mofetil (MMF).

Methods: Two suspected cases of MMF-related colitis were reviewed for clinical presentation, endoscopic appearance, and histology.

Results: MMF is widely used for maintenance immunosuppression to prevent allograft rejection. Dose dependent digestive toxicity is exhibited by nausea, vomiting, abdominal cramping, gastritis, duodenal ulcers, intestinal perforation and diarrhea. Our two patients presented with diarrhea, nausea, and abdominal pain. On colonoscopy, there was diffuse mucosal erythema extending from the cecum to the rectum in both patients. Colonic biopsies revealed mucosa with severe edema, moderate to severe chronic active colitis, and geographic distribution of hyperplastic crypts intermingled with atrophic crypts with cells with bizarre nuclear features. Although, there appears to be no statistically significant correlation between histological damage and the dose of MMF; it does appear that the severity of histologic changes correlated significantly with endoscopic degree of colitis.

Conclusions: MMF-associated diarrhea with colitis is rare. Gastrointestinal (GI) toxicity, usually manifested as diarrhea, is the most common side effect of MMF which may lead to malabsorption and weight loss. We described two patients who developed pancolitis while being treated with MMF. Pancoliconic biopsies in MMF-related colitis revealed marked inflammation, severe edema, and hyperplastic crypts. The severity of histologic changes correlated with the endoscopic degree of “colitis.” MMF toxicity appears to be more severe if the drug is introduced at a later point after transplantation. MMF-related diarrhea improves with decreasing dosage. However, reduction or cessation of MMF was associated with an increased risk for rejection.

Racial Differences in Colorectal Cancer
Kaleem M. Rizvon, MD, Omer K. Massoud, MD, Theodore M. Perlman, MD, Krishnaiyer Subramani, MD, Paul J. Mustacchia, MD.* Gastroenterology, Nassau University Medical Center, East Meadow, NY.

Purpose: A six year retrospective study was conducted to study the trends of colorectal cancer in African Americans in a tertiary care teaching hospital. The patient data was carefully reviewed to observe differences in age at presentation and cancer location among different racial groups.

Methods: Nassau University Medical Center (NUMC) is a tertiary care teaching hospital in Long Island, New York. The Tumor Registry at NUMC was analyzed for colorectal cancer diagnosis for six years between Jan 1998 and December 2003. In addition, patient medical records were also reviewed to obtain all the required information. A proximal location of the cancer was defined as a cancerous lesion identified on colonoscopic examination to be proximal to the splenic flexure.

Results: 186 patients were diagnosed with colorectal cancer during this 6 year period. There were 99 Men and 87 Women. 10 patients (2 African American and 8 other racial groups) were excluded due to incomplete information on tumor location. Among the remaining 176 patients, 47 patients were African Americans. African Americans were younger and found to have more proximal lesions. (Table 1)

Conclusions: African Americans have the highest Incidence of Colorectal Cancer (CRC) of any racial or ethnic group. Surveillance, Epidemiology and End Results (SEER) data between 1975 and 2000 show declining incidence rates among White Americans after reaching a peak in 1985. Among African Americans (AA), the rates have increased in men and remained stable in women. From 1996-2000 the incidence rates were 9.5% higher in AA Men and 17.5% higher in AA Women. Our retrospective study showed a higher percentage of proximal cancers in African Americans. In addition, African American patients were 4 years younger. Diagnostic screening practices should take into consideration this important race based difference in Colorectal cancer.

Table 1. Race Based Differences in Colorectal Cancer

<table>
<thead>
<tr>
<th>Markers of Disparities</th>
<th>African Americans</th>
<th>All other Races</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at Presentation</td>
<td>59</td>
<td>63</td>
</tr>
<tr>
<td>Cancer Location Proximal to Splenic Flexure (%)</td>
<td>34</td>
<td>25</td>
</tr>
</tbody>
</table>

Cholestyramine – Useful Adjunct for the Treatment of Fecal Incontinence
Jose M. Remes-Troche, MD, Ramazan Ozturk, MD, Mary Stessman, MD, Satish S.C. Rao, MD, FACP,* Division of Gastroenterology-Hepatology, Department of Internal Medicine, University of Iowa Carver College of Medicine, Iowa City, IA.
Purpose: There are limited options for drug therapy in fecal incontinence (FI). Biofeedback therapy (BT) or surgery remain the mainstay. Cholestyramine may alleviate diarrhea and incontinence by binding to bile salts but its use in FI has not been assessed. We report our experience with the use of cholestyramine, as an adjunct to BT in the treatment of diarrhea with FI.

Methods: Over a 5yr period, 21 patients (19 F, mean age 65 yrs) with FI received standard BT (biweekly pelvic muscle strengthening exercises, mean number of sessions 6) along with cholestyramine 2-6 gm (dose titrated according to response). All patients underwent anorectal manometry and saline continence tests. Daily stool frequency, stool consistency (Bristol scale), number of incontinent episodes, and satisfaction with bowel function (VAS) were prospectively assessed at baseline, after treatment, and at 1 year.

Results: There were 12 (57%) patients with predominant urge FI, 5 (24%) with passive FI, and 4 (19%) with fecal seepage. Predisposing factors for suspected bile salt malabsorption were: cholecystectomy in 7 (33%), hemi-colecctomy in 5 (15%), small intestinal bacterial overgrowth in 4 (19%), Crohn's disease 1 (5%), intestinal bypass in 1 (5%), and none in 3 (14%). The mean dose of cholestyramine was 3.6 ± 1.2 gm (median 4 gm). Twelve patients received 2 gm qhs, 7 received 4 gm qhs, and 2 received, 2 gm am and 4 gm qhs. Seven (33%) patients reported minor side effects that resolved with dose reduction (constipation 4, excessive gas/bloating 2, headache 1). However, one patient could not tolerate cholestyramine. Symptoms, bowel satisfaction and anorectal function improved after treatment (p < 0.05, see Table).

Conclusions: In selected patients with diarrhea, urgency and incontinence, cholestyramine can serve as a safe and useful adjunct to the management of FI. Most patients require small doses (2-4 gm qhs) and dose titration is essential. The improvement in stool characteristics favors a drug effect, over and above the potential benefits with BT on bowel function.

| Table 2 | | | | |
|---|---|---|---|
| Stool frequency per week | 18.5 ± 2.3 | 11 ± 2* | 14 ± 1.8* |
| Stool consistency (Bristol) | 5.5 ± 0.8 | 4 ± 2* | 4.2 ± 1* |
| # accidents per week | 4.6 ± 1.2 | 2.4 ± 0.7* | 1.5 ± 1.2* |
| VAS (0-100) | 17.1 ± 4 | 69.7 ± 6* | 70 ± 15* |
| Anal squeeze pressure (mmHg) | 77 ± 6 | 111 ± 9* | 101 ± 15* |
| Volume of saline retention (%) | 29 ± 9 | 48.5 ± 10* | 55.9 ± 22* |

Mean ± SD, *p < 0.05 vs. baseline

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Smoking and Colorectal Neoplasia: Is the Risk for Women Similar to That for Men?

Joseph C. Anderson, MD,* Zvi A. Alpern, MD, Brendan J. Wiggins, MD, Patricia M. Hubbard-Ells, ANP, Carol M. Martin, ANP. Gastroenterology, Stony Brook University, Stony Brook, NY

Purpose: A recent analysis of the CONCeRN and VA Cooperative Study 380 demonstrated that the risk for advanced neoplasia from smoking in women may be higher than that for men (Cash et al Gastro 130 A-186, 2006). Our goal was to measure the risk of colorectal neoplasia in our screening population of male and female patients.

Methods: We collected age, gender, family history of CRC, smoking history (pack years and year quit), medications, alcohol use, aspirin/NSAID use, exercise and fruit/vegetable intake from asymptomatic patients older than 40 years presenting for screening colonoscopy. Endoscopic findings and pathology were added to the database as well. We divided the patients into three groups: 1) Current smokers or those who had smoked more than 10 pack years and who were currently smoking or had quit in the past 10 years 2) Low exposure smokers or those who had smoked less than 10 pack years or who had quit over 10 years ago regardless of total pack years and 3) People who never smoked. Significant colorectal neoplasia (SCRN) was defined as villous tissue, high-grade dysplasia, large (> 1 cm), adenomas and multiple (> 2) adenomas of any size. We performed a multivariate logistic analysis to determine odds ratios for SCRN compared to having no neoplasia. For Table 2 we examined the risk for smokers versus those who never smoked leaving the low exposure patients out of the analysis.

Prevalence of SCRN in Male and Female Patients Categorized by Smoking History

<table>
<thead>
<tr>
<th>Smoking History</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>63/747 (8.5%)</td>
<td>57/693 (8.2%)</td>
</tr>
<tr>
<td>Low exposure</td>
<td>31/338 (9.2%)</td>
<td>16/252 (6.4%)</td>
</tr>
<tr>
<td>Current</td>
<td>50/287 (17.4%)</td>
<td>25/217 (11.5%)</td>
</tr>
</tbody>
</table>

Risk of SCRN in Female and Male Patients Who are Current Smokers

<table>
<thead>
<tr>
<th>Gender</th>
<th>OR</th>
<th>95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Females</td>
<td>2.13</td>
<td>1.15-3.93</td>
<td>0.016</td>
</tr>
<tr>
<td>Males</td>
<td>1.92</td>
<td>1.15-3.19</td>
<td>0.013</td>
</tr>
</tbody>
</table>

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Are Smokers a High Risk Group? Analysis of the Risk and Prevalence of Colorectal Neoplasia in a Screening Population Aged 40 to 50 Years

Joseph C. Anderson, MD,* Zvi A. Alpern, MD, Brandon J. Wiggins, MD, Patricia M. Hubbard-Ells, ANP, Carol M. Martin, ANP. Gastroenterology, Stony Brook University, Stony Brook, NY and Gastroenterology, St. Catherine’s Siena, Smithtown, NY.

Purpose: Age and a family history of colorectal cancer (CRC) are currently the factors used to determine the point at which screening for CRC is appropriate. One expert has suggested that smokers should be considered a high-risk group but more data is required to support this premise (Giovannucci et al, Dig Liv Dis 36:643-5, 2004). The goal of our study was to examine the risk factors associated with colorectal neoplasia in patients aged 40 to 50 years. Our hypothesis was that smoking would be associated with an increased risk for colorectal neoplasia in this age group.

Methods: We collected age, gender, family history of CRC, smoking history (pack years and year quit), medications, alcohol use, aspirin/NSAID use, exercise and fruit/vegetable intake from asymptomatic patients older than 40 years presenting for screening colonoscopy. Endoscopic findings and pathology were added to the database as well. We divided the patients into three groups: 1) Current smokers or those who had smoked more than 10 pack years and who were currently smoking or had quit in the past 10 years 2) Low exposure smokers or those who had smoked less than 10 pack years or who had quit over 10 years ago regardless of total pack years and 3) People who never smoked. Significant colorectal neoplasia (SCRN) was defined as villous tissue, high-grade dysplasia, large (> 1 cm), adenomas and multiple (> 2) adenomas of any size. We performed a multivariate logistic analysis to determine odds ratios for SCRN compared to having no neoplasia. For Table 2 we examined the risk for smokers versus those who never smoked leaving the low exposure patients out of the analysis.

Prevalence of SCRN in Smokers Aged 40 to 50 Years

<table>
<thead>
<tr>
<th>Smoking History</th>
<th>Current Smokers</th>
<th>Never/Low exposure</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalence</td>
<td>12.98 (12.2%)</td>
<td>15/273 (5.5%)</td>
<td>0.03</td>
</tr>
<tr>
<td>OR (95% CI)</td>
<td>2.38 (1.07-5.29)</td>
<td>1.0</td>
<td>0.03</td>
</tr>
</tbody>
</table>
Results: There were 2536 patients screened (1372 males and 1164 females). Table 1 shows that the males who currently smoke have the highest prevalence for SCRN. Table 2 shows that the OR’s for men and women are equivalent.

Conclusions: 1) Females who smoke have an equivalent risk for SCRN as male smokers. 2) These data have important implications in the screening and prevention of colorectal cancer in female patients.

Conclusions: Overall survival in colon cancer patients was mean 4.77 years (± 3.67 years) for stage I, 4.66 years (± 3.58 years) for stage II, 2.94 years (± 1.08 years) for stage III, and 2.94 years (± 1.00 years) for stage IV. Overall survival in rectal cancer patients was mean 5.85 years (± 3.11 years) for stage I, 3.30 years (± 1.13 years) for stage II, 3.02 years (± 0.60 years) for stage III, and 0.64 years (± 0.21 years) for stage IV. Overall survival among all colon and all rectal cancer patients was not significantly different at 10 years (figure 1).

Conclusions: Surgery for colorectal cancer is performed with low perioperative mortality and morbidity at our institution. Long-term survival depends on cancer-stage at surgery, overall 10 year survival does not differ among all colon and all rectal cancer patients.

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Correlation of Colonic Interstitial Stellate Cells with Subepithelial Collagen Layer Thickness
Sameer Talwalkar, MD, Purva Gopal, MD, Lauren Briley, MD, Kristine Krueger, MD, Mukunda Ray, MD, PhD.* Pathology, University of Louisville, Louisville, KY and Medicine, University of Louisville, Louisville, KY.

Purpose: Collagenous colitis (CC) is an important cause of chronic diarrhea of unknown pathogenesis, and confusion exists as to which histologic or clinical features best define the illness. Stellate cells have been described as the primary effector cell for hepatic fibrosis, and more recently implicated in the pathogenesis of fibrosis in chronic pancreatitis. The primary objective of our study was to determine if a relationship exists between absolute numbers of colon and rectal subepithelial collagen layer thickness and stellate cell numbers.

Methods: We randomly selected 32 cases from our pathology database, of whom had collagenous colitis determined by subepithelial collagen table of ≥10 microns, and 12 cases whose biopsies showed non-specific inflammation and collagen layer thickness <10 microns. All subjects had undergone lower endoscopy for evaluation of chronic diarrhea. The control group consisted of 4 cases with functional complaints, and non-specific findings on mucosal biopsies. Trichrome stain was performed to determine an average thickness of the subepithelial collagen table. Antibody to smooth muscle actin (SMA) was used to identify mucosal stellate cells via an automated immunohistochemical technique. The number of peri-cryptal and interstitial stellate cells was counted (10 hpf) independently by three pathologists.

Results: There was a linear correlation between the number of interstitial stellate cells and collagen layer thickness (r=0.93). There were no significant differences in the number of peri-cryptal stellate cells for the three groups.

Conclusions: Our study suggests that stellate cells may be the effector cell responsible for synthesis and deposition of the collagen layer in subjects with collagenous colitis. Further investigations of mucosal interstitial stellate cells, correlation with collagen thickness and clinical symptoms will be important in order to more accurately diagnose and treat collagenous colitis.
Specific recommendations for follow-up exam were available in 8 pts. Even though seven patients were recommended to have repeat exam in one or three years, only a single pt. completed a colonoscopy in the suggested interval. Median survival from diagnosis in those with a ‘missed’ or ‘inadequately resected’ CRC was 15 months, and 9/12 pts. expired by April 30, 2005.

Conclusions: Missed CRC diagnosis among increased risk veterans undergoing polyglycocol surveillance at our institution is rare. Veterans with ‘missed’ or ‘inadequately resected’ lesions present with advanced stage tumors. However, due to the age and comorbidities of our study population, the impact of delayed diagnosis of CRC on survival is unclear.

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Safety of a New Sodium Phosphate (NaP) Tablet Bowel Purgative vs a 2 L Polyethylene Glycol Electrolyte Lavage Solution (PEG) Plus Bisacodyl Tablets

Purpose: No published studies have compared the safety of NaP tablets (tabs) vs 2 L PEG as bowel prep. The current study assessed adverse events (AEs) related to and gastrointestinal (GI) safety of a new oral NaP tab (OsminoPrep™, Salix Pharmaceuticals, Inc) vs 2 L PEG plus bisacodyl tabs (HalfLytely®; Braintree Laboratories, Inc) as a bowel purgative for screening colonoscopy.

Methods: Patients (pts) ≥18 y were randomized in a phase 3, investigator-blinded, multicenter study to receive 32 (48 g) NaP tabs or 2 L PEG + 4(20 mg) bisacodyl tabs. NaP tabs were taken 4 at a time with 8 oz clear liquid the evening before (N 20) and 3 to 5 h prior to (N 12) colonoscopy. 2 L PEG + bisacodyl was taken per US prescribing information. AEs were recorded from the first dose of study medication to 48 h (+2 days) postcolonoscopy. Vital signs and clinical lab evaluations were conducted at screening, the day of colonoscopy, and 48 h (+2 days) postcolonoscopy.

Results: 207 pts taking NaP tabs and 208 pts taking 2 L PEG + bisacodyl took ≥1 tab or sip of study medication. Significantly fewer pts taking NaP tabs vs 2 L PEG + bisacodyl experienced ≥1 AE. The most frequently reported AEs in both groups were GI disorders, but these symptoms occurred in significantly fewer pts treated with NaP tabs. A small, comparable percentage of pts in both groups experienced dizziness and headache. The majority of AEs were mild, and fewer pts experienced moderate and severe AEs with NaP tabs (14% and 2%, respectively) vs 2 L PEG + bisacodyl (32% and 9%, respectively).

Conclusions: NaP tabs provide better GI tolerability vs 2 L PEG + bisacodyl as a bowel purgative for colonoscopy. Therefore, NaP tabs may increase patient tolerability and compliance and improve the likelihood of successful bowel preparation.

<table>
<thead>
<tr>
<th>Table 1.</th>
<th>Adverse Event</th>
<th>NaP tabs (N = 207)</th>
<th>2 L PEG + bisacodyl (N = 208)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any adverse event</td>
<td>137 (66)</td>
<td>170 (82)</td>
<td>0.0003</td>
<td></td>
</tr>
<tr>
<td>GI disorders</td>
<td>133 (64)</td>
<td>165 (79)</td>
<td>0.0007</td>
<td></td>
</tr>
<tr>
<td>Abdominal distension</td>
<td>71 (34)</td>
<td>112 (54)</td>
<td>&lt;0.0001</td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>74 (36)</td>
<td>92 (44)</td>
<td>0.0886</td>
<td></td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>64 (31)</td>
<td>97 (47)</td>
<td>0.0012</td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td>9 (4)</td>
<td>40 (19)</td>
<td>&lt;0.0001</td>
<td></td>
</tr>
<tr>
<td>Dizziness</td>
<td>8 (4)</td>
<td>12 (6)</td>
<td>0.4927</td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>10 (5)</td>
<td>9 (4)</td>
<td>0.8194</td>
<td></td>
</tr>
</tbody>
</table>

*Occurring in ≥5% of pts in any group.
Clinical Laboratory Evaluation of a New Sodium Phosphate (NaP) Tablet Bowel Purgative vs a 2L Polyethylene Glycol Electrolyte Lavage Solution (PEG) Plus Bisacodyl

David T. Rubin, MD, Charles Barish, MD, Sandra Lottes, PharmD, William P. Forbes, PharmD, University of Chicago, Chicago, IL; Wake Research Associates, LLC, Raleigh, NC and Salix Pharmaceuticals, Inc, Morrisville, NC.

Purpose: Transient electrolyte fluctuations in patients (pts) taking NaP bowel purgatives are well documented. This study assessed clinical lab profiles in pts taking a new NaP tablet (tab) purgative (OsmoPrep™; Salix Pharmaceuticals, Inc) or 2L PEG + bisacodyl tabs bowel preparation kit (HalfLytely™; Braintree Laboratories, Inc) for colonoscopy.

Methods: 32 NaP tabs were taken in split doses: 20 tabs the eve before and 12 tabs 3–5 h prior to colonoscopy. 2L PEG+BIS was taken per US prescribing instruction. Serum samples were collected within 2 days prior to colonoscopy (screening), the day of the exam (visit 1), and 48 h (+ 2 days) postcolonoscopy (visit 2).

Results: 207 pts (median age 56 y, range 20–80) taking NaP tabs and 208 pts (median age 56 y, range 20–83) taking 2L PEG+BIS who took ≥1 dose/sip of study drug were included in analyses. Mean changes in lab values were not associated with any symptomatic adverse events (AEs). One pt taking NaP tabs had asymptomatic hyperkalemia and was treated.

Conclusions: NaP tabs caused transient increases in inorganic phosphorus levels, resulting in no AEs. Fluctuations in other lab values were similar to 2L PEG+BIS and were also free of AEs. NaP tabs appear to have a favorable safety profile.

<table>
<thead>
<tr>
<th>Table 2.</th>
<th>NaP Tabs</th>
<th>PEG+BIS Tabs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Screening</td>
<td>Visit 1Δ</td>
</tr>
<tr>
<td>Cr (mg/dL)</td>
<td>0.91</td>
<td>−0.01†</td>
</tr>
<tr>
<td>BUN (mg/dL)</td>
<td>16.7</td>
<td>−3.8†</td>
</tr>
<tr>
<td>Na (mEq/L)</td>
<td>140.8</td>
<td>1.9†</td>
</tr>
<tr>
<td>K (mEq/L)</td>
<td>4.33</td>
<td>−0.62†</td>
</tr>
<tr>
<td>Cl (mEq/L)</td>
<td>103.1</td>
<td>−0.10†</td>
</tr>
<tr>
<td>Ca (mg/dL)</td>
<td>9.89</td>
<td>−0.57†</td>
</tr>
<tr>
<td>Phos (mg/dL)</td>
<td>3.63</td>
<td>3.74†</td>
</tr>
<tr>
<td>Bicarb (mEq/L)</td>
<td>24.41</td>
<td>0.19</td>
</tr>
<tr>
<td>Mg (mg/dL)</td>
<td>2.08</td>
<td>−0.08†</td>
</tr>
</tbody>
</table>

†Significant P value comparing mean change between treatment groups.
‡Significant P value comparing whether mean change from screening to visit is equal to 0.

Mortality Associated with Clostridium difficile Associated Diarrhea (CDAD) in a Community Hospital Setting

Sandhya Salguti, MD, Mary Naglak, PhD, Yoshibi Mallavarapu, MD, Cesar de la Torre, MD. * Internal Medicine, Abington Memorial Hospital, Abington, PA.

Purpose: Clostridium difficile is the most commonly diagnosed cause of infectious diarrhea and is associated with substantial morbidity and financial cost. Though extreme leukocytosis has been shown to be associated with increased mortality in CDAD, not much literature is available addressing the potential association of leukocytosis with underlying risk factors combined contributing to mortality.

Methods: A retrospective chart review was done on 50 patients who did not have any recognizable infectious or non-infectious cause of leukocytosis apart from the underlying C. difficile infection itself. Patients were classified into three groups based on their peak white blood cell (WBC) count as <15000, 15000–30000 and ≥30000. Mortality rate was compared between these three groups based on total peak WBC count and also combined with other factors such as presence of diabetes, elevated creatinine i.e. ≥1.5mg/dl, initial albumin level ≤3.0gm/dl, and presence of Systemic Inflammatory Response Syndrome criteria on admission, all of which were given a score of one and a total risk factor score was calculated with a possible range of 0 to 4.

Results: Of the 50 patients, 22 (44%) were males and 28 (56%) were females; 26 (52%) resided in a chronic care facility. Abdominal pain was recorded in 31 (62%) of the patients and diarrhea in all patients (100%). Mean age of the patients was 68 ± 20 years, mean length of stay was 9 ± 6 days. Forty (80%) patients had prior exposure to antibiotics, 27 (67.5%) received a single antibiotic and 13 (32.5%) received multiple antibiotics; quinolones being the most commonly used antibiotics (45%). The mortality rate increased as the peak white blood count increased with mortality rate reaching as high as 50% in patients with peak WBC count ≥30000 (p-value = 0.0078). There was an increase in mortality rate with an increase in risk factor score (p = 0.0047) when adjusted for WBC count (p = 0.058) and age (p = 0.8745) with mortality reaching 100% with a risk factor score of 4.

Conclusions: Our data suggests that mortality rate from C. difficile increases substantially as the peak total WBC count increases and underlying risk factor severity is a strong predictor of mortality in patients with Clostridium difficile. These data need to be validated in a larger prospective study.

Effects of Tritrichomonas muris on the Proteome of Mouse Colon

Akiko Kashiwagi, Hong Luo, MD, Hiroshi Yamamoto, VMD, Toshiyuki Shibahara, VMD.* Division of Laboratory Animal Science, Research Center for Bioscience and Technology, Tottori University, Yonago, Tottori, Japan; School of Health Science, Faculty of Medicine, Tottori University, Yonago, Tottori; and Division of Animal Resources and Development, Life Science Research Center, University of Toyama, Toyama, Japan.

Purpose: In recent years, various infectious agents are detected in the imported mice, wherein problem arises from a lot of transfers among international laboratories. Particularly, Tritrichomonas muris infection is feared since the frequency is high and the pathogenicity is uncertain. This time, to clarify the condition of the trichomonad infectious disease, we examined the effects of T. muris infection on the proteome of mouse colon where it infects specifically.

Methods: 1) The mice were randomly divided into two groups: normal control and infection that was infected by cohabitation with the trichomonad infected mice beforehand. 2) The colons were washed enough to remove the contents by saline. 3) Total protein was extracted from the colons, separated with two-dimension electrophoresis, visualized with silver stain and compared between the two groups. 4) The spots were selected and cut out, in which protein expression was different between the groups. 5) The protein in each selected spot was purified and 6) identified by mass spectrometry and mascot search.

Results: The proteins were expressed differently between the groups, which could be divided into two types: up-regulated and down-regulated proteins by infected with T. muris. Some proteins identified with relationship to immunity system, were up-regulation in infected mice.

Conclusions: It was suggested that mice infected with T. muris were not suitable for other immunology experiments at least for the colon experiments due to the infection could affect the colons, and infection on the mouse could be detected by proteomics. The present study constitutes the first attempt to understand the dynamics of T. muris-host intestine interactions by proteomics.
Long-Term Proton Pump Inhibitors (PPIs) Use Does Not Affect the Frequency, Growth, or Histologic Characteristics of Colon Polyps

M. Singh, MD, G. Dhindsa, MD, S. Friedland, MD, G. Triadafilopoulos, MD.* Gastroenterology, VA, Palo Alto, CA and Gastroenterology, Stanford University, Stanford, CA.

Purpose: To study the frequency, growth, and histology of colon polyps in patients on chronic PPIs therapy, as compared to those not receiving acid suppression.

Background: The clinical significance of the trophic effects of hypergastrinemia on the colonic mucosa is debated. Long-term PPI use in humans is considered safe but the effect of associated high serum gastrin levels on colon polyps is unknown.

Methods: We retrospectively reviewed medical records of 2868 consecutive patients who underwent colonoscopy from 6/2001 to 6/2002 and further reviewed those who had at least two (or more) complete colonoscopies performed at least 3 months apart. Patients with inadequate bowel preparation, incomplete removal or retrieval of any of the polyps were excluded. We compared 2 groups: Group A of 116 patients who used PPIs between the two colonoscopies, and group B of 194 patients who were not on acid suppressants. The frequency of colon polyps, their size after removal, and their histopathology were determined at baseline and at follow-up. We used t-test, Chi-square test and Mann-Whitney test for statistics.

Results: Both groups were similar for age, gender, weight, height, and risk factors for colon cancer. At baseline, the mean frequency of hyperplastic polyps (HP) was 0.599 in group A and 1.05 in group B (p < 0.002). Respectively, the mean frequency of tubular adenomas (TA) at baseline was 1.70 in group A and 1.80 in group B (p > 0.05). At baseline, the mean size of HP in group A was 1.31 mm and 3.07 mm in group B (p < 0.001); the mean size of TA in group A was 7.91 mm and 10.10 mm in group B (p > 0.05). At follow-up, the rate of HP in group A and B was 0.37 and 0.66 (p > 0.028; 95% CI of 0.03 to 0.55) and rate of TA was 0.89 and 1.18 (p > 0.05; 95% CI of −0.08 to 0.66) respectively. The mean size of HP was 1.15 mm and 1.82 mm (p < 0.028; 95% CI of −0.16 to 1.50) and that of TA was 4.09 mm and 4.00 mm (p > 0.05; 95% CI −2.29 to 2.11) in groups A and B respectively. There was no significant difference in the mean frequency and size of HP polyps between groups. Group B patients had significantly higher mean frequency and size of HP polyps but this was unchanged from baseline values.

Conclusions: Long-term use of PPIs does not influence the frequency, growth, or histology of colon polyps. The potentially detrimental effect of PPI-associated hypergastrinemia with its trophic effect on the colonic mucosa remains theoretical and of no clinical significance.

Osseous Metastases in Absence of Liver Metastases in Colon Cancer

Yash Trivedi, MD, Ankur Shest, MD, MPH†, Pritesh Patel, MD. Internal Medicine, Louisiana State University Health Sciences Center, Shreveport, LA.

Purpose: Colon cancer is second leading cause of cancer death in United States after lung cancer. Approximately 30% to 40% of patients with colorectal cancer have locoregionally advanced or metastatic disease at the initial diagnosis. Liver is most commonly the first site of visceral metastasis. We report a rare case of colonic adenocarcinoma metastatic to bone without involvement of the liver.

Methods: A 58-year-old male with history of Non-Hodgkin’s lymphoma was diagnosed with adenocarcinoma of cecum 6 months earlier. At the time of diagnosis, he had Stage III C (Duke C) moderately differentiated adenocarcinoma with T4N2M0G2. Patient underwent right hemicolectomy with ileocolic anastomosis, however he refused chemotherapy. Carcinoembryonic antigen (CEA) at diagnosis was 63. Patient presented six months later with diffuse bone pain. Bone scan and positron emission tomography showed extensive bone metastasis (mixed osteolytic and osteoblastic) in left iliac bone and multiple levels of thoracolumbar vertebrar. Laboratory evaluation was significant for CEA of 20.9 and PSA of 2.3. Computed tomogram of body did not reveal any metastasis to lung or liver. Bone biopsy of left iliac metastasis was consistent with metastatic adenocarcinoma of colon. During his hospital course he developed bowel obstruction and died of sepsis and respiratory failure.

Results: Colon cancer generally spreads to regional lymph nodes or to the liver via the portal venous circulation. In general, colorectal cancer rarely metastasizes to the lung, bone or brain without prior spread to the liver. Bone metastasis is most commonly seen with malignancy of prostate, breast, lung, kidney, bladder and thyroid. The overall incidence of osseous metastases from primary tumors of the gastrointestinal tract has been reported as ranging from 5.6 to 7.9%. Rectal carcinoma metastasizes to bone more often, in 3.8 to 10.5% of cases, while the incidence of skeletal metastases from colonic primary tumors is less than 5%. Metastases relating to a colorectal primary are usually osteolytic and less frequently osteoblastic, but mixed osteolytic and osteoblastic metastases have been reported. Most of these metastases occur in the lumbar spine and pelvis. Sundermeyer et al. studied 1020 patients with colorectal cancer and showed marked increase in incidence of bone metastasis (10.4%) attributed to use of multiple systemic chemotherapeutic treatments.

Conclusions: This case underlines the possibility of osseous metastases without liver metastasis in primary colon cancer.
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Evaluation of Laboratory Values in Patients Who Had Colonoscopy for Abnormality of the Colon on CT Scan

Pikesh K Patel, MD, Prospere Remy, MD,∗ Gastroenterology, Bronx Lebanon Hospital Center, Bronx, NY.

Purpose: There are no established guidelines, but most gastroenterologists perform endoscopy when referred a patient with abnormality of the colon on CT scan. It is difficult to predict what may be found on endoscopy based on patient symptoms. We performed this study to determine if any laboratory differences exists which can predict the likelihood of serious abnormality on endoscopy.

Methods: Retrospective analysis of 61 patients who had colonoscopy for abnormal colon following CT scan. We reviewed the CT abnormality, recent serum creatinine, hematocrit and serum albumin levels and the colonoscopy findings.

Results: The CT scan abnormalities were mass in 22 patients and bowel wall thickening in 39 patients. The average age of the patients was 58 years (range 20 – 85), 70% being over the age of 50 years. 42 patients were women and 19 were men. 7 patients had a history of rectal bleeding. All patients had a complete colonoscopy except for one which was aborted due to poor prep. The colonoscopy findings are shown in table 1. The patient's colonoscopy findings and the laboratory findings were analysed. The average serum creatinine, serum albumin and hematocrit for each group are shown in table 2.

Conclusions: Most of the patients in our study required colonoscopy for another reason other than CT abnormality (e.g. screening, rectal bleeding). Most patients (41/60) had benign findings (i.e. lipoma/normal/diverticulosis), 4/60 had carcinoma and 15/60 had erythema/ulceration/congestion. Patients who had either carcinoma, congestion, erythema or ulceration compared to patients with benign findings had lower serum albumin levels (2.9 – 3 vs 3.9 – 4.2) and lower hematocrits (29.6 – 32 vs 35.7 – 39.4). There were no differences in the creatinine levels in the various groups. Larger studies are needed to confirm these findings and determine if they may clinically relevant to patient management.

Colonoscopy findings and laboratory findings

<table>
<thead>
<tr>
<th>Findings</th>
<th>Serum creatinine mg/dL average (range)</th>
<th>Serum albumin g/dL average (range)</th>
<th>Hematocrit% average (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carcinoma</td>
<td>0.9 (0.7 – 1.2)</td>
<td>2.9 (2.5 – 3.4)</td>
<td>29.6 (28 – 31.5)</td>
</tr>
<tr>
<td>Congestion/erythema/ulceration</td>
<td>0.9 (0.6 – 1.6)</td>
<td>3 (1.9 – 4.4)</td>
<td>32 (24.8 – 46.5)</td>
</tr>
<tr>
<td>Diverticulosis</td>
<td>0.9 (0.1 – 1.5)</td>
<td>3.9 (2.9 – 4.6)</td>
<td>38 (26 – 47.3)</td>
</tr>
<tr>
<td>Lipoma</td>
<td>0.8 (0.6 – 1.1)</td>
<td>4.1 (3.8 – 4.4)</td>
<td>35.7 (33.7 – 39.7)</td>
</tr>
<tr>
<td>Normal</td>
<td>1 (0.4 – 3.9)</td>
<td>4.2 (3.1 – 5)</td>
<td>39.4 (34 – 46.2)</td>
</tr>
</tbody>
</table>

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Proton Pump Inhibitor Use and Risk of Colorectal Cancer. A Population Based Case Control Study

Douglas J. Robertson, MD,∗ Heidi Larsson, M.Sc., Soren Friis, MD, John A. Baron, MD, Henrik T. Sorensen, MD, Section of Gastroenterology, VA Medical Center, White River Junction, VT; Department of Clinical Epidemiology, Aarhus University Hospital, Aarhus, Denmark; Institute of Cancer Epidemiology, The Danish Cancer Society, Copenhagen, Denmark and Departments of Community & Family Medicine, Dartmouth Hitchcock Medical Center; Lebanon, NH.

Purpose: Proton pump inhibitor (PPI) use has been associated with serum gastrin elevations. Hypergastrinemia increases colorectal mucosa proliferation and has been associated with colorectal cancer (CRC) in humans. Our aim was to determine whether PPI use is associated with subsequent CRC risk.

Methods: We performed a population based case-control study in North Jutland County, Denmark. Using diagnostic codes we identified incident cases of CRC from the National Hospital Discharge Register. Using incidence density sampling we selected approximately ten controls from the Civil Registration System for each case matched on gender and birth year. Proton pump inhibitor use was measured by the number of prescriptions filled prior to CRC diagnosis and drawn from the Pharmaco-Epidemiological Prescription Database. Odds ratios for CRC were calculated for varying categories of PPI use using conditional logistic regression adjusted for relevant factors including NSAID use.

Results: From 1991 through 2003, 4231 cases of CRC were identified and were compared to 42139 matched controls. Odds ratios were slightly increased in all prescription ranges of PPI use, however; only use in the 11–20-prescription range was significantly associated with CRC (adjusted OR = 1.44 (1.03, 2.03)). More importantly, there was no trend of increased risk across categories (p = 0.08). Nor were those in the highest use category (> 20 prescriptions) at significant risk for CRC (adjusted OR = 1.13 (0.80, 1.61)).

Conclusions: While gastrin may be an important factor in the pathogenesis of some colorectal cancers, our study suggests that this does not translate into significant clinical risk for most PPI users.

Categorical Analysis of PPI Use and CRC

<table>
<thead>
<tr>
<th>PPI Prescriptions</th>
<th>Cases</th>
<th>Controls</th>
<th>Adjusted OR*</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–2</td>
<td>4052</td>
<td>40573</td>
<td>1.0 (reference)</td>
</tr>
<tr>
<td>3–10</td>
<td>104</td>
<td>969</td>
<td>1.09 (0.89, 1.35)</td>
</tr>
<tr>
<td>1–20</td>
<td>39</td>
<td>274</td>
<td>1.44 (1.03, 2.03)</td>
</tr>
<tr>
<td>&gt; 20</td>
<td>36</td>
<td>323</td>
<td>1.13 (0.80, 1.61)</td>
</tr>
</tbody>
</table>

** Adjusted for use of H2RA’s, NSAID, ASA, diabetes, cholecystectomy and alcohol

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Effect of Colonoscopy Preparation on Renal Function: A Retrospective Comparison of Oral Sodium Phosphate Versus Polyethylene Glycol

Ashwani K. Singal, MD, Alan S. Rosman, MD, James B. Post, MD, William A. Bauman, MD, Mark A. Korsten, MD,∗ Medicine, James J.Peters VA Medical Center, Bronx, NY and Spinal Cord Center of Excellence, James J.Peters VA Medical Center, Bronx, NY.

Purpose: Oral sodium phosphate (OSP) is commonly used for colonoscopy preparation. Cases of renal damage have been recently reported with OSP. We conducted a retrospective comparison of effect of OSP versus polyethylene glycol (PEG) on renal function.

Methods: Chart review was performed on 230 patients who underwent colonoscopy (144 prepared with OSP and 86 with PEG). Subjects included had serum creatinine of ≤ 1.5 mg/dl within 6 months prior to colonoscopy and follow-up creatinine within 3 months after colonoscopy. Parameters used for deterioration of renal function (expressed as mean ± SEM) were change in serum creatinine, ratio of change over baseline creatinine, and proportion of patients with > 50% increase in this ratio.

Results: Compared to patients given PEG, those receiving OSP were younger (69.6 ± 1.2 vs. 65.9 ± 1.0 years, p = 0.02) and less likely to have hypertension (72.2% vs. 56.4%, p = 0.02). Proportion with diabetes mellitus was similar in two groups (62.5% vs. 62.7%, p = 0.963). Use of OSP slightly increased creatinine from baseline of 1.0 ± 0.02 to 1.1 ± 0.02 mg/dl (p =
0.01 by paired t-test. Eight patients (5.6%) had > 50% increase in creatinine from baseline. Using logistic regression, there was no significant association of age, diabetes, hypertension, or baseline creatinine with worsening renal function. Compared with PEG, OSP resulted in no significant increase in creatinine (0.02 ± 0.04 vs. 0.05 ± 0.02 mg/dl, p = 0.10) and ratio of change in creatinine/baseline (0.015 ± 0.037 vs. 0.070 ± 0.020, p = 0.16). There was no significant difference in PEG vs. OSP with respect to proportion of patients with > 50% increase in creatinine from baseline (4.6% vs. 5.6%, p > 0.9). Two of the PEG patients had post-prep serum creatinine > 2.0 as compared to 1 patient in the OSP group. No patient developed clinically significant acute or chronic renal failure. Subgroup of patients with baseline creatinine ≤ 1.3 mg/dl had no significant difference in change in creatinine or ratio of change in creatinine/baseline.

Conclusions: In this retrospective study, clinically significant deterioration of renal function was uncommon with OSP or PEG in patients without renal disease. However, a small percentage of patients did develop mild deterioration of renal function which could not be predicted. OSP appears to be safe in patients with normal renal function.

<table>
<thead>
<tr>
<th>Preparation Quality</th>
<th>Senna</th>
<th>NaP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent</td>
<td>14</td>
<td>7</td>
</tr>
<tr>
<td>Good</td>
<td>27</td>
<td>28</td>
</tr>
<tr>
<td>Fair</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>Poor</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>P value</td>
<td>0.051</td>
<td></td>
</tr>
</tbody>
</table>

Tolerance of the Senna preparation and compliance with it were significantly better than conventional Sodium Phosphate. Overall cleansing quality appears to be comparable or slightly better.

Conclusions: Given the problems associated with currently available Colon cleansing regimens (Large volume and unpleasant taste of PEG-ES, recent safety concerns with Sodium Phosphate) an oral high dose of sodium phosphate sodium phosphate suspension to a conventional sodium phosphate lavage in adults undergoing elective colonoscopy.

Methods: Outpatients referred for elective colonoscopy were prospectively and randomly assigned to receive, the day before the procedure, either two doses of liquid Senna each comprised of 90ml (158.4mg equivalent) given at 1 pm and 9 pm (Senna group n = 50), or a standard Sodium Phosphate bowel prep (45 ml of NaP solution) two doses taken the day before the exam (NaP group n = 50). The primary outcome measure was the overall quality of colon cleansing utilizing the Aroncheck scoring scale (1 = excellent to 4 = poor/inadequate). Three investigators/endoscopists participated in the three month trial and all three were blinded to the type of prep assignment. Patient tolerance/compliance was assessed using a structural questionnaire: poor, fair, or good (Symptoms of intolerance, compliance). The data was analyzed using the Mann-Whitney U Test to compare the results of bowel cleansing and Patient tolerance/compliance.

Results:

Conclusions: Risk of brain tumors (Brain Tumor Polyposis – BTP), particularly cerebellar medulloblastoma, has been found to be higher in patients with Familial Adenomatous Polyposis (FAP) including children in comparison with the general population (Risk ratio 92 – 99). We have not been successful till now with genotype-phenotype correlations between APC gene mutations and CNS tumors. In this we sum up the results our registry experience with the published reports on BTP.

Methods: In the FAP pedigrees (5/72), from the established hereditary CRC registry, we scrutinized patients for brain tumors. We integrated our patients with BTP and known APC mutations with those reported in the rest of the world. We then compared the resulting mutation distribution of FAP/BTP with BTP and known APC mutations with those reported in the rest of the world.
Results: From the Twenty-six patients gathered from 22 families, the principal histologic – demographic subtype of brain tumors in BTP was medulloblastoma (17/26) in children under the age of 20 (mean age 14.7 SD 9.2). Other histologic subtypes included astrocytoma (4) and ependymoma (3). By Chi-square test of association analysis of the pooled APC mutation data showed an odds ratio of 9.73 (p <0.001) for medulloblastoma and 3.37 (p <0.005) for all brain tumor subtypes in patients with segment 2 APC mutation (codons 679 – 1224) compared to non-segment 2 mutation.

Conclusions: We found that among the patients with FAP and identifiable APC gene mutation, especially those with FAP and APC gene mutation in codons 686–1217, CNS tumors, particularly medulloblastoma developing in most cases, during childhood are more common. Whether this observation and the natural history of medulloblastoma in children rationalizes the necessity for aggressive, targeted surveillance of at – risk individuals can be determined only by further studies.

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Risk Factors for Colorectal Neoplasia in Women: Two Populations with Similar Results
Joseph C. Anderson, MD,* Zvi A. Alpern, MD, Brenden J. Wiggins, MD, Patricia M. Hubbard-Ellis, A.N.P., Carol M. Martin, A.N.P., Gastroenterology, Stony Brook University, Stony Brook, NY and Gastroenterology, St Catherine’s Siena, Smithtown, NY.

Purpose: Identification of risk factors for colorectal neoplasia have implications with respect to screening, triaging resources and prevention. A recent analysis of the CONCeRN trial demonstrated risk factors for advanced adenomas (Cash et al Gastro 130 A-186, 2006). Identifying these risk factors in another population would support the CONCeRN trial findings. Our screening population is different from their sample (see Table). Our goal was to determine if the risk factors for colorectal neoplasia in our sample are similar to the CONCeRN trial.

Demographics for CONCeRN and Stony Brook Populations

<table>
<thead>
<tr>
<th>Demographics for CONCeRN and Stony Brook Populations</th>
<th>CONCeRN (N = 1463)</th>
<th>SBU (N = 1164)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>58.9</td>
<td>57.4</td>
</tr>
<tr>
<td>BMI</td>
<td>26.2</td>
<td>27.6</td>
</tr>
<tr>
<td>Family History</td>
<td>15.7%</td>
<td>16.3%</td>
</tr>
<tr>
<td>White</td>
<td>77.0%</td>
<td>96.7%</td>
</tr>
<tr>
<td>Any Smoking</td>
<td>39.0%</td>
<td>40.3%</td>
</tr>
<tr>
<td>Smoking</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI &gt; 35</td>
<td>1.64 (1.01–2.66)</td>
<td>2.15 (1.26–3.67)</td>
</tr>
<tr>
<td>Family History of CRC</td>
<td>2.73 (1.18–6.31)</td>
<td>2.23 (1.21–4.10)</td>
</tr>
</tbody>
</table>

Risk Factors for Colorectal Neoplasia in the CONCeRN and Stony Brook Populations

Data for CONCeRN (Schoenfeld et al NEJM 2005)

Methods: We collected age, gender, family history of CRC, smoking history (pack years/year quit), meds, ETOH use, aspirin/NSAID use, exercise and fruit/vegetable intake from asymptomatic patients (> 40 years) presenting for screening colonoscopy. Endoscopic findings and pathology were added to the database. We divided the patients into 3 groups: 1) Current smokers or those who had smoked > 10 pack years and were currently smoking or quit in the past 10 years 2) Low exposure smokers were those who smoked < 10 pack years or who had quit over 10 years ago regardless of total pack years 3) People who never smoked. Significant colorectal neoplasia (SCRN) was defined as villous tissue, high-grade dysplasia, large (> 1 cm) adenomas and multiple (> 2) adenomas of any size.

Results: A multivariate analysis, adjusting for age was performed comparing the risks for SCRN and no neoplasia. When compared to the CONCeRN population, the risk factors we identified were very similar.

Conclusions: 1) Two trials with different populations identified smoking, BMI > 35 and family history as important risk factors associated with risk for colorectal neoplasia. 2) Data from both trials suggest that female who smoke or have a BMI > 35 should be identified as high risk for colorectal screening perhaps be screened at an earlier age than average risk individuals.

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High-Resolution Manometry Anorectal Manometry: A Comparison with Standard Manometry
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Purpose: High-resolution manometry (HRM) defines esophageal motility more precisely than standard manometry. This study was undertaken to evaluate anorectal motor function with HRM, and to compare it to standard manometry.

Methods: Patients presenting for abnormalities of pelvic floor function were studied with a new high-resolution anorectal manometry catheter and Manoscan (Sierra Scientific, Los Angeles, CA). At the distal tip of the catheter are 2 circumferential solid-state pressure sensors over which a balloon is fitted. 10 cm proximal to these sensors is an array of 10 circumferential solid-state pressure sensors spaced at 7mm on center. The catheter was positioned so it spanned the entire length of the anal canal. Manometrics were reviewed in 2 forms: the contour plot of HRM and standard line plots. This allowed direct comparison of the 2 analytical techniques.

Results: Manometric maneuvers performed were resting anal canal pressure, squeeze pressure, simulated defecation, and rectoanal inhibitory reflex. Resting pressure was greatest at the beginning of the study and dropped to a baseline. Catherer movement initiated a reflex increase in anal canal pressure. During the squeeze maneuver, pressure increased in the resting high pressure zone (HPZ), and in the sensors cephalad to the resting HPZ. With simulated defecation, anal canal pressure may increase, decrease or remain static. During this maneuver HRM detects pelvic floor movement that appears as normal relaxation with standard ARM. Rectal balloon distention decreased anal canal pressure in a volume-dependent manner. This relaxation started on the cephalad side of the HPZ and progressively extended across the sphincteric segment.

Conclusions: HRM provides information that is not easily gleaned from standard manometry. The increase in pressure just cephalad to the resting HPZ during the squeeze maneuver likely represents recruitment of the puborectalis. Progressive relaxation across the anal sphincter during the rectoanal inhibitory reflex may be important for sampling. HRM identifies artifacts introduced by movement of the catheter or the pelvic floor that are not easily discerned with standard manometry.

Clinical Value of CT Colonography in Patients with Strong Relative Medical Contraindications for Colonoscopy
Challa Ajit, MD, Mitchell S. Cappell, MD, PhD,* Susan Summerton, MD, Mindy Horow, MD, Charles Bongiorno, MD, Brett Inglis, DO, Philip O. Katz, MD. Gastroenterology/Radiology, Albert Einstein Medical Center, Philadelphia, PA.

Purpose: CT colonography (CTC) is a potentially valuable complimentary tool to conventional colonoscopy (CC). CTC may be particularly valuable in patients who are at high risk for CC due to severe medical illness, administration of anticoagulant therapy, blood dyscrasia, or intraabdominal conditions. We analyze the clinical feasibility and efficacy of CTC in this previously unstudied subgroup of patients.
Methods: Of 160 patients undergoing CTC at our institution from April 2005 through May 2006, 31 patients underwent CTC, rather than CC, due to medical contraindications. Patients undergoing CTC for colon cancer screening or for prior incomplete CC were excluded. CTC was performed by 64 or 16 slice detectors and read using Vitrea software. The colonic preparation was Fleet’s prep 1. Adequacy of colonic evaluation was quantitatively scored by dividing the colon into 9 segments e.g. cecum = 9, asc.colon = 8, rectum = 1.

Results: Of 31 patients satisfying the study criteria, 17 (55%) were female, 55% were black, and 42% were Caucasian. The mean age was 73.8 ± 13.3 years. Relative contraindications to CC included severe medical illness in 14 (45%), anticoagulation in 13 (42%), and other in 4. Twenty-nine (94%) of patients tolerated the procedure (2 [6%] did not tolerate air insufflation). Evaluation of all colonic segments was performed in 17 patients (55%), but was not possible in 14 patients (45%) due to inadequate colonic preparation. Colonic visualization at CTC was inferior in these 31 patients compared to 100 patients undergoing CTC for incomplete CC (mean visualization: 6.3 ± 3.7 vs 7.6 ± 2.6, p = 0.03). Eleven patients had colonic polyps (total 28 polyps). Nine had at least one polyp ≥0.5 cm or ≥3 polyps. The yield of colonic polyps was similar when CTC was performed for medical contraindications versus CTC performed for prior incomplete CC (p = 0.56). One suspected colon cancer on CTC (poor prep) was a false positive. One villous carpet of cecum was missed at CTC (poor prep). Diverticulosis was reported in 52% of patients.

Conclusions: CTC is technically feasible in patients with relative medical contraindications to CC, but often (45%) have incomplete colonic evaluation due to poor colonic preparation. False positive or false negative reporting can occur due to poor colonic preparation. Better colonic preparation may improve colonic evaluation by CTC in these patients.

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Increased Prevalence of Cytomegalovirus DNA in Neoplastic Colon Tissue
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Purpose: In vitro, CMV can transform cells and dysregulate many cellular pathways that are essential in the oncogenesis of colon carcinoma. If CMV plays a role in the oncogenesis of human colon carcinoma, the virus should have a significant presence in neoplastic colon tissue as compared to non neoplastic tissue.

Methods: We aimed to test this hypothesis by through a retrospective analysis of archival formalin-fixed, paraffin-embedded colon tissue specimens obtained between 2002 to 2005 through endoscopic biopsy of 44 patients with a histologic diagnosis of colon adenocarcinoma (N = 15), adenoma (N = 14) and healthy non-neoplastic colon tissue (N = 15). DNA was extracted from paraffin sections and quantified using real time polymerase chain reaction (PCR) analysis. 50 ng of DNA from each specimen was used to detect CMV DNA using nested PCR analysis.

Results: CMV DNA was detected in 10 of 15 (66.7%) colon carcinoma tissue specimens, 7 of 14 (50%) colon adenoma tissue specimens and in 1 of 15 (6.7%) healthy non-neoplastic tissue. There was a statistically significant difference between detectable CMV DNA in colon adenocarcinoma tissue and healthy non-neoplastic colon tissue (p <0.003), as well as, between colon adenoma tissue and healthy non-neoplastic colon tissue (p <0.02).

Conclusions: We found a greater prevalence of CMV DNA in colon neoplastic tissue as compared to healthy non neoplastic colon tissue. These results suggest a possible role for CMV in the oncogenesis of colon carcinoma. While our study was limited by small sample size, these findings merit further study to determine whether CMV does play an actual role in the oncogenesis of colon carcinoma.

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A Study of the Efficacy of Same Day, Same Colonic Preparation, CT Colonography in 100 Consecutive Patients with Incomplete Colonoscopy
Challa Ajit, MD, Mitchell S. Cappell, MD,* Susan Summerton, MD, Mindy Horow, MD, Brett Inglis, DO, Charles Bongiorno, MD, Philip O. Katz, MD. Gastroenterology/Radiology, Albert Einstein Medical Center, Philadelphia, PA.

Purpose: Although several studies have examined the efficacy of CTC in patients with incomplete CC, none have analyzed CTC performed on the same day as incomplete CC using the same colonic preparation. This CTC protocol can increase patient compliance and avoid a second colonic prep. This study analyzes the efficacy of CTC, performed on the same day using the same colonic prep, in detecting new lesions undetected by incomplete CC.

Methods: Analysis of 100 consecutive patients in terms of added clinical information provided by CTC performed the same day after incomplete CC using the same colonic prep. CT scans (16 or 64 detectors) were evaluated by 2-D followed by 3-D using Vitrea software. Adequacy or depth of colonic evaluation was quantitatively scored by dividing the colon into 9 segments e.g. cecum = 9, rectum = 1.

Results: Of 3700 colonoscopies performed between April 2005 through May 2006, 100 patients (2.7%) underwent CTC for incomplete CC. Patients on average were 68.9 ± 12.4 years old (72% female, 74% black). The primary indication for CC was change in bowel habits in 29%, screening for age >50 years in 20%, rectal bleeding in 19%, anemia in 10%, and other in 22%. The colon prep for CC was polyethylene glycol in 91%. CC was incomplete because of tortuous or fixed colon in 54%, diverticulosis in 23%, and other in 23%. CTC examined entire colon in 70% of patients. Colonic visualization at CTC was superior to that on CC in these patients (CTC complete in 70 vs CC complete in 0, p<0.00001, odds ratio = 231, OR CI: 38–1362; mean number adequately visualized segments in CTC = 7.6 ± 2.6 vs 4.0 ± 2.4 [depth of intubation in CC], p<0.00001). Patients with poor visualization at CTC tended to have a lower yield of colon polyps than patients with adequate visualization (7% vs 29%, p = 0.09). Major new colonic findings on CTC included colonic polyps in 27 patients (6 cancers on CC confirmed by CTC). Major new extracolonic findings included large abdominal mass in 7, metastatic disease in 3, and liver or lung nodules in 4.

Conclusions: CTC may be useful in patients with incomplete CC, even when done on the same day as colonoscopy without further colonic prep, but is limited by nonvisualization of about 18% of the colon in this situation. Despite this limitation, CTC detected new adenomas, unappreciated by incomplete CC, in 27% of patients. About 12% of patients had major extracolonic findings.

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Rifaximin Chaser Following Standard Therapeutic Cocktail for Breaking the Cycle of Multiple C. difficile Diarrhea Recurrences
Stuart Johnson, MD,* Minerva Galang, MD, Christopher Schriever, PharmD, Ciaran Kelly, MD, Dale Gerding, MD. Infectious Disease, Loyola University Medical Center, Maywood, IL; Infectious Disease, Edward Hines VA Hospital, Hines, IL and Celiac Disease Center, Beth Israel Deaconess Medical Center, Boston, MA.

Purpose: Recurrent C. difficile-associated diarrhea (CDAD) after metronidazole or vancomycin treatment is common. About 20% of patients experience at least one recurrence and some patients have multiple recurrences (mCDAD). As an empiric strategy to interrupt CDAD recurrence after treatment with vancomycin or metronidazole, we used rifaximin, a non-absorbed, semisynthetic rifamycin antibiotic, currently approved for treating non-invasive travelers’ diarrhea. We postulated rifaximin may be effective due to its high in vitro activity against C. difficile, high fecal concentrations after oral administration, and low relapse rates in the hamster model of CDAD.
Methods: Seven mCDAD patients agreed to an empiric strategy of rifaximin as a ‘chaser’ following their last vancomycin course. Oral rifaximin (400 to 800 mg/day in 2 or 3 divided doses for 2 weeks) was administered immediately after a suppressive course of vancomycin, before symptom recurrence. Rifaximin in vitro susceptibility was done on two isolates from one patient before and after rifaximin treatment.

Results: Patients were all women, aged 44 to 82 years who had between 5 and 7 CDAD episodes over a 5 to 14 month period. They had received multiple courses of metronidazole (N = 7), vancomycin (N = 7), and vancomycin in combination with rifampin (N = 3) or S. boulardii (N = 3). During follow-up (ranging from 2 to 12 months), 6 patients had no further CDAD episodes. One patient had a brief diarrhea episode 10 days after completing the rifaximin course; after a second course of rifaximin, she had no subsequent diarrhea. A C difficile isolate from this patient after the second rifaximin course, while she was asymptomatic, was identical to her pre-treatment isolate by restriction endonuclease analysis typing. Despite clinical resolution of mCDAD, the MIC of the second isolate (MIC > 256) was markedly higher than the pretreatment isolate (MIC = 0.0078).

Conclusions: Although potential development of post-treatment resistance needs further study, mCDAD recurrence was interrupted in all 7 patients using rifaximin for an off-label indication following standard CDAD therapy. Further controlled studies of this approach and those to elucidate the mechanism of this effect, such as the relative effect of rifaximin on the indigenous bowel flora, are warranted.

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Ambulatory Care for Constipation in the United States, 1997–2004
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Purpose: To evaluate the national trends in physician office visits associated with constipation between 1997 and 2004.

Methods: Data for this study were derived from the National Ambulatory Medical Care Survey (NAMCS) for the years 1997–2004. NAMCS is a nationwide survey based on a probability sample of office visits by ambulatory care providers. Subgroup analyses were performed by combining 3-years of data (1997–1999 and 2002–2004) to get more precise estimates. All analyses were weighted to reflect the complex sampling design of NAMCS.

Results: Physician-based office visits for constipation increased from 3066385 in 1997 to 8062885 in 2004. This represents an increase in office visits from 11.3 (95% CI: 8.4–14.1) in 1997 to 27.5 (95% CI: 15.9–39.1) per 1000 population in 2004. Rates of office visits for females were almost twice that of males in both, 1997–1999 and 2002–2004, periods. The elderly population (age > 65) had the highest rate of office visits in both time periods. However, the office visit rate increased the greatest for the pediatric population (age < 18), increasing from 9.7 visits to 29 visits per 1000 population. Evaluating racial and ethnic differences, we observed the highest rate of office visits in the 1997–1999 time-period for the African-American population (16.6 per 1000 population), however, the Hispanic population had the highest rate of visits (30.9 per 1000 population) in the 2002–2004 time period. We also observed significant geographic differences in office visits, with people in the South having the highest rate of visits in both periods.

The most commonly prescribed treatments for constipation in the 1997–1999 periods were docusate and lactulose, while the most commonly prescribed treatment in the 2002–2004 time period was polyethylene glycol.

Conclusions: There was a significant increase in physician office visits for constipation between 1997 and 2004. The highest rate of increase in office visits was for the pediatric population. We also observed geographic variation, racial differences and changes in medication prescribing for constipation.

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Isolated Right Colon Ischemia (IRCI) May Be the Heralding Presentation of Acute Superior Mesenteric Artery (SMA) Occlusion
John Sotiriadis, MD, PhD, Sang Lee, MD, Lawrence J. Brandt, MD, M.A.C.G.* Medicine, Albert Einstein College of Medicine, Montefiore Medical Center, Bronx, NY.

Purpose: In a previous study, we showed that IRCI had a poor outcome, requiring surgery or resulting in death, six and three times respectively more often than when ischemia involved other segments of the colon; 46.3% of patients with IRCI required surgery and 22.2% died. The SMA supplies blood to both the small intestine and the right colon and it is possible that the poor prognosis of IRCI may be explained by coincident acute SMA occlusion with resultant ischemic injury of the small intestine; the purpose of this study was to evaluate this possibility.

Methods: This study is a retrospective chart review of all cases of colon ischemia identified at Montefiore Medical Center between the years 1998 through 2005 in whom splanchic angiography was performed. Anatomic location of the ischemia, radiologic imaging, colonoscopic or surgical biopsy results, and patient outcomes were studied.

Results: 21 patients were identified with colon ischemia confirmed by biopsy or radiologic imaging; 7 with IRCI and 14 with non-IRCI. 5 of the 7 patients with IRCI and 4 of the 14 patients with non-IRCI had unfavorable outcomes. Of the 5 patients with IRCI and unfavorable outcomes, 3 had acute SMA occlusion. None of the 4 patients with non-IRCI that had unfavorable outcomes had an SMA occlusion.

Conclusions: Despite the small number of patients in this study, there is a suggestion that IRCI may be the presentation of otherwise silent SMA occlusive disease. Of 21 splanchic angiograms performed in patients with colon ischemia, occlusive disease of the SMA was seen in 4 patients, all of whom had IRCI. Of these 4 patients with IRCI, 3 required surgery (1 of these died postoperatively). IRCI is a disease with high mortality that may be the heralding presentation of acute SMA occlusion (4 of 7 patients with IRCI had acute SMA occlusion). Vascular imaging is an important initial test in managing patients with IRCI.

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Ethnic Variations in Colonic Pathologies Observed in Asian-Indian Immigrants Compared to Caucasians, African-Americans and East Asians
Lilian Deeb, MD, Srinivas Chervu, MD, MSPH, Adnan Muhammad, MD, Depali Prasad, MD, C.S. Pitchumoni, MD, M.A.C.G.* Gastroenterology, Hepatology and Clinical Nutrition, Saint Pater’s University Hospital, New Brunswick, NJ.

Purpose: The number of colonoscopies performed in institutions in the major metropolitan centers in the US offers an opportunity to evaluate ethnic differences in colonic pathologies. Asian-Indians (AI) from India, Pakistan, Bangladesh and Sri Lanka constitute a large group of immigrants in the last three decades.

Aim: The aim of this study is to evaluate the frequency distribution of colonic pathology in AI compared to Caucasians (C), African-Americans (AA) and East-Asians (EA, predominantly Chinese).

Methods: A retrospective chart study was performed, reviewing demographic data, ethnicity, indications and findings of colonoscopy in patients > 30 years of age, who presented to a University Hospital. The prevalence of diverticulosis, polyps, colon cancer and arteriovenous malformations (AVM) were determined in the four ethnic groups. Colonoscopy was performed for screening of colon cancer as well as for diagnostic purposes.

Results: A total of 1199 patients were reviewed: Caucasians: 551 (mean age ± Standard Deviation: 63 ± 13.07 years)
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African-Americans: 315 (60 ± 11.98 years)
East-Asians: 196 (56 ± 10.83 years)
Asian-Indians: 137 (57 ± 11.20 years).

Conclusions: Our study confirms observations of previous studies that strong ethnic differences exist in the distribution of colonic diseases.1
1- Compared to Caucasians, Asian-Indians and East-Asians have a significantly lower prevalence of diverticular disease, colon polyps, and cancer.
2- Prevalence of polyps was comparable in African-Americans and Caucasians, yet the former group had a significantly higher prevalence of cancer. This is in line with what was previously reported.2
These observations if confirmed based on larger studies may have relevance on customizing screening colonoscopy based on ethnicity.3 Further, it improves our knowledge in evaluating patients from various ethnic groups presenting with gastrointestinal problems.

REFERENCES

Mass Spectrometric Serum Markers of Colorectal Cancer
Katrin Stedronsky, PhD, Yilan Zhang, MSc, Douglas S. Barker, PhD.*
Research and Development, Miraculins Inc., Winnipeg, MB, Canada.

Purpose: The purpose of this study was to discover biomarkers in serum that can differentiate patients with colorectal cancer (CRCa) from healthy controls and patients with benign colorectal disease. CRCa is the third leading type of cancer, with approximately 150000 new cases and 56000 deaths estimated in the US in 2005. Early detection of CRCa can significantly improve survival rates versus diagnosis at later disease stages. Current colorectal cancer screening tools suffer from a variety of shortcomings, which can include poor sensitivity, poor specificity, expense, patient discomfort and limited application to screen patients at risk.

Methods: Proteomic screening of clinical serum samples by mass spectrometry was conducted to discover and characterize components of these samples for their ability to differentiate CRCa from non-CRCa patients.

Results: 27 discrete proteins/peptides were discovered that could differentiate CRCa patient samples from healthy control and/or benign colorectal disease patient samples. Application of these serum components as biomarkers in a variety of single-model classification algorithms with 10-fold cross validation showed sensitivity/specificity of approximately 80%/85%. The use of bagging met-analysis with 10-fold cross validation gave sensitivity/specificity of approximately 85%/85%.

Conclusions: The discovery of serum proteins and peptides with the potential to help detect and diagnose CRCa is presented.
Purpose: The overall miss rate of colonoscopy for colorectal neoplasms is commonly quoted to be 24%, using endoscopic technology ten years ago. Through recent advances in optics and CCD technologies, new colonoscopes are available. We aimed to study the miss rate of colonoscopy using wide angle of view with white light and narrow band imaging.

Methods: Two consecutive same day colonoscopies were performed in 118 patients. Wide-angle view colonoscopes (angle of view = 170°) with high resolution imaging capabilities were used (Olympus America Inc.). The patients were randomized to standard light (N = 60) or narrow band imaging (N = 58) during withdrawal. The patients then underwent a second examination by the same endoscopist using white light. Findings during each examination were collected. Interim data analysis is reported.

Results: The overall miss rate for adenomas was 12% – significantly less than data using prior technology (p = 0.007) – 17% for neoplasms ≤5mm, 9% for neoplasms 6–9 mm, and 0% for neoplasms ≥1 cm. All missed neoplasms were tubular adenomas. Mean withdrawal time was 8 minutes (SD = 2.7) and 6.5 minutes (SD = 2.1) for the first and second withdrawal, respectively.

Conclusions: Improved colonoscopic imaging technology allowed a significant reduction in missed neoplasm rates. The reduction is likely due to higher resolution and wider angle of view (170° versus 140°).

Table. Colorectal lesions on first (detected) and second (missed) colonoscopy.

<table>
<thead>
<tr>
<th>Lesion Type</th>
<th>White Light Imaging</th>
<th>Narrow Band Imaging</th>
<th>Total</th>
<th>Prior Technologiesa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detected</td>
<td>37 (86)</td>
<td>65 (89)</td>
<td>102 (88)</td>
<td>289 (76)</td>
</tr>
<tr>
<td>Missed</td>
<td>6 (14)b</td>
<td>8 (11)b</td>
<td>14 (12)c</td>
<td>89 (24)²</td>
</tr>
<tr>
<td>≤5 mm</td>
<td>5 (38)</td>
<td>4 (10)</td>
<td>9 (17)</td>
<td>81 (27)</td>
</tr>
<tr>
<td>6–9 mm</td>
<td>1 (5)</td>
<td>3 (13)</td>
<td>4 (9)</td>
<td>6 (13)</td>
</tr>
<tr>
<td>≥10 mm</td>
<td>0 (0)</td>
<td>1 (13)</td>
<td>1 (5)</td>
<td>2 (6)</td>
</tr>
<tr>
<td>Non-neoplastic Lesionsd</td>
<td>30 (38)</td>
<td>29 (72.5)</td>
<td>59 (80)</td>
<td>230 (72)</td>
</tr>
<tr>
<td>Missed</td>
<td>4 (12)</td>
<td>11 (27.5)</td>
<td>15 (20)</td>
<td>89 (28)</td>
</tr>
</tbody>
</table>

²Using Pearson chi-square test: missed lesion rate white light vs. NBI, p-value = 0.53
³Using Pearson chi-square test: missed lesion rate of new vs prior technologies, p-value = 0.0065
⁴Non-neoplastic lesions include hyperplastic, non-specific abnormalities, Lymphoid aggregates, and lost specimens.

Clinical Vignettes

Scratching beneath the Surface: EUS for the Diagnosis of Cholangiocarcinoma as a Cause of Pseudotumor of the Ampulla

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Ampullary pseudotumor is a rare disorder which can present with abdominal pain, jaundice and pancreatitis. We report a case of a distal cholangiocarcinoma causing a normal ampulla to protrude into the duodenal lumen, giving the appearance of an ampullary tumor. The benefit of endoscopic ultrasound before endoscopic ampullectomy is illustrated by this case. An 85 year white male with significant cardiac history was referred for endoscopic resection of an “ampullary tumor.” The patient presented to his gastroenterologist two months prior with complaints of painless jaundice. A CT revealed CBD dilation to 1 cm but no other pathology. At ERCP, a 2 cm “ampullary adenoma” was seen and a dilated CBD with distal tapering was identified. A stent was placed and endoscopic biopsies were obtained (pathology read as tubular adenoma). Endoscopic ultrasound (EUS) was performed at our institution but did not identify any ampullary abnormality. A polypoid tumor however, was identified within the distal bile duct (A) and thus ampullectomy was not performed. Although aware of the EUS findings, a surgeon at the original institution first performed a transduodenal ampullectomy which revealed a grossly and histologically normal ampulla. The operation was converted to a Whipple procedure where carcinoma was confirmed within the distal bile duct. Ampullary pseudotumor is commonly described as a benign disease of the ampulla which gives the appearance of dysplasia or overt malignancy. The etiology is often infiltration of the lamina propria by metaplasia, polymorphs, lymphocytes, plasma cells and histocytes, thought to be caused by prior stone passage. Benign tumors (leiomyoma, lipoma, neurogenic tumors, hemangiomas, hamartomas and carcinoids), sclerosing odditis and eosinophilia causing pseudotumor have all been described. In this case, EUS demonstrated a cholangiocarcinoma within the distal bile duct to be the cause, obviating the possibility of endoscopic resection. The need to consider adenoma within the bile duct or frank carcinoma in patients with ampullary adenoma presenting with jaundice is well illustrated.

[figure1]
Trauma, either blunt or penetrating is an uncommon cause of duodenal and pancreatic inflammation. Even more infrequently reported is duodenal penetration by a toothpick, resulting in inflammation of both duodenum and pancreas. We are reporting an interesting case of abdominal pain from duodenitis and pancreatitis caused by an accidentally ingested wooden toothpick. A 61 years old female with past medical history of hypothyroidism, hemorragic stroke in 2003 (leaving her with some residual dysarthria) and peptic ulcer disease of the duodenum (diagnosed 20 years ago when she had a similar kind of pain) presents with dull-aching epigastric pain of approximately two week duration. The pain was radiating to the back and associated with nausea and vomiting. The patient denied alcohol abuse. Initial labs showed a white cell count of 14300 with a left shift. Serum amylase and lipase were normal. Ultrasound of the abdomen was unremarkable for liver or biliary disease. Contrast CT scan of abdomen showed thickening of the second and third part of the duodenum and peri-pancreatic soft tissue stranding caudal to the pancreatic head and uncinate process – suggesting duodenitis and/or pancreatitis. In view of CT findings and patient’s symptoms, plan was made to endoscopically visualize the duodenum. Endoscopy showed a wooden toothpick lodged in the descending part of duodenum, penetrating the medial wall. The tooth pick was grasped with a snare and removed from the duodenal wall. It was then bent and retrieved. The day prior to the onset of symptoms, patient recalled drinking a bloody Mary which had a toothpick used to hold garnishes. She did not remember swallowing the toothpick. The day prior to the onset of symptoms, patient recalled drinking a bloody Mary which had a toothpick used to hold garnishes. She did not remember swallowing the toothpick.

What a Snare: Endoscopic Retrieval of a Penetrating Tooth-Pick
Tariq S.K. Tanoli, MD, * Jay P. Marshall, II, MD, Sajid Zafar, MD. Internal Medicine, St Lukes Hospital, Chesterfield, MO.

Papillary Mucinous Tumor of the Pancreas
Northern New York, GI Division, Glens Falls, NY.

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Endoscopic Treatment of Recurrent Cholangitis with Intraduodenal Papillary Mucinous Tumor of the Pancreas

Intraduodenal papillary mucinous tumor (IPMT) is an uncommon pancreatic cystic tumor. Occasional patients with IPMT are jaundiced, the etiology of which is sometimes unclear. Herein is reported a case of IPMT, where multiple episodes of cholangitis were treated endoscopically, and were followed by a prolonged asymptomatic period with expectant management. A 58 yo male presented in 1/03 with epigastric distress and hyperlipasemia. An abdominal CT revealed a “full” pancreatic head. He was anicteric and the liver biochemical tests were normal. ERCP revealed a “gaping” major papilla with spontaneous mucous egression. Cholangiography was normal. Pancreatography revealed a dilated pancreatic duct with amorphic filling defects, which proved to be mucous globules (by balloon extraction) and a stricture in the head region. A diagnosis of IPMT was made and after referral to a tertiary pancreatic referral center, he was deemed not to be a surgical candidate as there was superimposed portal vein thrombosis. One year later, over a 3-month period, the patient experienced 3 discrete episodes of cholangitis with jaundice and intense pruritis. During each episode, ERCP revealed amorphic filling defects in the CBD, which were extracted with a balloon catheter (through a biliary sphincterotomy). No biliopancreatic fistula was seen. Each episode of cholangitis resolved with this treatment. Given the frequency of cholangitic episodes, options of surgical biliary bypass, biliary SEMS placement and intrabiliary acetylcysteine instillation were entertained as longer-term treatment options. While initially deciding among these possibilities, the patient was followed, and no further episodes of jaundice/cholangitis occurred. With no other specific treatment, he now remains asymptomatic, having had his last episode of jaundice 20 months ago. Cholangitis due to obstruction of the CBD by mucous globules can complicate the natural history of IPMT. The anatomy/physiology, which led to biliary mucous accumulation in this case was unclear. Although a few episodes of biliary obstruction by mucous globules occurred in rapid sequence, the patient has subsequently remained asymptomatic (with normal liver biochemical tests) for a protracted period, without specific treatment. The occurrence of episodic cholangitis in IPMT (without biliary stricture) can be treated conservatively with periodic endoscopic biliary mucous extraction, which can potentially lead to a prolonged period of symptom quiescence.

Endoscopic Retrieval of a Proximally Migrated, Deeply Embedded Pancreatic Duct Stent Using a Rat Tooth Forceps
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Case Report: A 33-year-old female who had undergone multiple ERCPs for recurrent abdominal pain was admitted to our hospital with persistent pain and pancreatitis 9 days post-ERCP. Prior pancreatic duct (PD) stent placement was complicated by proximal migration into the PD. Multiple failed attempts at stent retrieval with a basket, stent retriever, balloon, and autotome all failed to successfully engage the stent, and only pushed the stent more proximally. Endoscopic retrieval of the migrated stent was then attempted at our institution. The PD was cannulated with a 3.9F sphincterome (Boston Scientific) preloaded with a 0.021 inch diameter guidewire (Wilson-Cook). Pancreatogram showed the stent deeply embedded in the tail. An initial retrieval attempt using a 4 mm × 2 cm Hurricane Rx Dilation Balloon (Boston Scientific) partially inflated alongside the stent to facilitate traction removal was unsuccessful. We then advanced a rat tooth alligator jaw grasping forceps (Olympus) to the tail, successfully grabbed the stent, and removed the stent by carefully withdrawing the forceps (Figure 1). Repeat pancreatogram revealed no evidence of contrast extravasation from the

PD. A 5F 10 cm Zimmon pancreatic stent (Wilson-Cook) was placed. The patient’s pancreatitis improved over the next several days.

**Discussion:** The majority of proximally migrated PD stents can be retrieved using the same techniques and devices that are utilized for the retrieval of migrated biliary endoprostheses. In difficult cases, surgical intervention or the use of novel techniques utilizing interventional radiologic accessories have been reported. In the present case, we demonstrated the removal of a deeply embedded, proximally migrated PD stent with the use of standard grasping forceps. We report the novel technique of using a rat tooth forceps for the retrieval of a deeply embedded PD stent. This modality is safe and demonstrates that standard endoscopic accessories can be utilized in favor of less readily available interventional equipment from fields outside of gastroenterology.

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**Parachute Sign: A Novel Endoscopic Sign That Heralds the Development of a Tracheoesophageal Fistula**

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An endoscopy was performed to rule out GI bleeding in an 85y m who had been in the ICU in multiorgan failure on ventilatory/trach support for 8 weeks. The exam revealed oral ulcerations and diffuse gastritis with coffee grounds. On slow withdrawal of the endoscope, an unusual finding was noted (see Figure 1). About one cm below the UES, a thin membranous septum that moved to and fro in rhythm with the patient’s respiration was seen. The oral-gastric tube was left in place to gravity drainage. The next day, the nursing staff noted that the drainage bag was filling rapidly with air under pressure. Later that day, the patient succumbed to multiorgan failure and expired. One complication that can develop in a patient with a tracheostomy is a tracheoesophageal (T-E) fistula. Once this complication is recognized, an acquired T-E fistula can be successfully managed with surgical repair or by the placement of a bronchial stent. T-E fistulas can manifest as copious production of secretions, aspiration, increasing dyspnea or persistent cuff leak. There has also been a report of T-E fistulas manifesting as massive gastric distention. However, to our knowledge, there are no reports of endoscopic visualization of the membranous septum of a T-E fistula. We have dubbed this finding the “parachute sign.” We believe recognition of this finding is important as early detection may direct the patient to appropriate treatment. Awareness of this finding is also important because it is just under the UES and therefore difficult to detect on insertion of the endoscope. As the septum spanning the T-E fistula is very thin, in the patient with risk factors, insertion of the endoscope must be undertaken with great care to avoid perforation.

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**A Rare Case of a Gangliocytic Paraganglioma**

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The pt is a 78 y/o female that GI was consulted on for a PEG tube placement. She was admitted to the hospital with bilateral pneumonia requiring intubation. Unfortunately, she had a complicated hospital course and required a tracheostomy and a PEG tube. The PEG tube was placed without difficulty however, in the second portion of the duodenum, there was a large, 3cm x 4cm periampullary polypoid mass. Multiple biopsies were taken which were consistent with an adenocarcinoma. CT scan of the abdomen and pelvis was essentially normal. Surgery was consulted and after a long discussion with the patient’s family, it was decided to perform either a trans-duodenal excision of the mass versus a pancreaticoduodenectomy. During surgery, a lymph node in the aorto-caval window was found which had areas of necrosis suspicious for metastatic disease. The surgeons opted to perform a trans-duodenal excision of the mass. The final pathology of the tumor was consistent with a gangliocytic paraganglioma of the ampulla of Vater. The margins were free of tumor however, the aorto-caval lymph node was consistent with metastatic disease. Post-operatively, the patient did well. She was eventually extubated, the PEG removed, and after a brief rehab stay, was able to go back home and live independently. Gangliocytic paragangliomas are rare, benign duodenal tumors. They were first discussed by Dahl, et. al. in 1957. The tumor has structural and immunohistochemical features of a neuroendocrine tumor. They are usually located in the 2nd portion of the duodenum close to the ampulla of Vater. The average age at presentation is 52 years and there is equal prevalence in men and women. The presenting symptoms frequently include abdominal pain, GI bleeding due to mucosal ulceration, intestinal obstruction and biliary obstruction. Grossly, these tumors generally appear...
polyoid. They can be sessile or pedunculated. The pathognomonic histologic features include identification of three distinct cellular elements; spindle cells, epithelial cells and ganglion cells. Treatment typically involves endoscopic resection for small duodenal lesions that do not show any evidence of metastatic disease. If there is suspicion of lymph node involvement, a pancreaticoduodenectomy with lymph node dissection is recommended. Overall, prognosis is uniformly excellent and no cases of distant metastasis or death secondary to this tumor have been reported.

Schwannoma of the Sigmoid Colon
Lisa A. Oliva, DO, Paul Y. Kim, DO, Sean A. Connelly, DO, Peter J. Molloy, MD.* Gastroenterology, The Western Pennsylvania Hospital, Pittsburgh, PA.

The pt is a 62 y/o female who presented to our GI lab for a screening colonoscopy. She was having no GI complaints including abdominal pain, melena, hematochezia, constipation or diarrhea. Her PMH was significant for type II DM controlled with one oral hypoglycemic agent. She also took a baby aspirin QD. Her family history was unremarkable. A full colonoscopy was performed and upon removal of the scope, two small hyperplastic-appearing polyps were seen in the sigmoid colon measuring approximately 4mm in size. They were removed with cold forces. Pathology of the specimens showed spindle cell morphology with palisading-like foci and entrapment of mucosal glands. Immunohistochemistry was strongly positive for S-100 protein and negative for epithelial membrane antigen, CD 117 and muscle specific actin. These findings are consistent with a schwannoma. Schwannomas are rare tumors that are derived from the cells of Schwann that form the neural sheath. They can be located anywhere in the body but are typically rare in the GI tract especially in the colon and rectum. They occur in the same incidence in men and women. The median age at diagnosis is 65 years. The most common presenting symptoms are rectal bleeding, colonic obstruction and abdominal pain however, they can also be completely asymptomatic. Schwannomas can be classified as gastrointestinal autonomic nerve tumors or, GANTs. These are a subgroup of gastrointestinal stromal tumors, GISTs, which also include a variety of other mesenchymal tumors including leiomyomas, leiomyosarcomas and leiomyoblastomas. Distinguishing these tumors from each other is based on immunohistochemical studies. Schwannomas are strongly positive for S-100 protein and for low affinity nerve growth factor receptor (p75), collagen IV and GFAP. They are negative for CD 117 (KIT), neurofilament proteins, smooth muscle duodenal mass and desmin. Two histologic types of schwannomas have been described; Antoni type A with densely packed spindle cells (Verocay bodies) and Antoni type B with loosely organized spindle cells (absence of Verocay bodies). They typically follow a benign course and have no connection with neurofibromatosis 1 or 2. They are treated with local resection either endoscopically or surgically depending on their size.

Duodenal Diverticulitis Presenting as Cholangitis
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The patient was a 72 y/o female who presented with cholangitis, and underwent an attempted ERCP. Unfortunately, due to what appeared to be a nearly circumferential, necrotic mass in the 2nd portion of the duodenum, the ampulla could not be visualized. A biliary surgeon was consulted during the ERCP and due to the highly suspicious appearance of the lesion for a malignancy, he planned for a probable Whipple procedure once the patient was more clinically stable. Multiple biopsies were taken during the ERCP which were negative for malignancy. Tumor markers sent which revealed a CA 19-9 of 55.3. The pt underwent an MR/MRCP which revealed multiple hepatic abscesses in the right lobe without any obvious biliary mass. She underwent both PTC drainage and CT guided drainage of the liver abscesses. During her hospital stay, her labs normalized. Despite this, she had persistent nausea and vomiting and remained hypoalbuminemic. She underwent a dedicated pancreatic CT scan which showed a fluid density collection in the pancreatic head suspicious for a peripancreatic diverticulum as well as soft tissue infiltration in the fat surrounding the 2nd portion of the duodenum. Due to her continued upper GI complaints, an EGD was done on HD #21. The EGD revealed a peripancreatic diverticulum with surrounding ulceration of the small bowel. The appearance was significantly improved from the initial exam. Duodenal diverticula occur in 3–23% of the population. While usually asymptomatic, they can lead to a significant amount of morbidity including diverticulitis and cholangitis as seen in our patient. Treatment is usually conservative including endoscopically cleaning the area to remove debris and broad spectrum antibiotics. If needed, surgical resection with a diverticulectomy or a Roux-en-Y duodenojunostomy can be performed.

Successful Treatment of Hepatocellular Carcinoma in a Patient with Hepatitis C without Cirrhosis
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Hepatitis C (HCV) infection may lead to cirrhosis and hepatocellular carcinoma (HCC). Recommendations have been made to screen patients for HCC who have HCV and cirrhosis. Screening is typically done with alpha fetoprotein (AFP) in combination with imaging, either ultrasound or CT scan at intervals of 6–12 months. We report a patient with HCV in whom HCC developed in the absence of cirrhosis and its successful surgical treatment. A 62 year old man was diagnosed with HCV (genotype 1) in 1998 during work up for asymptomatic mild elevation in transaminases. During evaluation for antiviral therapy in 2002 he had a liver biopsy which showed Grade 2 inflammation and Stage 1 fibrosis. The patient started treatment with pegylated interferon and ribavirin in 2003. The patient had 1–2 drinks of alcohol per week but had stopped prior to treatment. The patient discontinued treatment after week 12 in mid 2004 due to severe side effects including depression, fatigue and weight loss, all of which resolved with cessation of therapy. He was seen every 6 months for routine follow up. In October 2005, incidentally, an AFP and liver ultrasound was ordered. There was no biochemical or clinical evidence of cirrhosis and his AFP was normal at 5.0 ng/mL. The liver ultrasound showed a 4.6 cm echogenic mass. A subsequent multiphase CT showed 9×8 cm mass in left lobe of liver suspicious for HCC. An FNA of the mass which showed well differentiated HCC. This patient was referred for surgical resection of the lesion, and a left hepatic lobectomy was performed. The operative specimen revealed an 8 cm trabeccular well to moderately differentiated HCC, without vascular invasion and margins free of tumor, with a TNM stage T3, N0, M0. The non-neoplastic liver resected with the tumor showed grade 2 granulomatous inflammation and Stage 3 fibrosis but with NO cirrhosis or stage 4 fibrosis. The patient did well after surgery and is being closely followed up for recurrence. Our case highlights the risk of HCC in patients with HCV, and the risk may extend well after surgery and is being closely followed up for recurrence. Our case highlights the risk of HCC in patients with HCV, and the risk may extend well after surgery and is being closely followed up for recurrence. Our case highlights the risk of HCC in patients with HCV, and the risk may extend well after surgery and is being closely followed up for recurrence. Our case highlights the risk of HCC in patients with HCV, and the risk may extend well after surgery and is being closely followed up for recurrence.
Rifaximin in the Treatment of Refractory Crohn’s Disease

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Rifaximin is a minimally-absorbed broad-spectrum antibiotic successfully used in the treatment of travelers’ diarrhea. Several studies have suggested a benefit of antibiotics in the treatment of Crohn’s disease. Multiple open-label trials and a recent double blind, randomized placebo-controlled trial of rifaximin in mild-to-moderate Crohn’s disease have demonstrated clinical improvement and/or remission.

Case Report No. 1: A 39 year old man with an 11-year history of Crohn’s ileocolitis presented with 4 months of severe non-bloody diarrhea. The patient had previously failed to respond to high-dose mesalamine and antibiotics including ciprofloxacin and metronidazole. She was steroid-dependent and was unable to have her prednisone tapered below 10mg daily without her disease flaring. She developed severe vomiting on 6-mercaptopurine. She failed to respond to methotrexate and infliximab (5 mg/kg i.v.). Infliximab of 10mg/kg was effective but associated with optic neuritis after 2 doses. On physical examination she had cushingoid facies. Colonoscopy showed patchy colitis of the left colon with ulcerations. Treatment with rifaximin (400mg BID) resulted in complete resolution of her diarrhea within 3 weeks. The patient has been fully asymptomatic on rifaximin (400 mg daily) for 14 months. Rifaximin was effective therapy for 2 patients with refractory Crohn’s disease. Large well-designed double blind randomized placebo-controlled trials are needed to determine the role of rifaximin in the treatment of Crohn’s disease.

Microscopic Colitis: Always Microscopic and Always in the Colon?

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Microscopic colitis is a histologic diagnosis that encompasses two main entities: collagenous and lymphocytic colitis, each with typical pathologic features that occur in endoscopically normal colonic mucosa. However, there are atypical forms of microscopic colitis that may create confusion. We present such a case. A 57-year-old white female with biopsy-proven microscopic colitis on two prior colonoscopic examinations (2000, 2003) developed recurrent symptoms of watery diarrhea, accompanied by a 14-pound weight loss in late 2005. There was no vomiting, arthropyathy, visual disturbance, skin lesions, fever or rigor. A third colonoscopy was performed at an outside institution which, by report, showed diffuse mild erythema throughout the colon. Outside colonial biopsies were consistent with microscopic colitis and terminal ileal biopsies showed villous atrophy and intraepithelial lymphocytosis. The patient’s symptoms did not respond to bismuth salicylate. Based on the pathology reports, the non-specific endoscopic findings and the involvement of the terminal ileum, the patient’s primary gastroenterologist made the diagnosis of Crohn’s disease and initiated treatment with high-dose oral prednisone. The patient’s symptoms responded completely. She was then started on budesonide as the prednisone dose was being tapered. The patient was referred to our center for further diagnostic work-up and management recommendations. The colonic biopsies were reviewed by dedicated gastrointestinal pathologists at our institution and an atypical form of microscopic colitis was confirmed. The atypical features included cryptitis, crypt abscesses, focal acute ileitis and intraepithelial lymphocytosis in the terminal ileum. We recommended no further testing and tapering of prednisone along with a 12-week course of budesonide. The patient remains in clinical remission. Biopsies from the terminal ileum of patients with microscopic colitis are more likely to show intraepithelial lymphocytosis, villous atrophy and thickened subepithelial collagen than controls. Inflammatory bowel disease-like histologic features such as cryptitis and crypt abscesses are seen in 30–40% of patients with microscopic colitis. Minimal endoscopic abnormalities and even macroscopic signs of colitis may be present at endoscopic examination.
the etiology remains unknown. Liver transplantation in patients with PGCH is of particular concern given the high rate of recurrence. CASE REPORT: A 49-year-old Caucasian male with a history of gout and no prior risk factors for liver disease presented with acute jaundice and abnormal liver enzymes, including marked transaminas and a total bilirubin level of 40 mg/dL. The patient was not coagulopathic nor encephalopathic. Viral and autoimmune serologies were negative. A liver biopsy was performed, evidencing centrilobular cholestasis and scattered multinucleated giant hepatocytes within the hepatic globules. Given the patient’s rapidly deteriorating condition, parenteral steroids were started. Over the next few days, his clinical condition and liver enzymes began to improve. He was subsequently discharged on oral prednisone. One month after discharge, azathioprine was added to his drug regimen. His liver function tests are currently within normal range.

Discussion: PGCH could represent an underdiagnosed entity given that hepatocellular giant cells, the only diagnostic marker, may be expressed in low copy numbers, and many cases may easily escape recognition. The etiology of PGCH appears to be multifactorial, as the formation of giant cells has been seen in conjunction with viral, drug-induced, and autoimmune disorders. PGCH has also been described in relation to the use of several drugs, particularly methotrexate, 6-mercaptopurine, p-aminosalicylic acid, chlorpromazine, vinyl chloride, and clomethacin. PGCH has been associated with systemic processes including sarcoidosis, lymphoma, hypoparathyroidism and even after liver transplantation. The course of PGCH encompasses a wide spectrum of severity ranging from normalization of hepatic histology either spontaneously or with medical treatment, to progression to end-stage cirrhosis requiring transplantation or even death. Corticosteroid treatment has demonstrated significant clinical improvement in patients with PGCH and concurrent autoimmune disorders. PGCH should be considered among the differential diagnosis in patients presenting with cryptogenic cirrhosis and prompt identification may help prevent potential adverse outcomes.

542 Intussusception in a Young Patient with Ulcerative Colitis
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Intussusception in adults with inflammatory bowel disease is very rare. Eight cases have been reported with only three described in patients with ulcerative colitis. The lead points for the intussusception were pseudopolyps and recommended management was to resect the involved bowel without attempts at reduction. We report a 24-year-old woman with ulcerative colitis and sickle cell disease admitted with abdominal pain. She was diagnosed with ulcerative colitis 10 years previously when she presented with bloody diarrhea and abdominal pain. An incomplete colonoscopy was performed (secondary to patient discomfort), and revealed ulcerative colitis. Asacol was prescribed and taken in unknown dosage for 1½ years. She had multiple flares of disease activity over the years, characterized by abdominal pain and bloody diarrhea; each was treated with slow tapering prednisone regimens. She presented to our medical center with two days of unusually sharp right upper and lower quadrant abdominal pain associated with nausea, but without diarrhea, rectal bleeding or fever. A CT Scan revealed enlargement of the right and proximal transverse colon with intraluminal fat consistent with ileocolic intussusception (Figure 1). The patient underwent a right hemicolectomy without reduction of the intussusception. Examination of the removed colon revealed a 5 cm polyp in the terminal ileum consistent with a tubular adenoma that served as the lead point. Pathologic evaluation showed chronic inflammatory changes with intramucosal carcinoma. Three other polyps approximately 2 cm in size consistent with tubular adenomas were noted in the ascending colon. Given the findings on pathologic evaluation, should the patient have had a total colectomy? Intussusception is a rare complication of inflammatory bowel disease and treatment should incorporate optimal management of the underlying disease and the intussusception.

[figure1][figure2]

543 Diagnosis of Lymphoma in Overt Obscure GI Bleeding Aided by WCE
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A 54 year old man who had been taking 2.4g/day of ibuprofen for two weeks for arthritic pain presented to the ER with melena. EGD revealed multiple duodenal erosions, with no stigmata of recent bleed. His NSAID, the presumed culprit, was held and PPI initiated. However, the next day, he began again with melena and occasional hematochezia. During his hospitalization, he continued to bleed, at times actively. Work-up included colonoscopy, enteroscopy, bleeding scan, and mesenteric angiogram, all of which were negative except for erosions throughout the duodenum. Biopsies of the proximal duodenum showed chronic inflammation but no evidence of H. pylori or cellular atypia. In total, he required about 15 units of packed RBC. Given his overt obscure GI bleeding, capsule endoscopy was performed, showing the erosions in the proximal bowel and a larger, more distal small bowel ulceration (A). A repeat enteroscopy was then performed with multiple biopsies of the distal duodenum; these demonstrated large B-cell lymphoma (B).
The lymphoma was confined to the GI tract by CT scan. He subsequently started chemotherapy and has not rebled to date. This case highlights 2 major points: the presence of a serious disease obscured by a more common and benign pathology; and the increasing role wireless capsule endoscopy (WCE) has in the diagnosis of small bowel disease. First, this is a patient with GI bleed who had a clear risk factor for duodenal erosions (NSAIDs). However, his persistent bleeding forced a more extensive work-up, all of which was unrevealing until the WCE. The presence of more proximal duodenal erosions with negative biopsies confounded the picture, for if there was not a strong history of NSAIDs, perhaps there would not have been more proximal erosions and the first biopsies would have been taken of the more distal lesions, leading to an earlier diagnosis. [figure1][figure2]

Copper deficiency (hypocupremia) is a rare entity that can lead to serious morbidity. With advent of gastric bypass surgery, hypocupremia is being increasingly recognized in adult populations. We present a case patient with hypocupremia and profound neurological symptoms to stress the importance of this entity and its early diagnosis and treatment. We present a case of a 62 year-old white female who had Roux-en-Y gastric bypass surgery. Due to multiple nutritional deficiencies following surgery, she was receiving multivitamin supplements including iron and zinc supplementation as well as vitamin B12 injections. Ten years after her gastric bypass, she began having progressively worsening ataxia, paresthesias of lower extremities and hands, and generalized weakness. Her weakness continued to progress resulting in significant proximal muscle weakness as demonstrated by her difficulty in rising from seated position. Patient eventually became hospitalized for severe weakness requiring mechanical ventilation. On admission, an extensive nutritional evaluation was significant for undetectable copper level and elevated zinc level. MRI of spine showed abnormal T2 hyperintensity within the posterior columns of the spinal cord from the C7-T1 level to the skull base which has been previously described in patients with hypocupremia. Intravenous copper infusions were given to the patient during her hospitalization. She had dramatic clinical improvement which correlated with the normalization of serum copper level. The patient was eventually weaned from the ventilator and began demonstrating further improvement in her muscle weakness. Direct percutaneous endoscopic jejunostomy tube was placed and patient fed enterally. The patient was ambulatory prior to her discharge from the hospital. Hypocupremia is a rare complication following gastric bypass operation. Copper is primarily absorbed in the stomach and proximal small bowel, however, it is uncertain why hypocupremia occurs only in certain patients following gastric bypass. Previous literature has established an association with zinc overload state and hypocupremia. Zinc and iron supplementation have already been demonstrated in animal models to inhibit copper uptake in the proximal gut. The combination of gastric bypass and zinc overload likely caused our patient's hypocupremia. Her dramatic improvement after aggressive copper replacement stresses the importance of the timely diagnosis and treatment of hypocupremia.

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Acute Esophageal Injury with Cast Formation Induced by External Beam Radiation
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The incidence of acute esophageal injury has dramatically increased with the administration of external beam radiation for many locally advanced thoracic malignancies. We describe an extremely unusual manifestation of severe acute radiation-related esophageal injury. We report the case of an 81-year-old woman with stage IIIA non-small cell lung cancer, who was admitted after the development of hematemesis and odynophagia. She had received 6000 cGy of external beam radiation as part of a combined chemoradiotherapy regimen. Esophagogastroduodenoscopy noted circumferential denudation of the esophageal mucosa resulting in cast formation. Biopsies confirmed radiation related vascular degeneration and fibrosis. This case describes an extremely unusual manifestation of severe acute radiation-related esophageal injury. We will discuss its prevalence, risk factors for its development, endoscopic features, and the associated histologic findings.

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Management of Colonic Stent-Induced Luminal Obstruction Using Argon Plasma Coagulation
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The use of argon plasma coagulation (APC) to modify metal stents has been reported in a handful of case reports, and the experience is limited to APC transaction of distally migrated biliary elgiloy-based Wallstents. To our knowledge, the use of APC to relieve obstruction induced by nitinol-based Ultraflex stents in the colon has not been described.
**Case reports:** *Case 1:* A 52 y/o male underwent placement of an Ultraflex Precision colonic stent (8.7 cm long, 30 mm flare diameter, 25 mm body diameter) for an obstructing recto-sigmoid cancer. Difficulty with stooling recurred 3 months later. At endoscopy, the distal end of the stent was angulated and abutted against the rectal wall, causing an obstruction. The wire strands of the stent that were not embedded in tissue were trimmed using contact APC at 90 W and 2 L/min flow rate, with relief of obstruction (see figures) and continued ease of defecation at 1 month follow-up. *Case 2:* A 78 y/o male underwent palliative stenting of a 5-cm long, obstructing rectosigmoid cancer using a similar sized Ultraflex colonic stent, as described above. Obstructive symptoms, however, recurred 2 weeks later due to impingement of the proximal aspect of the stent against the contralateral wall of the sigmoid colon. Successful piecemeal sectioning of the stent was performed using APC, with significant improvement in stooling and abdominal distention. The patient subsequently died from metastatic complications 5 weeks later.

**Discussion:** Colonic obstruction may occur from protusion or angulation of the proximal or distal aspects of metal stents opposing the colonic wall. In this setting, APC at high power and flow rate appears effective and safe in trimming or transecting the free nitinol wire strands to relieve the stent-induced obstruction. [figure1][figure2]

**Challenging Diagnosis of Gastric Cancer**

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A previously healthy 25 year old female with history of gynecologic surgery was referred after multiple outside evaluations for a two-month history of post-prandial nausea, vomiting, left-sided abdominal pain and a 30 pound weight loss. Physical exam, abdominal x-ray and routine laboratory studies were normal. CT scan revealed thickening of the stomach wall. During the EGD, the stomach did not insufflate and we appreciated diffuse nodular inflammation throughout the gastric fundus and body with a normal appearing antrum. Multiple forceps biopsies were taken from the abnormal mucosa and histopathologic review demonstrated gastritis. Due to a high suspicion for malignancy we repeated the endoscopy and performed endoscopic mucosal resection (EMR), using a suction technique deep tissue was obtained. Pathologic diagnosis was infiltrating poorly differentiated adenocarcinoma with focal signet ring cells penetrating to the submucosa. The patient underwent total gastrectomy, multiple regional lymph nodes were positive for malignancy and the cancer was staged as T3N3Mx. The diagnosis of diffuse-type gastric cancer can prove challenging as endoscopic findings may be nonspecific and superficial biopsies can be falsely negative due to their submucosal origin. Endoscopy with biopsies is the diagnostic procedure of choice for gastric cancer. With a visible lesion, seven biopsies have a sensitivity of 98%. In early gastric cancers or carcinomas involving the submucosa and muscularis propria, sensitivity of typical forceps biopsy decreases to 50–60%. Currently, chromoendoscopy, magnification endoscopy and endoscopic ultrasound are diagnostic modalities being tried to increase diagnostic sensitivity. EMR is an accepted technique as an endoscopic alternative to surgical resection of superficial GI malignancies, but its role in diagnosis is undefined. As such, EMR for the diagnosis of diffuse type gastric cancer may be under utilized. Although the incidence of gastric cancer in the United States is declining, it remains an extremely morbid clinical entity. Most patients with symptomatic disease have advanced incurable disease at diagnosis, however when encountering the diffuse form of gastric cancer diagnosis may be delayed due to the challenge of obtaining adequate tissue samples. Due to the poor prognosis, early diagnosis of diffuse gastric cancer is imperative, as such, EMR may have a role in obtaining this difficult diagnosis.

**The Double Edged Stone**

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A 70 y/o female presented with a 2 day history of nausea and vomiting, and 1 day of severe diarrhea. She denied hematemesis, abdominal pain, melena, fevers, recent travel and sick contacts. She denied medication, tobacco, and etoh use and had no significant family history. Physical exam was pertinent for a T max 99.8, she was anicteric, had high pitched bowel sounds, a distended abdomen with minimal epigastric abdominal tenderness without rebound or guarding. The only abnormal lab was a wbc of 14000. Abdominal xrays were consistent with an incomplete SBO and air in the CBD. CT of the abdomen showed evidence of distention in the jejunum and ileum with several air-fluid levels. The gallbladder could not be identified and there was a presence of a 2cm rounded area of increased density located within the diluted ileum. HIDA scan showed non-visualization of the gallbladder. Upper GI series with small bowel follow through was consistent with a SBO. Pt. underwent an exploratory laparotomy which was revealing for a gallstone located in the terminal ileum, a cholecystoduodenal and cholecystocolonic fistula. The impacted gallstone and gallbladder were removed and the choledocoenteric fistulas (duodenum, transverse colon) were repaired. Gallstone ileus is a rare but well documented complication of gallbladder disease. It is
caused by migration of a gallstone through a cholecystocoelectric fistula. The clinical symptoms are dependent on the location of the fistula and stone. The majority of these types of fistulae are usually singular and cholecystoduodenal in location. Impaction of the gallstone, which most often is greater than 2cm is generally located in the terminal ileum. The overall incidence of internal biliary fistula is reported as 0.1 to 0.5%. The majority of patients with a cholecystocolic fistula are elderly and female (6:1). Diarrhea is the most common presenting symptom and the typical clinical features of gallbladder disease are absent. Our patient presented with a mixed picture; including symptoms of small bowel obstruction along with features consistent with a cholecystocolic fistula. The etiology of the diarrhea in our patient was likely secondary to bile salts. The combination of a SBO due to a cholecystoduodenal fistula along with severe diarrhea secondary to a cholecystocolic fistula is an extremely rare event and is unreported in the literature.

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Treatment of Diarrhea in Common Variable Immunodeficiency: A Novel Use for Budesonide
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Common Variable Immunodeficiency Disorder (CVID) is an immunological disease that can present with GI issues including chronic diarrhea, abdominal pain, and protein losing enteropathy. The mainstay of treatment, IVIG infusion, usually does not improve GI symptoms. Systemic steroids have been used but are associated with significant side effects. Enteric coated budesonide is a poorly absorbed oral corticosteroid used to treat Crohn disease. It is locally acting and has high first pass metabolism resulting in greatly reduced systemic exposure compared to traditional steroids. We report a patient with CVID and chronic diarrhea who significantly improved with budesonide. A 47 YOF with CVID associated diarrhea, abdominal pain, and bloating for several years had an exhaustive evaluation of her GI symptoms which was unrevealing. She had failed treatments with exclusion diets and loperamide. Prednisone provided some improvement of her GI symptoms. At the advice of her immunologist, she attempted a course with budesonide which significantly improved her GI symptoms. Given the absence of literature on this approach, a systematic evaluation of budesonide on this patient’s GI symptoms was undertaken.

The patient weaned budesonide over 1 week. 24 hour stool weight, fecal fat excretion, stool frequency, stool consistency (Bristol Stool Form Scale), abdominal pain, bloating, and serum IgG levels were assessed 4 days after complete cessation of budesonide and again 14 days after restarting budesonide (3mg tid). Diarrhea, abd pain and bloating occurred within 2 days of discontinuing budesonide. All parameters measured improved upon reintitiation of budesonide (table 1). No significant side effects were observed with budesonide. To our knowledge, this is the first report of a patient with CVID-related chronic diarrhea to be successfully treated with oral budesonide. Further, steatorrhea, abd pain and bloating also improved. Perhaps most interesting, serum IgG levels significantly increased with budesonide. This novel observation may provide clinicians with an effective and safe treatment option in this difficult group of patients.

Table 1.

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>After Budesonide</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stool weight (g/24h)</td>
<td>330</td>
<td>217</td>
</tr>
<tr>
<td>Fecal Fat (g/24h)</td>
<td>9</td>
<td>5</td>
</tr>
<tr>
<td>Stool Frequency (#/d)</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Consistency (BSFS)</td>
<td>5–7</td>
<td>3–4</td>
</tr>
<tr>
<td>Abdominal pain (0–4)</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Bloating (0–4)</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>IgG trough (g/dL)</td>
<td>389</td>
<td>684</td>
</tr>
</tbody>
</table>

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Disseminated Herpes Simplex 2 Infection with Hepatitis in a Patient Taking Alefacept for Psoriasis
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Disseminated Herpes Simplex 2 (HSV 2) infections are infrequent and have a guarded prognosis. We report a patient with psoriasis receiving Alefacept who developed HSV 2 hepatitis.

Case Report: A 50-year old woman presented with complaints of fever, epigastric pain, fatigue, and anorexia. Five days prior to admission, the patient had received the 11th weekly injection of Alefacept for the management of psoriasis. Initial physical exam was significant for fever of 40.6°C, tenderness in the epigastrium and RUQ, and hepatomegaly. Laboratory data revealed an AST of 1799 U/L, ALT 1891 U/L, total bilirubin 2.1 mg/dL, alkaline phosphatase 152 U/L. The PT was mildly elevated but corrected with Vitamin K. On the second day of hospitalization, the patient developed pustular erythematous lesions on her face, chest, arms, and legs. Viral cultures of the skin lesions revealed HSV 2 by immunofluorescence. IV Acyclovir was initiated. Serologic tests for routine causes of hepatitis were negative. Sogram revealed a distended gallbladder with wall edema but no gallstones and normal ducts. The total bilirubin peaked at 10.9 mg/dL at which time the AST was 352 U/L, ALT 330 U/L, and alkaline phosphatase 832 U/L. The patient was HIV seronegative. The patient had no history of genital herpes but her partner was seropositive for HSV 2. The fever resolved, liver tests gradually declined, and the skin lesions improved after the initiation of Acyclovir. After 20 days of hospitalization, the patient was discharged on po Valacyclovir to complete 6 weeks of anti-viral therapy. Alefacept is an immnosuppressive medication indicated for moderate to severe chronic plaque psoriasis. The mechanism of action involves binding to the CD2 receptor of lymphocytes and inhibiting their interaction with leukocyte function antigen 3. This interaction is necessary for the activation of T lymphocytes which leads to the secretion of numerous inflammatory mediators involved in psoriasis. In most cases, disseminated HSV 2 infections are infrequent and have a guarded prognosis. HSV hepatitis should be considered on initial presentation of immunosuppressed patients with abnormal liver tests even in the absence of mucocutaneous lesions. This is the first report of herpes hepatitis associated with Alefacept.

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Inlet Patch Presenting as a Peptic Stricture
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Case Report: A 73 year-old male presented to the emergency room complaining of difficulty swallowing which began abruptly after eating a salmon fillet. Four years ago he presented with similar symptoms and had a barium swallow which showed “narrowing of the esophagus.” Since then, he has had 8–10 of these episodes, all of which resolved spontaneously. The patient underwent urgent upper endoscopy. At 22 cm from the incisors, boneless salmon was seen proximal to a luminal narrowing in the esophagus. After gently pushing the fish forward, a smooth one cm stricture with surrounding edema and erythema was seen. Immediately proximal and contiguous with the stricture was an area of velvety, dark pink mucosa (figure 1). Biopsies were consistent with heterotopic gastric mucosa. The stricture was dilated with Savory dilators and the patient was started on pantoprazole. Six months later he remains asymptomatic.
Discussion: An “inlet patch” is an island of heterotopic gastric mucosa located in the proximal esophagus, within 3 cm of the upper esophageal sphincter. It can be recognized by its salmon-red, velvety mucosa with well-defined margins. The inlet patch was first described by Schmidt in 1805, and can be found in 2–4% of adults undergoing upper endoscopy. Its etiology is most likely congenital, and it very rarely has any clinical significance. There are, however, case reports of complications of inlet patches, including peptic strictures, overt bleeding, esophageal perforation, tracheoesophageal fistula, and even adenocarcinoma. Multiple studies have demonstrated that the parietal cells of an inlet patch can secrete a clinically significant amount of acid, and it is this acid which likely results in the complications described. By presenting this case, we hope to raise awareness that inlet patches can sometimes be clinically significant, and we remind the gastroenterologist of the importance of inspecting the proximal esophagus, which can be easily overlooked, when performing endoscopy for upper gastrointestinal symptoms.

Intestinal lymphangiectasia (IL) refers to dilated enteric lymphatics associated with impaired lymph drainage. In its most advanced and diffuse form, it can present as protein losing enteropathy. In very rare cases it can cause intestinal bleeding. Capsule endoscopy is a useful tool in initial diagnosis as it can present as protein losing enteropathy. In very rare cases it can cause intestinal bleeding. Capsule endoscopy is a useful tool in initial diagnosis as

![Figure 1](image)

Intestinal lymphangiectasia (IL) refers to dilated enteric lymphatics associated with impaired lymph drainage. In its most advanced and diffuse form, it can present as protein losing enteropathy. In very rare cases it can cause intestinal bleeding. Capsule endoscopy is a useful tool in initial diagnosis as it can present as protein losing enteropathy. In very rare cases it can cause intestinal bleeding. Capsule endoscopy is a useful tool in initial diagnosis as it can present as protein losing enteropathy. In very rare cases it can cause intestinal bleeding. Capsule endoscopy is a useful tool in initial diagnosis as it can present as protein losing enteropathy.

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Double-Balloon Enteroscopy To Complete Gastroscopy through a Redundant Ileo-Colonic Interposition

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Double-balloon enteroscopy (DBE) provides access to regions of small intestine that can’t be reached by standard techniques. DBE can also reach other areas that are inaccessible to standard endoscopy. DBE has been used to complete colonoscopy in difficult cases, for endoscopic retrograde pancreatography though Roux-en-Y anastomoses, to reach excluded stomach after Roux-en-Y bypass surgery, and to access bypassed or blind loops of small intestine. We used DBE to reach the stomach of a patient with a redundant intestinal interposition after standard endoscopy was not successful.

Case: A 61 year old man presented with recurrent acute gastrointestinal hemorrhage. Lye ingestion at age 16 led to esophageal strictures, and ileo-colonic interposition for esophageal replacement. Recurrent stricturing and dysfunction led to a revision surgery, with part of the interposition. Symptomatic dysfunction of the interposition led to multiple upper endoscopies over the years, but none of these had reached the stomach. The interposition had become redundant, creating a series of sigmoid loops proximal to the stomach. When he presented with acute gastrointestinal hemorrhage, upper endoscopy was performed to identify the bleeding source. Multiple attempts were made by different endoscopists, using gastroscopes and colonoscopes, but on each procedure, an area of angulation and looping was reached at 50 cm, beyond which advancement was not possible. The stomach was never reached, and a bleeding source was not seen. The Fujinon EN-450T5 double-balloon enteroscope and overtube system were then used for upper endoscopy. The balloons helped to shorten redundant loops, and the overtube was used to limit looping. The enteroscope identified an esophago-enteric anastomosis at 18 cm, an enterocolonic anastomosis at 50 cm, a colo-gastric anastomosis at 80 cm from the mouth, and a partial gastrectomy with two limbs of small intestine attached to the stomach. Both limbs of small intestine were intubated for over 20 cm. There was diffuse hemorrhagic gastritis, without other obvious bleeding sites. The interposition of intestinal segments to replace the esophagus can create redundant intestinal loops making it difficult to reach the stomach or duodenum using standard endoscopy. The overtube and shortening maneuvers used for double-balloon enteroscopy may be useful to gain endoscopic access to regions that are made inaccessible to standard endoscopy by esophageal replacement surgery.

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Autoimmune Enteropathy Mimicking Celiac Disease in an Adult

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Acute GI Bleeding from Focal Duodenal Lymphangiectasia

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Intestinal lymphangiectasia (IL) refers to dilated enteric lymphatics associated with impaired lymph drainage. In its most advanced and diffuse form it can present as protein losing enteropathy. In very rare cases it can cause intestinal bleeding. Capsule endoscopy is a useful tool in initial diagnosis as well as in determining the full extent of disease. Here we present a case of bleeding lymphangiectasia localized by capsule endoscopy to the distal duodenum. Surgical resection was curative. A 62 year-old healthy male presented with 1 week of melena and fatigue. He denied NSAID use, liver disease, or GI symptoms. Vital signs were stable. Physical exam was remarkable only for pallor; there was no ascites or edema. Admission labs were remarkable for hematocrit 13% (mean corpuscular volume 74 fL), absolute lymphocytes 700/μL, sodium 126 mmol/L, and albumin 3.1 g/dL. Platelet count, coagulation studies, creatinine, total bilirubin, transaminases, and urinalysis were all within normal limits. EGD revealed a large hemorrhagic cluster of white papules in the distal duodenum. Biopsy was normal. CT revealed no mass lesion of the pancreas or duodenum. Subsequent small bowel barium study and colonoscopy were normal. A diagnosis of duodenal lymphangiectasia was made. His hyponatremia was attributed to syndrome of inappropriate antidiuretic hormone (SIADH). Repeat hematocrit after two months was 21% (MCV normal). Sodium and albumin remained low (130 mmol/L, 3.4 g/dL). Repeat EGD showed no change in the lesion. Biopsy confirmed lymphangiectasia. Capsule endoscopy was ordered to evaluate the distal small bowel for additional pathology. The segment of white papules was identified in the distal duodenum with red blood seen just distal to the lesion. The remaining small bowel was normal with no evidence for diffuse intestinal lymphangiectasia. Push enteroscopy confirmed active oozing and the area was tattooed. Segmental proximal small bowel resection was performed. Intestinal Lymphangiectasia is a rare condition. Here we describe a case of acute GI bleeding from focal duodenal lymphangiectasia. Capsule endoscopy confirmed localized disease and surgical resection provided definitive cure.
Autoimmune enteropathy (AE) is a rare entity initially described in children with a history of diarrhea, malabsorption, and small bowel villous atrophy. These patients are unresponsive to dietary restrictions, such as a gluten free diet. This entity although uncommon has been reported in adults. We report a case of a patient who ultimately met the criteria for AE.

**Case:** A 57 year old male who was previously healthy presented with several months of weight loss and diarrhea. His family history was significant for a nephew with celiac disease. The work-up included an upper endoscopy with biopsies, which revealed villous atrophy (figure 1). A 48 hour fecal fat showed evidence of malabsorption. Celiac serologies were tested and were all negative. A gluten free diet was started, but after several months he showed no improvement and continued to lose weight. A CT scan of the abdomen showed colonic thickening, but colonoscopy and biopsies were negative. Capsule endoscopy showed non-specific focal areas of erythema in the jejunum. HLA DQ2/HLA DQ8 haplotypes were negative making the diagnosis of celiac disease unlikely. T-cell receptor gene rearrangement was checked by PCR and was not detected and ruled out enteropathy associated T-cell lymphoma. The patient met the clinical criteria for AE and was started on a course of prednisone resulting in resolution of his symptoms.

**Discussion:** In patients who have a clinical presentation of celiac disease with seronegative markers who are unresponsive to gluten free diet it is important to consider AE after enteropathy-associated T-cell lymphoma has been ruled out. AE is a chronic disease of the bowel with a similar presentation to celiac disease, which is responsive to immunosuppression therapy. [figure1]

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**Metastatic Melanoma Initially Diagnosed with Double-Balloon Enteroscopy in a Patient with Recurrent Gastrointestinal Bleeding**

Seth A. Gross, MD, Mark E. Stark, MD.* Gastroenterology and Hepatology, Mayo Clinic, Jacksonville, FL.

Evaluation of the small bowel has drastically improved with the introduction of capsule endoscopy, which is helpful in identifying small bowel pathology. However, capsule endoscopy is limited as it doesn’t allow biopsy or interventions. Double-balloon enteroscopy (DBE) is able to reach most abnormal areas seen on capsule endoscopy, and has the benefit of allowing diagnostic and therapeutic interventions. We report a case of metastatic melanoma initially diagnosed with biopsy of a small intestine mass during DBE.

**Case:** A 73 year old man presented with 5 days of melena and hemoglobin (Hb) of 11.9 g/dl, one month after having a normal physical exam, Hb, and screening colonoscopy. His bowel movement returned to normal and the bleeding appeared to have stopped, and no further evaluation was done. 8 weeks later he had another episode of melena and the Hb was 10.8 g/dl. Upper endoscopy showed antral gastritis and duodenitis, but no signs of bleeding. Capsule endoscopy showed bleeding in the distal small intestine, without a definite source. Physical exam was normal, except for hemoccult positive stool. Because capsule endoscopy suggested the bleeding source was in the distal small intestine, DBE was performed through the colon and ileocecal valve, using the Fujinon EN-450TS system. 70cm proximal to the ileocecal valve a hemorrhagic mass (3–4 cm diameter) was identified. Biopsies were obtained, and showed a malignant neoplasm. Special stains were positive for S100 and HMB45, consistent with a metastatic melanoma. The patient underwent a laparoscopy with partial small bowel resection to remove the bleeding tumor. Despite careful skin examination, a primary lesion was not found. Staging evaluation showed other metastases in the liver, chest, bones, and brain. He was treated with chemotherapy.

**Discussion:** Malignant melanoma involving the GI tract may be primary or metastatic, the latter being more common. Melanoma is the most common tumor with metastatic spread to the GI tract. Clinical presentation varies and can include bleeding, weight loss, obstruction, or malabsorption. In the past the diagnostic test of choice was enteroscopy, which is limited since histopathology can’t be obtained and surgery would be the next step for definitive diagnosis. This case illustrates the usefulness of DBE in diagnosing small intestine pathology that is not accessible to conventional endoscopy.
Hepatic Schistosomiasis Post-Liver Transplantation: Case Report of Severe Reactivation
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A number of parasitic infestations have been reported in immunocompromized individuals and in solid organ transplant recipients. However, allograft schistosomiasis after liver transplantation has not been previously reported. A 50-year-old gentleman underwent living donor liver transplantation (LDLT) for end stage liver disease secondary to hepatitis C. He had past history of schistosomiasis during childhood, and during pre-transplant evaluation had no schistosoma ova on stool examination or on rectal biopsy, and had low titer schistosoma antibodies. His donor was his 25-year-old blood group identical nephew, with no history of schistosomiasis and no schistosoma ova on similar evaluation. The explanted liver showed features of fibrosed old schistosoma lesions, and donor graft biopsy at time of transplant showed no evidence of schistosoma infection. The post-operative course was uneventful, and the patient was discharged on tacrolimus immunosuppression with normal liver tests. Six months post-LDLT he presented with abnormal liver tests (AST 290 IU/L, ALT 350 IU/L, alkaline phosphatase 173U/L, GGT 155 U/L). Serology showed high titer schistosomal antibodies, and positive soluble egg antigen. He reliably denied re-exposure to schistosomiasis. Liver biopsy showed schistosoma ova surrounded by bilarharzial granulomatous hepatitis, with mild endothelialitis and interface hepatitis. The patient received praziquantel 60mg/kg, which was followed by normalization of AST, ALT and GGT, reduction in antibody titer, and soluble egg antigen becoming negative. Reactivation of schistosomiasis following organ transplantation is possible, even with past infection that could have been inactive with low egg deposition due to the host immune response. Active schistosomiasis should be considered as one of the etiologies of transaminitis in liver transplant recipients coming from endemic areas.

Schwannoma of Colon — A Case Report
Adil M. Choudhary, MD, * Shams Tabrez, MD, Frederick French, MD. Division of Gastroenterology, Digestive Disease Institute, Roswell, NM.

CASE: We present the case of a 70 year old woman with history of hypertension, hypothyroidism, and breast cancer who was referred for routine colon cancer screening. She denied any change in her bowel habit or blood in her stools. She had no abdominal pain, nausea or vomiting. There was no history of any weight loss. Physical examination was completely normal. She underwent a colonoscopy which was remarkable for a 2 mm polyp in mid sigmoid colon which was biopsy was cauterized and biopsied. No other abnormalities were noticed except for small internal hemorrhoids. Biopsies from this polyp came back showing spindle cell proliferation within the lamina propria. Immunohistochemistry studies were done to further characterize the nature of this spindle cell proliferation with S-100, smooth muscle actin, and CD 117. The spindle cells were strongly positive for S-100 and negative for smooth muscle actin and CD 117. These findings were suggestive of a peripheral nerve sheath tumor such as a Schwannoma, which is an uncommon tumor of GI tract. Gastrointestinal stromal tumor (GIST) is excluded by the positivity of S-100 and negativity of CD 117. The patient later underwent a CT abdomen and pelvis which was completely normal. A repeat colonoscopy 4 weeks later did not show any residual polyp. The patient declined any surgical intervention.

Discussion: Schwannomas are rare tumors derived from the cells of Schwann that form the neural sheath. The tumors commonly present as polypoid intraluminal lesions, often with mucosal ulceration. Rectal bleeding, colonic obstruction and abdominal pain are sometimes presenting symptoms. All Schwannomas are strongly positive for S-100 protein. Even though most schwannomas are considered benign there are case reports of malignant schwannomas. Some authorities recommend radical excision with wide margins, due to their tendency to recur locally and become malignant, if left untreated.

Prophylactic Laparoscopic Total Gastrectomy for Hereditary Diffuse Gastric Cancer
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Introduction: Ten percent of gastric cancer (GC) cases are familial. Of the familial cases, one-third results from a mutation in the tumor suppressor gene CDH1, which normally encodes for a transmembrane protein, E-cadherin. The loss of E-cadherin leaves patients at high risk for developing diffuse gastric cancer. These individuals with 'hereditary diffuse gastric cancer’ (HDGC) have a high mortality if early diagnosis is not made. Despite its clear genetic origin, optimal management of HDGC family members is controversial. The utility and efficacy of current cancer screening programs for mutation carriers are unproven, which has given credence to the recommendation for prophylactic gastrectomy. We report the first prophylactic laparoscopic total gastrectomy.

Case Report: A 53 year-old Caucasian woman was referred to our clinic for a family history of gastric cancer. After an extensive pedigree analysis, it was apparent that her family had an autosomal dominant form of diffuse gastric cancer. The patient was asymptomatic, had no past medical history and her exam was unremarkable. She had the CDH1 gene mutation. Previous upper endoscopies with gastric biopsies were normal. After genetic counseling, she elected to undergo a prophylactic laparoscopic hand-assisted total gastrectomy. The gross specimen appeared normal. Microscopically there were 11 foci of invasive adenocarcinoma limited to the lamina propria in a background of diffuse (signet ring cell) adenocarcinoma in-situ. She had return of bowel function by day 3 and was discharged home on postoperative day 4. More than one-year after the surgery she is disease free and doing well.

Discussion: Genomics is playing a greater role in clinical medicine, as exemplified by our case, in which a patient with a CDH1 mutation within a family of HDGC underwent prophylactic laparoscopic gastrectomy. Despite the normal-appearing stomach, there were many microscopic foci of adenocarcinoma. Thus, the surgery was curative. Our case highlights the importance of taking a thorough family history and obtaining a pedigree analysis. In addition, it is evident that endoscopic screening in HDGC cannot rule out diffuse GC, as the stomach and biopsies can be normal despite the presence of adenocarcinoma. Therefore, our case supports the recommendation for prophylactic gastrectomy in HDGC. Furthermore, we report that successful prophylactic gastrectomy can be accomplished laparoscopically.

Upper Extremity Venous Thrombosis after Infliximab Therapy
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Introduction: Infliximab is a chimeric anti-TNF-α antibody that is effective in the treatment of inflammatory bowel disease. The reported side effects are mild in most cases. Of the infrequent side effects, potentially serious infections such as tuberculosis get the most attention in clinical practice. Vasculitis has also been reported, and there may be an increased rate of lymphoma or other malignancies. There have been a few reports of venous thrombosis in patients on infliximab therapy, but it is not yet considered a potential side effect. Herein, we report a
case of a young woman who suffered an upper extremity venous thrombosis while receiving infliximab therapy.

**Case Report:** A 34-year-old woman with a history of severe Crohn's colitis presented with pain on the dorsal aspect of her right forearm that began 4 days prior to presentation. The pain was progressively worse and associated with swelling and redness of the right forearm and wrist. The patient received an infliximab infusion in the same extremity 3 days before onset of symptoms. Her medications included fentanyl, methadone, mesalamine, and infliximab. She was a non-smoker and was not taking contraceptives. On physical examination, the skin on the dorsal aspect of the right forearm was tender, warm and erythematous. Lab tests showed normal white blood cell count, platelets, PT, PTT, D-dimer and homocysteine level. Bilateral upper extremity duplex ultrasound showed thrombosis of the right cephalic vein. She was admitted for observation and treated conservatively with warm compresses. A follow-up ultrasound was performed and showed chronic right cephalic vein thrombus with no evidence of progression, and her symptoms improved over 4-5 days. The exact relationship between infliximab and thrombosis remains to be determined. Studies have shown that anti-TNF-α antibodies block the procoagulating effect by blocking the generation of thrombin. However, whether or not anti-TNF-α antibodies have a paradoxical procoagulating effect is not known. Infliximab was potentially responsible for our patient's complication given the temporal relationship of thrombosis development and infliximab therapy, absence of other risk factors, and the occurrence of thrombosis in an unusual site. Physicians should be aware of venous thrombosis as a possible complication of infliximab therapy.

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**MRSA Hepatic Abscess Complicating Crohn’s Disease**

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Hepatic abscesses are a known rare complication of inflammatory bowel disease (IBD) with just over sixty reported cases. Most cases have occurred in patients with active Crohn's disease and the diagnosis is often delayed due to the misdiagnosis of an IBD exacerbation. The majority of abscesses are due to a single organism; however Staphylococcus aureus is a very rare cause. We present what we believe is the first reported case of a Methicillin-resistant Staphylococcus aureus (MRSA) hepatic abscess in a patient with Crohn's disease. A 33 year old man with a six year history of ileocolonic Crohn's disease, status post ileocolonic resection, and noncompliance with Crohn's medications due to financial concerns presented with a four day history of subjective fever and right upper quadrant pain. He was diagnosed with a "Crohn's exacerbation" and discharged on antibiotics and steroids. He returned two days later with a documented fever to 102 degrees and worsening pain. Our initial evaluation revealed tenderness to deep palpation in the right upper quadrant and normal liver function tests including transaminases and bilirubin. An ultrasound showed a 5 by 7 cm multilobular fluid collection in the right lobe of the liver consistent with an abscess. Subsequently, a CT scan confirmed this cystic lesion and revealed thickening of the terminal ileum. Blood cultures and ultrasound guided aspirate of the fluid collection grew MRSA. The patient was placed on intravenous vancomycin and a surgical consultation was obtained to determine the most appropriate drainage technique. A percutaneous drain was placed by the radiologist into the abscess with eventual clearance of the infection. The exact etiology of hepatic abscesses in IBD often remains obscure. Biliary sepsis is an uncommon source for these patients. The factors thought to cause abscesses in this group of patients include: intra-abdominal abscesses, fistulization, perforation, abdominal surgery, steroid treatment, malnutrition, and portal bacteremia. We believe this is the first reported case of MRSA causing a liver abscess in a patient with Crohn's disease. As MRSA becomes more prevalent, we are likely to see more cases in the future. Treatment would consist of antibiotics and drainage.

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**Venous Thrombosis and Cirrhosis Complicating Hepatic Sarcoidosis**

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Sarcoidosis is a multisystem granulomatous disorder of unknown etiology. Hepatic involvement by granulomas is common but cirrhosis and portal hypertension are rare (each <1%). We describe a patient with sarcoidosis involving the liver and bone marrow who presented with cirrhosis, portal hypertension, and thrombosis of the IVC, portal, and hepatic veins. A 33-year-old Caucasian man was diagnosed 8 years ago with sarcoidosis involving only the liver and bone marrow. Liver biopsy at that time revealed chronic inflammation, fibrosis, and multifocal noncaseating granulomas with negative fungal and AFB cultures. Bone marrow biopsy showed multiple granulomas as well. The patient was treated with steroids and methotrexate. He presented again in 2005 with fever, edema, and splenomegaly. Labs showed wbc 2.1 K/mcL, hemoglobin 11 g/dL, platelets 94 K/mcL, total bilirubin 1.6 mg/dL, albumin 2.5 g/dL, alkaline phosphatase 229 U/L. Transaminases and INR were normal. The repeat bone marrow biopsy again demonstrated multiple granulomas. An abdominal CT scan revealed cirrhotic-appearing liver, recanalized paraumbilical vein, marked splenomegaly (22 cm), multiple venous collaterals, esophageal varices and thrombosis of the portal vein and IVC but no ascites. Additionally, Duplex ultrasound showed thrombosis of the right and left hepatic veins but patent middle hepatic vein. An IVC venogram showed a non-obstructing thrombus at the level of the right renal vein. The entire work up for a hypercoagulable state and other possible etiologies of chronic liver disease was negative. An EGD revealed grade 2 esophageal varices and portal hypertensive gastropathy. The patient was treated with prednisone, beta-blocker for esophageal varices, and Lovenox for the extensive thrombosis. Sarcoidosis with cirrhosis and extensive thrombosis of the IVC, portal, and hepatic veins is uncommon. Pathogenesis of cirrhosis and portal hypertension in patients with sarcoidosis is not well understood. Cirrhosis may be caused by ischemia of the liver parenchyma due to primary vascular injury by granulomatous phlebitis with or without thrombosis, or may be a result of bile duct destruction by granulomas ("biliary type" cirrhosis). Portal hypertension in sarcoidosis may occur as a complication of cirrhosis, as a result of portal granulomas compressing the small portal veins, or due to granulomatous phlebitis (± thrombosis) of the portal or hepatic veins.

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**Pancreatic Adenocarcinoma Presenting as a Duodenocolic Fistula**

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**Introduction:** Malignant duodenocolic fistulas have been well described, with the majority arising from colon cancer. To date, only 3 cases of duodenocolic fistulas secondary to pancreatic adenocarcinoma have been reported in the English literature.

**Case Presentation:** A 72-year-old female presented with 6-weeks of progressive epigastric pain, nausea, febrile emesis, and diarrhea containing undigested food. Dehydration, and a 40-pound weight loss accompanied these symptoms. Initial lab studies revealed pre-renal azotemia, hemoglobin of 7.1 gm/dL, microcytosis, and iron deficiency. CT scan showed marked thickening of the duodenum, adjacent loop of small bowel and ascending colon, without liver abnormalities or lymphadenopathy. Upper endoscopy demonstrated a malignant-appearing duodenocolic fistula from the distal duodenal bulb to the distal ascending colon. Biopsies revealed high-grade adenocarcinoma, staining CK 7 positive, and CD 20/CDX2 negative, favoring a non-colonic source. Endoscopic ultrasound demonstrated a circumferential, irregular hypoechoic mass at the duodenal bulb without biliary or pancreatic duct dilatation, liver lesions or adenopathy. The patient underwent a Whipple procedure with right hemicolectomy, and right nephrectomy.
The gross specimen revealed a 9.5 × 8.0 × 8.0 cm ulcerated, fungating lesion originating in the pancreatic head and extending to the proximal duodenum, adjacent right colon, and right renal capsule. Microscopic examination revealed a moderately differentiated acinar cell carcinoma that stained positive for alpha-1-antitrypsin and antichymotrypsin. Lymphatic vessel invasion was present. The surgical margins and regional lymph nodes were uninvolved, including the celiac axis and superior mesenteric artery.

Discussion: We report a rare case of pancreatic cancer associated with duodenocolic fistula. Malignant duodenocolic fistulas are unusual and often arise from colon cancer. The symptom complex that developed in our patient is typical for these fistulas. We suggest availability of a pancreatic surgeon for duodenocolic fistulas, as was required in our patient.

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Spontaneous Necrosis of Colonic Polyps
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It is known that not all colonic polyps inevitably progress though the Morson polyp cancer sequence. The reasons behind this failure of progression remain unclear. One possibility is that some polyps may undergo spontaneous necrosis because of mechanical damage (such as torsion about the stalk) or outstripping their blood supply. We report two cases of spontaneous necrosis of a colon polyp. These cases occurred over a 9 year interval during which time 30000 colonoscopies were performed at our academic medical center.

Case 1: A 64 yr old WM was noted on a screening flexible sigmoidoscopy to have a 1 cm pedunculated polyp in the sigmoid colon. Biopsy was deferred and the patient was scheduled for total colonoscopy and polypectomy 31 days later. At the time of the follow up colonoscopy, the same polyp had a black, necrotic appearance and biopsy of the lesion confirmed that the polyp was necrotic.

Case 2: A 88 yr old WM underwent colonoscopy to evaluate hematochezia at which time a 5cm black, mobile mass with a leathery consistency was noted in the sigmoid colon. Biopsies were obtained and India ink was injected into the colonic wall to identify the area prospectively. Biopsies revealed necrotic tissue. Repeat colonoscopy 6 weeks later showed a small area of granulation tissue at the site of the tattoo; the previously noted mass was absent. We therefore report for the first time spontaneous necrosis of colonic polyps in 2 patients. This may be a rare event or one that is not reported or is unrecognized. The natural history of polyps is measured in years and the process of necrosis is one of only a few days. Thus the chances of visualizing the process of necrosis at colonoscopy are extremely small—2/30000 (0.006%) colposcopic exams. The mechanisms by which the process occurs remains unclear but likely involve failure of the blood supply. Similarly, we can only speculate on how frequently such an event occurs, but may be an important phenomenon to study in trying to further understand the adenoma-carcinoma sequence.

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Gastrointestinal Amyloidosis Presenting as Irritable Bowel Syndrome
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Primary amyloidosis is a rare disease which can present with a myriad of gastrointestinal symptoms. We present a patient with symptoms consistent with constipation predominant irritable bowel syndrome (IBS) who was ultimately determined to have gastrointestinal amyloidosis.

Case Report: A 40 year-old woman presented with complaints of long-standing gas, bloating, abdominal discomfort, and constipation associated with nausea. Her abdominal discomfort was exacerbated by stress and relieved by defecation. Occasionally, she reported small amounts of red blood per rectum after defecation. Her physical examination was unremarkable. Routine laboratory data and celiac serologies were within normal limits. Colonoscopy was normal and a benign appearing 0.5 cm sigmoid polyp was removed and sent for pathologic examination. The preliminary diagnosis was constipation predominant IBS. However, further examination of the polyp by both light and electron microscopy with congo red staining was consistent with amyloidosis. An additional work-up for cardiac, pulmonary, or renal involvement was negative. Primary amyloidosis is a rare chronic plasma cell disorder characterized by extracellular deposition of protein. Unlike our patient, most cases are diagnosed once the disease has reached advanced stages and rapidly progress to multi-organ failure. We propose that our patient developed intestinal dysmotility related to amyloidosis and therefore presented with complaints of bloating and constipation. The clinical manifestations of GI amyloidosis can be mistaken for other disease processes such as the irritable bowel syndrome. The endoscopic appearance also varies widely, as our patient developed a polypoid lesion related to amyloid deposition. Despite the high prevalence of the irritable bowel syndrome, clinicians must maintain a high index of suspicion for gastrointestinal amyloidosis in order to make the correct diagnosis and treat patients accordingly.

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Metastatic Prostate Cancer Presenting as Mediastinal Lymphadenopathy Identified by Endoscopic Ultrasound with Fine Needle Aspiration
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Introduction: Since the advent of endoscopic ultrasound (EUS) more than 25 years ago, it has become increasingly used for a myriad of indications. EUS is very helpful to diagnose and stage cancers originating from or in close proximity to the gastrointestinal tract, using fine needle aspiration (FNA) for tissue sampling when necessary. Mediastinal lymphadenopathy is most commonly caused by non-small cell lung cancer and lymphomas, but sarcoidosis and some infections also have a predilection for this location. Prostate cancer, on the other hand, is an uncommon cause of mediastinal lymphadenopathy. In the evaluation of mediastinal lymphadenopathy, computed tomography (CT), magnetic resonance imaging (MRI), and positron emission tomography (PET) are typically used for imaging, while mediastinoscopy, bronchoscopy or CT-guided percutaneous transthoracic needle biopsy (PTNB) are used for tissue sampling. Herein, we report the first case of metastatic prostate cancer identified by EUS with FNA of mediastinal lymph nodes (LNs).

Case Report: A 73 year old white man with known prostate carcinoma with bone metastasis treated with hormone and chemotherapy presented with shortness of breath. He smoked 1 pack of cigarettes daily for many years. His physical examination was unremarkable. Labs revealed mild anemia, thrombocytopenia and persistently elevated but stable PSA. CT of the thorax showed multiple mediastinal LNs and a right pleural effusion with interlobular septa and peribronchial thickening. These findings were concerning for lung cancer or lymphoma. He underwent upper EUS with FNA of a mediastinal lymph node. Cytology revealed adenocarcinoma consistent with prostate origin.

Discussion: Adenocarcinoma of the prostate is the second most common carcinoma in men. It most often metastasizes to regional lymph nodes and bones by hematogenous or lymphatic spread. Metastases to supradiaphragmatic nodes are rare, seen more commonly in patients with advanced stages, but 0.6–14% of patients with metastatic prostate cancer may present with mediastinal adenopathy initially. The utility of EUS-FNA as a diagnostic modality for mediastinal adenopathy has not been well known among physicians. Our case emphasizes the applicability of EUS with FNA in the evaluation of mediastinal LNs, and given the accuracy and safety of EUS, it should be integrated in the existing algorithms as a routine diagnostic procedure.
The Risk of Developing Cervical Neck Radiculopathy in Endoscopists as a Consequence of GI Procedures
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Cervical Neck Radiculopathy can be aggravated or caused by hyperextension or hyperflexion of the Cervical Spine. During the endoscopic procedures, frequently the endoscopist is not aware that this is occurring. The incidents of cervical radiculopathy are higher than most gastroenterologists realize. The positioning of the endoscopist in relation to the patients, i.e. the height of the stretcher, the distance from the patient to doctor, along with the height of the monitor are all important factors that need to be considered to help lessen the risk of developing cervical neck radiculopathy. The use of leaded vests during fluoroscopic procedures, for example ERCP, is obvious contributing factor contributing to Cervical Neck Radiculopathy. The added weight on the neck will contribute to developing cervical neck problems. Positioning of the endoscopist, in relation to the patient and to the height of the stretcher and monitor are often factors that are overlooked or not realized. Use of the monitor, at or below eye level. Use of the stretcher at level of the belt line. Along with, close distance within 3/4 of an arms length, help to avoid over extension of the neck. The monitor should be positioned near the head of the patient. Cervical Radiculopathy in the endoscopist is more common than often realized. The risk of developing it can be lessened by proper positioning of the equipment, patient, and physician.

Sidepocket in Esophagus
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80-year-old man presented with history of recurrent aspiration pneumonias. He reported a five year history of intermittent regurgitation and dysphagia with solids and liquids. Barium swallow showed a large epiphrenic diverticulum, and dilated esophagus with narrow gastroesophageal junction. Esophageal manometry showed absence of peristalsis, and incomplete relaxation of lower esophageal sphincter (LES), consistent with achalasia. He received botulinum toxin injection to LES with only temporary relief. He successfully underwent laparoscopic diverticulectomy, myotomy and fundoplication. His dysphagia resolved and he had no recurrence of aspiration pneumonia. Dysphagia is a common problem. It is generally recommended that barium swallow be done initially, which evaluates both structural and functional causes of esophageal dysphagia. Epiphrenic diverticula occur in the distal 10 cm of esophagus and are associated with high contraction pressures within esophagus together with impaired LES relaxation. Large symptomatic epiphrenic diverticula are seen rarely and management is usually dictated by symptoms and patient’s co-morbidity. Botulinum toxin injection to LES may be tried first. Pneumatic dilatation of LES is contraindicated in this context as it can easily perforate the diverticulum. If initial treatment improves LES pressure, the diverticulum may be left alone. If diverticulum is particularly large and continues to collect liquid and contribute to repeated aspiration, surgical intervention is usually considered. With advent of laparoscopic surgery with its lower post operative morbidity and mortality, it is now possible to perform surgery in many patients. Surgery usually combines diverticulectomy with myotomy, which is thought to reduce the risk of post operative esophageal leak, and fundoplication, an anti-reflux measure. [figure1]

Novel Use of Doppler and High Frequency Ultrasound Probe for Non-Ulcer Gastrointestinal Bleeding
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Case 1: 69-year-old female with atrial fibrillation presented for evaluation of iron deficiency anemia. EGD showed a 1 cm polyp in the cardia with some heme oozing from the tip of the polyp prior to any intervention (Fig 1). Since heme was noted, a 12 MHz miniprobe (Olympus Corp., Center Valley, PA) was used to further examine the polyp. There was a 1 mm anechoic space within the polyp consistent with an underlying vessel with intact muscularis propria beneath the polyp (Fig 2). After injection of normal saline and 5 cc of 1:20000 epinephrine, polypectomy was done. Three endoclips were placed at the polypectomy site. The patient had no bleeding post-procedure. The presence of a vessel in the polyp on miniprobe exam potentially helped in management of this patient leading to more aggressive prophylactic endoscopic treatment to prevent bleeding complications.

Case 2: 72-year-old male presented for evaluation of iron deficiency anemia. EGD had changes consistent with Bilroth II and erythema and erosions at the anastomotic rim which were biopsied. Persistent oozing was noted
from the biopsy site requiring bipolar probe therapy. Patient returned with hematemesis and had 3 subsequent EGDs with endoscopic therapy due to persistent bleeding from the biopsy site. An Endoscopic doppler probe (VTI DOP-US, Vascular Technology, Nashua, NH) assessed for underlying vessels and noted arterial pulsations. As a result, epinephrine was injected and multiple clips were placed. After therapy, repeat Doppler probe assessment revealed no pulsation. Therefore it was felt successful hemostasis was achieved. The patient had no further bleeding. This case demonstrates the value of Doppler probe assessment that guided more aggressive endoscopic hemostasis efforts in a patient having persistent bleeding after a biopsy.

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Endoscopic Treatment of a Hypopharyngeal Perforation Using a Polyflex Self-Expanding Plastic Stent
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A 69 year-old male came to ENT clinic complaining of dysphagia. He was diagnosed with cancer of the hypopharynx one year prior. Treatment consisted of combined chemoradiation therapy. His course was complicated by pharyngeal stenosis resulting in dysphagia. This was initially managed with an unguided 60-F Maloney bougie dilator. Five months later the patient returned with dysphagia. Repeat laryngoscopy revealed no distinct mass or stenosis, yet a decision was made to empirically dilate the hypopharynx. There was significant resistance while attempting to pass a 60-F bougie. The patient had severe chest pain after the procedure. An upper GI series showed hypopharyngeal dissection starting above the suprasternal notch. The false lumen extended to the distal 1/3 of the esophagus where contrast extravasated into the pleural space. In the OR, the false lumen of the esophagus was identified and the distal perforation exit was repaired with sutures. A drain was left in place within the false lumen with its tip 5cm distal to the proximal site of perforation. Following surgery, an EGD was performed to place a covered stent at the proximal perforation site. The UES was identified at 16cm, and a 10mm perforation site was identified at this location. A Polyflex (Boston Scientific) self-expanding plastic stent (20mm X 16mm) was placed with the proximal phalange at 15cm (Fig. 1, 2). The stent was well-tolerated with minimal discomfort, and the output from the drain lessened. Twelve days later the stent was removed and an esophagogram demonstrated healing of the perforation site. The patient was started on a clear liquid diet, and tolerated oral intake without symptoms. [figure1][figure2]

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Stretta Antireflux Procedure for the Successful Management of Severe and Unusual Regurgitant Problems
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Criticism of Stretta is often based on less than dramatic improvements in traditional endpoints and an uncertainty if the effect has truly improved reflux or just its perception. Herein are reported several circumstances of severe regurgitant phenomena improved dramatically by Stretta.
Case 1: A 69yo WM with COPD and severe neurologic dysphagia post CVA. Despite 100% tube feeding via PEG with PEJ conversion, repeated aspiration pneumonia occurred every 6 weeks. PPI's bid, and prokinetics were ineffective in preventing aspirations. A 24 hr pH study was strongly positive with Johnson/DeMeester scores of 42.8 and symptom related probability for regurgitation of 99%. Three mo post Stretta the patient was symptom free of reflux or regurgitation. 40 mo s/p Stretta their have been no documented aspirations, and only one hospitalization at 39 months for a left sided pneumonia.

Case 2: A 58yo WF s/p left pneumonectomy for bronchiectasis wakening with choking and sensation of stomach contents in her throat. Episodes were followed by severe respiratory infections in her remaining lung despite antireflux measures, PPI and prokinetics. Stretta was performed to protect her remaining lung. Regurgitant symptoms and aspiration related pulmonary infections ceased. At 55 mo post Stretta, the patient has avoided aspiration related pulmonary infection.

Case 3: A 59yo WF with GERD diagnosed with asthma at age 39. Asthma required 4 inhaled medications. Asthma occurred upon PPI cessation, and significant symptoms occurred 2 to 3 days per week despite bid PPI. Stretta was performed March 2001. At 6 mo, asthma symptoms abated, the patient was off PPI's using only one inhaler. Five years p Stretta no asthma exacerbation events have occurred. The GERD-HRQL score improved from 36 at baseline to 4.

Case 4: A 74yo WF s/p Billroth II gastrectomy, vagotomy with alkaline reflux esophagitis c/o positional cough and choking. UGI showed reflux of barium to the thoracic inlet. Stretta was performed 1/2/02 with marked improvement in regurgitant symptoms. GERD-HRQL score: 28 at baseline to 9 at 6 mo and to 1 at 12 mo. These cases illustrate the utility of the Stretta for the management of regurgitant phenomena. The desired outcomes were difficult in each circumstance, yet achieved in each case. Success could not have been a result of any sensory neurolytic effect. These cases provide a basis for additional study of the effect of Stretta on GERD induced regurgitant phenomena, including GERD-related asthma.

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Inflammatory Pseudotumor Mimicking Invasive Esophageal Cancer on Endoscopic Ultrasound: A Report of Two Cases
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Benign inflammatory esophageal masses, often termed 'pseudotumors', are an uncommon entity that can present like esophageal cancer. This case report describes two cases of benign inflammatory pseudotumors.

Case 1: A 66 year old male presented with hematemesis and solid food dysphagia. EGD revealed a mass in the distal esophagus. Biopsy showed granulation tissue with an eosinophilic infiltrate but no evidence of malignancy. EUS revealed a hypoechoic mass extending through the muscularis propria and pathologic-appearing celiac, peritumoral and subcarinal lymph nodes (T3N1M1a). After two months of ranitidine therapy, EGD and EUS showed complete resolution of the lesion.

Case 2: A 61 year old male presented with 3 months of solid food dysphagia. EGD with biopsy revealed Barrett’s mucosa with inflammatory atypia without dysplasia in the distal 10 cm of the esophagus. The patient was placed on omeprazole, but his dysphagia persisted and repeat EGD in 6 weeks showed distal esophageal narrowing with a linear ulcer. Ulcer biopsy showed acute and chronic inflammation within Barrett’s mucosa, indeterminate for dysplasia. EUS revealed a hypoechoic mass at the ulcer site that invaded through the muscularis propria; no pathologic-appearing lymph nodes were noted (T3N0M0). EGD 4 months after initial presentation revealed persistence of the ulcer despite omeprazole therapy. The patient was referred for esophagectomy, and final pathology showed only acute and chronic inflammation with microabscess formation within Barrett’s mucosa.

Discussion: Distinguishing between inflammatory pseudotumors and esophageal cancer can be difficult. Both lesions appear malignant by endoscopy and EUS, and because esophageal cancer can have significant peritumoral inflammation, the clinician may worry the negative pathology is due to sampling error, especially when EUS is suggestive of an invasive process or of nodal metastases, and do not want to delay cancer therapy. Because of the high malignant potential, the management of a refractory Barrett’s esophageal ulcer or pseudotumor can be especially challenging. Diagnosis of pseudotumors requires a high index of suspicion and histopathologic exclusion of other benign and malignant esophageal disorders, as these processes can look malignant on EUS.

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Spontaneous Acute Mediastinitis Secondary to Rupture Esophageal Diverticula in Patient with Esophageal Diverticulosis
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A 69yo WM with COPD and severe neurologic dysphagia post CVA. Despite 100% tube feeding via PEG with PEJ conversion, repeated aspiration pneumonia occurred every 6 weeks. PPI’s bid, and prokinetics were ineffective in preventing aspirations. A 24 hr pH study was strongly positive with Johnson/DeMeester scores of 42.8 and symptom related probability for regurgitation of 99%. Three mo post Stretta the patient was symptom free of reflux or regurgitation. 40 mo s/p Stretta their have been no documented aspirations, and only one hospitalization at 39 months for a left sided pneumonia.

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We are presenting a patient who had spontaneous perforation of esophageal diverticulosis with limited mediastinitis. The patient is a 45-year-old white male who presented with fever, hypoxemia, and chest pain. He was in a good state of health until one month before presentation, when he developed solid food dysphagia with emesis (on one occasion). Three days prior to presentation he developed right sided chest pain, with radiation to back. The pain worsened and became associated with SOB. CT was negative for PE. The patient’s pain intensified further, requiring him to be transferred to our hospital. Upon arrival he exhibited the following signs and symptoms: fever, chest discomfort, red throat, and decreased breath sounds to auscultation on the right. Remainder of PE was negative. Repeat CT of the chest with contrast showed air in the mediastinum but no contrast leak. Patient was started on broad spectrum antibiotics, esophagram with gastrografin and barium showed no extra-luminal leak but multiple diverticula in the esophageal wall (Figure 1). Patient underwent thoracentesis with removal of inflammatory fluid. Patient was placed on liquid diet and he continues to improve with conservative therapy and he was discharged home. Endoscopy 6 weeks later confirmed the presence of the diverticulosis (Figure 2). The patient remained symptoms free 4 months after initial presentation. Diffuse intramural esophageal diverticulosis is a rare entity that was first described in 1960. Multiple cases have been reported, most of them presenting with dysphagia, this case is unique because the initial presentation was with mediastinitis and the patient was treated conservatively with good result. [figure1] [figure2]

Tongue and Colon MALT Lymphoma with No Other GI Involvement
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Colonic MALT lymphoma has a lesser occurrence than stomach MALT lymphoma. Here we are reporting a case of tongue and colon MALT diagnosed simultaneously without any other GI involvement. The patient is an 82-year-old female presenting with several months of mild oropharyngeal dysphagia, along with a “tickling” sensation in the left throat area. Upon physical exam, she was found to have a tumor at the base of the tongue. A CT of the neck revealed a 3 × 3 cm mass in the left oropharyngeal region with extension to the left side of the larynx. The biopsy was consistent with a low grade B-cell lymphoma, MALT type, strongly positive to CD20. PMHx: Asthma, HTN, hiatal hernia. appendectomy, cholecystectomy, hysterectomy and history of PUD, 5 years ago treated with triple H. Pylori therapy. PE was remarkable for a tongue lesion surrounded by erythema. Labs: Normal CBC. The patient underwent a PET scan for staging, which was positive in the neck and colon. Colonoscopy was performed, which demonstrated an ulcerated friable mass at the base of the cecum (Figure 1). A biopsy from the area was consistent with the same MALT tumor (CD 20 positive). (Figure 2). Patient also underwent an EGD and capsule endoscopy, both of which yielded negative results, she was H. Pylori (−). Patient undergoing treatment with the radioimmunotherapeutic with Tositumomab and Iodine I 131 Tositumomab (Bexxar). Colonic MALT lymphoma represents 2.5% of all GI MALT’s. It has the endoscopic appearance of a single mass. This case is unusual because of the presence of MALT lymphoma in two different unrelated locations in the GI tract. [figure1] [figure2]

Duodenal Outlet Obstruction Caused by Abdominal Aortic Aneurysm with Dissecting Hematoma
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Duodenal obstruction as the presenting symptom of AAA is quite uncommon, having been reported only about 20 times since Osler first described it in 1905. These AAAs are invariably large (usually >6cm) or rapidly expanding. Definitive treatment is repair of the AAA. The aim of this case report is to recognize the presentation of duodenal outlet obstruction and to understand its workup and differential diagnosis. An 83 year old male with a history of coronary artery disease, peripheral vascular disease, and chronic renal insufficiency was well until 2 months prior, when he developed post-prandial nausea and vomiting. He had associated abdominal distention and discomfort and a 10 pound weight loss. Abdominal exam revealed a soft
abdominal bruit without succussion splash, palpable mass, or distention. Laboratory parameters were normal. Enteroscopy revealed a distended duodenum. In the third portion there was an eccentric narrowing that could not be passed, with no pulsatile activity. Biopsies showed denuded mucosa. A small bowel series showed a distended duodenum and a partial obstruction in the horizontal portion of the duodenum (1). Changing position did not alleviate the obstruction. MRA showed a 4.8cm abdominal aortic aneurysm (AAA) with a chronic longitudinal dissection with hematoma (2a) compressing the duodenum (2b). Given his multiple co-morbidities, vascular surgery was deferred, and the patient underwent a duodeno-jejunostomy. He did well post-operatively and was discharged tolerating a full diet without symptoms. The aortic relationship to the duodenum gives rise to compression and fistulization; with the aging American population, we must recognize these effects. Compression can occur from the aneurysm itself or secondary to an associated hematoma, as in this patient’s case. [figure1][figure2]

Large Solitary Ovarian Metastasis from Colorectal Cancer Diagnosed by EUS and Not by CT Scan

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46 yr female had a colonoscopy revealing an obstructing circumferential mass at 15cm. Biopsies showed an invasive rectal adenocarcinoma. CT scan demonstrated a large rectal mass. EUS performed for staging showed a hypoechoic mass that was suspicious for a T3 lesion with penetration through the muscularis propria into the adventitia. An 8mm oval peri-tumorous lymph node was also visualized which was suspicious for malignant invasion. Inferior to the mass, EUS visualized another extra-rectal hypoechoic mass with anechoic areas. The mass measured about 5cm and was seen in the peri-rectal area (Figure 1) Laparoscopic colorectal surgery was performed and revealed a moderately differentiated rectal adenocarcinoma. Another pelvic mass was also noted (consistent with EUS findings) and found to be an ovarian metastasis (Figure 2). EUS was able to demonstrate a second
mass not otherwise visualized on CT. The surgeon was alerted of the EUS finding prior to the planned laparoscopic colectomy. Based on this finding, the surrounding area was explored for a second mass and a pelvic tumor was found. On retrospective review of the CT pelvis after surgery the radiologist could still not diagnose the ovarian lesion separate from the primary rectal tumor due to their close proximity. However, on EUS we were able to clearly see on real-time imaging that there was a distinct peri-rectal mass apart from the primary rectal tumor. This case demonstrates the value of EUS. Since though not common, an ovarian metastatic lesion was detected. Combining information from imaging modalities such as CT and EUS may be even more important when minimally invasive surgical techniques are employed for cancer surgery to provide the surgeon with the maximal amount of pre-operative information. [figure1][figure2]

Role of EUS with FNA in Subepithelial and Peri-Rectal Masses
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Rectal subepithelial lesions are less frequently encountered than UGI lesions. EUS with FNA has been less frequently utilized for rectal subepithelial and peri-rectal masses compared to UGI, mediastinal and pancreaticobiliary masses. We present 5 patients who had EUS with FNA for further differentiation of a subepithelial or peri-rectal mass noted on endoscopy or cross sectional imaging.

Case 1: 62 yr female presented with RLQ pain with a 2 × 3 cm pararectal mass seen on CT. EUS showed a 4 cm complex mass with hypoechoic and anechoic components. FNA revealed a moderately differentiated adenocarcinoma suggestive of ovarian or endometrial origin. Surgical pathology confirmed a moderate to poorly differentiated papillary serous adenocarcinoma consistent with an ovarian primary.

Case 2: 60 yr old female had EUS of a rectal submucosal mass noted on MRI. On endoscopy, a submucosal mass was seen close to the anal verge. On EUS, a 5 × 7 cm hypoechoic mass with internal echogenic foci and cystic spaces was noted. It appeared to be contiguous with the muscularis propria. FNA was consistent with gastrointestinal stromal tumor (GIST) and was c-kit positive. Subsequent surgery confirmed the diagnosis.

Case 3: 40 yr male with AIDS had large mass on CT scan extending from prostate to the pelvic wall causing rectal compression. EUS showed a large hypoechoic mass which measured 5 × 4.5 cm. All five layers of the rectal wall appeared intact. Transrectal EUS revealed malignant cells consistent with a B-cell lymphoma.

Case 4: 33 yr male diagnosed with a T3 rectal adenocarcinoma was also noted to have a submucosal indentation which was distal to the mass. EUS showed a hypoechoic lesion measuring 5.5 × 4.5 cm contiguous with the muscularis propria. EUS FNA demonstrated an adenocarcinoma that masqueraded as a GIST. Surgery confirmed this diagnosis.

Case 5: 55 yr male had a rectal submucosal lesion with areas of erythema. EUS showed a hypoechoic to isoechoic lesion measuring 3.2 cm located in the submucosa. FNA demonstrated fibroadipose tissue consistent with a lipoma. Due to the atypical EUS and endoscopic findings, the patient underwent surgery which also revealed a lipoma. Our case series includes various lesions presenting as subepithelial masses including ovarian cancer presenting as a pararectal mass, anorectal GIST, lymphoma, adenocarcinoma with a subepithelial component, a rectal lipoma with atypical features. EUS with FNA is an important modality to differentiate subepithelial and peri-rectal masses.

Small Bowel Pseudopolyps: A Unique Finding on Capsule Endoscopy in a Patient with Crohn’s Disease
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Small bowel pseudopolyps in association with inflammatory bowel disease have rarely been reported. We report a case of small bowel pseudopolyps initially seen on capsule endoscopy and confirmed on laparoscopy in a patient with Crohn’s Disease.

Case Report: A 72 year old woman with a 13 year history of Crohn’s disease primarily involving the ileum complained of progressive weight loss, anorexia, fatigue, and lower abdominal discomfort. Her past medical history includes chronic obstructive pulmonary disease and ischemic cardiomyopathy. Her Crohn’s disease had been managed medically; she was receiving Budesonide 6 mg daily and 6-MP 50 mg daily. The patient had a 54+ pack year history of tobacco use but had discontinued tobacco 7 years ago. Physical exam revealed a frail woman with a normal abdominal and rectal exam. Laboratory studies were remarkable for a normocytic anemia with a Hb of 10.7 g/dL (11.5–15.5) and a mildly elevated ESR 45 mm/hr (0–30). The albumin was 2.0 g/dL (3.5–5.0); the comprehensive metabolic panel was otherwise within normal range. Colonoscopy and CT scan of the abdomen and pelvis were unrevealing. Due to the persistent abdominal pain and weight loss, a capsule endoscopy was performed. In the distal small bowel, areas of nodular mucosa, granularity, edematous villi and small ulcers were seen. In addition, a nodular mass was visualized in the distal small bowel. A CT guided enteroclysis study confirmed a polyloid lesion in the distal ileum in addition to a mild stricture and thickening of the distal ileum. The patient underwent a laparoscopic ileocolic resection which revealed multiple pseudopolyps with ulcerated areas of the small bowel ranging in size from 0.2 to 1.5 cm in diameter. Additional pathologic findings were consistent with active Crohn’s ileitis. There are scant reports of small bowel pseudopolyps in association with inflammatory bowel disease. As the histologic analysis of this patient’s pseudopolyps are indistinguishable from large bowel pseudopolyps, we infer that there is no malignant potential but rather the pseudopolyps may be the result of chronic, active inflammation. This case also illustrates the diagnostic impact of newer small bowel imaging techniques such as capsule endoscopy and CT enteroclysis.

Primary epiploic appendagitis is a relatively uncommon condition caused by torsion and infarction of the appendages epiploicae of the proximal or distal colon. The resultant inflammatory response leads to a localized area of right or left sided lower abdominal pain. The condition may mimic acute appendicitis or diverticulitis. However, epiploic appendagitis is typically a self-limited condition which does not require surgery.

Case Report: A 35 year-old man presented to the office complaining of the acute onset of left lower quadrant pain for 3 days. He denied fever, chills, nausea, vomiting, relationship to food or position, change in bowel habits, or blood in the stool. Physical exam was remarkable for a focal area of severe tenderness in the left lower quadrant. Complete blood count, basic chemistry panel, and hepatic panel were within normal limits. CT of the abdomen revealed focal thickening of the wall of the proximal sigmoid colon with hazy pericolonic fat planes; within the center of the inflammatory changes was a focus of fat, consistent with epiploic appendagitis. With conservative treatment, his pain resolved within one week. Nearly 4 months later, the patient returned with the complaint of similar left lower quadrant abdominal pain. Physical exam, laboratory data, and CT of the abdomen were consistent with recurrent epiploic appendagitis in the region of the sigmoid colon. Again, the patient was treated conservatively and his pain resolved. Due to the recurrence of presumed appendagitis, a colonoscopy was performed which was unremarkable.
We report a case of recurrent epiploic appendagitis which responded to conservative treatment. However, for patients who develop recurring appendagitis, surgical options which involve ligating and resecting the inflamed appendage may warrant consideration. Fortunately, our patient responded to conservative treatment despite the recurrence.

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Hepatitis B Virus DNA Suppression with Entecavir Therapy in a HBsAg-Negative Decompensated Chronic HBV
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Entecavir has not been approved for the treatment of chronic hepatitis B (HBV)-related cirrhosis. Hence, we recommend a large randomized clinical trial of entecavir among patients with decompensated HBV-related cirrhosis. It appears that entecavir is safe to use among patients with decompensated cirrhosis. Post-transplant outcome without having any drug-related complication. It was treated with entecavir 0.5 mg daily and had a significant reduction in HBV DNA, but maintained high bilirubin and INR with ascites. Since his clinical status did not improve (MELD Score 40) despite having significant reduction in HBV DNA with entecavir therapy, he underwent cadaveric liver transplantation. He has complicated postoperative course including intra-abdominal bleeding and a repair of anastomotic bile duct. However, with the continued use of entecavir and hepatitis B immunoglobulin including other immunosuppressive agents after transplantation he maintained non-detectable HBV DNA with normalization of transaminases after 12 weeks post-transplantation.

Discussion: There is no data in literature on entecavir for the treatment of chronic HBV-related decompensated cirrhosis. However, entecavir is much more effective compared to lamivudine for the treatment of chronic HBV with well compensated liver disease and has no drug-related resistance after 1 year of therapy among naive patients. To the best of our knowledge, this is the first report to show the effectiveness of entecavir in suppressing HBV DNA in a chronic HBV-related decompensated cirrhotic patient with successful post-transplant outcome without having any drug-related complication. It appears that entecavir is safe to use among patients with successful HBV-related cirrhosis. Hence, we recommend a large randomized clinical trial of entecavir among chronic HBV patients with decompensated cirrhosis.

Table.

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Chlamydia Trachomatis – An Unusual Cause of Proctitis and Lower Gastrointestinal Bleeding

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Introduction: Chlamydia trachomatis (C. trachomatis) is an uncommon infectious agent in the lower gastrointestinal (GI) tract but can account for up to 20% of proctitis in homosexual men. The diagnosis is often missed or delayed because symptoms and pathology can often mimic inflammatory bowel disease (IBD). Case: A 23 year old previously healthy African-American male presented with a 6 month history of constipation and intermittent rectal pain. The patient had experienced intermittent bright red blood per rectum for 4 weeks and fatigue/weakness for 2 days. On presentation, he was orthostatic with the following lab values: Hgb 7.0g/dL, MCV 82fl, iron 5mcg/dL, ferritin 1ng/mL, TIBC 387mcg/dL and Fe saturation 1.3%. The patient was stabilized and underwent colonoscopy which showed deep, exudative ulcers from the anal verge extending to 8cms. There was significant, circumferential edema and erythema associated with luminal narrowing. The remainder of the colon and terminal ileum appeared normal. Biopsies of the affected area revealed acute ulceration, cryptitis, crypt abscess and glandular dropout most consistent with inflammatory bowel disease (IBD). Viral, bacterial and stool cultures, special stains for CMV and HSV and OP were all normal. Rectal biopsies for C. trachomatis were eventually found to be positive. At admission, the patient denied sexual activity. After C. trachomatis was isolated, the patient revealed that he engaged in homosexual anal-receptive intercourse. The patient was treated with a course of doxycycline with symptom resolution. Discussion: The differential diagnosis of lower GI bleeding is quite broad. While inflammatory and vascular etiologies are most common, infectious causes must be ruled out. This is especially true of young patients without previous history of GI symptoms. C. trachomatis is an uncommon cause of lower GI bleeding which can mimic IBD in gross and microscopic appearance and delay proper treatment. Our patient’s age, symptoms and initial biopsy results all appeared to support the diagnosis of IBD. Had C. trachomatis not been sought, this patient may have been improperly treated long term for IBD. Significant barriers often exist in obtaining an accurate history, including social fear and poor patient-physician rapport. Therefore, clinicians need to have a high index of suspicion for sexually transmitted diseases in patients presenting with proctitis.

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An Unusual Presentation of Gastrointestinal Bleeding from a Brunner’s Gland Hamartoma Located in the Distal Ileum
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A 95 year old man was admitted with multiple episodes of painless hematochezia. Laboratory on admission: HCT 24%, Hb 7.9 g/dL, MCV 80 fl, ferritin 15 ng/ml and iron 23 umol/L. Both normal as were liver tests and coagulation profile. A nuclear medicine bleeding scan also showed no evidence of active bleeding. Colonoscopy revealed scattered wide mouth diverticulosis of the sigmoid colon with maroon colored liquid stool in the area of the cecum and the terminal ileum. A wireless capsule endoscopy showed no active bleeding in the stomach, jejunum and the very proximal ileum. However, the capsule did not reach the cecum after 7.5 hours. Subsequently an abdominal plain film failed to visualize the capsule. Small bowel series was repeated and a long tubular filling defect was identified in the distal ileum. A second wireless capsule endoscopy was performed and identified a polypoid mass with surface ulceration in the distal ileum. Colonoscopy was performed to localize and attempt removal of the lesion. A 3 cm polypoid lesion with superficial ulcerations was located 12cm proximal to the ileocecal valve but was unable to be endoscopically removed. The patient underwent surgical resection of the terminal ileum. The surgical pathology specimen revealed a 4.0 cm polyp shaped like a staghorn antler with a tubular stalk and three polypoid branches. Several areas on the tips of the branches of the polyp appeared hemorrhagic and ulcerated. Microscopic examination revealed that the polyp was lined by specialized small intestinal epithelium.
with edematous villi, and several hyperplastic appearing glands. Underlying this epithelium were multiple nests of Brunner’s glands. In the center of the polyp there was fibrous tissue and thick walled vessels feeding each branch of the polyp. The diagnosis was a Brunner’s gland hamartoma (BGH). This is the first report of a distal ileal Brunner’s gland hamartoma causing lower GI bleeding. The majority of reported BGH are located in the proximal small bowel, the duodenal bulb (57%), D2 (27%), D3 (7%), in the jejunum (2%), and proximal ileum (2%). The clinical presentation of BGH varies. The main clinical manifestations are obstruction, GI bleeding, abdominal pain, nausea and vomiting, and anemia. Up to 50% are asymptomatic. Signs of GI bleeding occurs in 61% of patients (melana 43%, hematemeses 13%, occult positive 11%). Brunner’s gland hamartoma of the distal ileum must be added to our list of benign mass lesions causing lower GI bleeding.

583  Affect of One Dose of Zegerid® on a 4 Day pH Study in a Trauma Victim
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A 29 yo male presented with complaints of pyrosis and periodic dysphagia for > 5 years despite use of OTC medication. Endoscopy and two 48-hour periods of monitoring esophageal pH using the Bravo™ System were arranged: 48 hours off all medications, followed by an additional 48 hours after one dose of Zegerid® (omeprazole/sodium bicarbonate). The pH study demonstrated a DeMeester score of 60.2 while the patient was not taking antisecretory therapy. The total time pH <4 was 15.7% with total symptomatic reflux events being 68. [figure1] At 0700 on the third day the patient took Zegerid. After one dose of Zegerid the DeMeester score decreased from 60.2 (baseline off-treatment value) to 24.2. Total pH time <4 decreased to 8.1% and symptomatic reflux events were only noted one time. At 2300 the patient was in a MVA and sustained a lower extremity fracture. The following day (day 4), while in the OR for ORIF of the fractured leg, esophageal pH was not monitored from 10:30 until 1415. During that period the patient was started on pantoprazole 40 mg IV BID. On day four his DeMeester score was 12.9. His esophageal pH study on Zegerid and Pantoprazole is as follows: [figure2]

Discussion: This is a case of significant GERD documented with 4 days of ambulatory esophageal pH monitoring. After just one dose of Zegerid the patient had marked improvement in symptoms and DeMeester score. This study was performed during a stressful situation including trauma and confinement to the recumbent position. Data was not recorded while the patient was in the OR. The study demonstrates nearly 23 hours with a pH >4 following a single dose of Zegerid 40 mg. Comparable esophageal acid control is seen with intravenous Pantoprazole 40 mg BID. This case study demonstrates nearly 23 hours of esophageal acid control after one dose of Zegerid Oral Suspension. The potential for an oral PPI to be used effectively in a hospitalized patient instead of an IV PPI has been demonstrated and warrants further investigation.

584  Extensive Intrahepatic Cholelithiasis with Large Biliary Abscesses in Primary Sclerosing Cholangitis
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Primary sclerosing cholangitis may have an aggressive course, requiring liver transplantation early in life. We report here a patient first diagnosed with primary sclerosing cholangitis at 12 years of age who underwent liver transplantation at age 25. A 24-year-old male was referred for liver transplant evaluation because of primary sclerosing cholangitis complicated by
The Endoscopic Appearance of a Gastrointestinal Stromal Tumor in a Pediatric Patient

Pramoda Muniyapppa, MD, Marsha Kay, MD, Pediatric Patient

Gastrointestinal Stromal Tumor (GIST) is a mesenchymal tumor that is rare in children. We report a case of GIST in a pediatric patient presenting with melena, anemia and gastric submucosal masses. A 16 year old female presented after an episode of syncope preceded by one episode of melena. Physical exam was normal except for hemoccult positive stool. Labs included a Hgb of 6.1 g/dl; CMP and coagulation studies were normal. She was transfused with 2 units of PRBC and emergent EGD was performed. EGD demonstrated 3 submucosal sessile masses in the gastric antrum ranging in size from 1–3 cm with normal overlying mucosa except for one of the lesions, which was ulcerated. Endoscopic biopsies stained positive for CD 117 and were consistent with GIST. Radiologic workup with CT, MR, and PET imaging demonstrated the endoscopically visualized masses. MRI and PET imaging also revealed a solitary 1 cm lesion within the liver. She underwent partial gastrectomy and open biopsy of the hepatic lesion. Histology confirmed GIST with hepatic metastasis. She received postop chemotherapy consisting of Imatinib Mesylate, and has done well without disease recurrence with a follow up of nine months. Typically with GIST, EGD will demonstrate a normal surface mucosa and a firm, smooth, yellowish submucosal mass, which can be ulcerated. In some cases these tumors can be missed because of their frequent submucosal and extraluminal growth. This case, to our knowledge, is one of the first reports of the endoscopic appearance of GIST in a pediatric patient. Endoscopic ultrasound (EUS) is an important aid to differentiate submucosal masses seen by EGD. By EUS GISTs will typically have a hypoechoic appearance and will originate from the muscularis propria. EUS was unnecessary in our patient because the biopsies obtained by EGD were deep enough to provide a pathologic diagnosis. Although a rare entity in children, we conclude that the possibility of GIST should be considered in pediatric patients with endoscopically visualized submucosal gastric masses.
A Combined Medical-Surgical Approach for Treatment of Fulminant CD Colitis Due to Clostridium difficile

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The incidence of Clostridium difficile (CD) colitis is rising, perhaps due to the use of antibiotics and proton pump inhibitors, and clinicians will likely see more complex cases of CD colitis. In case series, mortality following subtotal abdominal colectomy to treat patients with fulminant CD colitis ranges up to 100%. Colostomy formation has been suggested for intervention in toxic megacolon, and intravenous (IV) immunoglobulin has been suggested for treatment of fulminant CD colitis. We present a case of fulminant CD colitis in which the patient improved after combining these 2 approaches to develop a new treatment strategy.

Case: This is a 21-year-old female with congenital HIV (CD4 count: 102) on HAART therapy. During a recent hospitalization at another facility for a fungal jaw infection, diagnosis of CD colitis was made by both stool toxin examination and colonoscopy. She received oral vancomycin and was discharged 5 days prior to this hospitalization. She presented with worsening of diffuse abdominal pain and diarrhea; she had a fever of 102.3°F with a heart rate of 138; on abdominal examination she had diffuse abdominal tenderness with voluntary guarding. Leukocytosis was found with a white blood cell count 18,000 with 41% bands. She received metronidazole orally and IV, as well as vancomycin orally and via enemas. Abdominal CT scan revealed pancolitis with cecal thickening. After 24 hours megacolon was not present on abdominal x-ray series. Progression was supported by persistant fever, abdominal pain, voluntary guarding and rebound tenderness; surgery was suggested. A loop ileostomy was performed in which a loop of ileum was brought to the skin. A Foley catheter was placed into the cecum and vancomycin was instilled through this catheter. She received vancomycin enemas and IV and oral metronidazole. On post-operative day 1, she received a dose of IV immunoglobulin at 400 mg/kg. During the next 7 days, her illness resolved with no further fever, diarrhea, or abdominal pain.

Discussion: This case report supports the notion that formation of a diverting loop ileostomy and topical antibiotic therapy into the cecum in combination with IV immunoglobulin is an effective and safe treatment for select individuals with fulminant CD colitis. This new paradigm appears promising because it involves a less invasive surgical procedure with reduced mortality.

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Polycystic Ovary Syndrome (PCOS) and Non-Alcoholic Steatohepatitis (NASH) – An Emerging Population for the Hepatologist?

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Polycystic ovary syndrome (PCOS), one of the most common hormonal disorders affecting women, has an estimated prevalence of 5–10%. Many patients have an elevated body mass index (BMI), and the pathogenesis is related to androgen excess and insulin resistance. Nonalcoholic steatohepatitis (NASH) is characterized by hepatic steatosis, inflammation, and fibrosis. While the cause of NASH is unknown, it is also associated with insulin resistance, female gender and an elevated BMI. There is no documented association in the literature between PCOS and NASH. Given that PCOS patients suffer from insulin resistance and an elevated BMI, it stands to reason that this population may be at risk for significant steatohepatitis. Furthermore, as PCOS patients tend to be young, an early diagnosis of NASH may have therapeutic benefit, as treatment could slow the progression of hepatic inflammation and fibrosis. Two outpatients highlight the importance of recognizing this at-risk population. AR, a 30-year-old female with PCOS was referred for elevated liver tests. She had no risk factors for exposure to parenterally transmitted viruses or toxins, and no individual or family history of autoimmune disease. Physical exam was notable for a BMI of 29 kg/m². AST/ALT were 73/103. All other serologic and metabolic studies were unremarkable. Liver biopsy (See figure) revealed significant steatosis, inflammation, and stage 2 fibrosis. AG, a 26-year-old female with PCOS, was also referred for elevated liver tests. Her BMI was 26 kg/m² and her laboratory profile was notable for an AST/ALT of 97/94. All other studies were within normal limits. Liver biopsy revealed significant steatosis, inflammation, and stage 3 fibrosis. Many young women afflicted with PCOS have insulin resistance and are at risk for NASH. The patients highlighted were asymptomatic, as are most when NASH is in its early stages. NASH can lead to end-stage liver disease, and thus, larger studies are warranted to investigate the prevalence, natural history, and therapeutic options for NASH in the PCOS population, to thereby halt progression of hepatic fibrosis in this young population.

Cheilitis Granomatosa: Crohn’s Disease of the Lip?

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To increase awareness of the unusual manifestations of extraintestinal Crohn’s disease by reporting a solitary granulomatous lesion of the lower lip in a patient with Crohn’s colitis. A biopsy of the lower lip was taken from a patient with active Crohn’s disease who complained of swelling of the lips. A 53 year old female with long standing Crohn’s disease (CD) described several months of discomfort and swelling of the lower lip. Physical examination revealed a fissure of the median line of the lower lip with swelling, that, on palpation, had a superficial granular texture and rubbery non pitting edema. Her serum chemistries, liver enzymes, CBC and CRP were normal. Biopsy of the lip revealed small noncasing granulomas, subepidermal lymphoedema, and inflammatory infiltrates. Cheilitis granulomatosa (CG) or Miescher’s cheilitis, swelling of the lips, was first described in 1945, but its causes remain unknown. Allergic reactions to cobalt or food additives have been implicated. CG may be considered a subtype of orofacial granulomatosis (OFG), which is the chronic swelling of the lips and the lower half of the face with oral ulcerations and hyperplastic gingivitis. Alone it can be viewed as a monosymptomatic variant of the Melkersson- Rosenthal syndrome.
syndrome (facial paralysis, swelling of the face and lips and furrows in the tongue). It has also been noted in systemic diseases sarcoidosis and CD. Only 5% of patients with CD ever develop CG. Pathological specimens may reveal non-necrotizing granulomas, edema, lymphangiectasia, and/or perivascular lymphocytic infiltration. Nevertheless, the diagnosis is made clinically based on a patient’s history, symptoms and physical examination. Some authors believe a topical anesthetic with systemic corticosteroids is the most effective, while others recommend intralernal steroids. Jens recommended local steroid therapy in patients on low dose systemic steroids if OFG occurs without gastrointestinal signs. Surgical intervention may only be considered if the disease in the quiescent stage and there is pronounced disfigurement. Although pathologically, the two entities appear grossly similar, it is unclear what the relationship is between cheilitis granulomatosa and Crohn’s disease. Further immunological, microbiological and histological testing must be performed to delineate the similarities and differences between these two entities and further define their relationship.

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Self-Expanding Silicone Stents for Treatment of Post-Operative Colorectal Stricture in Hirschsprung’s Disease
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Endoscopic stenting of benign colonic strictures is not routinely performed due to possible stent migration, bleeding, and perforation. Options for endoscopic treatment of benign colonic strictures are limited. Removable silicone stents are now used for successful treatment of benign esophageal strictures.

Cases: Two infants (MB) and (AC) underwent Soave pull-through for treatment of Hirschsprung’s Disease. Both patients’ post-operative courses were complicated by rectal strictures. They underwent fluoroscopically guided balloon dilations and then daily dilations. Due to persistent strictures, AC and MB were referred at 11 and 14 months for consideration of stenting. They underwent sigmoidoscopy revealing anastomotic strictures that were dilated and self-expanding silicone airway stents were placed. After three weeks, AC’s stent was removed. Repeat sigmoidoscopy at 10 weeks revealed patent lumen and normal mucosa. MB passed the first three stents within 4 days of placement over a period of 2 months. However he was asymptomatic for the next 6 months. When he represented after six months with increasing constipation and abdominal distension, a 22 mm. x 50 mm. stent was deployed. Sigmoidoscopic stent removal at 4 weeks revealed a widely patent lumen and mucosal erythema. These are the first reported cases of self-expanding silicone stents for the successful management of benign colorectal strictures in children. Resolution of rectal stricture via stenting avoided surgery for the time being. Airway stents were selected because of their smaller diameter and availability in many sizes—ensuring an individual fit. Similar techniques may be used in adults.

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Recto-Prostatic Fistula: A Serious Complication of Radiation Therapy
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Gastroenterologists often care for patients with radiation proctopathy, however, more serious GI complications of radiotherapy can occur.

Case 1: 63 y/o man presented with severe, progressive rectal pain and hematochezia. PMH included chronic renal insufficiency & moderately differentiated prostate cancer treated with brachytherapy & external beam radiotherapy 16 months prior. Sigmoidoscopy revealed a large rectal ulcer communicating with a large cavity [Fig. 1]. Biopsies revealed necrotic tissue without neoplasm. He declined surgery and was treated with osmotic laxatives & analgesics. Over 7 months, recurrent UTIs resulted in worsening renal insufficiency. Pelvic MRI revealed an irregular, 3.5 x 1.2 cm cavity extending from the rectum to the prostate & bladder. He was treated with chronic suppressive antibiotics & definitive surgery was recommended.

Case 2: 70 y/o man presented with severe rectal pain exacerbated uncontrolled despite narcotics & hydrocortisone enemas. PMH included brachytherapy for early-stage prostate cancer 1 yr prior. Endorectal US revealed a large sinus tract extending from the rectum into a deep cavity. Pelvic MRI revealed a 3.0 x 2.5cm air-filled cavity in the prostatic bed [Fig. 2]. Due to intractable pain he underwent laparoscopic sigmoid colostomy. Postoperatively he developed recturia and recurrence of pain. He subsequently underwent abdominoperineal resection, radical cystoprostatectomy & urinary ileal conduit formation.
Teaching Points: 1) Recto-prostatic fistulization is a rare but catastrophic complication of radiotherapy for prostate cancer. 2) Radiation-induced mucosal injury is due to endarteritis with resulting chronic ischemia. In severe cases, ischemic injury is transmural and results in fistula formation. 3) Cancer-therapy related fistulae frequently require aggressive surgical therapy for their management.

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Esophageal Intramural Metastases from Esophageal Adenocarcinoma Associated with Barrett’s Esophagus
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Intramural esophageal metastases from esophageal squamous cell carcinoma and from gastric cardia adenocarcinoma are well described, but have not been reported in esophageal adenocarcinoma associated with Barrett’s esophagus (BE).

A 45 year old man presented with dysphagia, epigastric pain, and a 5 kg weight loss. EGD showed a mass in the distal esophagus (figure 1a) and two nodules in the mid-esophagus (figure 1b). The gastric cardia was uninvolved. There was no evidence of BE above the primary mass. Pathology from the primary mass and the nodules both revealed identical adenocarcinoma. EUS staged the lesion as T3N1. After receiving chemoradiation, his symptoms improved and he gained weight. Follow-up EGD showed no masses. Biopsies from the distal esophagus (figure 2a) revealed BE and from the mid-esophagus (figure 2b) showed squamous mucosa. The midesophageal nodules likely represent intramural metastases as they were not associated with BE and were histologically identical to the primary. The patient went for surgery and a gastric implant of adenocarcinoma was found. Given stage 4B disease, no resection was performed and the patient was offered further chemoradiation.

Esophageal intramural metastases can be seen in 15% of patients with esophageal SCC and 4–11% of patients with gastric adenocarcinoma. This is the first reported case of intramural metastases from esophageal adenocarcinoma associated with BE. The mechanism is likely to be submucosal lymphatic invasion that, as flow stagnates, allows malignant cells to extend into the esophageal wall. Accordingly, most patients have lymph node involvement. As this represents a more advanced stage, the presence of intramural metastases usually portends a poorer prognosis.
Autoimmune Pancreatitis (AIP): A Case Series Illustrating Outcomes and Importance of Early Recognition

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Despite vast amount of knowledge attained regarding the clinical, serological, radiological, and pathological characteristics of AIP, it remains an elusive diagnosis to make with significant repercussions to patients. This report illustrates two patients with this condition.

Patient A: A 79 year-old male presented with painless jaundice. An ERCP was performed and a biliary stent was placed. A 1.2 cm mass adjacent to the common bile duct was seen on EUS. IgG, ANA, AMA, and ASMA were normal. A Whipple’s procedure was performed and revealed no malignancy. He presented two years later with abdominal pain and multiple pseudocysts and pancreatitis was seen on CT. The previous biopsy of the pancreas was reinterpreted as AIP. Prednisone was started, and the patient improved.

Patient B: A 56-year old female presented with epigastric pain. Physical examination and ultrasound were unremarkable. Lipase and sedimentation rate were elevated. Imaging revealed pancreatic changes suspicious for malignancy. Excisional biopsy specimen was consistent with AIP. The patient opted for surveillance and remained asymptomatic for several months. She later presented with an exacerbation, was started on prednisone, and quickly improved. After Sarles’ first description of AIP, similar pathological findings were found in patients with other autoimmune disorders. Our cases demonstrate the all-too-often outcome of diagnosis established only after surgery. Prospectively evaluated diagnostic criteria for AIP do not exist. Serum IgG, specifically IgG4, and positive autoantibodies are suggestive of AIP. Imaging often reveals focal or diffuse parenchymal inflammation. ERCP often reveals irregular narrowing of the main pancreatic duct and absence of lateral branches. Neither imaging nor laboratory findings are specific. Histology demonstrates periductal lymphocytic infiltration and fibrosis. EUS-obtained biopsies provide adequate samples. Although our patients were not diagnosed with AIP prior to surgery, post-surgical review of the specimens supported a later diagnosis of AIP and allowed for proper treatment and follow-up.

- AIP remains an elusive diagnosis.
- Patients who have been diagnosed with idiopathic pancreatitis after surgery may benefit from review of their pathology specimens to exclude AIP.
- As our ability to diagnose AIP improves, more patients will avert unnecessary surgery.

HSV Esophagitis in an Immunocompetent Individual Successfully Treated with Acyclovir

Michael E. Kader, MD, Ashok Shah, MD. Gastroenterology, University of Rochester, Rochester, NY.

An 18-year old male presented to the ED with one week of fever, odynophagia, and increasingly severe substernal chest pain worsened by eating or drinking. The patient was previously healthy and admitted to binge alcohol use on the weekends as well as occasional tobacco use. He initially denied any recent sexual activity. Physical examination revealed a healthy appearing white male in no acute distress. Cardiac as well as gastrointestinal examination was unremarkable. There were no oral or genital ulcerations seen on exam. Laboratory values and tests were unremarkable with pertinent negatives including cardiac enzymes, electrocardiogram, and chest x-ray. Gastroenterology consultation was obtained and EGD was performed. Examination of the esophagus demonstrated a severely inflamed and edematous mid/distal esophagus with numerous punctate ulcers and exudate formation. There was also one area with submucosal hemorrhage. Multiple biopsies were taken and the patient was started empirically on acyclovir and fluconazole given the above findings that were thought to be consistent with a possible viral versus fungal esophagitis. The patient demonstrated a marked improvement over the next 48 hours. Biopsy results revealed marked ulceration with overlying fibrinopurulent exudate. Stains for fungus were negative. Throat cultures were positive for herpes simplex virus. Subsequent HIV serologies were negative. Fluconazole was discontinued and the patient was discharged on a one-month course of acyclovir for HSV esophagitis. At one-month follow-up, the patient was completely asymptomatic. Upon further questioning at this time, he admitted to participating in oral sex with multiple female partners in the prior weeks. HSV esophagitis has been well described in immunocompromised individuals but is rare in the immunocompetent. Acyclovir therapy has been reported as successful in several patients in the pediatric literature with HSV esophagitis as well as one immunocompetent adolescent in the adult literature. In our patient, HSV was likely contracted from a female partner during oral sex. Acyclovir therapy provided a prompt resolution of his symptoms within 48 hours. We conclude that HSV esophagitis should be in the differential diagnosis of odynophagia in sexually active immunocompetent patients and such patients may have a prompt response to acyclovir treatment.
PSV is a chronic inflammatory condition of the oral mucosa often associated with UC. It was first described over a century ago by Hallopeau. Likewise, PSC is an inflammatory hepatobiliary manifestation of inflammatory bowel disease which results in fibrosis and stricture of bile ducts. There are only 5 case reports identifying PSV, PSC and IBD in an individual patient during the last century, however none were ever biopsy-proven and/or imaging-proven cases. We report a patient with confirmed active UC, PSV and PSC.

**Case:** This is a 19 y/o white male with history of bloody diarrhea, weight loss and worsening liver tests. Evaluation via colonoscopy revealed endoscopy and biopsy confirmed universal active UC. MRCP suggested PSC (fig. 1) with confirmatory liver biopsies. One year later, despite therapy with mesalamine (2.4 gm/day), ursodeoxycholic acid (1.7 gm/day) and intermittent prednisone, patient developed uncontrolled UC with multiple oral pustules and superficial ulcerations (fig. 2). Histology of oral lesions revealed an intense neutrophilic inflammatory infiltrate suggestive of PSV, which remained unresponsive to both steroids and antibiotics. Direct and indirect immunofluorescence was negative for pemphigus vegetans. Six months after IV infliximab the patient was free of symptoms. Sigmoidoscopy revealed nearly complete resolution of colitis. Initial liver tests depicted marginal improvement, however, a follow up MRCP depicted interval progression of the intrahepatic biliary stricture.

1. We document co-existance of proven UC, PSC, and PSV.
2. Infliximab therapy was effective treatment for UC and PSV without benefit in PSC during a 6 month observation. [figure1][figure2]

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**Splenic Rupture as a Complication of Colonoscopy**

*Micahael E. Kader, MD,* Ashok N. Shah, MD. *Gastroenterology, University of Rochester, Rochester, NY.*

A 60-year old male with a history significant only for hypertension underwent screening colonoscopy in our institution. The procedure was significant for finding scattered left colon diverticulae as well as removal of 5mm and 1mm sessile sigmoid polyps with hot snare cautery. During the procedure, a moderate amount of sigmoid and left upper quadrant (LUQ) external pressure was used to pass the splenic and hepatic flexures. The patient tolerated the procedure well and was discharged home after an uneventful two-hour observation period.

Several hours after reaching home, the patient developed increasingly severe diffuse abdominal pain as well as dizziness. EMS services reported a diaphoretic, hypotensive male upon arrival. The patient was transported to our institution via ambulance. Examination upon arrival was significant for hypotension and diffuse abdominal tenderness. Hematocrit at this time was 39 with subsequent values falling to 26 without evidence of gastrointestinal bleeding. Free air series was performed which demonstrated air filled colon with no evidence of extraluminal air. Subsequent CT scan demonstrated a 7×1.1cm area of active extravasation of contrast over the LUQ with surrounding hematoma consistent with actively bleeding splenic rupture (see image). The patient was taken to the operating room for emergent splenectomy. Surgical and pathological evaluation demonstrated a capsular tear with no other pathology. His recovery was uneventful.

Splenic rupture is a rare but increasingly reported complication of colonoscopy. To this date, approximately 34 cases have been reported. Reported risk factors include splenic adhesions, excessive traction of the splenocolic ligament during transcolic pressure maneuvers or colonoscopic navigation, and multiple polypectomies. In the above patient, the risk factors included the application of transcolic pressure as well as multiple polypectomies. Clinicians must be aware of this possible complication of colonoscopy for timely diagnosis and management. [figure1]

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**Conservative Treatment of Non-Resolving Pneumoperitoneum after EUS-FNA and EMR by CT-Guided Needle Decompression**
An 83 year old man was seen for EUS evaluation of a gastric antral nodule with high grade dysplasia diagnosed on previous endoscopy. The patient opted to undergo endoscopic resection of the lesion. EUS revealed a 10 mm hypoechoic antral lesion limited to the mucosa which was removed as a single specimen using the cap-EMR technique. The mucosal defect was closed using three clips. An oval hypoechoic lesion in the left lobe of the liver measuring 10 mm x 10 mm was identified on EUS. Three FNA passes were performed with a standard 22ga needle from a trans-gastric approach. Post procedure, the patient complained of abdominal pain, distension, and nausea. An obstructive series revealed a large pneumoperitoneum. The patient was started on IV fluids, antibiotics, and kept NPO. An upper GI series assessing for a perforation site showed no extravasation of contrast. Due to his comorbidities, conservative management was continued since the patient remained stable. On post-procedure day three, a CT scan redemonstrated large persistent pneumoperitoneum without extravasation of contrast. On post-procedure day five, the patient's abdominal discomfort from the pneumoperitoneum was unchanged. As the patient was not a candidate for surgical exploratory laparotomy, a decision was made to attempt to decompress the abdomen via CT-guided percutaneous catheter decompression. The patient was taken to interventional radiology for the procedure. A 6Fr catheter was delivered into the pneumoperitoneum through the anterior wall of the abdomen, until no residual free air was visualized. Before and After CT images are shown in Figure 1A, 1B. Immediately, the patient's abdominal discomfort resolved. Patient remained pain free. Follow up abdominal series showed no free air. He quickly advanced to a general diet, antibiotics were discontinued, and was discharged home. Recognition of non-surgical, or benign pneumoperitoneum may serve to be useful in those patients who are otherwise stable, but do not appear to be spontaneously resolving.

Non-Steroidal Anti-Inflammatory Drug Induced Gastrointestinal Strictures: Two Case Reports
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Non-steroidal anti-inflammatory drugs (NSAIDs) are commonly taken for a variety of pain syndromes. NSAIDs can rarely cause strictures and their prompt recognition is important to effectively manage with endoscopic techniques, thereby avoiding surgical intervention. We report the diagnosis and endoscopic management of two patients who presented with unexplained symptoms of chronic abdominal pain.

Case 1: A 49 year old female with a history of migraine and chronic abdominal pain was admitted to a local hospital with exacerbation of her abdominal pain. CT scan was suggestive of bowel obstruction. EGD revealed a pyloric channel ulcer. Exploratory laparotomy revealed diffuse ileus without mechanical obstruction. She was then transferred to our hospital. Repeat EGD revealed severe pyloric stenosis. Colonoscopy revealed an ascending colon diaphragm with “pin-hole” luminal stricture (Video available). Endoscopic dilation of the pyloric and the colonic stricture was done.

Case 2: A 44 year old female with history of osteoarthritis underwent colonoscopy for chronic abdominal pain. Severe circumferential stenosis was found in the ascending colon that precluded passage of the colonoscope. She was placed on oral Prednisone and a month later repeat colonoscopy with balloon dilation of the stenosis was done with passage of the colonoscope beyond the stricture. Both patients had marked symptom improvement after the endoscopic dilation. They recalled using NSAIDs for migraine and osteoarthritis for several years. Their NSAIDs were discontinued and their pain syndromes are now managed with Non NSAIDs. Diagnosis of NSAID related strictures requires a high index of suspicion for prompt diagnosis and appropriate management. Endoscopic balloon dilation of NSAID induced strictures is an effective and safe mode of treatment, thereby avoiding surgical intervention. [figure1][figure2]
Hepatic artery pseudoaneurysms are rare. Potential causes include blunt or penetrating trauma, liver surgery and far less common, percutaneous interventional procedures, such as biopsy or percutaneous transhepatic cholangiography. We report a case of a hepatic artery pseudoaneurysm secondary to percutaneous liver biopsy with subsequent hemobilia.

**Case Presentation:** A 68-year-old man with chronic Hepatitis C infection was found to have a liver mass on CT scan. The patient had a percutaneous liver biopsy done with pathology revealing moderately differentiated hepatocellular carcinoma. He was subsequently admitted 2 weeks later with complaints of melena and coffee-ground emesis. On admission the patient was found to have a hemocrit of 17% and was transfused with packed red cells. Upper endoscopy revealed grade 2 non-bleeding esophageal varices and a large amount of red blood in the second portion of the duodenum. Celiac and hepatic angiogram revealed a pseudoaneurysm supplied by a branch of the artery supplying the posterior segment of the right lobe of the liver. Also noted was filling of a bile duct adjacent to the pseudoaneurysm consistent with an arterial-biliary fistula. The hepatic artery was embolized using polyvinyl alcohol particles and the follow-up angiogram showed no visualization of the pseudoaneurysm or bile ducts. The patient's hematocrit subsequently stabilized and the bleeding ceased.

**Summary:** Hemobilia can present acutely after simultaneous perforation of intrahepatic bile ducts and blood vessels such as in hepatoma; or, more commonly from gradual erosion of a biopsy-induced hematoma or pseudoaneurysm into a bile duct presenting as massive gastrointestinal bleeding. The diagnostic test of choice is angiography, which offers the advantage of therapeutic embolization at the same time. Surgery is the definitive treatment if nonoperative management fails.

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**Migration of Mesh into Cecum Following Laparoscopic Inguinal Hernia Repair**

David Elijah, MD, Francis Kleckner, MD, Prasad Kulkarni, MD.*
Gastroenterology, James A Haley VA Medical Center and USF, Tampa, FL.

Laparoscopic inguinal hernia repair has gained popularity in the past few decades as the minimally invasive procedure of choice. A variety of techniques are in practice and complications of these are being increasingly appreciated. Migration of surgically placed mesh during laparoscopic inguinal hernia repair into adjoining structures is a rare complication. We report herein the first case of delayed migration of surgical mesh into the cecum.

**Case report:** A 76 y.o. male veteran underwent laparoscopic bilateral inguinal hernia (TEP) repair with bilateral mesh placement in 1996. A screening colonoscopy in 1999 did not report any abnormality in the cecum. In early 2005, patient started having pain in the RLQ-right groin area. CT abdomen revealed persistent, extensive, mass like infiltration of the postsurgical site in the right inguinal region. Differential diagnosis included a chronic infectious or inflammatory process versus extensive chronic post-surgical scarring. Colonoscopy for further evaluation revealed cecal foreign material consistent with migration of previous surgical mesh into the cecum. The patient underwent successful exploration with cecectomy, right hemicolectomy and removal of infected mesh.

**Discussion:** Migration of surgical mesh into adjoining organs after laparoscopic inguinal hernia repair is rare but well-recognized. Reported sites of migration include urinary bladder, scrotum, sigmoid colon but cecal migration has not been reported so far. We review and discuss the possible mechanisms of migration, different clinical presentations, approaches to treatment and preventive aspects of this unique surgical complication that gastroenterologists are increasingly likely to come across.

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**Biliary Sarcoidosis: A Case and Review**

Robert E. Kraichely, MD, Amindra S. Arora, MBBSCh.* Division of Gastroenterology and Hepatology, Mayo Clinic, Rochester, MN.

**Case Presentation:** A 53-year-old gentleman with a history of sarcoidosis presented with right mid-abdominal pain, low-grade fever, nausea, vomiting and anorexia. He had just completed a steroid taper. He was icteric, and pertinent laboratory findings were an elevated bilirubin at 2.6 mg/dl (normal range 0.1–1.0), alkaline phosphatase at 288 IU (normal range 2–144), AST 38 (normal range 12–31), and ALT 49 (normal range 9–29). An ultrasound and CT of the abdomen were unremarkable and did not show biliary dilatation. However, a MRCP demonstrated intrahepatic bile duct dilatation in the left hepatic lobe. The left hepatic duct tapered abruptly without mass or obstructive stone. Percutaneous transhepatic cholangiography demonstrated strictures of multiple segmental intrahepatic bile ducts resulting in mild to moderate dilatation of both the right and left ductal systems. These strictures arose from the hilar region. The extrahepatic duct was patent but diminutive. The patient was placed on antibiotics and prednisone and with resolution of his fevers and decrease of the serum bilirubin. All blood cultures were negative. He had no evidence of inflammatory bowel disease on colonic biopsies.

**Discussion:** Hepatic involvement of sarcoidosis is common, but its presentation is often subclinical and typically presents with elevated alkaline phosphatase and elevated gamma glutamyl transferase. Cholestatic liver disease secondary to sarcoid is uncommon. In addition, reports of bile duct depletion and severe cholestasis with existing sarcoidosis are typically from granulomatous or fibrotic destruction. In this case, a patient with known sarcoidosis developed cholestasis and symptomatic cholangitis within weeks of discontinuing systemic corticosteroid therapy secondary to biliary strictures. Biliary strictures are rare in sarcoidosis, even when hepatic involvement is clinically apparent, but they are nonetheless very important to recognize to guide effective treatment.

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**Fatal CMV Colitis in an Immunocompetent Patient**

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**Case Presentation:** A 44-year-old patient with chronic liver disease presented with severe abdominal pain. He had a history of CMV infection and had been treated with ganciclovir. On admission, he was found to have a liver mass on CT scan. The patient had a percutaneous liver biopsy done with pathology revealing moderately differentiated hepatocellular carcinoma. He was subsequently admitted 2 weeks later with complaints of melena and coffee-ground emesis. On admission the patient was found to have a hemocrit of 17% and was transfused with packed red cells. Upper endoscopy revealed grade 2 non-bleeding esophageal varices and a large amount of red blood in the second portion of the duodenum. Celiac and hepatic angiogram revealed a pseudoaneurysm supplied by a branch of the artery supplying the posterior segment of the right lobe of the liver. Also noted was filling of a bile duct adjacent to the pseudoaneurysm consistent with an arterial-biliary fistula. The hepatic artery was embolized using polyvinyl alcohol particles and the follow-up angiogram showed no visualization of the pseudoaneurysm or bile ducts. The patient's hematocrit subsequently stabilized and the bleeding ceased.

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Cytomegalovirus (CMV) infection of the gastrointestinal tract is a well-known entity in immunocompromised individuals. However, CMV colitis in immunocompetent patients has rarely been reported. The prognosis is usually not good leading to toxic megacolon or death due to multi-organ system failure. We report a case of fatal CMV colitis in an immunocompetent patient. A 66-year-old female with h/o diabetes was admitted with fever for 2–3 days. She denied abdomen pain, vomiting, diarrhea or blood in the stool. Physical exam showed pulse of 110, BP of 180/80 and temperature of 38.6 C. Chest X-ray was negative. WBC was 14.2 with Hb of 13 gm/dl and platelets of 210. GI service was consulted after 3 days when she had maroon stool and bright red blood per rectum. Her Hb dropped from 13 to 9 gm/dl. Colonoscopy showed dark red blood with clots up to the cecum and few sigmoid diverticula. Cecum could not be cleared of blood clots. EGD showed mild antral gastritis with mild distal esophagitis and superficial ulcers in the mid and the distal esophagus. CT abdomen showed rectal wall thickening. HIV test was negative. 2 days later she again had a large episode of bright red blood per rectum. Repeat colonoscopy showed dark red blood with clots in the colon up to the cecum and again cecum could not be cleared of the blood clots. She continued to have rectal bleeding for which she had subtotal colectomy which showed IC valve ulcer with nuclear and cytoplastic inclusion like changes representing CMV on the pathology. Gancyclovir was started but the patient expired 2 days later. Only 44 cases of CMV colitis in immunocompetent patients have been reported so far. Diagnoses in these patients was often delayed because invasive biopsy is necessary to demonstrate the typical “owl eye” intranuclear inclusion bodies of CMV. CT abdomen may reveal colonic wall thickening as was seen in our case. Cecum was the most frequently involved site in HIV patients but in immunocompetent patients sigmoid colon was the most frequently involved site. Higher mortality was among patients with immunomodulating diseases and those requiring surgical intervention as was in our case. CMV colitis although rare in immunocompetent patients should be considered in the differential diagnoses of severe lower GI bleeding when other causes fail to explain the cause of the disease.

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**Plasma Exchange (PE) as Treatment of Hypertriglyceridemia-Induced Acute Pancreatitis (HTGAP)**

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Effective treatment of HTGAP is not clearly established. Immediate drop of TG level is needed which cannot be achieved with low fat diet, lipid lowering agents, pancreatic enzyme replacement and even with heparin and insulin. Although PE has been increasingly used to reduce TG levels during AP, data on its effectiveness is limited. We report 2 cases of HTGAP treated with PE resulting in favorable outcome. Pts 1 & 2 are 27 and 43 yr old females, both prior cholecystectomy admitted with epigastric pain, nausea and vomiting. CT scan showed enlarged edematous pancreas with peri-pancreatic fat stranding and fluid more severe in pt 2. Pancreatic necrosis was not seen. It was recommended that PE be performed within 48 hrs to avoid AP-related complications. PE should be considered as first-line treatment of HTGAP and should be applied as early as possible to prevent progression of inflammation and associated morbidity and mortality.

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**Cecum Adenocarcinoma Protruding through the Anus. Report of an Unusual Case**

Masahiro Shinoda, MD,* Hirofumi Kawakubo, MD, Tetsu Hatano, MD, Tai Imori, MD, Seiichiho Ishii, MD. Surgery, Kawasaki Municipal Hospital, Kawasaki, Kanagawa, Japan.

Intussusception in adults is relatively rare. This can be ileoileal, ileocolic, or colocolic, i.e. the immediate proximal part of the intestine telescoping into the distal portion of the intestine. Here we report a twenty nine-year-old lady with a cecoanal intussusception prolapsing through the anus. She had abdominal discomfort during a year before the onset. She came to our hospital with a complaint of a mass, which was 5 × 3 cm in size, protruding from the anus. She also presented with abdominal distention, abdominal pain, and vomiting. Plain radiographs of the abdomen showed a small amount of gas in the small bowel in the lower part of the abdomen. We pushed the mass back into the rectum and did a barium enema, which demonstrated a filling defect in the rectum at the beginning. The pressure of the barium continued to push the defect to the oral side and at last released the mass originated from the cecum. Her complaints markedly improved after the enema. Endoscopic examination revealed a protruding type tumor, which was 5 × 3 cm in size, in the cecum. Pathological finding of the biopsy specimen was moderately to severely differentiated serrated adenoma. At the subsequent operation, the tumor was confirmed to be originated at the bottom of appendix in the Cecum. Partial resection of the cecum containing the tumor and appendix was performed. Pathological finding of the resected specimen was mucosal well differentiated adenocarcinoma in adenoma. Since we performed the operation through a small pararectal incision, the left side colon was not observed, but the right side colon was observed not to be fixed retroperitoneum. In this case, a 5 × 3 cm cecal tumor served as the leading point of the intussusception and protruded through the anus. Cecoanal intussusception is extremely rare and this adult case presented here is the first one reported in the world scientific literature.

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**Massive Lower Gastrointestinal Bleeding in a Patient Newly Diagnosed with Human Immunodeficiency Virus**

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Neither Cytomegalovirus (CMV) or Mycobacteria tuberculosis (MTb) is commonly associated with massive intestinal bleeding. We present a patient with newly diagnosed HIV infection and MTb who had massive
hematochezia from ileocolic ulcerations found to be positive for CMV and MTb. A 31 year old male with newly diagnosed HIV and pulmonary MTb presents with 2 months of intermittent hematochezia. Initial exam showed no active bleeding. Abdominal CT suggested tuberculous peritonitis. Paracentesis and sputum examination showed acid fast bacteria. Four drug MTb treatment was initiated. Five days later, massive hematochezia occurs with hemodynamic instability requiring 9 units of blood transfusion. Pan-endoscopy showed multiple right colonic and ileocecal ulcers with bleeding proximal to the examined ileum. A right hemicolectomy with ileal resection showed skipped pebble appearing granulomatous lesions in the affected intestine and ulcers with associated omental adhesions. Histologic examination demonstrated cells containing cytoplasmic inclusions consistent with CMV along with AFB positive caseating granulomas. Patient did well post-operatively and he was discharged after 12 days on pharmacologic treatment for MTb and CMV. Massive hematochezia from MTb has traditionally been reported rarely, but recent case series show an incidence of 4–9%. Endoscopic evaluation and histologic demonstration of MTb is the gold standard of diagnosis. Anti-tuberculous medical therapy combined with endoscopic therapy have been reported as successful treatment modalities for tuberculous enteritis or colitis. Surgical therapies are reserved for uncontrollable bleeding, perforation, or obstruction. Common symptoms of intestinal CMV include pain and diarrhea, bleeding is reported to occur in 10% of cases. Severe bleeding is rare. Diagnosis of CMV colitis can be obtained by viral culture, detection of CMV antigen or genome in the tissue, or demonstration of typical cytopathology. Standard medical treatment includes intravenous Gancyclovir or Foscarnet individually or in combination. Octreotide has been reported to halt massive bleeding in case reports. CMV colitis has traditionally been more likely than luminal MTb to be a cause of significant bleeding in patients with advanced HIV, but the incidence of MTb causing massive hematochezia may be rising.

CT Angio and Capsule Endoscopy Correlation in a Patient with Sclerosing Mesenteritis
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We are presenting a patient with sclerosing mesenteritis that underwent CT Angio and capsule endoscopy in an attempt to explain his symptoms. The patient is an 81-year-old male who began experiencing abdominal pain in June 2005, more recently followed by excessive watery stools, vague periumbilical pain, and a significant amount of weight loss. He underwent a CT scan of the abdomen, which demonstrated fullness in the small bowel mesentry. A repeat CT scan, a few months later, showed an increase in this fullness and required a diagnostic open surgical biopsy because of the deep location. The biopsy was consistent with sclerosing mesenteritis.

Successful Paternity of a Healthy Child While Taking Methotrexate for Crohn’s Disease
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Inflammatory bowel disease commonly has onset during a patient’s reproductive years. This leads to the difficulty of achieving disease control with medications that allow for a successful and healthy conception. The efficacy of the different medications used for treatment of inflammatory bowel disease has been established in women for use during pregnancy. Methotrexate is one of these medications. Due to the known teratogenic and abortifacient effects of methotrexate, discontinuance is advised if child bearing is desired. If definitive adverse effects on pregnancy have been established with a mother’s use, similar conclusions are deduced regarding a father’s use. Therefore, there are limited studies regarding the methotrexate’s effects on the paternal childbearing. This is a report of successful paternity of a healthy child while taking methotrexate for Crohn’s disease.

Case Report: The patient was a 32 year-old male with a 9 year history of Crohn’s disease. He was on asacol and prednisone at time of first presentation and was started on 6-mercaptopurine. He did not tolerate this regimen secondary to side effects, including severe joint pains and headaches, and was changed to methotrexate 25mg subcutaneous weekly. His disease and symptoms responded well to this treatment, and he has been maintained in remission to the present date on this agent. Upon initiation of therapy and during treatment, the patient was cautioned about conceiving while taking methotrexate. He was educated on the known effects on conception including birth defects and pregnancy termination. In addition, a literature review focusing solely on paternal use was done with results summarized to patient.
Gastric Ulcer Due to Helicobacter heilmannii in a Pediatric Patient

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Helicobacter pylori infection is known to cause chronic gastritis and peptic ulcer disease in patients of all ages. Recently, an increased rate of non-H. pylori, non-NSAID peptic ulcer disease due to Helicobacter heilmannii has been reported in adults and children. This case report describes a 14-year-old Caucasian male who presented with an acute onset of epigastric pain and vomiting for 4 days progressing to hematemesis. He was previously healthy but had taken four doses of ibuprofen and one dose each of promethazine and ondansetron during the 2 days prior to admission. Physical examination revealed epigastric tenderness to palpation without rebound or guarding. Complete blood count and chemistry profile yielded normal findings. EGD revealed superficial erosions in the gastric fundus and corpus and two shallow ulcers in the gastric antrum that were 1 and 0.5 cm diameter. Antral biopsy revealed that the testing for the presence of Helicobacter heilmannii infection should be considered in children with gastric ulcers.

Fatal Intraperitoneal Hemorrhage after Paracentesis

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Fatal intraperitoneal hemorrhage resulting from large volume paracentesis (LVP) is uncommon, reported to occur in less than 1% of cases.

Case Report: A 54-year-old Caucasian man with alcoholic cirrhosis (Child class C) underwent an outpatient LVP. An ultrasound (U/S) exam identified a pocket of ascites in the infraumbilical region. A total of 7.8 liters of clear, yellow ascitic fluid was removed, a 100gms of albumin were given IV, while the patient remained asymptomatic. Upon catheter removal, a small amount of blood was seen at the entry site. The bleeding promptly stopped with minimal pressure. Within an hour of completing the LVP, the patient became hypotensive and tachycardic. Lab studies revealed a hemoglobin of 1.8 g/dl. A noncontrast CT showed marked perisplenic, perigastric varices, dilated umbilical veins as well as intraperitoneal blood. A subsequent angiogram showed marked vasoconstriction of all visceral vessels and did not identify an actively bleeding vessel. Reviewing old CT scans showed small periumbilical varices which were not seen on follow up imaging when his abdomen was distended with fluid. Despite resuscitative efforts, the patient expired approximately 12 hrs after the paracentesis.

Discussion: We surmise the mechanism of hemorrhage was due to the rupture of an intra-abdominal varix. The paracentesis catheter may have directly punctured a varix or the rapid withdrawal of ascitic fluid led to a significant decrease in intraperitoneal pressure resulting in an increase in the pressure gradient across the wall of the mesenteric varices leading to a rupture and bleed. Traditionally the midline approach has been recommended as a safe area for needle insertion because of the relatively avascular median umbilical ligament. However, the rising prevalence of obese patients has led many to approach the procedure from the left lower quadrant (LLQ) where the abdominal wall is thinner than the midline and has a greater depth of ascites. The absence of varices on U/S was likely due to the increased intraabdominal pressure produced by the tense ascites, compressing and obscuring any intra-abdominal varices present. This case illustrates that the midline approach to paracentesis can lead to significant complications from variceal rupture. To limit this complication, we propose paracentesis should be initially approached from the LLQ.
pancreatitis, sclerosing pancreatitis and tumefactive pancreatitis depending upon pathologic findings and extrapancreatic manifestations (sclerosing cholangitis, primary biliary cirrhosis, retroperitoneal fibrosis). Common presentation is a mass either in the head/bile ducts with increased IGG4. Other criteria include a high titer of non-organ specific auto antibodies, response to steroids, ductal changes at CT and strictures at ERCP. It is under identified but the clinical course of the disease can be modified if diagnosed preoperatively. [figure1][figure2]

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“Strong Work”: An Unusual Cause of Clinical Deterioration in a Patient with Ulcerative Colitis on 6-MP
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Infection with the intestinal nematode *Strongyloides stercoralis* is common in individuals from endemic tropical regions, and an asymptomatic carrier state can persist for years or even decades. However, in the setting of an immunocompromised host, overwhelming larval infection, known as the hyperinfection syndrome, can develop, and may ultimately result in death. Immunosuppressive medications such as those used to treat ulcerative colitis (UC), including corticosteroids and 6-mercaptopurine (6-MP), are a well-described risk factor for developing hyperinfection with *Strongyloides stercoralis*. This case report describes a 62-year old man with UC who developed worsening gastrointestinal and constitutional symptoms in the setting of escalating doses of 6-MP. A flexible sigmoidscopy was performed and revealed moderate to severe colitis, with yellowish-white plaques in the sigmoid colon (figure 1). Biopsies were taken, and the colonic aspirate was also sent for ova and parasite examination. Microscopic examination of the aspirate revealed the characteristic rhabditiform larvae seen in *Strongyloides stercoralis* infection. (figure 2). Given the patient’s clinical presentation, hyperinfection syndrome was suspected, and the offending medications were discontinued. The patient was treated for 10 days with dual therapy consisting of albendazole and ivermectin, and he responded appropriately. *Strongyloides stercoralis* hyperinfection has rarely been reported in patients with UC, and to the author’s knowledge, this is the first such case documented within the United States. A high clinical index of suspicion and a pertinent travel history may be necessary to make the diagnosis early so that appropriate medical therapy can be administered and complications avoided. [figure1][figure2]

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Gastrointestinal Stromal Tumor: An Atypical Presentation of Upper Gastrointestinal Bleeding
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Case An 86 year old male presented to the ER with a 1 day history of coffee ground emesis, weakness and nausea. Pertinent medication use included daily aspirin and occasional NSAIDs. The patient remained hemodynamically stable in the ER, but the nasogastric lavage showed bloody return that did not clear. Urgent EGD was performed and a large adherent clot in the fundus was visualized. The patient was transferred to the ICU for monitoring. The next day, melena with hypotension occurred with a 4gm drop in hemoglobin. Repeat EGD was performed revealing a 7mm umbilicated submucosal mass in the gastric fundus, 1cm from the gastroesophageal junction with stigmata of recent bleeding. An upper endoscopic ultrasound was performed and revealed a mass lesion in the gastric cardia originating from within the muscularis propria. The mass was hypoechogenic with well-defined borders, consistent with the ultrasonographic diagnosis of gastrointestinal stromal tumor (GIST). Endoscopic submucosal resection was not attempted due to bleeding risk. The patient and family refused surgical intervention.
Instead, angiographic embolization of the left gastric artery branch supplying the GIST was successfully performed. The patient had no additional bleeding, resumed a normal diet and was discharged 3 days later.

**Discussion:** GIST are defined as mesenchymal tumors arising from the GI wall, mesentery, omentum or retroperitoneum. GIST were initially thought to represent smooth muscle tumors of the GI tract. They were formerly classified as leiomyomas and leiomyosarcomas. It is now proposed that GIST originates from the Interstitial cells of Cagal (ICC) or may evolve from pluripotential stem cells that differentiate toward a pacemaker cell phenotype. The true incidence of GIST is unknown. Unconfirmed estimates of the annual incidence in the U.S. are about 5000 to 6000 cases/year. The majority of GIST occurs in the stomach (60–70%). When in the stomach, GIST are associated with UGIB, abdominal pain or a palpable mass. Embolization for GIST to control UGIB has only been reported once in the literature previously. At that time, it was used to control bleeding and limit the extent of planned surgical resection. This case is the 2nd to use this method to control UGIB in a case of GIST and the 1st to control recurrent bleeding associated with GIST. This may impact clinical management of GIST upon endoscopic discovery without active bleeding.

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**Crohn’s Disease Presenting as Fever of Unknown Origin**

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Crohn’s ileitis is usually suspected when patients present with abdominal pain and/or diarrhea. There are few reports in the literature of Crohn’s disease presenting primarily as fever of unknown origin (FUO).

**Case report:** 4 years before diagnosis, this healthy 32yo male began experiencing episodes of fever to 104°F with sweats once every 3–4 months. In between episodes he felt entirely well. More recently he noticed occasional mild dull periumbilical pain. He had a normal stool every other day. Previous evaluations for infectious and rheumatologic causes of fever were negative. Flex sig six and two years ago for evaluation of BRBPR were negative. PMHx, FHx, allergies, and/or diarrhea. There are few reports in the literature of Crohn’s disease presenting primarily as fever of unknown origin (FUO).

**Discussion:** The distinctive features of this case are the absence of significant abdominal pain and diarrhea, and the prolonged duration of intermittent fever before diagnosis. The findings at colonoscopy led to the differential dx of GIST, lymphoma, infectious enteritis or foreign body reaction. Double-ASCA positivity was highly suggestive of Crohn’s disease, however, and confirmed at pathology. Crohn’s disease should be in the differential dx of FUO.

A 68-year-old woman was referred for occult gastrointestinal (GI) bleeding and iron deficiency anemia. Patient underwent surgery for peptic ulcer 35 years ago. Physical examination was normal. Stool was positive for occult blood. Laboratory data confirmed iron deficiency anemia. Upper endoscopy and colonoscopy done elsewhere were reported normal. Capsule endoscopy was unremarkable. Push enteroscopy revealed a 5cm polyp in the afferent loop of Billroth II anastomosis. Endoscopic resection was difficult due to the size of the polyp. Biopsy of the polyp showed inflammatory changes. Patient underwent surgical polypectomy with wedge resection of the small bowel. A 6×3×4cm polypoid mass was noted. Pathological examination confirmed Brunner’s gland hamartoma. There has been no recurrence of anemia in the ensuing 15 months. Brunner’s gland hamartoma, also known as Brunneroma or Brunner’s gland adenoma, is a rare, benign, proliferative lesion arising from the Brunner’s glands of the duodenum, accounting for 10.6% of benign tumors of the duodenum. In 1688 Brunner gave a precise anatomic description of the duodenal submucosal glands and coined the term “pancreas secundarium.” In 1846 Middeldorpf correctly identified these glands as a separate entity, which he proposed be named Brunner’s glands. Salvioli reported the first adenoma of Brunner’s gland in 1876. The etiology remains obscure. It presents predominantly in the middle age. The size of the lesion is generally 1–2 cm in diameter. The most common location is the duodenum rarely extending to the proximal jejunum. Brunner’s gland hamartoma is nodular hyperplasia of the normal Brunner’s gland with an unusual admixture of normal tissues, including ducts, adipose tissue and lymphoid tissue. It is a tumor without malignant predisposition. Fujimaki et al. reported one patient with a focus atypical gland. Clinical manifestations include GI hemorrhage and intestinal obstruction. Duodenal intussusception was reported in 2 patients. Patients with diarrhea owing to duodenal motor disturbances have also been reported. When the lesion is small or pedunculated, endoscopic polypectomy is the choice. Open surgical excision is reserved for large tumors. There is no reported recurrence after excision.

To our knowledge there has not been any prior report of giant Brunner’s gland hamartoma in the afferent loop after Billroth II gastrojejunostomy. An awareness of this lesion in such a patient as the cause of occult GI bleeding will help with accurate diagnosis and management.

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**A Perplexing Case of Occult Gastrointestinal Bleeding**

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Acute Pancreatitis Secondary to Extracorporeal Shock Wave Lithotripsy (ESWL)

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**Rifaximin Antibiotic Therapy Followed by Flora-Q Probiotic Therapy for Patients with Flames of Crohn’s Disease Despite 6-Mercaptopurine Maintenance Therapy: A Case Series of “Ecologic Niche” Therapy**

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As the pathogenesis of Crohn’s disease probably stems from immunoregulatory dysfunction triggered by enteric bacteria, creating an “ecologic niche” by suppressing antigenic bacteria and cultivating healthy bacteria may have therapeutic potential. Antibiotics have been found to be therapeutically useful in treating Crohn’s disease. In this case series, three patients with Crohn’s disease who were not candidates for rescue with infliximab and who experienced flares while receiving 6-mercaptopurine were successfully treated with the nonabsorbed (<0.4%) oral antibiotic rifaximin followed by maintenance therapy with a probiotic, Flora-Q. See table for results.

These results suggest that treatment with rifaximin followed by maintenance probiotic therapy with Flora-Q might provide a therapeutic benefit for patients with inflammatory bowel disease. Randomized, controlled studies on the use of rifaximin for Crohn’s disease are warranted.
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Introduction: ESWL is a relatively noninvasive and effective procedure for the management of nephrolithiasis. Given its widespread use, increased numbers of serious complications are being reported in both the kidney and <1% of the time in surrounding organs. Injuries reported to the gastrointestinal tract include gastric erosions, retroperitoneal hemorrhage, splenic rupture, hepatic hematoma, bile duct injury and bowel perforation. We report the case of a patient who developed acute pancreatitis after undergoing ESWL for left-sided nephrolithiasis.

Case Report: A 35-year-old male presented with persistent, severe, diffuse abdominal pain, left flank pain and two episodes of painless hematuria with associated nausea, constipation, and bloating. The patient had undergone ESWL for left-sided nephrolithiasis one day prior to admission with a total of 500 shocks at 22kV. Physical exam was significant for an abdomen that was diffusely tender to palpation, greatest in the left upper quadrant without rebound tenderness or guarding. Urinalysis was significant for hematuria. The patient had an elevated white blood cell (WBC) count of 15000 (mL, and an elevated serum amylase of 251 U/L (normal 25–125 U/L) and lipase of 406 U/L (normal 7–60 U/L) respectively. CT scan with contrast was significant for a small hematoma in the left kidney and small amount of fluid in the tail of the pancreas without evidence of necrosis. A clinical and radiologic diagnosis of acute pancreatitis was made. Gallstones, alcohol abuse, drugs, hypertriglyceridemia and hypercalcemia were ruled out as etiology of his pancreatitis. Given the patient’s history and chronologic clinical course the patient was diagnosed with ESWL induced pancreatitis. He improved clinically with conservative bowel rest. TheWBC count normalized and the amylase and lipase values continued to trend down at the time of his discharge from the hospital.

Discussion: Mild elevations of serum and urinary amylase and serum lipase have been noted after ESWL but clinically significant pancreatitis is rare. Shock wave energy at the stone's surface produces mechanical compressive and tensile forces producing stone fragmentation. Shear forces produced by transient cavitation may damage nearby organs. With an increasing number of ESWL procedures being performed these days, consulting gastroenterologists need to be mindful of the collateral damage.

AIDS Associated Arteriopathy as Etiology of Non-Infectious Recto-Colonic Ulcerations in an Adult: The First Reported Case
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AIDS associated arteriopathy (AAA) of the gastrointestinal tract in adults has not been previously reported. We report the case of a young adult with AIDS and non-infectious recto-colonic ulcerations and postulate that the ulcerations may constitute a complication of AAA.

Case Report: A 35 yo male with history of HIV with AIDS, non-Hodgkin’s lymphoma, and MAI presented with fever, rectal pain and bleeding. Four months prior to admission, the patient underwent excision of a rectal ulcer, which revealed thick walled vessels with medial hypertrophy and intimal fibrosis within the granulation tissue. A few beaded acid-fast rods, consistent with Nocardia species were noted in adjacent crypts. Follow up colonoscopy revealed multiple ulcerations throughout the colon characterized microscopically as Candida associated colitis. The patient was treated for Nocardia and had complete resolution of his symptoms. 10 weeks later, he presented with diffuse abdominal pain and hematochezia. A repeat colonoscopy revealed a large, irregular fungating, friable cecal mass with biopsy changes similar to those in the rectal ulcer as well as luminal obliteration by organizing thrombi and no inflammation in the adjacent non-ulcerated cecal mucosa. Infections, inflammatory and neoplastic etiologies were ruled out. The patient underwent a right hemicolectomy with ileo-colonic anastomosis with complete resolution of his pain. Microscopically, the cecal mass had vascular changes similar to those of the biopsy. AAA was the presumed etiology.

Discussion: AAA is characterized by intimal fibrosis and fragmentation of the elastic fibers of medium sized arteries as well as fragmentation and calcification of the internal elastic membrane, with luminal narrowing. These changes have been described in children in organs such as the heart, lung, kidney, intestine, brain and spleen. Isolated cases complicated by coronary artery aneurysm, esophageal stricture and colonic perforation have been reported. Increased exposure to endogenous and exogenous elastases resulting from multiple infections secondary to the immunodeficiency in AIDS have
been postulated as the pathogenetic mechanism. We report the first case of these vascular changes in the gastrointestinal tract of an adult with AIDS.

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A Case of Fulminant Hepatic Failure Secondary to Metastatic Small Cell Lung Carcinoma
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Despite its aggressive nature and high prevalence, there are few case reports on metastatic small cell lung carcinoma resulting in hepatic failure. We present a case of fulminant hepatic failure that upon autopsy was determined to be secondary to metastatic small cell lung carcinoma. A 54 year old male with a history of coronary artery disease, diabetes mellitus and tobacco abuse was admitted with a four-day history of right upper quadrant abdominal pain and anorexia. Exam was significant for jaundice and tender hepatomegaly. LFTs revealed AST 540 U/L, ALT 525 U/L, alkaline phosphatase 385 U/L, and total bilirubin 5.3 mg/dL. In addition, creatinine was 0.9 mg/dL, INR 1.09, lactate 7.6 mmol/L, CK 400 U/L, LDH 7151 U/L. Doppler ultrasound of the liver vasculature was unremarkable. CT of abdomen noted only hepatomegaly without focal lesions and ascites. CXR showed a 1 cm nodule in RML. The complete serologic work-up for the etiology of liver failure was noteworthy only for positive HBV core total antibody (reflective of prior hepatitis B infection) and elevated ferritin with normal HFE gene assay. Soon after admission, a sharp decline in the patient’s clinical status was noted with development of confusion, respiratory failure, hypotension and severe lactic acidosis. By day three of admission, labs showed AST 15870 U/L, ALT 4650 U/L, total bilirubin 9.8 mg/dL, creatinine 4.3 mg/dL, INR 4.1, pH 6.8, lactate 17.3 mmol/L. Soon thereafter, the patient developed asystole and expired. Autopsy revealed a 5200 gm liver without cirrhosis and diffuse white pinpoint plaques throughout the parenchyma. Microscopic analysis determined the etiology of the plaques to be diffuse infiltrative metastatic small cell carcinoma with concurrent hepatic necrosis. Also noted were metastases to the lung, bone, lymphatics and spinal soft tissues. Although small cell lung cancer accounts for nearly one fourth of all lung cancers and is usually metastatic at time of presentation, there are few reports of hepatic failure secondary to metastatic invasion. Published case reports, however, have also noted a pattern of hepatomegaly and extreme elevations in LDH/ALT ratios, often without radiologic evidence of a focal lesion. This case confirms previously-noted modes of presentation and should increase the clinician’s awareness of potential manifestations of a common malignancy.

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Unusual Lymphoma Found on Routine Colonoscopy—What’s Hiding in Your Colon?
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Introduction: Primary malignant lymphoma of the large intestine is a rare condition, accounting for only 0.2% of primary neoplasms of the large intestine. Furthermore, intestinal extranodal marginal zone B-Cell lymphoma (MZL) of mucosa-associated lymphoid tissue (MALT) type is extremely rare. We present a case of MALT lymphoma involving only the colon.

Case Report: A 57 year old female presented to her primary care physician’s office for a routine health exam. Review of systems was negative for weight loss, fatigue, fevers, chills and night sweats. The patient denied any hematochezia or alteration in bowel function. Physical exam was remarkable for a rectal polyp palpable on digital rectal exam. Stool was hemoccult negative. Laboratory studies revealed normal CBC, creatinine, calcium and hepatic function. Patient underwent colonoscopy which revealed a five mm rectal polyp and a 4 cm frond-like villous mass at 60cm. The rectal polyp was hyperplastic. The mass histologically demonstrated lymphoma features and subsequent hemicolectomy was performed. Surgical specimen was consistent with extranodal marginal zone B-cell lymphoma of MALT type.

Discussion: MZL accounts for approximately 8% of all NHL. The stomach is the most common site of MZL of MALT type. The ileum is the most common small bowel site. MALT lymphomas, when found in the large bowel, most commonly effect the rectum. Clinically, MALT lymphoma is typically indolent, remaining localized for prolonged periods. When found, it usually requires surgical excision and current conjunctive chemotherapy (Rituximab). Histologically, MALT is characterized by lymphoepithelial lesions and reactive lymphoid follicles. It is important to histologically distinguish between MALT lymphoma and mantle cell lymphoma because the latter carries poor prognosis. Unlike mantle cell, MALT lymphomas are negative for CD1 and CD5 tumor markers. This case represents an unusual finding on a routine screening colonoscopy in an asymptomatic patient. In addition, our patient is unique in that she does not have evidence of NHL in the presence of an isolated colonic MZL of MALT type. She continues to do well after resection and is receiving conjunctive chemotherapy.
Efficacy of Infliximab in a Patient with Autoimmune Hepatitis—Primary Biliary Cirrhosis Overlap Syndrome (AIH-PBC)

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AIH-PBC is a rare form of liver disease, presently managed by steroids, immunosuppressants, ursodeoxycholic acid, and liver transplant. Previous studies suggested a critical role for tumor necrosis factor-α (TNF) in pathogenesis. Safe, effective, specific anti-TNF-α therapies are now available and standard of care for Crohn’s disease, rheumatoid arthritis, and other diseases involving TNF, but have never been reported in AIH-PBC. We report a 43 year old female with autoimmune thyroid disease, diabetes, and ANA+ rheumatoid factor+ arthritis, who was diagnosed with AIH 7 years ago, initially treated with prednisone and imuran. Approximately 6 years later, she developed significant elevations of alkaline phosphatase (ALP). Addition of ursodeoxycholic acid was ineffective and she was listed for transplant. For additional patients with AIH-PBC, and possibly even PBC patients, should be considered.

Effect of Infliximab on Steroid Use and Liver Indices

Date | Prednisone (mg/day) | ALP (IU/L) | AST (IU/L) | ALT (IU/L)
--- | --- | --- | --- | ---
8-16-05 | 20 | 673 | 71 | 72
11-03-05 | 15 | 369 | 33 | 33
12-07-05 | 12.5 | 273 | 28 | 24
1-04-06 | 10 | 244 | 23 | 17
1-18-06 | 5 | 264 | 20 | 16

Pre-Sacral Synovial Sarcoma Discovered on Routine Screening Colonoscopy

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Synovial sarcoma is a rare tumor that most commonly presents as a tender mass in the upper or lower extremity near large joints. It is only rarely found in the torso. A 57 year old female with no significant medical history presented for a routine screening colonoscopy. She had no complaints, experienced normal bowel habits, and maintained a stable weight. Colonoscopy to the cecum was normal except for severe extrinsic compression in the rectum which prompted the performance of a CT scan of the abdomen and pelvis. This scan revealed a heterogeneously enhancing pre-sacral mass measuring approximately 7.3 cm in AP dimension, 6.6 cm in width, and 7.5 cm in sagittal length that extrinsically displaced and compressed the rectum. Perirectal fatty tissues appeared normal, containing no signs of infiltration. MRI of the pelvis confirmed intact tissue planes between the mass and adjacent muscle and bone. The patient underwent a trans-sacral resection of the retrorectal mass, recovered uneventfully, and was discharged home on post-op day #2. Histology revealed spindle cells with nuclear pleomorphism, multinucleated giant cells, atypical mitoses, areas of fibrosis and necrosis. Immunohistochemical stains were positive for epithelial membrane antigen, cytokeratin, and neuron-specific enolase, negative for S100, smooth muscle actin, and the melanoma antibody HMB45, a pattern consistent with synovial sarcoma or epithelioid sarcoma. Electron microscopy revealed ultrastructural features consistent with synovial sarcoma. A subsequent metastatic workup was negative, and the patient is currently undergoing post-operative radiation therapy. Approximately 800 new cases of synovial sarcoma are recorded each year in the U.S., comprising 5–10% of all soft tissue sarcomas. Synovial sarcomas derive from undifferentiated mesenchymal cells and are most commonly located in the extremities. Synovial sarcomas located in the pre-sacral space are rare, and a synovial sarcoma as an incidental finding on screening colonoscopy has not been previously described. Overall prognosis is poor with local recurrence or metastasis occurring in approximately 80% of patients. Five-year survival is 23–64%, and depends on age at diagnosis, size of the tumor, histological grade and subtype. It has been shown that certain fusion genes also correlate with poorer metastasis-free survival. Consequently, it is important to diagnose synovial sarcomas early on, and extrinsic compression of the lumen seen on colonoscopy can be an early manifestation.
Pneumomediastinum Associated with Hyperemesis Gravidarum
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Pneumomediastinum is a rare complication of pregnancy, usually occurring during the second stage of labor or immediately postpartum. Only nine cases of pneumomediastinum occurring during the first trimester of pregnancy have been described. We report a case and describe the management of hyperemesis gravidarum that was complicated by pneumomediastinum. An 18yr old female G1P0 at 9 weeks gestation presented to the ED with sudden onset of severe chest pain. She had been vomiting frequently for 4 days, and her symptoms gradually worsened until she developed intractable vomiting and mild shortness of breath. On physical exam, she was tachycardic with a heart rate of 123 BPM, respiratory rate 24 breaths/min. Her oxygen saturation was 98% on room air. Lungs were clear to auscultation. Chest radiograph was unremarkable. CT scan of the chest revealed a large amount of air outlining the mediastinal structures consistent with a large pneumomediastinum. The CT scan revealed no pneumothorax, bullae or blebs. A subsequent gastrografin esophagram did not show any evidence of esophageal perforation. The patient was started on 100% oxygen in an attempt to enhance reabsorption of mediastinal air. Hydromorphone and ondansetron were used for symptomatic relief, and amoxicillin/clavulanate was started empirically. OB/Gyn confirmed fetal viability. The patient’s symptoms rapidly improved, and she was discharged on hospital day 4. Given the setting of violent and frequent retching and lack of any pulmonary parenchymal abnormalities on CT scan, a small esophageal tear as the etiology of the pneumomediastinum could not be excluded. It is important to recognize pneumomediastinum as a rare complication of hyperemesis gravidarum and also to bear in mind the potential complication of tension pneumomediastinum which can be fatal and needs emergent surgical intervention. Although availability of rapid imaging has made the diagnosis relatively straightforward, an important task is to determine the etiology of the pneumomediastinum since esophageal perforation may also be a surgical emergency. Of the nine cases of pneumomediastinum during the first trimester reported in the literature to date, the etiology was found to be esophageal rupture in five cases. Of these cases, surgical treatment was required in only one patient; the others responded to conservative management. A review of these cases suggests positive outcomes can be attained solely with observation, high concentration oxygen therapy, and symptomatic treatment.

Subserosal Eosinophilic Gastroenteritis Presenting in an HIV Patient
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A 49-year-old female was admitted to our hospital complaining of chest pain, nausea, vomiting and a new onset watery diarrhea. She had a history of relatively controlled HIV with a CD4 count of 438/mm³ and a CD4:CD8 ratio of 0.3. Her history also included an ischemic cardiomyopathy, asthma and hypertension. She denied any recent changes of her medications. EGD revealed an aperistaltic stomach and diffusely firm, nodular stomach wall. Biopsies from endoscopy only revealed oxyntic gastric mucosa. The patient also had a 71% peripheral eosinophilia. Extensive gastric wall thickening on CT prompted a full thickness gastric biopsy which revealed dense eosinophilic infiltrates involving only the muscularis and subserosal layers consistent with eosinophilic gastroenteritis. The CT also revealed right colonic and distal ileal wall thickening which may explain the patient’s diarrhea. The patient’s vomiting and diarrhea responded promptly to steroid therapy after exclusion of parasite infection. Eosinophilic gastroenteritis is an unusual disorder which must be considered in the differential diagnosis of a patient with peripheral eosinophilia and GI symptoms. [figure1][figure2]

Chronic Lymphocytic Leukemia of the Stomach
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A 76-year old male, with an 8-year history of Chronic Lymphocytic Leukemia (CLL), was referred due to early satiety and a 25-lb weight loss. He did not report any abdominal pain, nausea, or change in bowel habits. He had...
Congenital Double Pylorus

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We report a rare case of congenital double pylorus in an 80-year-old gentleman who complained of post prandial epigastric discomfort and heartburn of approximately 6 months’ duration. Double pylorus is an uncommon condition which can be congenital but is usually acquired as a result of peptic ulcer disease. Although almost 100 patients with acquired double pylorus have been described, only a few cases with congenital double pylorus have been reported. Congenital double pylorus can be derived from either a gastric diverticulum or a duplication cyst. Other congenital abnormalities such as an aberrant pancreatic duct in the antral wall and malrotation of the gut can be associated defects. Chart review and review of available literature using Medline and relevant bibliographies of published articles. Patient was scheduled for a barium meal examination by his primary care physician for further evaluation of his symptoms. Findings were consistent with a small hiatal hernia and an accessory pyloric canal originating from the lesser curvature of the stomach to the duodenum. No signs of acute or chronic peptic ulcer were noted. Biopsies obtained from the main and accessory pyloric channel showed normal mucosa and a muscularis mucosa layer present in both the channels. The patient was successfully treated conservatively with antacids. [figure1]

This case represents an unusual presentation of congenital double pylorus in an elderly male patient.
Large Bronchogenic Cyst – A Rare Cause of Dysphagia
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Bronchogenic cysts are congenital in origin. While relatively rare, they are the most common cystic lesions of the mediastinum. Patients with bronchogenic cysts usually present with cough, chest pain, fever and dyspnea. We present a case of a large bronchogenic cyst causing esophageal compression and presenting as dysphagia.

Case Presentation: A 34 year old African-American female with no significant medical history presented with complaints of progressive dysphagia for solids for 1 month, associated with pleuritic chest pain, back pain and shortness of breath. There was a 10 lb. weight loss during this period. Physical examination and laboratory studies were unrevealing. Chest x-ray revealed a very well defined, sharply demarcated mass-like structure at the right hilum. CT scan showed a 5cm x 5.2cm homogeneous subcarinal mass. Upper endoscopy showed extrinsic compression of the esophagus with no evidence of intrinsic obstruction. The patient underwent Video Assisted Thoracic Surgery (VATS), with the finding of a bronchogenic cyst in close proximity of the right lower lobe. This was dissected out and removed. Histopathology confirmed a foregut cyst, bronchogenic type. Postoperatively, the patient had significant improvement in her symptoms. She still complains of mild dysphagia, which is likely functional, secondary to long-standing extrinsic compression. She is scheduled for esophageal manometry for further evaluation.

Summary: Bronchogenic cysts occur as developmental abnormalities of the primitive foregut. They present mostly with respiratory distress in infancy or early childhood and less commonly in adults. In adulthood, they usually remain asymptomatic, but can become infected and fluctuate in size causing obstructive symptoms. The diagnosis is based on histopathology confirming the presence of respiratory epithelium in the resected cyst. Definitive treatment is resection of the cyst, either via open resection or by VATS.

Pancreatitis Following Biopsy of the Papilla of Vater
Ritesh Jha, MD, Matthew McKinley, MD,* Medicine, North Shore University Hospital, Manhasset, NY.

Introduction: Endoscopic and radiographic appearance of a small neoplasm confined to the ampulla of Vater may be normal. However, larger intra-ampullary tumors appear as a prominent papilla or a mural mass. It is recommended that an abnormal appearing papilla, if seen, be biopsied in order to rule out malignancy. Known consequences of obtaining a papillary biopsy include hemorrhage and perforation. Pancreatitis following biopsy of a prominent papilla of Vater is a rare phenomenon. We report the case of a patient who developed pancreatitis following biopsy of a prominent papilla of Vater.

Case: A 60 year old male with a history of chronic gastroesophageal reflux disease had undergone surveillance upper gastrointestinal (UGI) endoscopy which noted mildly prominent major and minor papillae along with gastritis. Biopsy specimens were taken without complication. Pathology reports reported normal mucosa from the minor papilla and hyperplastic mucosa with a suggestion of adenomatous change from the major papilla. Follow up UGI endoscopy three months later once again noted mildly prominent major and minor papillae. Three biopsy specimens were obtained from both papillae and the patient tolerated the procedure well. Six hours post procedure the patient developed severe abdominal pain which worsened following meals. He was seen in the office the following morning. Abdominal examination revealed mild epigastric tenderness, without rebound or guarding, and non-moanotic bowel sounds. Laboratory studies showed a serum amylase of 217 IU/L (normal ≤ 98), lipase of 2272 U/L (normal ≤ 286) and a total bilirubin of 1.04 mg/dL (normal ≤ 1.5). A complete blood count, as well as tests of liver function and renal function were within normal limits. The patient was diagnosed with pancreatitis and followed as an outpatient. His symptoms improved rapidly on a clear liquid diet and his diet was slowly advanced. Five days later he was pain free and tolerating his normal diet. He remains free of symptoms one year later.

Discussion: There are reports in the literature of pancreatitis following biopsy of an ampullary adenoma, and following endoscopic treatment of papilla of Vater adenomas. We believe this is the first reported case of pancreatitis following biopsy of a prominent papilla of Vater. Perforation and hemorrhage are well known consequences of obtaining mucosal biopsies. Although rare, it is important for practitioners to be aware of the possibility of developing acute pancreatitis following biopsy of a prominent papilla of Vater.

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any form of leukemia who present with unexplained diarrhea. As our patient demonstrates, systemic therapy addresses both the underlying leukemia and its GI manifestations.

**Minocycline: A Rare Cause of Hepatitis and Erythema Nodosum**

John T. Bassett, MD, Jeff Walker, MD, Inku Hwang, MD.*

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Autoimmune hepatitis (AIH) has been associated with various infections and medications including minocycline. We present a rare case of biopsy confirmed autoimmune hepatitis and erythema nodosum in a patient taking minocycline.

**Case:** A 34-year-old woman presented for evaluation of aminotransferase elevations, night sweats, fatigue, myalgias, arthralgias and an erythematous nodule on the left ankle. Symptoms followed a waxing and waning course over 5 months. Persistent malaise and worsening of the skin lesion led the patient to seek evaluation which revealed markedly elevated aminotransferase levels. Her medical history was significant for acne vulgaris for which she took minocycline over the preceding four years, with doses ranging from 100 to 200 mg daily. Physical examination revealed a tender 4 cm area of edematous nodular erythema on the medial left ankle. On presentation, her ALT was 2257 U/L & AST was 1237 U/L and alkaline phosphatase was 167 U/L. Bilirubin was normal. Right upper quadrant ultrasound was normal. ANA titer was 1:1280. Antihistone antibodies were also elevated at 2.8. Serum IgG was elevated at 2090 (reference range 751–1560). Anti-smooth muscle antibodies were negative. Viral serologies were negative except for EBV IgM which was elevated (EIA titer 5.82). However, subsequent immunostains from the liver biopsy which were reviewed by the Armed Forces Institute of Pathology were negative for EBV and was consistent with autoimmune hepatitis. Skin biopsy of the patient’s ankle was consistent with erythema nodosum. The patient’s symptoms resolved within days of stopping her minocycline, and transaminases returned to normal over a four week period and have remained within reference range at 3, 6 and 12 month intervals.

**Discussion:** Minocycline-related autoimmune disorders develop an average of 2 years (range, 3 days to 6 years) after starting drug therapy and typically occur in females under 40 years of age. While minocycline has been reported to cause acute and chronic hepatitis as well as erythema nodosum, this is the first case to our knowledge, in which a patient developed both at the same time and which were biopsy proven. This case serves to underscore the need for monitoring of patients on minocycline with a prompt discontinuation of the medication if erythema nodosum or elevated aminotransferases develop.

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**Whipple’s Disease in the Post Liver Transplant Patient**

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55-year-old male with a history of NSAID use was admitted with three days of multiple episodes of melena and a near-syncopal episode. He denied symptoms of anemia such as shortness of breath, weakness, or fatigue. Unintentional weight loss of four pounds over past month was reported. Family history was negative for gastrointestinal malignancies. Physical exam was remarkable for general pallor and pale conjunctiva. Laboratory: WBC 12.1, hemoglobin 7.8, platelets 117. After fluid resuscitation, hemoglobin was 4.7. Transfusion of 2 units of blood corrected hemoglobin to 7.0. Endoscopy revealed a 3 × 4 cm pedunculated polyp with an ulcerated stalk. Using standard snare polypectomy technique, the polyp was resected (figure 1). The ulcer site was treated endoscopically with good hemostasis. Pathology identified a 3.4cm Brunner’s gland adenoma with no evidence of malignancy (figure 2).
A 58-year-old Korean male with a history of cadaveric liver transplantation for chronic hepatitis B presented to the ER after a fall and loss of consciousness at home. He complained of fatigue, weakness, decreased oral intake, and 75–90 lb. weight loss over the past four years since transplantation. He reported 8 to 10 watery, non-bloody bowel movements daily for the past year unrelated to meals. He denied fevers, chills, nausea/vomiting, dysphagia, arthralgias, abdominal pain or steatorrhea. EGD and colonoscopy two years prior were unremarkable. Medications included hepatitis immune globulin, cyclosporine and mycophenolate mofetil. Social, family, travel and occupational history were non-contributory. On exam, he appeared to be a weak, cachectic man who weighed 75 lb. (BMI 11.7). There was temporal wasting, sacral decubitus ulcer, and hemocult negative stool with no other pertinent findings. Initial lab data showed: Hb 8 (12–16 g/dl), iron 15 (50–149 ug/dl), vitamin B12 203 (243–894 pg/mL), protein 4.8 (6.5–8 g/dl), albumin 2.6 (3.6–4.8 g/dl). INR, LFTs, HIV, and PPD were normal. Stool cultures, O& P and C. difficile were negative. CT of the chest and abdomen, bone scan, PET scan, and bone marrow biopsy revealed no evidence of malignancy. The patient had frequent, watery, foul-smelling stools, a poor appetite and fever. EGD revealed a notched, scalloped and fissured duodenal mucosa. Biopsies showed villous atrophy with diffuse infiltration of the lamina propria with macrophages that stained positive with periodic acid Schiff (PAS). The diagnosis of Whipple’s disease was made and the patient was placed on intravenous antibiotics.

Discussion: In this report, we describe the first known case of Whipple’s disease in the post liver transplant patient. 696 cases have been reported between 1907 and 1987 with an annual incidence of 30 cases per year since 1980. In a review of 664 patients by Dobbins in 1987, 86% of patients were white males with macrophages that stained positive with periodic acid Schiff (PAS). The diagnosis of Whipple’s disease was made and the patient was placed on intravenous antibiotics.

Disease Activity Index (CDAI) scores were determined retrospectively, with remission defined as CDAI score <150 and secondary efficacy endpoints determined as 70-point or 100-point reductions from baseline CDAI score. Data from 18 patients were analyzed, and the median baseline CDAI score was 237. Patients were treated with rifaximin 200 mg t.i.d. for a median of 13 weeks. Remission was achieved in 67% of 18 patients, and 70-point and 100-point reductions in CDAI score were observed in 50% and 39% of these patients, respectively. Seven patients (39%) exhibited disease of the small intestine only, and 5 of these (71%) achieved remission. This small observational study suggests that nonsystemic antibiotic therapy may provide clinically meaningful improvements in patients with CD. Nonsystemic antibiotics may play an important role in the management of patients with inflammatory bowel disease, and further investigations of monotherapy and adjunctive antibiotic therapy are warranted.

Extrapulmonary Small Cell Carcinoma of Liver: A Case Report
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We report a case of extrapulmonary small cell carcinoma of the liver. Neuroendocrine tumors include all tumors exhibiting neuroendocrine characteristics, such as small cell carcinoma, carcinoid tumor and islet cell tumor of pancreas. Neuroendocrine tumors can involve various organs such as lungs, G.I. tract, pancreas, endometrium and ovaries. Small cell carcinoma has a high incidence of early dissemination due to its aggressive nature. Small cell carcinoma can be of pulmonary and extrapulmonary origin. Extra pulmonary small cell carcinoma mainly affects middle aged or elderly population, with greater than 70% of affected patients being older than age 50. Extra pulmonary small cell carcinoma is an uncommon malignancy that shares many of the histologic features of pulmonary small cell carcinoma. So far, approximately 55 cases of primary hepatic neuroendocrine tumors have been reported in English literature. Chart review and review of literature using Medline and relevant bibliographies. A 68 year old man presented with abdominal pain, nausea, vomiting, jaundice and weight loss. Liver panel was consistent with cholestatic jaundice. Ultrasound of abdomen revealed heterogeneous and increased echogenicity of the liver with hepatosplenomegaly. CT scan of the abdomen demonstrated enlarged liver with heterogeneous parenchyma. EGD, ERCP and Colonoscopy were negative. Liver biopsy revealed a focus of malignant cells which were positive for synaptophysin and TTF-1 and negative for chromogranin. Post liver biopsy work up included CT scan of chest which revealed atelectasis with no discrete lesions. Extensive work up did not reveal involvement of any other site. Our patient decided not to undergo chemotherapy and chose to be hospice care. Clinical progression of his disease was rapid and he died within two months of diagnosis. Primary hepatic neuroendocrine tumor is very rare. This diagnosis is considered after an occult primary neuroendocrine malignancy outside the liver has been excluded by intensive search. We report a rare case of extrapulmonary small cell carcinoma of liver presenting as cholestatic jaundice. [figure1]
Potential Benefit of Aminosalicylate Therapy for Treatment of Irritable Bowel Syndrome

Jeffrey M. Aron, MD. Division of Gastroenterology, California Pacific Medical Center, Center for Inflammatory Bowel Diseases, San Francisco, CA.

Recent evidence suggests that irritable bowel syndrome (IBS) has a major inflammatory component that alters physiologic responses in the gut and brain. The efficacy of low-dose 5-aminosalicylates (5-ASAs) is described herein for IBS patients who failed to respond to standard therapy, including tegaserod and alosetron. All patients satisfied Rome II criteria for IBS. Exclusive criteria included fever, bloody stools, weight loss, celiac disease, or microscopic or collagenous colitis on colonoscopic biopsies. Proper diet, exercise, and relaxation were emphasized. Patients received mesalamine (Asacol® 400–800 mg/d, Pentasa® 250–500 mg/d), balsalazide (Colazal® 750–1500 mg/d), or olsalazine (Dipentum® 500–1000 mg/d). Treatment response was defined as complete (relief of all symptoms of pain, bloating, altered stool frequency, stool shape/form, and general well-being), partial (relief of 4 of 5 symptoms described above), or none (relief of <4 symptoms). Patients were evaluated every 3 weeks for the first 4 visits and every 4 to 6 months thereafter. 93 patients were assessed from October 2002 to May 2006. Complete and partial response rates for each type of IBS are shown in the table (IBS-D = diarrhea-predominant irritable bowel syndrome, IBS-C = constipation-predominant irritable bowel syndrome, and IBS-A = alternators). After 3 weeks, dose increases were required in 9 of 20 patients with IBS-C and 4 of 13 with IBS-A receiving mesalamine (Asacol or Pentasa), compared with 4 of 11 patients with IBS-C receiving balsalazide. Overall treatment response was maintained for a mean of 7.6 months (range 3–42 months). Twelve patients who voluntarily discontinued treatment experienced relapse within 3 to 6 weeks, and all achieved complete remission within 3 weeks after resumption of previous therapy. Low-dose 5-ASA therapy effectively reduced the symptoms of IBS in patients who failed previous therapy. Given this interesting observation, a prospective, randomized, double-blind study will be undertaken to critically evaluate low-dose balsalazide for IBS.

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<tr>
<th>Treatment Response</th>
<th>Patients, n</th>
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<tr>
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<td>IBS-D (N = 43)</td>
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<tr>
<td>Mesalamine</td>
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<tr>
<td>Complete</td>
<td>18</td>
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<td>Partial</td>
<td>3</td>
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<td>None</td>
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<td>Balsalazide</td>
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<td>Olsalazine</td>
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A “Dizzying” Diagnosis: Esophageal Cancer Presenting as a Paraneoplastic Syndrome

Christopher A. Aoki, MD, Walter Trudeau, MD. Gastroenterology and Hepatology, University of California, Davis, Sacramento, CA.

Case Description: A 55 year old man gradually developed the inability to focus his gaze, whole body tremors, persistent nausea, vomiting and weight loss. Despite multiple ER visits, CT and MRI of his brain, the etiology of his symptoms were unknown. On physical examination he had horizontal nystagmus when fixing on objects. Myoclonus was noted on the left arm, head and trunk. His plantar reflex was withdrawn. Cerebrospinal fluid was negative for infection and no malignant cells were identified. Due to concerns for a paraneoplastic syndrome a CT of the chest and abdomen were performed and revealed asymmetric thickening of the distal esophagus, and several enlarged and potentially necrotic lymph nodes in the paraesophageal and retroperitoneal abdomen. All laboratory tests were normal. Esophagogastroduodenoscopy revealed a 4 cm necrotic mass in the distal esophagus, located within a long segment of Barrett’s esophagus. Biopsies of the mass showed poorly differentiated adenocarcinoma, and surrounding biopsies confirmed Barrett’s metaplasia with mild dysplasia. An increased fluorodeoxyglucose activity within the distal esophagus and a cluster of metabolically active lymph nodes at the celiac axis consistent with metastatic disease was discovered on PET scan. The patient was treated with intravenous and oral steroids which resulted in resolution of his nystagmus and improvement of his myoclonus. The patient is currently being evaluated for chemotherapy.

Discussion: The most common presentation of esophageal adenocarcinoma is dysphagia, however it has been associated with a number of paraneoplastic syndromes including acrocraiotasis paraneoplastic, hyperparathyroidism, vasculitis and cerebellar degeneration. This is the first case report of opsonoclonus-myoclonus associated with an esophageal adenocarcinoma. Opsonoclonus-myoclonus syndrome is most commonly found in pediatric patients with neuroblastomas, but it has also been described in patients with advanced breast and lung cancers. There have also been case reports of association with pancreatic and gastric cancer. The etiology is unknown but is believed to be immune-mediated due to the occasional presence of anti-neuronal antibodies and improvement with immunosuppressants. Esophageal adenocarcinoma should be added to the list of malignancies associated with opsonoclonus-myoclonus syndrome, and a thorough evaluation of the gastrointestinal tract should be considered in patients who present with this syndrome.
Clopodogrel (Plavix®) Induced Fulminant Hepatitis
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Clopodogrel is a widely used anti-platelet aggregation agent. It has been widely considered that this drug did not have the side effects that ticlodipine has, which is another anti-platelet aggregation agent part of the same thienopyridin family. We report the 1st case of lethal fulminant hepatitis in a patient on clopidogrel.

Observation: 63 year old male with past medical history significant for type 2 diabetes, hyper-lipidemia and coronary artery disease. Treatment with clopidogrel was initiated after coronary angioplasty performed in December 2004. Liver function tests were normal prior to the coronary angioplasty. 6 weeks after initiation of clopidogrel therapy, he developed icterus, hemoptysis and acute change in mental status with rapid progression to a comatose state. Hepatic tests at that time showed elevated bilirubin, amino-transferases at 7 times normal, cholestasis and hepatic insufficiency with prothrombin index at 27%. Viral serologies for hepatitis A, B, C and D and CMV, as well as the immunologic work-up were all negative. Also, there has been no other recent change in therapy or any intake of or exposure to toxic products. Abdominal ultrasound exam was normal. This presentation rapidly evolved to death with multi-organ failure and a hemorrhagic syndrome.

Discussion: Hepatotoxicity of ticlodipine is well recognized and widely reported in the literature. However, only 3 cases of moderate cholestatic and/or cytolytic hepatitis due to clopidogrel have been reported. There are currently no reported cases of fulminant hepatitis due to clopidogrel. In our patient, the diagnosis of fulminant hepatitis due to clopidogrel was made due to the temporal relationship between the start of clopidogrel therapy and the occurrence of fulminant hepatitis (6 weeks), and the negativity of an extensive etiologic work-up. Clopidogrel is currently very widely used for the treatment of cardio-vascular and neurologic pathologies. Even though its hepatotoxicity is rare, clinicians should be aware that severe and lethal forms could occur.

Esophageal Variceal Bleeding in Pregnancy: Case Report and Review of the Literature
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Pregnancy in cirrhotic patients is rare due to reduced fertility and the older age of these patients. Maternal complications of portal hypertension, to include esophageal variceal bleeding can have substantial morbidity and mortality for both mother and fetus. Pregnancy profoundly affects systemic hemodynamics and may contribute to rapid worsening of portal hypertension and increase the risk of variceal bleeding.

Case: A 40 year old female with a past medical history of cirrhosis, secondary to HCV and a history of alcohol abuse, who was 34 weeks and 4 days pregnant presented with massive hematemesis. The patient had been abstinent from alcohol for the previous two years. The patient presented with an initial blood pressure of 60/palpation and an hemoglobin of 8.7. Her platelet count was 66 and INR was 1.3. The patient was started on an octreotide drip and admitted to the MICU where she was intubated and resuscitated. Following resuscitation the patients blood pressure increased to 90/60, however the fetus developed bradycardia requiring emergent Cesarean section in the MICU. Immediately following delivery the patient underwent upper endoscopy which revealed 3 trunks of grade 2 esophageal varices. The varices were banded x6 and Octreotide was continued for a total of 72 hours. The patient had no further GI bleeding during her hospitalization. The patient was started on nonselective beta-blocker therapy at discharge. The healthy infant was monitored in the NICU for four days then discharged home in stable condition. Repeat EGD three weeks after discharge found 3 trunks of grade 2 esophageal varices which were again banded x6.

Imression: this patient demonstrates secretory diarrhea likely due to bacterial overgrowth. Previous antibiotic therapy with ciprofloxacin was not broad enough to cover possible anaerobic contamination. Rifaximin is an oral, non-systemic, gut-selective antibiotic with minimal absorption by the GI tract. Its in vitro activity is against both gram-positive, gram-negative, aerobic and anaerobic isolates. Its use in pediatrics has been limited to infectious diarrhea but it has been approved for use in the treatment of traveler's diarrhea in adults but not approved for use in children. It has been shown to be useful in gut decontamination for treatment of hepatic encephalopathy, and anecdotally in IBD and bacterial overgrowth in adults. Due to the disruption of his quality of life secondary to daily normal saline infusions, use of this non-approved agent was tried. Ciprofloxacin, which is not approved for use in children, was already tried without success. Metronidazole was not attempted due to its poor palatability as a suspension and also due to side effect profile. Rifaximin was well tolerated in our patient and had no side effects. Treatment was short term with long term results significantly improving our patient's quality of life.
Introduction: McKittrick-Wheelock syndrome is a rare condition characterized by a rectal villous adenoma causing dehydration from diarrhea with severe hyponatremia, hypokalemia, metabolic acidosis, and acute renal failure. Case: A 63-year-old male with multiple admissions for hyponatremia was admitted with obtundation and dehydration. Labs showed Na⁺ = 100 mEq/L, K⁺ = 5.2 mEq/L, creatinine = 5.0 mg/dL, urine Na⁺ = 10 mmol/L. He was resuscitated with normal saline, but over 10 days, developed status epilepticus and abdominal distension. An abdominal CT depicted colonic distension and a rectosigmoid mass. (Fig A) Colonoscopy found 2.5L of thick mucoid fluid in the rectum, and underneath, a circumferential mass measuring 13cm long. Biopsies of the lesion revealed villous adenoma without dysplasia. (Fig B) Analysis of the rectal fluid showed Na⁺ = 151 mEq/L, K⁺ = 11.7 mEq/L, and Cl⁻ = 133 mEq/L, suggesting a secretory diarrhea. Indomethacin (25 mg PO TID) was given to decrease rectal effluent and help maintain electrolytes.

Discussion: McKittrick-Wheelock syndrome is a rare cause of hyponatremia. The diarrhea is secretory with stool Na⁺ being isotonic to serum Na⁺ and stool K⁺ being 5-15x higher. The secretagogues cAMP and prostaglandin E2 (PGE₂) alter intestinal electrolyte transport. Assays of secretory villous adenoma tissue have found 6x higher cAMP content and 17-38% higher cAMP protein dependent kinase activity. High levels of PGE₂ have also been measured in villous adenoma related rectal effluent. Indomethacin is a way to block PGE₂ production by inhibiting cyclooxygenase, thereby decreasing rectal effluent and normalizing electrolyte imbalance prior to mass resection. McKittrick-Wheelock syndrome should be considered in the differential of recurrent severe hyponatremia.

Cytomegalovirus (CMV) infection of the gastrointestinal tract is commonly seen in immunocompromised patients. There have been few reported cases of CMV enterocolitis in immunocompetent patients. The reported cases of CMV proctitis in immunocompetent patients are typically elderly patients or patients who have had a preceding infectious, allergic, or traumatic insult. We report a case of a cytomegalovirus (CMV) rectal ulcer and CMV hepatitis in a healthy 22-year-old woman without a preceding insult to her gastrointestinal tract.

Case Report: A 22-year-old female presented to the emergency room with complaints of fever, intermittent blood per rectum, tenesmus, and multiple constitutional complaints including anorexia, lethargy, and arthralgias. Physical exam was significant for fever of 39° C. She was mildly ill appearing with exam notable for scattered sub-cm posterior cervical adenopathy and a tender rectal exam with bright red blood. Initial laboratory data was unremarkable. During her hospital course, the patient developed a marked reactive lymphocytosis and elevated liver tests with an AST 506 U/L and ALT 834 U/L. The bilirubin and alkaline phosphatase remained normal. Contrast enhanced abdominal computed tomography was significant for a hazy appearance of the soft tissues adjacent to the distal rectum. Colonoscopy revealed severe rectal inflammation with nearly circumferential ulceration. Pathologic examination of the rectal ulcer revealed diffuse active inflammation without signs of chronicity. Viral inclusions were not seen, yet further histochemical staining was positive for CMV. CMV by PCR, CMV IgM Ab, and CMV viral blood cultures were positive. The patient was diagnosed with primary CMV proctitis and presumed hepatitis. Valacyclovir was initiated. The patient was HIV seronegative and T cell subsets were within normal range. Protein electrophoresis did not disclose an immunodeficient state. Her fever, constitutional symptoms, and rectal bleeding gradually resolved and her liver tests normalized. We report a case of primary CMV infection with rectal ulceration and acute CMV hepatitis in an otherwise healthy young woman. Gastroenterologists should be aware of the possibility of CMV colitis and CMV hepatitis in immunocompetent patients even if they have not had a preceding gastrointestinal illness.

Aeromonas hydrophilia and Citrobacter braakii Septicemia from Cholecystitis/Cholangitis in a 90 Year Old Immigrant

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A 90 year old Korean lady presented to hospital with complaints of right upper quadrant pain accompanied by fever and vomiting of 2 days duration. Ultrasound examination identified a dilated common bile duct (CBD) with pericholecystic fluid. An endoscopic retrograde cholangiopancreatographic revealed a distal ductal stone with purulent bilious fluid. Due to the presence of a papilla within a distal ductal diverticula a sphincterotomy was not performed. Blood cultures were positive for Aeromonas hydrophilia and Citrobacter braakii. Both organisms were sensitive to 3rd and 4th generation antibiotics.
A 48 y/o female with chronic constipation presented to the ER with abdominal girth and crampy abdominal pain, distension of 2 weeks. She had no bowel movements or passing flatus for 8 days. She normally has 3–4 bowel movements a week. She had increasing abdominal girth with crampy abdominal pain and distension of 2 weeks. She reported no bowel movements or passing flatus for 8 days. She normally has 3–4 bowel movements a week. She had increasing abdominal girth with crampy abdominal pain, nausea, and non-bilious vomiting. She took senna, lactulose and miralax, without any relief. The patient had an upper gastrointestinal series 3 weeks ago. Prior surgeries included hysterectomy, cholecystectomy, and appendectomy. Patient was afebrile and hemodynamically stable. Multiple well-healed abdominal scars were seen. Bowel sounds were hypoactive. There was significant abdominal distension and diffuse tenderness; no rebound or guarding.

Rectal vault was empty: Labs: WBC of 15.3, BMP, amylase, lipase and UA were normal. An X-ray showed a dense round radiopaque structure in the left hemipelvis (Fig 1). CT of pelvis showed a 3.5 × 2.8cm dense radiopaque foreign body in the sigmoid colon (Fig 2). Flexible sigmoidoscopy showed a whitish-gray barium stool ball causing complete obstruction at the recto-sigmoid junction. It was broken using regular and rat toothed forceps and removed using a snare and roth net basket.

Discussion: There are isolated case reports of “barolith” induced colonic obstruction following a barium meal study. This case is unusual as the patient was young, and had no stenosing colonic lesion, however she had chronic constipation and intestinal adhesions.

Implication: Complications arising from barium retention/inspissation can be avoided if precautions are taken in high risk patients i.e. poor gut motility, pathological bowel disease and dehydration. Instructions about maintaining good hydration, laxative use and to seek medical care if no bowel movement occurs are important in preventing this rare complication.

[figure1][figure2]
a large irregular mass occupying the second portion of the duodenum. The mass appeared to originate from the ampulla. Multiple biopsies were taken. Endoscopic ultrasound could not clarify the source of the mass. An FNA was performed with an Olympus 22 guage needle. Cytology results revealed "normal cells." Due to persistent bleeding, the patient underwent surgical resection of the lesion, pancreaticoduodenectomy. Surgical pathology revealed that the lesion was 12.5 cm x 5.7cm x 8 cm composed of sheets of heterotopic pancreatic tissue, benign appearing. The patient recovered and remains well. Heterotopic pancreas is a rare entity, identified incidentally and warranting no intervention. However, our patient presents with a unique form of heterotopic pancreas not previously described. This case represents the largest heterotopic pancreas reported. In addition, the symptoms of massive upper gastrointestinal bleeding have not been previously described. Initial attempts at establishing the diagnosis including CT, endoscopic biopsy, and endoscopic ultrasound with biopsy were unsuccessful. Surgical excision was needed to establish the diagnosis and treat the persistent bleeding. Although rare, heterotopic pancreas should be considered in the differential diagnosis of masses causing upper gastrointestinal bleeding. A 53 year old caucasian male was referred to us for evaluation of intermittent rectal bleeding and constipation of 4 months duration. He denied any anorexia and weight change. There was no family history of colon cancer or polyps. Patient underwent colonoscopy for further evaluation which revealed Internal hemorrhoids and benign appearing diminutive colon polyps in Ascending and Sigmoid colon. Polypectomy specimen from sigmoid colon revealed extensive eosinophilic and degenerated compilation of ovoid to irregular material in submucosa.Congo red stain showed green birefringence and SAP immunostain was positive suggestive of amyloidosis. Stain for prealbumin, beta-2 microglobulin and SAA were negative. There was also a suggestion of Lambda light chain restriction. There was no features of systemic amyloidosis. Lack of diffuse colonic involvement also argued against systemic disease. Negative serum protein and bone marrow examination led to the final diagnosis of localized “amyloidoma” of colon. This case illustrates the importance of atleast biopsing even the most diminutive polyp especially in left colon, which are hyperplastic mostly, as sometimes even a small polyp can lead to a diagnosis of widespread disease.

Chronic Colonic Ischemia Mimicking Colon Cancer and Presenting as a Recurrent Mass
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Ischemic colitis typically presents as an acute disease with bleeding, diarrhea, and abdominal pain. Endoscopic characteristics, include ulceration and inflammation. We present a case of a patient undergoing a screening colonoscopy found to have a recurrent large cecal mass found to be due to chronic ischemia of the colon. A 60 year old asymptomatic Hispanic woman with no significant medical history presented for a screening colonoscopy. She denied abdominal pain, hematochezia, diarrhea, and weight loss. She denied taking any medications. Physical and laboratory examination were within normal limits. Colonoscopy revealed a 3 cm polypoid mass in the cecum with no surrounding edema or mucosal hemorrhage. Multiple biopsies were taken. Histologic evaluation revealed classic changes of chronic ischemia. The patient was managed conservatively. Repeat Colonoscopy three months later showed interval resolution of the polypoid mass in the cecum. Six months later she was admitted with right lower quadrant dull aching abdominal pain. CT scan showed mass in the cecum and proximal ascending colon. Colonoscopy done showed a recurrent mass in the cecum and proximal ascending colon with edema and ulceration. Multiple biopsies were taken and revealed ischemic colitis. Mesenteric angiography was normal. Hematologic evaluation failed to reveal a coagulopathy. The patient improved and has remained well. Ischemic colitis is a distinct subtype of ischemic bowel disease most often limited to the superficial mucosa. Colonoscopy typically identifies ulceration, pseudopolyps, hemorrhagic nodules, submucosal bleeding, cyanotic or necrotic mucosa with ulceration. Often there is a segmental distribution with abrupt transition between injured and normal mucosa. Although ischemic colitis may present with polypoid lesions, this is the unique case of ischemic colitis presenting as a large recurrent colonic mass.

Liver Amyloidosis
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We present the case of a 56 years old caucasian man, presenting to our hospital in March 2006 with painless jaundice for 3 months. His physical examination was unremarkable except for jaundice, and a palpable liver 2 cm bellow the costal arch. He refered gray stool and dark urine, some degree of pruritus, no abdominal pain or fever. He denied having taken any medication before the onset of the complaints, or any risk behaviour for viral hepatitis. Analytically he presented with cholestasis (GGT = 644 U/l, alkaline phosphatase (AP) = 521 U/l, bilirubin = 186.4 mg/l, AST = 62 U/l, ALT = 58 U/l).The abdominal ultrasound and CT showed no biliary dilation nor biliary obstruction. The viral serology (HCV, HAV, HBV, EBV, CMV, HSV), and autoantibodies were all negative. He performed a percutaneous hepatic biopsy that revealed amyloid deposition, with sinusoidal predominance, and marked cholestasis. The molecular analysis of the liver specimen identified the amyloid as AL kappa type. His renal function was preserved, he had no proteinuria, no free light chains in serum or urine and the immunoelectro- trophoresis showed no signs of monoclonal gammopathy. His heart function was normal. A bone marrow biopsy was done, and revealed amyloid deposits. He was started on ursodeoxycholic acid 750 mg/day, and bilirubin began improving, although GGT and AP remained in the same range. He was presented to the hematoooncology group for a treatment decision, and is waiting to begin chemotherapy with vincristine, Adriamycin and dexamethasone.

Splenic AV Fistula: A Rare Cause of UGIB and Mesenteric Ischemia
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In the United States, most cases of portal hypertension result from intrinsic liver disease. However, when no liver disease is obvious, rarer etiologies must be carefully evaluated. Here we discuss the case of a splenic arteriovenous fistula (AVF) that led to severe portal hypertensive bleeding and gastrointestinal ischemia. A 34 y/o black female with no significant past medical history presented to our institution with 10 days of watery diarrhea and diffuse post-prandial abdominal pain. 5 days prior, she went to an outside hospital with these same complaints, where she was given a diagnosis of gastroenteritis and sent home with PPI. In our ER she underwent CT scan, which showed diffuse bowel wall thickening and significant

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ABSTRACT WITHDRAWN

Localized Colon “Amyloidoma”
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portal hypertension (esophageal, gastric, and rectal varices and enlarged splenic and portal veins). She had no history of or significant risk factors for liver disease. While awaiting admission, she had hematemesis and hematochezia with a change in her hemodynamic status. Emergent endoscopy revealed Grade III esophageal varices, ischemic-appearing stomach and duodenum, and a large fundal pool of blood with pulsatile arterial spurring. After control of bleeding with epinephrine injection and evacuation of the fundal pool, large gastric varices were noted, but the bleeding had subsided. Given these findings, balloon tamponade of the gastric varices was achieved with a Minnesota tube. The CT and subsequent liver duplex failed to reveal evidence of portal venous outflow obstruction. Urgent angiography was performed to further evaluate the “idiopathic” portal hypertension. This revealed a large splenic AVF, treated with the placement of multiple coils in the mid-splenic artery. After the procedure she had no further bleeding, pain, or diarrhea and was tolerating a full diet. Repeat CT showed improvement in the bowel wall thickening. She was discharged home with surgical follow-up for consideration of splenectomy. Splenic AVF is a rare cause of forward portal hypertension in association with mesenteric ischemia. Patients can present with complications of portal hypertension, as seen in our patient. The diagnosis may be difficult to make without arteriogram. On CT scan early filling of the portal vein on the arterial phase can give a clue to this diagnosis and was seen in retrospect in our patient. The diagnosis of splenic AVF should be considered in the differential diagnosis of portal hypertension and mesenteric ischemia, especially in the absence of liver disease.

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Primary Lymphoma of the Liver Presenting with Two Years of Unexplained Intermittent Jaundice

A 57 year old black male with MGUS, chronic eosinophilia, two-year history of pruritus and intermittent jaundice presented with 10 lb weight loss. Physical exam was unremarkable. Labs revealed a bilirubin 15, ALP 474, AST 129, ALT 166 and eosinophilia. An MRCP showed biliary dilatation and choledolithiasis. ERCP revealed bile draining from the ampulla and the CBD could not be cannulated. The LFT's improved and it was felt that the patient passed a stone. An open cholecystectomy with cholangiogram was performed and revealed a stricture at the bifurcation of the common hepatic duct; biopsy of which showed fibrosis. Post-op the patient's bilirubin and LFT's normalized. Two months post-op, a 2.5 cm lesion was seen in left lobe of the liver and was felt to be either post-op edema vs malignancy. An MRI showed an ill defined lesion at the porta hepatis and no biliary dilatation. The patient subsequently was diagnosed with prostate ca and began to receive external beam radiation. A few months later the patient presented with painless jaundice and pruritus. Total bilirubin 27, ALT 416, ALP 84, AST 135. Liver biopsy showed portal fibrosis with chronic inflammation and piecemeal necrosis suggestive of sclerosing cholangitis and immunostaining showed non-specific reactive changes. The bilirubin and LFT's again normalized on their own. At 4 month follow up the liver lesion doubled in size and repeat biopsy showed necrotic hepatocytes and immunostains favored lymphoma. 3 month follow up CT revealed again doubling of the mass to 7.5cmx6.5 cm with narrowing of biliary tree at porta hepatis. LFT's and bilirubin at that time were normal. Surgical resection of the tumor at this point showed diffuse B cell lymphoma. The patient was treated with 6 cycles of R-CHOP and has done well. Primary hepatobiliary non-Hodgkin’s lymphoma (NHL) is a rare disease, accounting for 1% of extra nodal NHL. It can be associated with unexplained jaundice or irregular narrowing of major bile ducts. Unfortunately, biopsy results are often non-specific, and patients in the past have received liver transplants with the explanted liver showing NHL. Surgical intervention is indicated when an accurate diagnosis cannot be made pre-op. An accurate diagnosis is important because with chemotherapy complete remission has been seen in up to 83% of cases with a 5yr survival of 70%.

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Echinococcal Cyst Rupture Resulting in Obstructive Jaundice and Pancreatitis
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Hydatid cysts are caused by tapeworms with E. granulosus infection being the most common. Most patients are asymptomatic, however complications can arise from cyst rupture. We describe a case of cyst rupture into the biliary system with resultant obstructive jaundice and pancreatitis, an infrequent complication of hydatid cyst. A 63 year-old healthy Greek male was referred for abdominal pain. A CT scan showed a 14 x 7.4 cm multi-septated cyst with an ill-defined cyst wall located within the dome of the liver and a normal biliary tree. Echinococcal IgG level was strongly positive. Due to his symptoms, a four-week treatment regimen of Albendazole was initiated. The patient experienced abdominal pain, emesis, and fever within three weeks. Repeat CT scan showed that the cyst had become organized and decreased in size. New findings of perihepatic free fluid, peripancreatic edema and infiltrative changes, and biliary ductal dilatation were also seen. Laboratory investigation revealed direct bilirubin 5.9, aspartate aminotransferase 270, alanine aminotransferase 382, alkaline phosphatase 414, amylase 984, and lipase 628. Emergent ERCP revealed a large amount of white linear cast-like gastric debris and solid white debris was seen protruding from the ampulla. Cholangiogram revealed multiple filling defects and marked intra and extrahepatic dilatation. A large sphincterotomy was performed and pearly white solid and gelatinous hydatid membranes were seen extruding from the ampulla. After multiple balloon sweeps, the CBD was flushed until clear return was seen and no further filling defects were seen on a final cholangiogram. Microscopic examination of the collected debris revealed tapeworms with hooklets suggestive of E. granulosus. Liver enzymes normalized and repeat CT showed regression of the hepatic cyst. The patient remained asymptomatic on continued Albendazole therapy. Most patients with hydatid cysts remain asymptomatic for years and the cysts are often discovered incidentally. This case demonstrates that pancreatitis and cholangitis can arise from cyst rupture as infrequent complications of hydatid cysts; emergent biliary decompression is essential if this occurs. Furthermore, surgery can be averted in cases of E. granulosus if cyst regression is achieved with medical therapy.

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Segmental Budd Chiari Syndrome: A Rare Complication of Transjugular Intrahepatic Portosystemic Shunt
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Segmental hepatic ischemia following placement of transjugular intrahepatic portosystemic shunt (TIPS) is extremely rare (only 2 cases previously described in literature) and thought to be due to thrombosis of the hepatic vein above the stent graft. We describe a case of segmental Budd Chiari Syndrome (BCS) developing following TIPS placement for ascites in a patient with veno-occlusive disease (VOD). A 65 year-old Caucasian male with acute myelogenous leukemia relapsed and was treated with salvage Gemtuzumab (Mylotarg) and subsequent allogenic stem-cell transplant 4 years prior to presentation. Post-transplant course was complicated by chronic graft-versus-host disease (GVHD) involving skin, lung, and liver. Five months prior to admission, he noted an increase in abdominal girth and
lower extremity edema. Over the next several months, the ascites increased requiring multiple paracenteses (SAAG > 1.1) and became refractory to diuretic therapy. A transjugular liver biopsy showed a hepatic venous wedge gradient of 25 mmHg and marked sinusoidal fibrosis, hepato-portal sclerosis, and mild GVHD consistent with VOD. In view of the post sinusoidal outflow obstruction, relatively good liver synthetic function, and since the patient was not a transplant candidate, TIPS was placed from middle hepatic vein to the left portal vein for the management of ascites. Ultrasound performed the following day confirmed patency of TIPS. The patient’s ascites improved immediately following TIPS. Two days later, he was found to have an acute worsening of his transaminases with AST of 432 and ALT of 1169 u/l with normal bilirubin. CT scan showed a wedge-shaped hypo-dense region in left hepatic lobe consistent with ischemia. Branches of the hepatic artery and portal vein were patent within the affected liver segment. The middle hepatic vein was not clearly visualized, and given the distribution of the ischemia was likely thrombosed. He was managed conservatively with hydration and monitoring and transaminases improved over the next few days. However, he developed respiratory decompensation and eventually, multi-organ system failure. His family opted to withdraw further care. No autopsy was performed. We present a case of segmental BCS – an ex-}

...the ischemia was likely thrombosed. He was managed conservatively with hydration and monitoring and transaminases improved over the next few days. However, he developed respiratory decompensation and eventually, multi-organ system failure. His family opted to withdraw further care. No autopsy was performed. We present a case of segmental BCS – an ex-
Discussion: expired in the hospital 5 months after his initial admission. Initiating HAART and chemotherapy, the tumor progressed and the patient performed during surgery was consistent with Burkitt’s lymphoma. Despite a clinical and endoscopic picture of IBD, this should be considered in the differential of HIV patients presenting with symptoms and biopsies suggestive of inflammatory bowel disease. There have been a few case reports of patients presenting with symptoms and biopsies suggestive of inflammatory bowel disease and later found to have colonic lymphomas. Our case report is the first describing a patient with HIV who was given the diagnosis of Crohn’s disease and later found to have Burkitt’s lymphoma. Due to the importance of early diagnosis of Burkitt’s lymphoma, this case should be considered in the differential of HIV patients presenting with a clinical and endoscopic picture of IBD.

Burkitt’s Lymphoma Masquerading as Crohn’s Disease in a Patient with HIV: A Unique Presentation

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Case Report: A 28 year-old African American male with known HIV, CD4 count of 301 and on no HAART therapy, presented to the emergency room with a complaint of one month history of progressive constipation, weight loss and dull left lower quadrant pain that radiated to his back. His only PMH was HIV which was diagnosed in 1998. Flexible sigmoidoscopy demonstrated a semi-circumferential, solitary, friable mass in the rectum at 5cm with ulcerated mucosa. The biopsy specimen exhibited changes consistent with Crohn’s disease. The patient was empirically started on mesalamine with no gastro-intestinal complaints.

Persistent Ulcerative Ileitis of 15 Years Duration in an Asymptomatic Patient

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Many infectious, inflammatory, or drug-related processes may present in the terminal ileum or ileocecal valve. Routine ileoscopy during colonoscopy may identify ulcers in the pre-valvular segment of the terminal ileum or the ileocecal valve itself in patients without known Crohn’s disease. Although ileoscopy is commonly practiced, there is no clear consensus on how to proceed if ulcerations are identified. In a recent study, 40 patients with ulcerative ileitis were identified during 1900 consecutive ileoscopies performed over a 5 year period by a single examiner in a community setting. Most of these patients were undergoing screening colonoscopy; however, 33 of the 40 patients reported regular use of nonsteroidal anti-inflammatory drugs (NSAIDs). We report a case of asymptomatic terminal ileum and ileocecal valve ulcerations in a single individual that have persisted for more than 15 years in the absence of any known precipitating factors.

Case: A 51 year old white female with a past medical history significant for fibrocystic breast disease presented for routine screening colonoscopy in 1990. At the time of initial presentation, the patient was taking a daily aspirin for its cardio-protective effects, and hormone replacement therapy. Her physical exam, blood profile, and coagulation studies were unremarkable. Colonoscopy revealed multiple shallow non-malignant appearing ulcerations varying from 3–8 mm in the terminal ileum and the ileocecal valve. Biopsies revealed acute and chronic inflammation with ulceration. The patient discontinued her aspirin therapy for 5 months with a second colonoscopy revealing multiple ulcerations ranging from 2–6 mm in the same locations. Subsequent colonoscopies were performed in 1994, 1999, and 2004 with significant change in the appearance, location, or histology of the ulcerations. The patient is currently 66 years of age and remains in good health with no gastro-intestinal complaints.

Discussion: The identification of ulcerative ileitis may occur with routine ileoscopy during colonoscopy. Currently, there is not much literature regarding the identification and outcomes of ulcerative ileitis in asymptomatic individuals. To our knowledge, this case report describes the longest single observation of ileal ulcerations in an asymptomatic patient.

Evolution of the Pylorus from a Double to a Triple Lumen

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Gastroduodenal fistulae are rare with double lumen pylorus found in 0.001–0.4% of procedures and triple lumen pylorus reported in only 3 cases in the
Reactivation of Chronic Hepatitis B Leading to Fulminant Hepatic Failure in an Immunosuppressed Patient

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The dangers of immunosuppression in patients that are known to be hepatitis B surface antigen positive have been described in the literature. It is proposed that steroids increase the rate of viral replication leading to an increased risk of reactivation. We report a case of fulminant hepatic failure (FHF) secondary to reactivation of hepatitis B in an immunosuppressed patient. A 50 year old male with a history of meningioma status post resection two months prior treated with high dose steroids for cerebral edema presented with progressively worsening bilaterally lower extremity edema that was refractory to escalating doses of oral diuretics. He also noted worsening right upper quadrant pain and jaundice. He denied any risk factors for viral hepatitis including sexually activity, IV drug abuse or travel to endemic areas. His medications included dexamethasone 4mg four times a day. His exam was significant for severe lower extremity pitting edema, sclera icterus, right upper quadrant tenderness and ascites. Initial lab values revealed an AST of 328 IU/L, ALT of 732 IU/L, Total Bilirubin of 9.9 mg/dL, PTT of 31.8 seconds and INR of 2.1. Upon admission, his initial hepatitis panel was HepBsAg+, HepBeAg+ and HepBeAb-. His HBV viral load was 2 billion. His anti-HCV and HDV DNA PCR were both negative. The patient quickly developed signs of hepatic encephalopathy and was started on lactulose and lamivudine. He was evaluated for liver transplant, but rejected because of his recent brain surgery with associated intracranial swelling. The patient’s condition worsened and he expired 4 weeks later of hepatorenal syndrome and respiratory failure. This case demonstrates a known danger of the immunosuppression in patients with chronic latent hepatitis B. For our patient, the etiology of his FHF was thought to be due to the high dose steroids that the patient was prescribed for cerebral edema. Unfortunately, our patient was unaware of his hepatitis B status and gave no risk factors on initial history. This is a common issue and should be taken into account by healthcare providers. Knowledge about this potential risk is especially timely given the increased use of long term immunosuppressive therapies by a variety of specialties. Awareness of this potentially fatal complication will lead to increased screening of patients for HBV prior to initiating immunosuppressive treatment.
who experiences abdominal pain or pancreatic enzyme elevations, in the setting of rectal mesalamine, should alert the clinician to the possibility of drug-induced pancreatitis. Possible mechanisms include immunological hypersensitivity and oxidative cell injury. There is a need for further elucidation of this phenomenon and its pathophysiology.

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**Colonic Varices Secondary to Superior Mesenteric Vein Stenosis in a Patient with Crohn’s Disease**

Todd N. Witte, MD, Christopher R. Entwisle, MD, Marie L. Borum, MD, FACP, M. Aamir Ali, MD.* Division of Gastroenterology & Liver Diseases, The George Washington University, Washington, DC.

Albeit rare, colonic varices are usually seen in the anorectum in the setting of portal hypertension, although idiopathic and familial cases of colonic varices have also been described. Cases have also been reported resulting from mesenteric hypertension secondary to portal or mesenteric vein (MV) thrombosis. The association of inflammatory bowel disease and MV thrombosis is well recognized. We are aware of only one case series describing Crohn’s disease resulting in MV stenosis and subsequent portal hypertensive lower gastrointestinal varices. The series described 3 patients with small bowel (SB) varices. We report a case of superior MV stenosis resulting in colonic varices in a patient with Crohn’s disease. The patient is a 43 year old male with Crohn’s ileitis and proctitis, who had been in remission on oral mesalamine since the diagnosis 2 years prior. The patient presented with several weeks of intractable nausea and vomiting, intermittent melolic stools, and a reported 25 pound weight loss over 2 months. Physical examination was unrevealing and bloodwork was only remarkable for mild anemia. A CT-scan showed thickened distal SB, with possible narrowing of the superior MV with colonic collaterals. A SB follow-through was normal. The patient was started on antibiotics and immunosuppressive medications, with mild improvement. Upper endoscopy was unremarkable. Colonoscopy revealed erythematous mucosa and pseudopolyps in the distal ileum with an intrinsic stricture. Varices were seen in the ascending and transverse colon. An opening was seen at the rectosigmoid junction with passage of air and stool, suggesting stricture. Varices were seen in the ileo-sigmoid fistula and multiple SB stenosed superior MV and ileocolic veins, which resulted in decompression of the varices. The patient was unable to tolerate upper endoscopy. pH-metry with Bravo revealed pathologic reflux on day #2 with regurgitation symptoms strongly correlated with acid reflux events. A barium esophogram showed a normal contour, however motility was not assessed as the procedure was terminated secondary to coughing and aspiration of contrast. A gastric emptying study was normal. Dysphagia and regurgitation did not improve with high dose proton pump inhibitor therapy. As benzodiazepines did not improve symptoms in the past, the patient was treated with steroids and intravenous immune globulin (IVIG), which resulted in transiently improved axial muscular rigidity and dysphagia. SMS is a rare disorder characterized electromyographically by continuous motor discharge. Several cases of dysphagia have been described which were responsive to benzodiazepine therapy. To our knowledge, this is the first report of esophageal manometric findings in a patient with SMS. Our findings suggest not only striated muscle, but also smooth muscle involvement. Smooth muscle involvement has been previously reported in the form of delayed gastric emptying. The lack of acid reflux on day #1 of pH-metry raised a question of possible residual effect from conscious sedation, however the patient’s symptoms have not sustained a response to medical therapy.

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**Esophageal Dysmotility Confirmed by Esophageal Manometry in a Patient with Stiff-Man Syndrome and Dysphagia**

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Stiff-man syndrome (SMS) is a rare autoimmune condition characterized by “tin soldier” rigidity of axial muscles. Nearly 150 cases have been reported with 6 reports of pharyngeal or esophageal dysphagia. We report the first case of esophageal dysmotility documented by esophageal manometry in a patient with SMS and dysphagia. A 37 year old African American male with SMS was referred for progressive regurgitation and dysphagia to solids and liquids since the diagnosis 2 years prior. The dysphagia was less noticeable with thickened liquids or soft foods. The patient denied odynophagia, pyrosis, early satiety or constipation. Esophageal manometry revealed low amplitude contractions to wet swallows with no significant antegrade propulsion. A few secondary peristaltic waves of adequate amplitude were seen. [figure1] The patient was unable to tolerate upper endoscopy. pH-metry with Bravo revealed pathologic reflux on day #2 with regurgitation symptom strongly correlated with acid reflux events. A barium esophagram showed a normal contour, however motility was not assessed as the procedure was terminated secondary to coughing and aspiration of contrast. A gastric emptying study was normal. Dysphagia and regurgitation did not improve with high dose proton pump inhibitor therapy. As benzodiazepines did not improve symptoms in the past, the patient was treated with steroids and intravenous immune globulin (IVIG), which resulted in transiently improved axial muscular rigidity and dysphagia. SMS is a rare disorder characterized electromyographically by continuous motor discharge. Several cases of dysphagia have been described which were responsive to benzodiazepine therapy. To our knowledge, this is the first report of esophageal manometric findings in a patient with SMS. Our findings suggest not only striated muscle, but also smooth muscle involvement. Smooth muscle involvement has been previously reported in the form of delayed gastric emptying. The lack of acid reflux on day #1 of pH-metry raised a question of possible residual effect from conscious sedation, however the patient’s symptoms have not sustained a response to medical therapy.

**Maintenance Ciprofloxacin**

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While patients with IBD are at an increased risk of associated thromboembolic complications, it is unusual for an IBD patient to complain of easy bruising or bleeding. Patients with Crohn’s disease often benefit from antibiotic therapy, the best studied being metronidazole and ciprofloxacin. We report a case of a patient with Crohn’s Disease in which easy bruising was associated with maintenance antibiotic therapy.

**Case:** The patient is a 35 year old Caucasian female with Crohn’s colitis diagnosed approximately 2 years prior, and is status-post surgical repair of an anovaginal fistula. There is no small bowel involvement of Crohn’s disease, and she maintains a normal diet. The patient has been managed with oral mesalamine and 6-mercaptopurine (6MP), with active metabolites within the therapeutic range. There was clinical improvement with ciprofloxacin in the past, but this was stopped secondary to the patient becoming pregnant. Following a spontaneous abortion, ciprofloxacin was restarted twice daily, in addition to continuing 6MP and mesalamine, and clinical remission was achieved. 5 months later the patient complained of easy bruising. Bloodwork was normal, except for an INR of 1.20. Bruising and coagulopathy resolved when oral vitamin K was given and ciprofloxacin was held. Her clinical course necessitated resumption of maintenance ciprofloxacin, again with a clinical response but complicated by easy bruising. For the past 4 months, the patient has taken oral vitamin K every other day in addition to continuing ciprofloxacin, and notes bruising only when not regularly taking daily, in addition to continuing 6MP and mesalamine, and clinical remission was achieved. 5 months later the patient complained of easy bruising. Bloodwork was normal, except for an INR of 1.20. Bruising and coagulopathy resolved when oral vitamin K was given and ciprofloxacin was held. Her clinical course necessitated resumption of maintenance ciprofloxacin, again with a clinical response but complicated by easy bruising. For the past 4 months, the patient has taken oral vitamin K every other day in addition to continuing ciprofloxacin, and notes bruising only when not regularly taking 6MP and mesalamine, with mild improvement. Upper endoscopy was unremarkable. Colonoscopy revealed erythematous mucosa and pseudopolyps in the distal ileum with an intrinsic stricture. Varices were seen in the ascending and transverse colon. An opening was seen at the rectosigmoid junction with passage of air and stool, which was consistent with an entero-colonic fistula when injected with contrast dye. The patient underwent angiogram with balloon angioplasty of the stenosed superior MV and ileocolic veins, which resulted in decompression of the varices. Surgical resection of the ileo-sigmoid fistula and multiple SB stenosed superior MV and ileocolic veins, which resulted in decompression of the varices. The series described 3 patients with small bowel (SB) varices. We report a case of superior MV stenosis resulting in colonic varices in a patient with Crohn’s disease. The patient is a 43 year old male with Crohn’s ileitis and proctitis, who had been in remission on oral mesalamine since the diagnosis 2 years prior. The patient presented with several weeks of intractable nausea and vomiting, intermittent melolic stools, and a reported 25 pound weight loss over 2 months. Physical examination was unrevealing and bloodwork was only remarkable for mild anemia. A CT-scan showed thickened distal SB, with possible narrowing of the superior MV with colonic collaterals. A SB follow-through was normal. The patient was started on antibiotics and immunosuppressive medications, with mild improvement. Upper endoscopy was unremarkable. Colonoscopy revealed erythematous mucosa and pseudopolyps in the distal ileum with an intrinsic stricture. Varices were seen in the ascending and transverse colon. An opening was seen at the rectosigmoid junction with passage of air and stool, which was consistent with an entero-colonic fistula when injected with contrast dye. The patient underwent angiogram with balloon angioplasty of the stenosed superior MV and ileocolic veins, which resulted in decompression of the varices. Surgical resection of the ileo-sigmoid fistula and multiple SB stenoses was then performed. Pathology review revealed SB adenocarcinoma arising from the ileal aspect of the fistula, with positive lymph nodes. Severe intestinal inflammation from Crohn’s Disease can result in stenosis of the varices. This is the first reported case of a patient with Crohn’s disease and superior MV stenosis resulting in colonic varices.

**SWALLOW**

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*All amplitudes in mmHg*
compliant. Dietary vitamin K is absorbed by active transport in the upper small bowel, while endogenous bacterial-produced vitamin K is absorbed by passive transport in the terminal ileum and colon. Broad-spectrum antibiotics, such as ciprofloxacin, are known to impair the vitamin K producing intestinal bacteria. As our patient does not have small bowel disease, and maintains good nutritional status, we conclude that the ciprofloxacin is responsible for the reversible bruising and coagulopathy. This case highlights the need to recognize this side effect, particularly in Crohn’s disease patients that may be on maintenance antibiotic therapy.

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Diclofenac Hepatotoxicity
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Approximately 15% of patients taking diclofenac develop mild transaminase abnormalities, with severe hepatotoxicity in 1-2 cases/million prescriptions and a case fatality rate of approximately 10%. Because millions of people are treated successfully without adverse reaction, diclofenac toxicity is not often considered in the differential diagnosis for abnormal liver enzymes. We present a case of hepatotoxicity secondary to diclofenac use, which was initially thought to be acute viral hepatitis. A 64 yo female on atorvastatin for > 1 year, started taking diclofenac. Routine blood work 1–2 months later was abnormal. Laboratory work was next obtained while overseas on vacation (week 2), which included a (+) hepatitis A (HAV) IgM, leading to a diagnosis of acute hepatitis A and instruction to stop atorvastatin. Upon her return, bloodwork (week 6) included a normal coagulation profile, (+)HAv total antibody and (−)HAV IgM. The patient then showed improvement (week 9). 1 month later the patient was referred with malaise, worsened jaundice and abdominal pain (week 13). After clarifying the continued intermittent use of diclofenac, the patient was instructed to stop all NSAIDs and 1 week later liver enzymes were slightly improved. Repeated testing twice showed negative HAV total and IgM antibodies; negative serology for hepatitis B, C, CMV and HSV; and negative autoimmune markers. In order to better distinguish between drug-induced hepatitis and serology-negative autoimmune hepatitis, a liver biopsy was obtained and the patient was started on prednisone while awaiting pathology review, which was consistent with an immune hepatitis, a liver biopsy was obtained and the patient was started on prednisone and (−)HAV IgM. The patient then showed improvement (week 9). 1 month later the patient was referred with malaise, worsened jaundice and abdominal pain (week 13). After clarifying the continued intermittent use of diclofenac, the patient was instructed to stop all NSAIDs and 1 week later liver enzymes were slightly improved. Repeated testing twice showed negative HAV total and IgM antibodies; negative serology for hepatitis B, C, CMV and HSV; and negative autoimmune markers. In order to better distinguish between drug-induced hepatitis and serology-negative autoimmune hepatitis, a liver biopsy was obtained and the patient was started on prednisone while awaiting pathology review, which was consistent with a drug-induced hepatitis. The patient was instructed not to resume any NSAID except aspirin, and prednisone was tapered. Liver enzymes have remained normal 15 weeks after cessation of prednisone. The patient was referred for hip replacement and is doing well off NSAIDs. This case highlights the idiosyncratic nature of diclofenac hepatotoxicity. The case reinforces the need to elicit a complete drug history. One unusual aspect of this case involves the false-positive HAV IgM reported by the overseas physicians, and the false-positive HAV IgG later obtained by the primary physician. [figure1]

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Iatrogenic Jejunal Perforation during Duodenal Stricture Dilatation Secondary to Groove Pancreatitis
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A 35 y/o female with a history of alcoholic chronic pancreatitis was transferred for open surgical repair of an iatrogenic, proximal jejunal perforation during endoscopic balloon dilatation of a presumed benign duodenal stricture. Three months previously, she had undergone gastrojejunostomy secondary to duodenal obstructive symptoms. The stricture was located in the duodenal e-sweep and perforation occurred just distal to the stricture in the afferent jejunal limb while attempting retrograde dilation. Following primary closure, the patient underwent an MRI to evaluate the stricture and a focal 1.5 cm fluid collection was found in the pancreatic head adjacent to the second portion of the duodenum with associated pancreatic head enlargement. EUS revealed mass-like enlargement of the pancreatic head with a focal 1.5 cm fluid collection and chronic inflammatory changes in the body and tail. EUS-FNA of the fluid collection and surrounding pancreatic parenchyma revealed cell block portions featuring spindle cell proliferation with nuclear atypia, marked cellularity and high mitotic activity. Based on subsequent immunohistochemistry, the pancreatic head lesion appeared to be a malignant spindle cell neoplasm with smooth muscle differentiation. Uneventful pancreaticoduodenectomy was performed three months following her perforation. Pathology revealed fibrosis of the adjacent pancreas, Brunner’s gland hyperplasia, and bundles of smooth muscle within the duodenum that were interspersed with dilated ducts containing inpsissated secretions. All findings were consistent with a diagnosis of paraduodenal pancreatitis, or groove pancreatitis. Groove pancreatitis is a rare form of segmental chronic pancreatitis that involves the anatomic space between the head of the pancreas, the duodenum, and the common bile duct. It has been associated with alcoholic chronic pancreatitis and its etiology is thought secondary to disruption of normal pancreatic secretory flow via the minor papilla. The differential diagnosis of patients with external duodenal compression, chronic pancreatitis, and pancreatic head fullness should include groove pancreatitis. This is the first reported case of iatrogenic perforation during endoscopic treatment of a duodenal stricture secondary to groove pancreatitis.

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Fatal Hepatitis B Reactivation in a Healthy Carrier Receiving Rituximab Anticancer Therapy
Ronald M. Levy, MD, Stanley M. Cohen, MD.* Gastroenterology/Hepatology, Rush University Medical Center, Chicago, IL.

Hepatitis B (HBV) has been shown to reactivate in stable patients exposed to significant immunosuppression. We report a case of a patient with fulminant HBV reactivation following administration of rituximab-based chemother-apy. A 54 year old Chinese male with a history of being “a healthy carrier” for HBV was diagnosed with Waldenstrom’s Macroglobulinemia. He completed a course of rituximab and fludarabine. He presented to the hospital six weeks later with fevers, emesis, and progressive right upper quadrant pain. His past medical history was significant for the HBV diagnosed 15 years earlier. His liver enzymes and viral DNA were always normal (including just prior to chemotherapy), he never had a liver biopsy, and never required treatment. Family history revealed that both his mother and brother had HBV. He denied any use of alcohol, tobacco, or illicit drugs. Initial physical exam revealed a temperature of 101.0°, scleral icterus, moderate right upper quadrant tenderness, and no asterixis. Initial laboratory data revealed a total bilirubin of 6.2 mg/dL, AST 10647 U/L, ALT 4743 U/L, INR 2.2, and an HBV DNA greater than 17000000 copies/mL. Abdominal ultrasound with dopplers was negative except for minimal ascites. Upon admission, the patient was placed...
on oral anti-viral agents and prednisone, and was emergently listed for liver transplantation. On hospital day two, his mental status rapidly deteriorated. On hospital day five, his intracranial pressure became refractory to medical management, and he expired from cerebral herniation.

Discussion: Our case demonstrates a fulminant HBV reactivation following rituximab-based chemotherapy. Rituximab is a monoclonal antibody directed against the CD 20 antigen on B-lymphocytes. HBV reactivation with fulminant hepatitis, hepatic failure, and death has been reported in patients receiving rituximab-based therapy. The FDA has required the manufacturer to notify prescribing physicians. Recent studies have demonstrated a role for prophylactic oral nucleoside analogues in the prevention of HBV reactivation in patients receiving anti-cancer therapy. In summary, HBV reactivation can occur following the administration of immunosuppressive agents. The use of prophylactic anti-viral medications should be considered prior to chemotherapy in patients with HBV.

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“Downhill” Variceal Hemorrhage Due to Central Venous Catheter-Induced Superior Vena Cava Stenosis
Saurabh S. Dhawan, MD.* Medicine, University of Tennessee, Memphis, TN.

“Downhill” varices, first described by Felson and Lessure in 1964, are a rare complication of superior vena cava (SVC) obstruction which mostly is malignancy-related, but may also result from central venous catheter (CVC) placement.

Case report: A 34-year-old woman with end stage renal disease and a history of multiple CVC placements for hemodialysis, presented with 3 days of melena and dyspnea. She denied prior GI bleeding, liver disease, NSAID or alcohol use. Physical exam revealed right arm, right breast and facial swelling. She had a history of multiple CVC placements, causing intrathoracic collateral formation and esophageal varices. These are further classified as “uphill” varices (caudo-cephahal blood flow) which are primarily lower esophageal, seen in portal hypertension and the most common type; and “downhill” varices (caphalo-caudal blood flow) which are either upper esophageal or whole length, seen in SVC obstruction and are rare. Obstruction above the ayzygous vein entry produces upper-mid level varices due to shunting of blood to the ayzygous vein to finally return via the SVC; but if below this point then whole length varices result to shunt blood entirely to the IVC, as seen in this case. Recent AVG induced hyperdymicity could have caused the patient’s decompensation. This is a rare case of SVC stenosis induced by multiple CVC placements, causing intrathoracic collateral formation and esophageal plexus engorgement producing classic “downhill” varices and massive GI bleeding. Treatment by stenting of the SVC stenosis resolved the varices.

A 30 year old male patient with congenital T cell immunodeficiency had complete esophageal obstruction following an episode of cryptococcal meningitis requiring prolonged nasogastric intubation. Subsequently, he had daily regurgitations with several hospitalizations for aspiration pneumonia. A Barium study revealed a dilated esophagus with no contrast reaching the stomach. A PEG was placed to maintain nutrition. He was referred to GI for endoscopic management due to poor surgical candidacy. Two endoscopes were introduced, first through the mouth and a second through the PEG site. Fluoroscopy showed a 3 cm isthmus of tissue separating the two endoscopes. A new track was created using an endoscopic ultrasound needle introduced from the esophageal side under fluoroscopy (with a guidewire advanced through it, received by the gastroscope and pulled out through the PEG site). This was subsequently diluted using a biliary dilator. A 24 F PEG tube was inserted orally, pulling the PEG through the new track, and cinching the bumper to the bottom of the esophagus. Finally, the distal portion of the PEG tube was delivered through the pre-existing gastrostomy site and connected to intermittent suction. To maintain nutrition, a separate gastrostomy tube was placed. The patient had complete resolution of his aspiration pneumonia upon follow up with CT scan showing resolution of pulmonary infiltrates without evidence of esophageal leak. Six months later, the “esophageal” PEG tube was removed endoscopically and the esophagogastric communication (EGC) was dilated using a balloon. A self-expandable silicone stent was deployed under fluoroscopy across the EGC. Gastrografin study confirmed the stent patency without leakage (Fig.1). The patient was able to swallow liquids and was later advanced to soft mechanical diet. Antegrade esophageal dilation was not possible in our case. We were able to create and maintain a new lumen endoscopically using the antegrade and retrograde approach. Our novel approach can be used to restore esophageal continuity in cases of complex and obstructive esophageal diseases, and thus avoid major surgeries. [figure1]

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Antegrade and Retrograde Endoscopic Approach in the Establishment of a Neo-Esophagus: A Novel Technique
Mohammad Al-Haddad, MD, Surakit Pungpapong, MD, Michael B. Wallace, MD, Massimo Raimondo, MD, Timothy A. Woodward, MD.* Gastroenterology, Mayo Clinic, Jacksonville, FL.

While the lifetime risk of fistula development in patients with Crohn’s disease is not insignificant (20% to 40% in most series), duodenal fistulae are
uncommon. To the best of our knowledge, there have been no previous reports of a duodeno-renal fistula.

**Case Report:** A 58-year old woman with severe peripheral vascular disease and a 35-year history of fistulizing Crohn’s disease was admitted with significant discomfort in the context of a rectovaginal fistula. A small bowel series was obtained which revealed multiple areas of stricturing, dilatation, and tethering in the duodenum and proximal jejunum. An EGD demonstrated an obstructing deformity in the second portion of the duodenum. The mucosa was edematous, granular, and irregular (figure 1). Multiple biopsies were taken from this region. These biopsies demonstrated acutely inflamed renal cortical tissue (figure 2). While she did eventually undergo surgical correction of her rectovaginal fistula, the duodenal fistula was treated conservatively with bowel rest, total parenteral nutrition, ciprofloxacin, metronidazole, and mesalamine. Immunomodulation was not given due to concurrent mycobacterial infection. Duodenal fistulae are an uncommon complication of Crohn’s disease. To the best of our knowledge, this represents the first report of a duodeno-renal fistula as well as the first report of renal pathology being obtained via diagnostic upper endoscopy. [figure1][figure2]

PSC is a progressive liver disease resulting in liver failure. Our case is about a man hospitalized for acute pancreatitis, and it was his pancreatitis which led to a thorough evaluation and diagnosis of PSC. There have been four other case reports found where pancreatitis was the initial presentation of PSC. A 21 y/o M, with a history of acute pancreatitis, presented with abdominal pain and nausea. He was admitted for management of pancreatitis, and a GI consult was obtained. Lab studies showed elevated amylase, lipase, LFTs, and ESR. Imaging showed dilation of parts of the biliary tract system, and a brush biopsy was normal. A liver biopsy then showed pathology consistent with early PSC with portal-portal bridging fibrosis. UCDA was started with symptomatic relief. Later, he developed diarrhea and was diagnosed with UC. PSC is characterized by intra and extrahepatic bile duct inflammation and fibrosis. The exact etiology is unclear. Patients may present with fever, RUQ abdominal pain, night sweats, chills, pruritus, jaundice, fatigue, weight loss, or steatorrhea. Examination may show stigmata of liver disease. Lab findings include increased p-ANCA, serum IgM and IgG levels. All patients develop liver failure, so the goal of medical therapy is symptomatic relief and delaying disease progression. Current regimens include UDCA alone or in combination with steroids or other immunomodulators. It was only after several bouts of pancreatitis that our patient received a work up resulting in a liver biopsy, diagnosing PSC. Our case is unusual because acute pancreatitis has rarely been described as the initial presentation of PSC. There is a close association between PSC and UC, which our patient was diagnosed with later.


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**Relationship between Capsule Endoscopy Gastric Passage Time and Physical Body Characteristics**

**Elena Hunanyan, Khondker Islam,* Moneera Haque. Medicine, Loyola University Medical Center, Maywood, IL.**

**Aim:** To investigate the relationship between Capsule Endoscopy Gastric Passage Time and physical body characteristics. This is a retrospective study done in Loyola University Medical Center. Capsule Endoscopy report was reviewed in 114 patients who had this procedure done for occult GI bleeding and anemia in 2005. Gastric passage time (GPT) is defined by the time of capsule endoscopy in minute to travel from gastroesophageal junction to duodenal bulb. Normal individual is defined by BMI less than 25, overweight BMI 25–30 and obesity BMI more than 30. Multivariate analysis was done to evaluate the effects of BMI, Height, weight, age and sex on gastric passage time of capsule. Total number of patients in the study was 114 who had capsule endoscopy done in Loyola University Medical Center in 2005. Age of the population ranges from 16 to 106 years. Mean age was 64 years. Male to female ratio was equal. Mean gastric passage time (GPT) is 27.4 min. Mean gastric passage time in normal individual is 25.9 min. Mean gastric passage
time in overweight patient is 34.3 min. Mean gastric passage time in obese patient is 24.9 min. Mean height for all patient is 66.5 inches. Mean GPT for all patient with height of 66.5 inches and lower is 28.8 min and higher than 66.5 inches is 26 min. Mean weight for male is 191.4 lbs. Mean GPT for males 191.4 lbs or less is 25.9 min and mean GPT for males more than 191.4 lbs is 33.7 min. Mean weight for female is 171.8 lbs. Mean GPT for females with weight higher than 172 lbs is 21.7 min. Although GPT in overweight patient (34.3 min) is higher than normal individuals (25.9 min) and obese patient (24.9 min), no difference is noted between normal and obese patients. No trends is observed when investigated GPT dependency on height. Relationship between Weight and GPT is consistent with the relationship of BMI and GPT. GPT increases with increasing weight in males, and decreases with increasing weight in females. It was observed that mean GPT for males increased with increasing BMI, however, in females, mean GPT decreased with increasing BMI. Similar mean GPT values for overweight males and females. Obese Males have the highest mean GPT, while the obese females have the lowest mean GPT. Although Capsule Endoscopy is used to evaluate small bowel, GPT could be estimated and the value could be validated with gastric emptying study.

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Nodular Regenerative Hyperplasia in a Patient with Cystic Fibrosis and Hemoglobin C Disease

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A 25 year old woman with cystic fibrosis and hemoglobin C disease was referred to the hepatologist for evaluation of an acute elevation in liver function tests. She reported intermittent, crampy abdominal pain that improved with 3 watery bowel movements daily. On physical examination, the patient was a young, thin black woman in no acute distress. Her abdominal exam disclosed hepatosplenomegaly. She had no stigmata of chronic liver disease. A trend of hyperbilirubinemia, transaminases, and alkaline phosphatase in a four-month period. A colonoscopy revealed normal mucosa. Random biopsies of the colon demonstrated an expanded infiltration of the lamina propria. An MRCP reported irregular narrowing and tapering of the main right and left intrahepatic ducts with an irregular contour of the common bile duct. Given the suggestion of primary sclerosing cholangitis, a liver biopsy was obtained which noted small regenerative nodules of alternating atrophic and hyperplastic hepatocytes consistent with nodular regenerative hyperplasia (NRH). NRH can present with a spectrum from asymptomatic disease to end stage liver disease. The incidence may be higher than reported as mostly the symptomatic cases are drawn to the attention of a practitioner. NRH has been noted to increase with age. The disease becomes clinically important when patients present with portal hypertension due to compression of portal vessels by nodules, obliteration of the portal vein, or increased splenic blood flow. The pathogenesis of NRH is not well understood but hypothesized to be the result of a vascular or pre-neoplastic process. There is a known association between NRH and hepatocellular carcinoma. It is unknown which lesion is the predecessor and which follows. Treatment is primarily directed at the complications of portal hypertension, an underlying disease state, or avoidance of an offending agent. Clinically, there are a number of NRH associations including medications, rheumatologic, immunologic, lymphoproliferative, myeloproliferative, endocrine, gastrointestinal, hematologic, pulmonary, and renal disorders. To date, there has only been one case report of NRH in a patient with cystic fibrosis associated colitis. As NRH has been associated with sickle cell disease, the patient's history of hemoglobin C disease may have also contributed to the development of NRH.

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Acquisition of Protein S Deficiency by Liver Transplantation

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Purpose: Liver transplantation is a life-saving procedure for patients with end-stage liver disease. Post-transplantation complications that threaten the longevity of the graft, such as rejection and recurrent disease, are well-recognized. However, the acquisition of systemic disease from a transplanted liver is rare.

Methods: Case report and review of the literature.

Results: A 62 year old Caucasian male with a history of hereditary hemochromatosis received a liver transplant in June 2004. The patient had no history of thrombotic events prior to transplantation or a family history of hypercoagulability. In fact, prior to an elecctive splenectomy in 1998 for thrombocytopenia, his bleeding time was 10 minutes (normal <7.5 minutes) and he bled significantly during surgery. The donor, a 29 year old woman, similarly had no prior history of thrombotic events and had not used any oral contraceptives. There were no findings of thromboses intraoperatively during organ recovery. The patient’s immediate post-operative course was unremarkable with no bleeding complications. At month 9 post-transplantation, the patient developed a left lower extremity thrombosis and at month 17 post-transplantation, an ileal vein thrombus developed resulting in resection of 12 cm of necteric ileum and ileostomy. Work-up following his ileal resection revealed protein S deficiency, suspected to be an acquired deficiency from his transplanted liver. His protein C, antithrombin 3 levels were normal and antcardiolipin antibody, prothrombin mutation and Factor V Leyden studies were negative. A review of the literature reveals one prior case of acquired protein S deficiency after liver transplantation.

Conclusions: With the limited availability of donors for liver transplantation and the inability to obtain rapid test results to evaluate for hypercoagulable states in donors, the pre-transplant diagnosis of conditions such as protein S deficiency will continue to rely upon clinical history. However, as highlighted by our case, the development of thrombosis post-transplantation should prompt a work-up for acquired hypercoagulable conditions, recognizing the role of the transplanted liver as a potential source.


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Abdominal Pain in a 22 Year Old with Cystic Fibrosis

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Cystic fibrosis is a genetic disorder of the exocrine system resulting in abnormal clearance of mucus and electrolytes affecting multiple organ systems including pulmonary, endocrine, and gastrointestinal. We present an unusual cause of intussusception and ileocecal prolapse in a cystic fibrosis patient.

Case: A 22 yo male with PMH of cystic fibrosis, insulin dependent DM, chronic constipation, and biliary cirrhosis presented with worsening RLQ abdominal pain for 1 day associated with nausea and emesis. The patient admitted to chronic RLQ pain for the past one year usually resolved after increasing intake of polyethylene glycol and docusate. He remained afebrile with a normal white blood cell count. Physical exam was significant for bilateral rhonchi, hepatomegaly, and RLQ tenderness. No palpable abdominal mass. A CT demonstrated mid jejunal- ileal intussusception and a probable ileocecal intussusception with marked distortion and edema. Follow up CT one day later showed resolution of small bowel intussusception and residual ileocecal deformity. Colonoscopy revealed rectal varices and ileocecal prolapse with mucosal ischemia. Given the concern for ongoing bowel ischemia the patient underwent exploratory laparotomy which revealed a 6 cm ileocecal prolapse with multiple fecoliths. There was no evidence of true intussusception. Pathology specimen demonstrated acute inflammation and necrosis. The patient did well post operatively and was discharged to home.

Discussion: Advances in the pulmonary management of CF patients have increased the median survival of these patients. Many patients with CF exhibit...
a variety of gastrointestinal complaints most notably constipation. This case demonstrates the importance of a diligent evaluation in the adult CF patient to exclude presence of intussusception, distal intestinal obstruction (DIOS) and even IBD. Frequently endoscopic evaluation can help delineate those cases appropriate for conservative treatment versus operative management. In this case our patient had self limited small bowel intussusception with persistent ileocecal prolapse mimicking intussusception on radiographic studies. This patient continues to be followed in our gastroenterology clinic and requires aggressive bowel regimen in hopes of preventing future GI complications related to underlying CF.

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Spontaneous Colonic Perforation in a Liver Transplant Patient
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As experience with liver transplantation has increased, immunosuppression regimens have become more refined which has greatly improved graft survival. Mycophenolate mofetil (MMF) is commonly used to allow for dose reduction and withdrawal of calcineurin inhibitors and glucocorticoids, and is finding more frequent use in patients with renal disease. MMF is well tolerated, but gastrointestinal side-effects, including nausea, vomiting, and diarrhea, are prominent and appear to be dose-related. We present a case of spontaneous colonic perforation in a liver transplant recipient on MMF. A 59 year-old female presented to her local Emergency Department complaining of fever, chills, cough, and fatigue. Her past medical history included diabetes mellitus and primary biliary cirrhosis (PBC) requiring orthotopic liver transplantation in 1995. Her outpatient immunosuppressive regimen included tacrolimus 1mg bid and MMF 500mg bid, added three years prior for chronic rejection. A screening colonoscopy 4 years prior was normal. The patient was admitted to the intensive care unit and found to have left lower lobe pneumonia with effusion and diabetic ketoacidosis. Intravenous MMF was begun and oral medicines were held. On the 4th hospital day she developed a significant leukocytosis on broad spectrum antibiotics and diffuse abdominal pain ensued without associated diarrhea or hematochezia. A non-contrast CT scan of the abdomen revealed free air under the left hemidiaphragm and bowel wall thickening. Emergent laparotomy showed a perforation of the distal sigmoid colon. A sigmoid colostomy and Hartmann’s pouch procedure were performed. Pathology demonstrated serositis with perforation and demonstrated no viral inclusions. CMV immunostain was negative. Her post-operative course was complicated by necrosis of the ostomy site and distal colon subsequently requiring re-operation. She developed multiorgan failure and died. Early experience with MMF in renal transplant recipients suggested a favorable safety profile. MMF has been associated with apoptotic colitis (resembling graft-versus-host-disease) in renal transplant patients with diarrhea and with delayed anastomotic healing in rat colons. Rare cases of gastrointestinal hemorrhage, ischemia, and perforation have been reported in the renal literature, but to the best of our knowledge our case represents the first case of spontaneous colonic perforation in a liver transplant recipient.

Discussion: Internal pancreatic fistulas are uncommon complications of chronic pancreatitis. In most cases, the diagnosis can be made from CT scan, ERCP and MRP, where disruption of the main pancreatic duct is noted. Medical therapy options, including total parenteral nutrition, chest tube placement, octreotide, and nasopancreatic drain, have resulted in resolution of the fistula in 1/3 of the cases described previously. Pancreatic duct stenting has proven to be successful in some cases if done early in the course of the disease. Approximately 50% of the cases described in literature had to undergo surgery, with distal pancreatectomy being the most common resection performed. This choice of treatment is usually considered once medical treatment fails, or in cases where medical therapy is considered less effective, as in the cases of complete ductal disruption. Our patient had significant distal pancreatic duct disruption on top of extensive chronic pancreatitis, making the surgical option more practical. [figure1]

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Spontaneous Internal Pancreatic Fistula Presenting with Persistent Pleural Effusion
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A 50 year old male patient presented with unexplained shortness of breath for one month. He had no known co- morbidities. His social history was significant for excessive alcohol consumption. Physical exam revealed decreased breath sounds on the right side with dullness to percussion. No abdominal tenderness was noted. Chest radiograph revealed a large right sided pleural effusion, which reformatted shortly after pleurocentesis. Magnetic resonance cholangiopancreatography (MRCP) showed changes of chronic pancreatitis with outpouching from the main pancreatic duct, raising the suspicion a pancreatico-colic fistula. Pleural fluid amylase level was elevated at 43920 U/L. Endoscopic retrograde cholangiopancreatography (ERCP) revealed irregular pancreatic duct with significant contrast leak from the tail, communicating with the right hemicrurax (Fig. 1). Due to significant disruption of pancreatic duct, the decision was made to proceed with distal pancreatectomy. Surgical pathology revealed a 2 cm size fistula originating from the distal pancreatic duct. The patient had an uneventful recovery from surgery.

Discussion: Internal pancreatic fistulas are uncommon complications of chronic pancreatitis. In most cases, the diagnosis can be made from CT scan, ERCP and MRP, where disruption of the main pancreatic duct is noted. Medical therapy options, including total parenteral nutrition, chest tube placement, octreotide, and nasopancreatic drain, have resulted in resolution of the fistula in 1/3 of the cases described previously. Pancreatic duct stenting has proven to be successful in some cases if done early in the course of the disease. Approximately 50% of the cases described in literature had to undergo surgery, with distal pancreatectomy being the most common resection performed. This choice of treatment is usually considered once medical treatment fails, or in cases where medical therapy is considered less effective, as in the cases of complete ductal disruption. Our patient had significant distal pancreatic duct disruption on top of extensive chronic pancreatitis, making the surgical option more practical. [figure1]

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Kayexalate Induced Colonic Necrosis: An Important Clinical Entity
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There have been uncommon reports of Kayexalate induced colonic perforations. The purpose of this vignette is to delineate an unusual presentation of this rare but serious complication from Kayexalate.

Case Report: A 71 year old woman with a history of end-stage renal disease presented to UC Irvine Medical Center for hematochezia. The patient noted bloody bowel movements after her hemodialysis session one day prior to admission. Her abdomen was nondistended, soft, and nontender throughout. Rectal exam demonstrated gross red blood and no palpable mass. Her initial hemoglobin was 8.7 g/dL. No known history of recent Kayexalate use was elicited. A nasogastric tube was inserted and negative for any blood. The
patient was given 6 liters of polyethylene glycol per the nasogastric tube in preparation for a colonoscopy. During the colonoscopy, a large blood clot imbedded in a round defect at 18 cm. Active bleeding was noted around the edge. Epinephrine was injected around the defect and the bleeding ceased. When the clot was suctioned out of the defect in an attempt to unmask the bleeding lesion, there was mesentery seen underneath the clot. The patient was taken to surgery after perforation was confirmed. During surgery, purulent material was found in the pelvis and no gross fecal soiling was noted in the peritoneum. A segmental colonic resection was performed and the patient had an uncomplicated post-operative course. The surgical pathology revealed focal ischemic necrosis with perforation and abundant eosinophilic crystals consistent with Kayexalate. Evidence suggests that Kayexalate induces a direct toxic effect on the gastrointestinal mucosa. The intestinal vasculature of renal patients may predispose to vasoconstriction due to elevated angiotensin levels as a result of high renin levels which may contribute to the ischemic necrosis found in such lesions. However, the exact mechanism for these changes remains unclear. Rectal bleeding and perforation from a necrotic ulcer is a rare but important complication which can occur from Kayexalate treatment. This case highlights the importance of early recognition of this complication in patients with end stage renal disease who present with hematochezia or suspected perforation, even with a remote or unclear history of ingestion.

A 61 year old female was commenced on MABThera and CHOP chemotherapy for non-Hodgkin’s lymphoma. Prior to treatment aminotransferase levels were normal and she had no risk factors for liver disease. Despite initial improvement, she later presented with decompensated liver disease. Retrospective review of liver function tests in relation to chemotherapy doses revealed that she had had fluctuating aminotransferases with each cycle. The rise was opposite to what would be expected of drug induced hepatotoxicity with peak values on the day of chemotherapy and subsequent normalization a week afterwards. Immunosuppressive therapy enables hepatitis viral replication with subsequent widespread infection. Cessation of chemotherapy partially restores immunocompetence leading to rapid destruction of hepatocytes and consequent hepatic necrosis. Based on the liver enzyme pattern, a diagnosis of hepatitis B was made. She was commenced on lamivudine therapy with initial improvement. Subsequent serology confirmed the presence of active hepatitis B infection despite no previous risk factors. Although the lymphoma responded well to treatment she eventually succumbed to fulminate viral hepatitis. Non-Hodgkin’s lymphoma is routinely treated with chemotherapy but in the presence of Hepatitis B this can be potentially fatal. Although reactivation of viral hepatitis in these patients is well documented, this case emphasizes the need to screen for Hepatitis B in all patients (irrespective of lack of risk factors) who will be undertaking a necrotic ulcer is a rare but important complication which can occur from Kayexalate treatment. This case highlights the importance of early recognition of this complication in patients with end stage renal disease who present with hematochezia or suspected perforation, even with a remote or unclear history of ingestion.

Case 1: An 84-year-old man presented with two days of nausea and recurrent coffee-ground emesis. His medical history included a shallow duodenal bulb ulcer on endoscopy one month earlier, and a large (3 cm) solitary gallstone in the gallbladder on abdominal imaging six months previously. On admission, plain abdominal radiographs revealed a markedly distended stomach. Endoscopy revealed a large gallstone impacted in the duodenal bulb, prohibiting passage of the endoscope. Magnetic resonance cholangiopancreatography (MRCP) demonstrated a cholecysto-duodenal fistula. Due to the size of the impacted stone, fragmentation using mechanical lithotripsy was not feasible. Therefore, intracorporeal endoscopic electrohydraulic lithotripsy (Northgate Technologies, Inc., Arlington Heights, IL) using the Micro II 1.9 French lithotripsy probe at a setting of 70–100 watts was used to successfully fracture the stone into small fragments. Clinically, the patient’s gastric outlet obstruction resolved. Follow-up endoscopy three days later revealed no remaining stone fragments in the duodenum.

Case 2: A 69 year-old man presented with four days of right upper quadrant pain, nausea and vomiting in the setting of known cholelithiasis. After treatment for presumed cholecystitis, he was taken to the operating room for laparoscopic cholecystectomy. Significant inflammation was encountered in the peripancreatic region; thus cholecystectomy was deferred and a percutaneous drain was placed. A post-operative CT scan suggested extravasation of oral contrast from the duodenum toward a peripancreatic fluid collection, and a round filling defect was demonstrated in the proximal duodenum on upper GI. Subsequent endoscopy revealed a large obstructing gallstone in the duodenal bulb. Intracorporeal endoscopic electrohydraulic lithotripsy was performed at 70–90 watts with successful fragmentation of the stone. An opening to a fistulous tract was then identified in the duodenal bulb. The patient improved clinically and was discharged 15 days after endoscopy, with plans to pursue cholecystectomy in the outpatient setting. These cases illustrate the potential for effective endoscopic therapy for this historically surgical condition, which is particularly desirable in elderly patients with significant medical comorbidities.
Coexisting CFT and SPINK1 Mutations in a Child with Severe Chronic Pancreatitis


Chronic pancreatitis is rare in children. A number of potential etiologies have been identified, including gene mutations of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR), the cationic trypsinogen gene (PRSS1) and pancreatic secretory trypsin inhibitor (SPINK1). It is not clear whether individuals with the combination of CFTR and SPINK1 are at increased risk for chronic pancreatitis. We present a case of a 12 year old male who had mutations in both the CFTR and SPINK1 and early onset of severe chronic pancreatitis.

Case report: The patient was a 12 year old male who had been previously healthy, although he had intermittent vague abdominal pain for several years. He had no history of chronic respiratory disease. The family history was unknown. At 12 years of age he was hospitalized 3 times for pancreatitis. Abdominal ultrasound and magnetic resonance cholangiopancreatography showed a dilated pancreatic duct with atrophy and calcifications of the gland. Endoscopic retrograde cholangiopancreatography showed chronic pancreatitis with moderate side branch ectasia, and a diffusely dilated (6mm), irregular pancreatic duct with numerous filling defects. Sphincterotomy was performed and a white, soft, stone-like material was removed from the duct with a partially inflated balloon. A temporary pancreatic duct stent was placed acutely and the patient was started on therapy with pancreatic enzymes. After this, the patient remained free of abdominal pain. An evaluation determined that the patient had 2 CFTR gene mutations, (Delta F508, the most common mutation, and D1152H, a rarely described mutation) and an additional SPINK1 mutation. This patient developed severe chronic pancreatitis at an early age and was found to have 2 CFTR mutations and a SPINK1 mutation. The CFTR mutations predispose to abnormalities in pancreatic duct secretion, whereas the SPINK1 mutation causes damage at the level of the acini. The combined effects of these defects may explain why this patient developed chronic pancreatitis at an early age.
A Rare Cause of Lower GI Bleeding
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Case Summary: A 42-year-old African American female with stage 3B cervical cancer presented to the emergency department after a syncopal episode. Cervical cancer was diagnosed six years ago and radiation with chemotherapy was completed one year later. Her symptoms were fatigue, nausea and vomiting with a 25lb weight loss during the last two months. She had one episode of painless hematochezia. She was cachectic. Her vital signs were normal. The abdominal exam was benign. Her hemoglobin was 9.0gm/dL, a decline from 10gm/dL one month ago. Other lab values including coagulation parameters were normal. On colonoscopy, a non-circumferential mass with stigmata of recent bleed was found in the proximal transverse colon. Pathology revealed moderately differentiated squamous cell carcinoma invading colonic mucosa consistent with metastatic carcinoma of cervical origin. A CT scan revealed significant metastasis to the abdominal wall and therefore the patient was deemed not a good candidate for surgery. Given the extensive metastasis, hospice care was pursued. Discussion: Unusual presentations of metastatic cervical cancer to the GI tract include SBO, acute cholecystitis, oral lesions and PUD. Metastasis to the colon has been reported from tumors of the stomach, breast, ovary, cervix, kidney, lung, bladder, prostate and melanoma. Cervical cancer metastasizing to the colon is a rare occurrence. Metastasis to the GI tract occurs with a frequency as high as seven percent in patients with recurrent cancer who have multiple-organ involvement. In our case, the presentation of painless hematochezia in the setting of previous radiation suggests proctitis or other more common causes of lower GI bleed. A colonic mass of cervical origin was not suspected. Our case report supports a handful of publications documenting metastasis to the colon from squamous cell cervical cancer. It becomes essential to remind ourselves of the uncommon but real possibility of gastrointestinal tract metastasis in patients with advanced cervical cancer who are presenting with GI symptoms. [figure1]

Acute Symptomatic Small Bowel Obstruction Due to Capsule Impaction: A Case Series
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Capsule impaction is a well recognized complication of small bowel capsule endoscopy, with an incidence ranging from 0.75 to 21%, depending on the indication. To date, there have been no reported cases of capsule impaction causing acute symptomatic small bowel obstruction. We now present 3 cases of acute small bowel obstruction due to capsule impaction. Case 1: A 71-year-old woman had iron deficiency anemia in the setting of negative upper endoscopy, colonoscopy, small bowel follow-through, enteroclysis and push enteroscopy. She developed severe abdominal pain, vomiting and leukocytosis 16 hours after capsule ingestion. Emergent surgery was performed to remove the capsule which was impacted at a previously undiagnosed ileal Crohn's stricture leading to perforation. Case 2: A 64-year-old woman with Gardner's syndrome and a history of colectomy and subsequent episodes of small bowel obstruction underwent capsule endoscopy in order to define the site of obstruction. She experienced drastically increased abdominal pain 24 hours after capsule ingestion, and emergent enteroscopy was required to retrieve the capsule which had become impacted at a previously undiagnosed annular cancer in the distal duodenum, ultimately treated with surgical resection. Case 3: An 85-year-old man with recurrent small bowel obstruction due to radiation enteritis underwent capsule endoscopy in an attempt to localize the site of obstruction in preparation for surgical intervention. He returned with severe abdominal pain and emesis 3 days later. At surgery, the capsule was found to be impacted at a radiation stricture in the ileum and was removed with resection of the surrounding small bowel. These 3 cases show that acute symptomatic obstruction and even perforation can occur as a result of capsule impaction, especially in patients at high risk for obstruction because of their past history. We propose that the possibility of acute symptomatic small bowel obstruction be included in the informed consent for capsule endoscopy. Patients should be warned that emergent surgery may be needed to remove an impacted capsule; this may have implications for patients living far away from the medical center who plan on traveling home immediately after capsule endoscopy.
rate of HBV DNA by the end of a 6 month treatment period with tenofovir ranges from 30–80%. However, there are no prospective randomized studies that assess long-term antiviral efficacy and durability of HBV suppression. Our case describes the clinical and virological response of HBV after abrupt cessation of tenofovir in a co-infected patient, and underscores the importance of compliance with antiviral therapy. Clinicians should be aware of the possibility of HBV flare after cessation of dual acting anti-HIV/HBV drugs such as tenofovir.

To our knowledge this is the first case report of severe rectal bleeding from a rectoprostatic fistula in a patient that received EBRT for prostate cancer. [Figure1]
examination. Abdominal CT revealed a pelvic mass involving most of the bladder, with extension to sigmoid colon. Air in the bladder was consistent with the clinical suspicion of colovesical fistula (Fig. 1A). Colonoscopy revealed a large unilateral cauliflower mass in sigmoid colon; biopsy documented a well differentiated adenocarcinoma (Fig. 1B). Cystoscopy found a large mass protruding into the urethra through the bladder neck. Urine cytology showed malignant cells, cluster of tall columnar cells, with palisaded nuclei, plus positive extracellular mucin stain, most likely consistent with colonic adenocarcinoma (Fig 1C). The diagnosis of colon cancer was confirmed by Immunoperoxidase that showed positive CEA (II-7) and cytokeratin 20 (KS20.8) expressed by tumor cells and was negative for cytokeratin 7. Exploratory laparotomy revealed sigmoid colon cancer with extension to bladder and pelvic wall. Surgery included radical resection of the cancer (margin negative for malignant cell under microscope), colostomy, pelvic dissection, and radical cystoprostatectomy with ileal conduit. Two weeks later the patient was transferred to rehabilitation. Dilemma of cancer origin may arise if it involves both colorectum and urinary bladder. Pre-surgical evaluation should include abdominal CT, colonoscopy, cystoscopy and diagnosis by histology and immunopathology. [figure1]

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Asymptomatic Gastric Metastasis from Breast Carcinoma

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Metastatic disease to the stomach from breast carcinoma is uncommon. Though most metastases are symptomatic with abdominal pain as the most common complaint, about 5% of metastases could be asymptomatic. We report a case of breast cancer with metastatic disease to the stomach that was asymptomatic and had near normal gastroscopy.

Case report: A 56-year-old female with known history of Barrett’s esophagus presented for her surveillance upper endoscopy. She denied associated abdominal pain, nausea, vomiting, odynophagia, dysphagia, or involuntary weight loss. Her past medical history was significant for right modified radical mastectomy with lymph node removal for lobular carcinoma of the breast approximately 7 years ago. This was treated with adjuvant chemotherapy and postoperative radiation. She also had history of stage II squamous cell carcinoma of the vagina approximately 4 years ago and was treated with external beam radiation along with platinum chemotherapy. Her physical examination was unrevealing. She underwent an EGD that showed short segment Barrett’s esophagus, a diminutive benign appearing gastric polyp and antral erosions (Figures 1 & 2). Endoscopically there were no gastric lesions as nodules, ulcers or large polyps to suggest malignancy. Biopsies from the distal esophagus confirmed Barrett’s esophagus without any dysplasia. But biopsies from gastric polyp and antrum revealed metastatic lobular carcinoma of the breast (Linitis Plastica pattern with involvement of lamina propria). Radiological work up including PET scan, MRI head and bone scan failed to show any metastatic involvement of other organs. This case illustrates lobular breast cancer metastasizing to the stomach without any symptoms and also without any specific endoscopic findings. [figure1][figure2]

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Minnesota Tube for Bleeding Rectal Varices

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A 51 year old man with Child’s C hepatitis C cirrhosis, paroxysmal atrial fibrillation was admitted with decompensated cirrhosis, increasing ascites, and hepatic encephalopathy. As a part of pre-transplant work-up, he underwent...
colonoscopy which showed polyps in the descending colon as well as nonbleeding rectal varices. Polypectomy was performed with no immediate complications. Within 24 hours of discharge, he presented with bright red rectal bleeding which led to hemorrhagic shock and admission to the intensive care unit, requiring massive blood and blood products transfusion. Emergency mesenteric angiogram was non-diagnostic. Despite the correction of his coagulopathy, he continued to bleed requiring emergent laparotomy, left hemicolectomy, and colostomy. Postoperatively he had another episode of bleeding and he was taken back to OR for ligation of feeding vessels to rectal varices in addition to intra and extraluminal packing. In the interim, he underwent TIPS procedure for portal hypertension. One day later he returned to OR to have the packings removed, only to find the rectal varices still oozing. It was decided to place Minnesota tube to apply direct pressure using inflated gastric balloon to rectal varices. Due to the presence of rectal stump, which was around 15 cm, 10cm of the tube was cut. The tube was inserted into the rectal stump and gastric balloon was inflated with 200mls of air with immediate cessation of bleeding. The gastric aspiration port was aspirated every 2 hours. The balloon remained inflated for the next 24 hours with no evidence of further bleeding.

**Discussion:** Minnesota tube can be used as rescue treatment for bleeding rectal varices when all other modes of therapy failed to stop bleeding. There has been similar case reports describing the use of Sengstaken-Blakemore tube in patients with rectal bleeding due to angiodysplasia, post partum hemorrhage. However, this is the first case that describes the use of Minnesota tube which has a larger gastric balloon in patient with rectal bleeding due to varices. [Figure1]

**Epsilon-aminocaproic Acid (EACA):**

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Epsilon-aminocaproic acid (EACA) is a potent anti-fibrinolytic agent that is used in the treatment of excessive bleeding resulting from a systemic fibrinolytic state. It has also been used as an adjunctive therapy in treatment of patients with thrombocytopenic hemorrhage. Although increased risk of thromboembolic disease has been reported during treatment with EACA, ischemic colitis has not been previously described.

**Case Report:** A 67 year old man was admitted with mild, crampy, lower abdominal pain and bloody stools for 1 day. He had hypertension and chronic myelomonocytic leukemia with associated anemia and thrombocytopenia that had improved after splenectomy 6 months previous. Six days prior to admission (PTA) he was was started on EACA, 1g every 6 hours, by his oncologist for recurrent epistaxis. Three days PTA he was also started on amoxicillin for an upper respiratory tract infection. Other medications included amiodopine, atenolol and folic acid. He had used no tobacco or alcohol in > 3 years. On physical examination he was afebrile and had an unremarkable abdominal exam. Red blood was noted on rectal examination. He had a leukocyte count of 20000/mm³ platelet count of 45000/mm³ and hemoglobin of 12.4 g%. C. difficile toxin titer and stool cultures were negative. Fecal leukocytes were detected. The patient was placed on bowel rest and IV fluids. Colonoscopy revealed mucosal necrosis and hemorrhagic nodules from mid ascending to mid transverse colon with sharp demarcations. Biopsy revealed acute colitis with ulceration and necrosis consistent with ischemic colitis. Both EACA and amoxicillin were held. His symptoms resolved without specific treatment in 2 days. At one month follow up the patient continues to be off EACA and has not reported further episodes of rectal bleeding.

**Discussion:** We report the first case of EACA related ischemic colitis in an adult male without obvious thromboembolic risk factors. Although he was on amoxicillin, which has been implicated in hemorrhagic colitis, this condition can be differentiated from ischemic colitis both by colonoscopic appearance and histology. Given his history of hypertension and smoking atherosclerotic small vessel ischemia cannot be excluded, and may be contributory, though it most commonly affects the “water shed” areas due to limited collateralization. The onset of ischemia in our patient coincides with the introduction of EACA suggesting a medication induced etiology. We caution physicians to be aware of this potential complication when using EACA.

**Ischemic Colitis Associated with Epsilon-Aminocaproic Acid Therapy**

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Giant colon diverticulum (GCD) is a rare complication of colonic diverticulosis with only 135 cases reported. GCD has a significant rate of complication (28%) and operative mortality (5%) thus requires early elective surgery. There are 3 types of GCD: Type I is a pseudo-diverticulum with remnants of muscularis mucosa and muscularis propria in the wall; Type II or inflammatory GCD contains only reactive scar tissue in the wall, it results from a mucosal perforation with an abscess cavity in contact with the colon lumen; Type III GCD is a true diverticulum with all layers of colon wall.

**Case 1:** A 74-year-old man presented with chronic abdominal pain, constipation, diarrhea, positive fecal occult blood and weight loss. A 9 × 9 cm mass with air-fluid level adjacent to sigmoid colon was found by abdominal CT (Fig. 1A). Colonoscopy was not performed to avoid perforation. Repeat CT 24 hrs after PO contrast reported barium in the mass. Abdominal exploration revealed evidence of peritonitis and a perforated walled off cavity communicating with the sigmoid colon. Segmental sigmoidectomy and transverse colostomy (for significant inflammation) was performed. Type II GCD was confirmed by histology, and malignancy was ruled out. Patient was transferred to rehabilitation after surgery. He was able to walk in 2 months and gained weight.
Case Report: AIDS defining illness. and pulmonary actinomycosis as an acquired immunodeficiency syndrome

Introduction: Actinomyces are anaerobic gram-positive bacteria found in the soil, oral mucosa, GI tract, female genital tract and bronchial tree. These organisms have low pathogenicity and cause disease mostly through invasion of breached mucosa in immune-compromised hosts. Risk factors for actinomycosis include injection drug use, diabetes, alcoholism and poor dentition. We report a patient with odynophagia who was found to have esophageal and pulmonary actinomycosis as an acquired immunodeficiency syndrome (AIDS) defining illness.

Case Report: A 47 year old homeless man with poly-substance abuse presented with odynophagia and a productive cough. Physical exam revealed poor oral hygiene, oral thrush and cachexia. Rapid-HIV test done in the emergency department (ED) was positive with a CD4 count of 3. He was placed in respiratory isolation and started on treatment for community-acquired pneumonia, candidiasis and pneumocystis carinii pneumonia prophylaxis with azithromycin, ceftriaxone, fluconazole and bactrim, respectively. Serial AFB smears were negative. An EGD showed multiple small and large esophageal ulcers. The patient was discharged before the biopsy results were available. Histology revealed numerous clusters of actinomyces. Special stains for cytomegalovirus were negative. The patient presented to the ED 3 months later and CT scan of the thorax showed multifocal infiltrates, and the patient was started on moxifloxacin for pulmonary actinomycosis. ED 3 months later and CT scan of the thorax showed multifocal infiltrates, and the patient was started on moxifloxacin for pulmonary actinomycosis. A subsequent small bowel series revealed a nodular polyloid filling defect in the distal terminal ileum and cecum. Colonoscopy revealed a deformed and ulcerated ileocecal valve, congested and edematous cecal mucosa, and multiple superficial ulcerations in the terminal ileum. Biopsies confirmed architectural distortion, cryptitis and crypt abscess formation consistent with Crohn’s disease. Given the reported effectiveness of swallowed steroids in crohnophilic esophagitis, the patient was started on a fluticasone propionate inhaler, two sprays swallowed twice daily. The patient was also started on 6-mercaptopurine (6-MP) for her ileocolonic disease. After one week of therapy with fluticasone, her dysphagia had resolved. Repeat EGD showed complete healing of the previously noted esophageal ulcers.

Discussion: Crohn’s disease involving the esophagus is rare. Most patients also have extra-esophageal involvement. Symptoms may include dysphagia, odynophagia and chest pain. Endoscopic findings are non-specific, but superficial aphthous ulcerations are most common. Strictures and fistulas are seen in severe cases. The most common histologic findings are ulcers and a chronic lymphocytic infiltrate. Optimal management is not well established, but most patients are treated with systemic steroids and antisecretory agents. Immunomodulators have been used in difficult cases. Endoscopic dilation is helpful in stricturing disease, but surgery may be required in refractory cases. There are no previous reports of topical steroids in the management of esophageal Crohn’s disease. Although our patient was concomitantly started on 6-MP, the therapeutic effect of this agent is delayed and unlikely to have played a role in the healing of her esophageal ulcers.

Liver Disease from Asymptomatic Constrictive Pericarditis
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Introduction: Congestive hepatopathy is a known complication of severe cardiac disease, and is typically identified in the context of an established cardiac diagnosis and profound cardiopulmonary symptoms. We report a case in which liver impairment was the sole clinical manifestation of constrictive pericarditis, illustrating the need for gastroenterologists to consider cardiogenic liver disease even in patients lacking typical signs and symptoms.

Case Presentation: A healthy 28 year old male underwent an elective laparoscopic hernia repair and was noted to have an abnormal appearing liver and mild ascites. The patient reported five years of moderate daily alcohol intake but denied risk factors for viral hepatitis. He denied abdominal pain, pruritus, jaundice, chest pain and exertional dyspnea. He took no prescription or herbal medications. There was no family history of liver disease. Physical exam revealed an elevated JVP (15 cm), an enlarged, non-tender liver and mild pedal edema, with an otherwise normal cardiopulmonary exam, and no evidence of splenomegaly, ascites, or spider angiomata. DATA: TB 2.0, AST 32, ALT 33, ALK 203, Alb 4.3, INR 1.9, Hb 12, and Plts 213 K. Serologies for viral hepatitis, autoimmune markers, ceruloplasmin, iron studies, and α-1
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antitrypsin were negative. Abdominal U/S showed an enlarged liver, mild ascites, patent hepatic/portal veins, and no ductal dilatation. Liver biopsy showed peri-venular dilatation with sinusoidal hemorrhage and no fibrosis. Echocardiogram demonstrated normal RV/LV function w/o valvular disease or pericardial effusion. Cardiac catheterization showed equalization of diastolic pressures suggestive of constrictive pericarditis. Cardiac MRI confirmed a thickened, adherent pericardium. The patient underwent a successful pericardiectomy.

Discussion: In 1896, Pick presented a case of “pericarditic pseudocirrhosis of the liver” in which he highlighted the difficulties in distinguishing primary liver disease from that due to long-standing pericardial disease. This case illustrates the important role gastroenterologists can play in the diagnosis of occult cardiac disease. The identification of elevated jugular venous pressure in the presence of abnormal liver synthetic function can represent critical clues to establishing a diagnosis of constrictive pericarditis and secondary congestive hepatopathy. This case should prompt clinicians to heighten their suspicion for underlying cardiac disease in patients with liver dysfunction even in the absence of characteristic cardiopulmonary signs and symptoms.

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EUS Guided FNA for Mediastinal Mass and/or Lymphadenopathy Due to Infection
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Echofetures of malignant lymph nodes overlap with benign lymph nodes. EUS FNA is useful for differentiating neoplastic and non-neoplastic lymph nodes. EUS FNA may also be valuable for diagnosis of infection; based on cytomorphology and cultures. Three cases in which EUS provided diagnosis of mediastinal infection are presented. 60 yr. male presented with cough and a 3.5 cm mediastinal mass on CT scan. EUS FNA of the mass was performed. Aspiration consisted of fibrinopurulent exudate and branching, beaded bacilli. These findings were suggestive of Nocardia and later confirmed by cultures. 26 yr. male, with known HIV, presented with nonproductive cough. CT scan showed mediastinal lymphadenopathy. EUS FNA of the subcarinal lymph nodes was performed. Aspirates revealed caseating necrosis and many acid fast bacilli. Cultures of EUS-derived sample later grew M. tuberculosis. 35 yr. male with HIV presented with worsening cough despite completing antibiotics for MRSA and M. kansasii. CT scan revealed a large mediastinal mass. EUS FNA was performed of the mass. Kinyoun staining was positive for beaded bacilli with curved ends, typical of M. kansasii. There are a few isolated reports of infections diagnosed by EUS. We present a series of 3 cases of mediastinal infection diagnosed by EUS. In all 3, a preliminary diagnosis of the organism was made, and in 2 of 3, the organism was cultured from EUS-derived material. EUS of the mediastinum allowed for prompt diagnosis and treatment. Often AIDS patients have multiple infections, and EUS-FNA is useful for definitive diagnosis.

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Oral Sodium Phosphate Laxative Induced Acute Renal Failure in Patient Undergoing Colonoscopy
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Oral sodium phosphate is a relatively safe non-prescription bowel-cleansing regimen used for colonoscopy preparation. We present a patient who developed oliguric acute renal failure after receiving oral sodium phosphate. A 61 year old African American woman with prior medical history of hypertension, iron deficiency anemia and normal renal function (Creatinine = 0.8mg/dl with an estimated MDRD GFR 92 ml/min/1.73m2) underwent colonoscopy for her anemia. Home medications included ramipril and a hydrochlorothiazide/triamterene combination. The patient consumed two 45ml doses of oral sodium phosphate along with approximately 3–4 liters of water in preparation for the colonoscopy. The colonoscopy findings were unremarkable. Within five days of procedure, the patient noted inability to urinate. She was found to have acute renal failure (elevated Creatinine = 3.5mg/dl with estimated MDRD GFR 17ml/min/1.73m2) and the following electrolyte findings; Sodium 134mmol/l, Potassium 3.8mmol/l, Chloride 96mmol/l, Bicarbonate 20mmol/l, Blood Urea Nitrogen 37mg/dl, Phosphorus 7.6mg/dl and Calcium 8.6mg/dl. A renal ultrasound was negative for hydronephrosis. Urinalysis was essentially benign with a spot Protein/Creatinine ratio of 1.5.
A kidney biopsy revealed acute tubular necrosis. The patient was treated conservatively with oral and intravenous hydration. Over the next few days she started to urinate about one liter daily. Her kidney function normalized three weeks later. The presentation of oliguric acute renal failure after oral sodium phosphate is rare though reported previously. The cause of renal failure in these reports was acute nephrocalcinosis resulting from deposition of calcium and phosphate in the tubules and interstitium; of itself a rare acute phenomenon. Our patient showed no evidence of nephrocalcinosis. The pathophysiology of acute renal failure in our case likely involved volume depletion and transient hyperphosphatemia exacerbated by the concomitant use of an ACE-I inhibitor and diuretics. Acute renal failure is a seemingly rare complication of bowel cleansing with sodium phosphate. Further studies measuring renal function pre and post oral sodium phosphate administration in patients on ACE inhibitors and/or diuretics are needed to better define the prevalence of this condition. Greater awareness of this entity will provide further insight into potential adverse reactions with oral sodium phosphate preparations.

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**Endoscopic Revision of an Esophageal Polyflex® Stent**

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Options are limited for the management of individuals with benign recurrent esophageal strictures who have failed proton pump inhibitor therapy. Esophageal stents are helpful in these individuals, however these temporary stents are usually removed after 6–8 weeks. Management of complications and efficacy beyond 11 months has not been reported. We present, in this report, a case of endoscopic repair of a disrupted Polyflex® stent (Boston Scientific Corp) 18 months after placement.

**Case:** This is a report of an 81 y/o woman with a 3-year history of a benign esophageal stricture who presented with increasing dysphagia to liquids and solids with secondary 50 lb. weight loss. Her past management had included repeated esophageal dilation with biopsies and twice daily proton pump inhibitor therapy. At upper endoscopy she had a distal esophageal stricture extending from 37 to 40 cm from the central incisors with no evidence for a hiatal hernia. Multiple biopsies were consistent with gastroesophageal reflux disease with no evidence of Barrett’s metaplasia, dysplasia, or malignancy so she underwent placement of a 12 cm x 18 mm Polyflex® plastic stent. At follow-up 8 weeks later, she reported complete resolution of dysphagia and had regained 12 lbs. At that time she refused to have the stent removed, as recommended by the manufacturer. Repeat endoscopy at 6 months and 11 months had demonstrated a completely intact stent in excellent position. At 18 months, repeat endoscopy for stent follow-up showed separation and proximal inversion of the stent. The remainder of the stent remained patent and in good position. She had no symptoms of dysphagia or odynophagia. A standard rat-tooth forceps was used and with mild-moderate amount of upward traction, the separated and inverted portion of the stent was removed. The remainder of the stent remained in position and patent at the end of procedure. Since placement of the stent, she has regained 40 lbs. Endoscopic revision of an esophageal Polyflex® stent is possible. In select individuals with benign esophageal strictures, placement of a Polyflex® stent provides a safe and effective long-term option (now > 18 months) for management of dysphagia and weight loss.

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**Eosinophilic Esophagitis and Esophageal Perforation**

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Eosinophilic esophagitis (EE) has been described in both adults and children. We report a patient with esophageal perforation due to EE. A 69 year old female was admitted for sudden onset of odynophagia and dysphagia after eating meat, followed by retching and hematemesis. Surprisingly, EGD revealed a blood filled esophagus and a 4–5 cm full thickness upper esophageal defect without active bleeding. Additional findings of concentric rings and diffuse distal esophageal narrowing were compatible with eosinophilic esophagitis based on classic endoscopic appearance. The impacted food bolus was successfully removed at the index endoscopic examination. Following the bolus extraction, gastrograffin esophagram showed extravasation of contrast. CT scan confirmed the presence of mediastinal air and pleural effusions. Non-operative management was initiated with antibiotics and total parenteral nutrition. Repeat esophagogram at 5 days was normal and a soft diet was gradually introduced and tolerated. EE is an uncommon disorder in which the esophagus is infiltrated with eosinophils. It is associated with food allergies, asthma, allergic rhinitis, atopic dermatitis, urticaria, GERD, multiple esophageal rings, and eosinophilic gastroenteritis. It is seen more commonly in children and young adult males. Esophageal dysmotility and a characteristic furrowed esophagus are frequently observed. Multiple rings and strictures account for dysphagia and potential for food impaction. EE is diagnosed by direct visualization and supported by esophageal biopsy. There is no definitive treatment, but symptomatic treatment, allergy testing, food elimination, and steroids are management options. Dilatation of long concentric ringed strictures should be undertaken with care due to the potential for esophageal rents and increased risk of perforation. Acid suppression alone
A 27yo man with untreated AIDS came to the emergency department reporting fevers, 10–15lb weight loss, nausea, vomiting, and epigastric pain for one week. Upper endoscopy was performed, showing numerous round erythematous macules, each about 5mm in diameter, arranged in linear patterns along the gastric mucosa (Fig 1). Biopsy revealed a lymphohistiocytic inflammatory reaction and intracellular budding yeast surrounded by clear halos, consistent with cryptococci (Fig 2). The patient was found to have a positive serum cryptococcal antigen with a titer of 1:8000. He subsequently complained of headache and was diagnosed with cryptococcal meningitis via lumbar puncture. His symptoms abated with Amphotericin B and fluconazole therapy. *Cryptococcus neoformans* remains the most common pathogen causing systemic mycosis in patients with the acquired immunodeficiency syndrome (AIDS), but has rarely been reported to affect the gastrointestinal tract. When discovered anteromortem on endoscopy, the esophageal appearance has seldom been described. Reported appearances vary, and have been described as multiple small gastroduodenal nodules with or without central erosions, focal gastritis with erosions, and multiple white plaques in the duodenum. To the best of our knowledge, we describe herein the fifth reported case in the literature of symptomatic cryptococcal gastroduodenitis in a patient with AIDS. To date, this particular endoscopic manifestation of the disease has not been reported.

A Unique Endoscopic Manifestation of Gastroduodenal Cryptococcosis
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A 24 year old pregnant female, at 3 weeks gestation, presented with RUQ abdominal pain associated with abdominal distention and progressive SOB for 2 weeks. The pregnancy was the product of in-vitro fertilization (IVF). Physical examination showed an anicteric conjunctiva. Chest examination showed a decreased air entry in both lung fields. Abdominal examination revealed a fluid wave with shifting dullness. Levels of aspartate aminotransferase, alanine aminotransferase and albumin at presentation were 120 IU/ml, 114 IU/ml and 2.8 gm/dL, respectively. Serologic tests for autoimmune and viral hepatitis were negative. Serum human chorionic gonadotropin (hCG) was 515 mIU/ml, with a follow up serum hCG over 1000 mIU/ml. Transvaginal ultrasound showed a normal gravid uterus with a detectable gestational sac, prominent ovaries and large amount of ascites. Abdominal ultrasound with doppler revealed normal echogenic liver and patent hepatic vessels. Diagnostic and therapeutic paracentesis showed no evidence for spontaneous bacterial peritonitis. Based on history, clinical findings and lab values, the diagnosis of ovarian hyperstimulation syndrome (OHSS) was made. After conservative management, the patient was discharged 7 days later. On discharge, her liver tests were normalizing, ascites was improving and she felt much better. The patient continued follow up care with her private obstetrician.

Discussion: OHSS is a rare iatrogenic complication of ovarian stimulation, which was described in 1943. The overall incidence of OHSS is 1–10% in IVF and embryo transfer cycles. The incidence of deaths is 1 in 500000 cases. OHSS can be divided into mild, moderate or severe forms. The pathophysiology is not completely understood, but the release of vasoactive substances from the stimulated ovaries has been suggested. Specific gastrointestinal (GI) complications include ascites, liver dysfunction, malnutrition and ileus. Liver dysfunction in OHSS was first reported in the 1980’s and occurs in 25–30% of severe forms. When present, abnormal liver tests should be considered as an indicator of severity for the syndrome. Prevention and early recognition are the most important factors in treatment. The syndrome is usually self-limiting and conservative management often is sufficient. OHSS needs to be considered in pregnant patients who present with GI manifestations and history of IVF.

Acute Facial Nerve Palsy Secondary to HSV-1 Reactivation during Peginterferon alfa-2a and Ribavirin Therapy of a Hepatitis C Patient
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Neuropathy has been infrequently (<1%) reported as a potentially serious adverse event associated with standard interferon therapy. Peg-interferons...
have improved pharmacokinetics and antiviral efficacy; however, the potential for their adverse events is not significantly different compared to the conventional interferon alfa. Three cases of acute facial nerve palsy have been described in literature in association with standard interferon therapy. None of these were found to have any definite etiology. No association of facial nerve palsy with peginterferon alfa-2a was ever reported in the past. 58 years old female with chronic hepatitis C infection developed acute episode of unilateral facial nerve palsy and severe ear ache at week 41 of peginterferon alfa-2a and ribavirin therapy. Laboratory evaluation revealed significantly high titers of herpes simplex virus 1 (HSV1) IgG antibody. The neurologic examination otherwise was completely intact. Patient was managed with oral prednisolone and acyclovir with complete recovery in six weeks. The anti-HCV therapy was discontinued. We believe the facial nerve palsy in our patient was most likely due to reactivation of HSV1. This would probably be the first case report in medical literature of acute facial palsy secondary to HSV1 reactivation during combination therapy with peginterferon alfa-2a and ribavirin. Although facial nerve palsy is extremely uncommon, the physicians must be aware of this potential side effect and its appropriate management while treating their hepatitis C and B patients with peg-interferons. [figure1][figure2]

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An Unusual Cause of Acute Liver Failure

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Diffuse hepatic infiltration by metastases has been recognized as a rare cause of acute liver failure (ALF). ALF due to metastatic transitional cell carcinoma is extremely rare. We report the first case of ALF due to diffuse hepatic infiltration of metastatic transitional cell carcinoma in the US. A 59-year-old man with a history of transitional cell carcinoma of the right ureter (G2, T2, N0, Mx) who underwent complete surgical resection in 07/2004. He failed to follow up with the urology clinic post surgery. One month prior to admission, the patient started to have pruritus all over his body. One week prior to admission, the patient started to have jaundice. He also complained of a vague fullness in the right upper quadrant. Physical examination was significant only for jaundice, multiple excoriations on the skin, and mildly tender hepatomegaly. The laboratory studies were significant for protein 7.6, albumin 2.7, total bilirubin 15, direct bilirubin 12.7, ALT 117, AST 141, alkaline phosphate 1505, and INR 1.3. All the following studies were negative: HAV, HBV, HCV, HIV, ANA, AMA, ASMA, AKLMA, anti-dsDNA. An ultrasound showed hepatomegaly at 18 cm with “diffuse fatty infiltration,” and no intrahepatic or extrahepatic biliary dilatation. A liver biopsy showed multiple clusters of malignant cells in the parenchyma and blood vessels; immunohistochemical stains (CD34 +, D2–40 -, CK7 +, thrombomodulin +, CK20 -) were consistent with metastatic transitional cell carcinoma. The patient rapidly developed encephalopathy and coagulopathy. He deteriorated to multi-organ failure and expired 2 weeks after admission. Metastases to the liver occur mainly as discrete single or multiple lesions. However, in ALF, liver infiltration by tumor cells typically has a diffuse pattern that is often not detected by imaging studies. The release of cytokines from neoplastic cells has been postulated to cause interlobular bile duct destruction and portal fibrosis. The consequence is obstruction of sinusoidal microcirculation and ultimately hepatocyte ischemia and death. The prognosis is extremely grave. Most patients die of multiorgan failure within six to ten days. The presence of malignant disease is an absolute contraindication for liver transplantation. Diffuse liver infiltration from a urothelial cancer is extremely rare. There are only 5 cases from Europe in the medical literature. This appears to be the first reported case of ALF due to diffuse hepatic infiltration of metastatic transitional cell carcinoma in the US.

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Small Bowel Adenocarcinoma Diagnosed by Wireless Capsule Endoscopy
A 67-year-old male with a history of melena and iron deficiency anemia, was referred for Wireless Capsule Endoscopy (WCE). 9-months earlier, he noted the onset of increased fatigue and shortness of breath on exertion, along with intermittent episodes of the passage of dark stools. 4-months later he was admitted to the hospital for melena and a drop in hemoglobin. He required 2 units of packed red cells. EGD revealed multiple shallow antral ulcers with dark heme and multiple erosions in the duodenum. Colonoscopy was normal. He was started on Prevacid. 1-month later, he was re-admitted for melena and a drop in hemoglobin, and was transfused 3 units of packed red cells. EGD and Push enteroscopy were performed, which was normal up to 160 cm. He had no abdominal complaints. His appetite was good; weight stable. Additional medical problems included COPD and Chronic Hepatitis B, well compensated Cirrhosis. Medications included Prevacid and Iron. His physical examination was unremarkable. Stools were guaiac positive. Hemoglobin was 9.5, MCV 63, Serum Iron 15, Ferritin 20. Small bowel series was normal. CT of the abdomen revealed hepatosplenomegaly with suggestion of underlying cirrhosis. WCE revealed a polyoid, ulcerated defect, 6-minutes beyond the ligament of Treitz. There was a marked delay in transit through this segment. Fresh blood was noted in the mid-jejunum. Laparoscopy revealed a 7-cm mass, 30-cm distal to the ligament of Treitz. Wide resection was performed, with resection of the adjacent mesentery and lymph nodes. Pathology revealed moderately well differentiated adenocarcinoma, invading through the muscularis propria into the sub-serosa; there was an adjacent tubular adenoma. Metastatic carcinoma was present in 1/5 lymph nodes. CT abdomen did not reveal any distant metastasis. The patient was started on platinum based chemotherapy, and is doing well 4-months post-operative. The diagnosis of small bowel tumors is often difficult due to the rarity of these lesions, and the non-specific presenting symptoms and signs. Most are asymptomatic until the tumor has spread beyond the stage of surgical cure, and contributes to the delay in the diagnosis. WCE is a non-invasive test that provides visualization of the small bowel. Early use of WCE in the evaluation of obscure GI bleeding and iron deficiency anemia may facilitate a more prompt diagnosis of small bowel tumor.

**CMV Enteritis in an Immunocompetent Infant**

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A 3 month-old male presented with a one-week history of fever, decreased oral intake, vomiting and watery, non-bloody diarrhea. He was solely breast fed and he had a negative family history for atopy. During the admission, he developed hypotenremia, hypoalbuminemia and mild transaminitis. Stool was guaiac positive and cultures were positive for Staphylococcus aureus for which he was given a seven-day course of antibiotics. Repeat stool studies were negative. A malabsorption work-up was negative and he was started on total parenteral nutrition for caloric support. His diarrhea continued and he underwent an endoscopy which demonstrated slightly decreased duodenal folds. Histologically, his gastric biopsies revealed mild reactive changes with minimal chronic inflammation and increased eosinophils in the stomach and eosinophilic and neutrophilic infiltration with the presence of CMV inclusion bodies in the duodenum. He was HIV- with normal Ig levels and T-cell count. He was treated with ganciclovir but his diarrhea persisted. A course of steroids were given for possible allergic enteritis and his diarrhea improved. He was subsequently started on nasogastric feedings with a hydrolysate formula. A follow-up endoscopy revealed normal villous architecture without any significant increase in inflammatory infiltrate. Incuding this patient, five cases of CMV enteritis occurring in breast fed males between 5 and 8 weeks of age have been reported. CMV enteritis in an immunocompetent infant is rare with variable clinical presentations. Associated symptoms include hypotenremia, transaminitis and cow’s milk protein allergy. Definitive treatment options are not established. Early diagnosis is key to prevent prolonged hospital stays and need for TPN and NG feedings.

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**Crohn’s Disease Manifested as Rhinitis**

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This vignette relates an extremely rare manifestation of Crohn’s disease and underscores the necessity of considering Crohn’s disease as the underlying cause of symptoms of obscure etiology. Past medical history was obtained, and physical examination and biopsies were performed on one patient with complaints of rhinitis. A 54 year old female with a history of active Crohn’s colitis presented to her otolaryngologist with a complaint of rhinitis. She had persistent upper respiratory symptoms of cough and nasal congestion for several months that did not respond to various non-prescription medications. She also noted pain and irritation, localized to the inside of the right nostril, increasing in intensity over the last two to three weeks with small amounts of clear nasal discharge. Physical examination revealed a well appearing female in no distress. She was normotensive and afibrile. She was noted to have bilateral high septal deflections. No nasal tenderness or purulent discharge was noted. Her serum chemistries and complete blood count were within normal limits. Nasal endoscopy was normal. Biopsy, however, showed edema, giant cells and multiple noncaseating granulomas in the right nasal passage. Extraintestinal manifestations of Crohn’s disease of the gastrointestinal tract are a well recognized phenomena. Biopsy typically shows edema of the lamina propria, perivascular inflammation with infiltrates and noncaseating granulomas with multinucleated Langerhans type giant cells. The differential diagnosis in this case included Wegener’s granulomatosis and Crohn’s disease. Nasal involvement is extremely rare. To date,
only five cases of nasal Crohn’s disease have been reported and is typified by chronic mucosal inflammation, obstruction, bleeding and occasionally septal perforation. All prior five patients were treated with oral steroids and or systemic corticosteroids with good results. Nasal involvement in Crohn’s disease is extremely rare. Its findings after benign physical and endoscopic examination of the nasal passages suggest that this may be an underreported phenomenon.

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Whipple’s Disease in Arkansas
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42 y/o male presented with 2 month hx diarrhea, periumbilical abdominal discomfort, 35 pound weight loss, and iron depletion anemia. Pmh significant for 1) poor compliance with medical rec’s and f/u. 2) 8 yr hx seronegative polyarthritis 3) hx “allergic dermatitis.” Pertinent positive on ROS was mild DOE. He had 2 mild cognitive alteration. Physical exam showed wt 226, normal vital signs. Rest of exam normal except for 1: pitting pretilial edema. Lab data: CBC – wbc 6.700 with normal differential, hemoglobin 11, MCV 70. Chem 12 normal except for alk phos 176.ESR 56. Serum albumin 3.7. INR 1.0 TTG IgA & IgG antibodies negative. Serum iron 20 and ferritin 15. Stool giardia antigen negative. Stool c.difficile negative, stool wbc negative. EGD showed diffuse scalloping of the duodenal mucosa. Colonoscopy showed diffuse spiculation of the ileal mucosa. Small bowel bx’s revealed mild acute and chronic inflammation with increased numbers of PAS (+), acid-fast negative macrophages in the lamina propria. On whole blood, Tropheryma whipplei DNA PCR was detected. He was tx’d with 2 wks of IV Rocephin 2g daily and then started on Bactrim DS one bid for one year. Within weeks his abdominal pain and diarrhea resolved. He gained weight easily. 3 months after tx started he was hospitalized with pleuritic chest pain and dyspnea and had negative V/Q scan and venous dopplers of the legs. CXR showed small left pleural effusion. O2 sat 94%. Echocardiogram showed small pericardial effusion, left atrial enlargement, trace mitral regurgitation, small pleural effusion and ejection fraction 60%. He was treated with Factiv for 7 days and nsaid tx and his symptoms resolved. He took Bactrim DS for one year. Two months after completion of bactrim tx, he sought medical care for painful paresthesias of his feet. He noted hyperphagia with a 54 pound weight gain. He denied having diarrhea, abdominal pain, bleeding. CBC and chem 12 wnl. T. whipplei PCR on whole blood was sent and repeat upper endoscopy scheduled. What is the appropriate follow up and management of this patient? What is the best usage of endoscopic biopsy and PCR testing in follow up? Is there a role for lumbar puncture and PCR testing of CSF? Should PCR testing be done from blood sample or small bowel tissue? Should an alternative antibiotic be used for relapse? I have photographs of the endoscopic findings and histology.

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Recurrent Aortoenteric Fistula
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Aortoenteric fistula is a rare but often devastating cause of GI bleeding. It is most commonly the secondary type, when a previously placed abdominal aortic graft erodes into the distal duodenum causing a life threatening GI hemorrhage. Failure is the rule unless it is recognized early and treated promptly. A recurrent aortoenteric fistula is exceedingly rare with only a handful of cases reported in the medical literature. A 64-year-old woman presented with hematemesis and melena. Medical history was remarkable for an abdominal aortic aneurysm s/p uncomplicated elective graft repair in 1993 with subsequent development of an aortoduodenal fistula in 2000 manifested as severe GI bleeding. This was managed at our institution with emergent surgery (infected graft removal, over-sewing of the aorta, and creation of a axillary-femoral artery bypass) with full recovery. On physical exam the patient appeared comfortable. She was orthostatic and had a clean vertical abdominal scar without a pulsatile mass. Abdomen was soft and not-tender. Emergent EGD utilizing a pediatric colonoscope revealed a significant amount of non-adherent blood clots in the descending duodenum without active bleeding. No lesions or active bleeding sites were identified on the examination. A CT scan and technetium 99m pertechnetate tagged RBC scan revealed active bleeding in the distal duodenum adjacent to an aneurysmal abdominal aortic stump. Emergent laparotomy revealed a large aortic stump pseudaneurysm with a pin size hole communicating with the distal duodenum. The pseudaneurysm and duodenum were repaired and the fistulous communication was excised. An omentoplasty was performed in order to buffer the separation between the aortic stump and duodenum. The patient had an uneventful post-operative course and was discharged to a rehabilitation facility twelve days later. This most unusual case highlights the importance of recognizing the clinical presentation of an aortoenteric fistula and how it is an infrequent but often lethal cause of severe GI bleeding. Moreover, although such cases are quite rare, it does not preclude its recurrence. One must approach each patient with severe GI tract bleeding with a broad differential diagnosis keeping in mind both their current risk factors as well as their past history.

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A Revisit to an Uncommon Disease, a Case of Weight Loss and Lymphadenopathy
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We report a case of a 29 year old African American male afflicted with the disease, who presented with 2 to 3 months of weakness and weight loss (10 lbs). He described mild abdominal discomfort, migratory arthralgias, night sweats, loose, watery stools, and occasional postprandial chest pain. His physical exam was significant for guaiac positive stools and extensive cervic- al, axillary, and inguinal lymphadenopathy. A computed tomography scan of the abdomen and pelvis showed widespread periaortic, perigastric, and perihpatic lymphadenopathy. An upper endoscopy was performed, which revealed edematous duodenal white mucosa with white plaques and superficial erosions. On endoscopic biopsy, villous atrophy and an abundance of PAS-positive macrophages in the lamina propria were present, consistent with Whipple’s disease. The patient was initiated on therapy with IV Ceftriaxone and Streptomycin for 2 weeks, and then maintained on Bactrim for 1 year, with complete resolution of his symptoms. Whipple’s disease is a rare systemic disease caused by infection with a gram positive bacillus, Tropheryma whipplei, which has an affinity for the gastrointestinal tract. It predominantly afflicts white males of European ancestry in their 5th or 6th decade of life, suggesting a genetic predisposition. Diagnosis depends on tissue sampling (usually biopsies of the proximal and distal portions of the duodenum) with subsequent PAS staining performed. In this report, an African-American male presented with the disease, which is quite rare. Our case highlights the importance of considering Whipple’s disease in patients with appropriate symptoms, despite the ethnic background.

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Giant Cell Tumor of the Common Bile Duct: A Rare Benign Neoplasm
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Giant cell tumors usually occur in the bone/tendon sheath of children and adolescents. Other less common sites include the pancreas, mediastinum, skin, larynx and thyroid. To date there have only been 4 reported cases in the literature of giant cell tumors of the extrahepatic biliary tree. A 60 year old Hispanic male with diabetes and atrial fibrillation was found to have
a common bile duct mass incidentally on CT of the chest, during a work up for pneumonia. The patient was asymptomatic and physical exam was unremarkable. Laboratory values were notable for an alkaline phosphatase of 175 U/L, GGTT of 230 U/L, AST of 63 U/L and ALT of 64 U/L. The total bilirubin, viral serologies and tumor markers were normal. The CT showed a dilated common bile duct of 2.3 cm with a 1.7 cm mass projecting into the lumen of the distal common bile duct from the right lateral wall. The patient underwent an ERCP that revealed a dilated common bile duct of 2.2 cm, with a 2 x 4 cm intraluminal filling defect attached to the right wall of the distal common bile duct. A sphincterotomy and basket sweeps were performed, with soft tissue debris extracted. Pathology revealed multinucleated giant cells admixed with mononuclear cells. The patient then underwent surgical resection with a Whipple’s procedure. Gross pathology revealed a 1.5 cm polypoid lesion in the common bile duct and histology was significant for multinucleated osteoclast-like giant cells and many mononuclear cells. Findings were confirmed by the Armed Forces Institute of Pathology as a giant cell tumor of the common bile duct. The patient is healthy at 1-year follow up. Polypoid lesions of the gallbladder and extrahepatic biliary tree are rare and primarily include cholesterol polyps, inflammatory polyps, adenomyoma, adenomas, leiomyomas and carcinoids. Since the first case report in 1986, only 4 cases of a giant cell tumor of the gallbladder or extrahepatic biliary tree have been reported. A recent case review of the 4 cases demonstrated that these tumors are similar histologically and immunohistochemically to giant cell tumors of the bone/tendon sheath, staining positive for CD68 and CD163 and pursue a benign course. Yet it is important to distinguish these tumors from anaplastic spindle and giant cell carcinomas with osteoclast-like giant cells of the gallbladder, which are malignant and pursue an aggressive course. This case represents an extremely rare, benign tumor of the extrahepatic biliary tree.

Splenic Artery Embolization for Non-Bleeding Gastric Varices and Hypersplenism Due to Isolated Splenic Vein Thrombosis

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Splenic artery embolization has been used with success for treatment of bleeding gastric varices secondary to splenic vein thrombosis. We present a case of isolated splenic vein thrombosis causing non-bleeding gastric varices and hypersplenism which was successfully treated with splenic artery embolization. A 56 year old man with hemochromatosis previously treated with phlebotomy presented with intermittent epigastric abdominal pain and thrombocytopenia. The subsequent workup included an evaluation for cirrhosis and portal hypertension including a liver biopsy and hepatic wedge pressure measurements which were normal. Further evaluation included a normal bone marrow biopsy. A CT scan and duplex ultrasound revealed an enlarged spleen of 15 cm as well as a suggestion of gastric varices and nonvisualization of the splenic vein. Splenic vein thrombosis was confirmed by MR venogram. Hematological evaluation revealed no hypercoagulable state and there was no history of pancreatitis or other explanation for the isolated finding of splenic vein thrombosis. Subsequently, an EGD revealed significant gastric varices. It was decided that a surgical splenectomy would be high risk due to multiple abdominal venous collaterals and that a medical splenectomy with splenic artery embolization is indicated to decompress venous collaterals prior to a planned surgical splenectomy. After the embolization, follow-up endoscopies have shown improvement in gastric varices and repeat laboratory evaluation has shown normalization of platelet counts even after ten months of follow-up. The decision was made not to proceed with surgical splenectomy at this time. There are only a few reported cases of isolated splenic vein thrombosis without a clear etiology. Splenic vein thrombosis is well known to cause hypersplenism and gastric varices. Spleenic artery embolization has been described for 25 years and is mainly utilized in patients with bleeding gastric varices and hypersplenism, usually prior to splenectomy. This procedure is traditionally reserved for high risk surgical patients as it has been reported to have complications such as hematomata or splenic abscess. We suggest this procedure as an effective treatment modality while monitoring clinically for complications or evidence of splenic regeneration at which time surgical therapy could be considered.

Precipitation of a Barium Enema: An Unusual Cause of Large Bowel Obstruction

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This vignette highlights an unusual complication of a common procedure as well as the techniques, that when followed, will help avoid its occurrence in the future. A radiograph of the abdomen confirmed the diagnosis of the precipitation of a barium enema. A 50 year male with a past medical history of constipation presented to emergency department complaining of 2 days of abdominal pain, bloating and constipation. The pain localized to the left lower quadrant. Although he denied any fever or chills, he noted intermittent nausea, with any oral intake. He stated that he had not had a bowel movement in 3 days. The patient had a colonoscopy and polypectomy one month prior to admission, however, endoscopy was not completed due to inadequate prep and thus cecum was not visualized. The patient then received a barium enema three days prior to presentation. On presentation, the patient was in obvious discomfort. Vital signs were within normal limits. His abdomen was soft with normal bowel sounds, but mildly distended with a palpable mass in the left lower quadrant. Rectal Examination revealed a hard mass 3 cm above the anal verge with white fatty stool impacted in the rectum. An x ray of the abdomen revealed retained contrast through the large bowel and massively dilated contrast filled rectum. The patient was manually impacted and given several tap water enemas. After the patient had several bowel movements and improved symptomatically he was discharged for an outpatient follow up with his gastroenterologist. Complications of barium enemas, though rare, include perforation, barium impaction, water intoxication, allergic reactions, and cardiac arrhythmias. Vora and Chapman report 2 cases in 348433 barium examinations(1/175000 enemas). Factors that may contribute to impaction are slow transit time, colonic inertia and dehydration. Thus, impaction can usually be preempted if patients are encouraged to maintain their oral fluid intake and in those with a history of constipation, employ a mild laxative after examination until the barium has been removed from the bowel. Barium enemas are still one of the well recognized modes of screening for colon cancer as well as alternative colon-imaging test in the setting of a failed colonoscopy. We would like to draw a special attention to prescribing barium enemas to patients with constipation.

Esophageal Carcinoma Presenting as Small Bowel Metastasis and Obscure GI Bleed

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It is very unusual for esophageal carcinoma presenting as obscure gi bleed secondary to small bowel metastasis. This patient was initially diagnosed with primary esophageal carcinoma and was treated with surgery and radiation. Patient presented with obscure gi bleed after several months and the evaluation by esophagogastroduodenoscopy and colonoscopy did not show any pathology to explain the gi bleed(melena). Small bowel evaluation through radiology and capsule endoscopy raised the issue about mass lesion at the distal ileum and pt underwent surgical excision of the lesion. Pathology of the lesion was consistent with metastatic esophageal carcinoma. Here we followed the standard workup for obscure gi bleed including egd,colonoscopy, sbft and capsule endoscopy. Capsule endoscopy really helped to make the
diagnosis by demonstrating the mass lesion in distal ileum. That lead to surgery since patient had symptoms secondary to lesion. Unusual presentation of esophageal carcinoma as obscure gastrointestinal bleed secondary to small bowel metastasis.

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Familial Cyclical Vomiting Syndrome: A Case Report and Review of the Literature
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Cyclical Vomiting Syndrome (CVS) has been recognized for over 100 years. It is characterized by recurrent episodes of intense nausea and vomiting, with normal health between the emetic crises. Attacks are self-limiting, lasting several hours to over a week, and their duration is often stereotypical for each patient. Episodes of CVS are most commonly precipitated by infections, physical or emotional stress, excitement, or specific foods, and often commence during the night or early morning. Familial occurrence of CVS has not been described often, and therefore genetic causes of CVS have not received much attention. There have been only two case reports of familial cyclical vomiting in the published literature. Here, we describe a third case of the two-generation family in which five patients suffer from CVS.

Case Report: The Proband is a 35 year-old-female who was diagnosed with CVS at the age of fifteen. The attacks would typically start in the morning and the number of episodes varied between four per hour to a total of six during the whole attack. The frequency of the attacks varied between two and four per week. Attacks often were triggered by allergies, infections and stress. Extensive workup ruled out gynecological, neurological and gastrointestinal causes. Treatment with anti-emetics resulted in considerable relief of nausea and number of emesis. Change of residence (to avoid allergens) helped in the control of both allergy related symptoms and CVS. Other family members diagnosed with CVS included her brother and cousin (brother), her two daughters aged 12 and 14.

Discussion: Here we report a family in which five subjects (three females and two males) suffer from a stereotypical syndrome of episodic vomiting. The symptoms of these patients are consistent with the criteria of CVS. To the best of our knowledge, only two published reports of familial occurrence of CVS exists in the literature. Boles and Williams reported the possibility of mitochondrial inheritance in this group of familial CVS patients. The role of genetics and inheritance pattern in these familial patients with CVS need to be further investigated.

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Fundic Gland Polypl
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Fundic gland polyplyps (FGPs) are the most common gastric polyplyps in patients with familial adenomatous polyposis (FAP). FGPs have traditionally been regarded as nonmalignant, possibly hamartomatous lesions. We report a patient with familial adenomatous polyposis who had abdominal pain and hematemesis and found to have high-grade dysplastic fundic polypls on endoscopy.

Case report: 36-year-old Puerto Rican male with past medical history of Familial Adenomatous Polyposis Syndrome and Colon cancer status post colectomy and colostomy 11 years ago presented with abdominal pain in epigastriac region. He also had multiple episodes of vomiting with coffee ground vomitus. He had a strong family history of colon cancer with mother and sister diagnosed with colon cancer. On physical examination, vitals were stable and the abdomen was soft with mild epigastric tenderness and positive bowel sound. He had right colostomy with black stools in colostomy bag. Abdominal x ray showed no obstruction and pneumoperitoneum. The laboratory tests showed a WBC count of 9000(µl) and platelet count of 204000(µl) and hemoglobin of 9.1 g/dl. Blood chemistries, liver function tests and coagulation profile were normal. He was treated with intravenous lansoprazole and admitted in ICU for monitoring. In the ICU patient was seen by gastroenterologist and underwent endoscopy with biopsy that revealed severe esophagitis, erosive gastritis and multiple fundic polyplyps with high-grade dysplasias. Second upper endoscopy was done after one week that showed gastric polyposis and healed esophagitis. Seven polyplps were removed and sent for histopathology, which showed a mixture of fundic gland polypl and tubular adenomatous polypl with high-grade dysplasia. Treatment options total gastrectomy versus serial EGD with polypectomy was discussed with patient. He refused gastrectomy, stated that he will think about alternative treatment and signed out against medical advice.

Discussion: In this case, the patient was previously diagnosed with Familial Adenomatous Polyposis and Colon Cancer found to have multiple fundic polyplps with high-grade dysplasia. Familial adenomatous polyposis is associated with gastroduodenal polypls in 40 to 100 percent of patients. Although fundic gland polyplps are considered benign, there are reports of dysplasia in fundic gland polyplps and reports of carcinoma arising adjacent to, or in continuity with, fundic gland polyplps. Because of the risk for cancer, all gastric polyplps should ideally be removed and examined microscopically for histological characterization.

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Gallbladder Cancer Presenting as Leptomeningeal Carcinomatosis
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Leptomeningeal carcinomatosis is defined as a dissemination of tumor cells throughout the meninges and ventricles. It is a rare manifestation of gastrointestinal cancers. Rarely, gallbladder cancers can metastasize to the meninges. We describe a patient with leptomeningeal carcinomatosis as the initial manifestation of gallbladder cancer.

Case description: An 81 year-old Caucasian female with past medical history significant for hypertension and coronary artery disease who presented to the emergency department with intractable headache, vomiting, and ataxia of gait of 2 weeks duration. A plan CT scan of brain was normal. Esophagogastroduodenoscopy was normal with intact mucosa and peristalsis; multiple jumbo biopsies of stomach were negative for malignancy. CT Scan of abdomen and pelvis with contrast revealed asymmetric thickening of gallbladder’s wall, and lytic lesion of lumbar vertebral body L12, no hepatic or pancreatic lesions were seen. Ultrasound of gallbladder showed cholelithiasis and confirmed an asymmetric thickening of the gallbladder’s wall. CT guided biopsy of the spinal lesion revealed signet-ring cell adenoscarcinoma with mucinous features. Immunoperoxidase stain was positive for CA19–9, positive for CK7, weak positive for CK20, and negative for TTF, consistent with pancreatic-biliary cancer. Serum CA 19–9 was 9295 U/ml (normal level less than 37 U/ml). Serum CEA level was within normal limit. MRI of brain without and with contrast showed abnormal enhancement along the cerebellum and cerebellar vermis suggesting of leptomeningeal carcinomatosis. Patient refused any further workup or treatment and went for hospice.

Discussion: Gallbladder cancer (GBC) is an uncommon and highly fatal malignancy. Majority of GBC cases are found incidentally in patients undergoing exploration for cholelithiasis. Leptomeningeal carcinomatosis can rarely be the initial manifestation of GBC. In the present case, the occult GBC metastasized directly to the meninges without evidence of involvement of the liver or pancreas. This is one of the very few reported cases manifesting as such in the medical literature.

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Metastatic Adenocarcinoma of the Esophagus in a 27 Year Old – A Case Report
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This case describes a 27-year-old male presenting with metastatic esophageal adenocarcinoma without gastrointestinal symptoms or underlying Barrett’s Esophagus. A 27 year-old Caucasian male with no past medical history presented with two weeks of progressive dyspnea on exertion. There were no dysphagia or GERD symptoms noted. Physical exam was significant for tachycardia with increased jugular venous distension, bibasilar crackles, and 2+ lower extremity edema. An EKG revealed electrical alternans and a bedside echocardiogram confirmed the presence of a large pericardial effusion with tamponade physiology. Pericardiocentesis yielded 1.25 L of hemorrhagic fluid for which cytology was positive for malignant cells, consistent with metastatic adenocarcinoma. Immunopathology demonstrated the cells to be CA 19.9 and CK 7 positive while CK 20, ER, PR and TTF were negative, consistent with an upper gastrointestinal malignancy. An EGD revealed a large, friable mass 3 cm proximal to the GE junction (fig 1). Pathology demonstrated poorly differentiated adenocarcinoma without evidence of Barrett’s Esophagus. The patient began chemotherapy with cisplatin, docetaxol, fluorouracil and was discharged home. There has been a rise in the incidence of adenocarcinoma of the esophagus, the causes of which are partially understood. The typical patient diagnosed with esophageal cancer is a Caucasian male between the age of 55 and 75. The prevalence of esophageal and gastric cardia cancer in patients younger than 40 years of age is rare and ranges from 2.0 to 7.5%. The presence of Barrett’s Esophagus (BE), or intestinal metaplasia of the lower esophagus, is the principal risk factor for the development of the tumor, although up to one third of patients with esophageal adenocarcinoma lack evidence of BE. This case presentation demonstrates how 1) esophageal adenocarcinoma is occurring in a younger patient population than previously described. 2) Esophageal adenocarcinoma can occur without gastrointestinal symptom or the presence of intestinal metaplasia. [figure1]

Case report: A 25-year-old Ecuadorian man with no past medical history presented with severe upper abdominal pain, vomiting, diarrhea, and tenesmus. Two weeks prior to this admission patient was admitted with severe lower abdominal pain. At that time, CT scan of abdomen and pelvis with contrast was suspicious for proximal colitis. He underwent colonoscopy with random biopsies of colon and terminal ileum and it came back normal. In addition, stool workup including ova and parasite was negative. He was discharged home with outpatient follow-up with gastroenterologist. A week later, he again developed pain in the lower abdomen and was seen by his gastroenterologist as an out patient who repeated CT scan of abdomen and pelvis with contrast which showed colitis in the distal colon. Patient was sent home on hyoscymine. Two days prior to this admission patient again had abdominal pain with nausea and vomiting so he called gastroenterologist who gave him lansoprazole and instructed him to come to ER if vomiting and abdominal pain persist. Despite the use of lansoprazole, abdominal pain and vomiting persisted so he came to ER. Abdominal examination showed a soft, mildly tender abdomen with no rebound tenderness. The white cell count was 14 × 103/L, with 42% neutrophils, 17% lymphocytes, 5% monocytes, and 36% eosinophils. This time gastroenterologist thoroughly reviewed the case and came on conclusion that the finding that he did not take into consideration during the first admission was peripheral eosinophilia. He did upper gastrointestinal endoscopy with multiple biopsies to rule out EG. The biopsy of small bowel revealed small bowel mucosa with normal villous pattern and patchy intense sheet-like infiltrate of eosinophils. After ruling out the possibilities of IBD, malignancy, infections, and autoimmune disease, Eosinophilic Gastroenteritis was diagnosed. Patient was treated with low dose of prednisone for four weeks. He responded well clinically.

Discussion: A case of male patient with EG was presented in this work where a diagnosis could be easily missed. It should be suspected when patients have peripheral eosinophilia with gastrointestinal discomfort and where standard examinations could not give the explanation.

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Eosinophilic Gastroenteritis
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Eosinophilic gastroenteritis (EG) is a rare disease of unknown origin characterized by patchy or diffuse infiltration of eosinophils in gut wall. We are presenting a case of a man who had recurrent abdominal pain, vomiting, occasional diarrhea, peripheral eosinophilia and fluctuant colitis on CT scan of abdomen.

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Treatment of Severe Clostridium difficile Colitis with Intravenous gamma Globulin
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A 57 year old male was admitted due to two weeks of diarrhea which followed treatment of an infected finger with amoxicillin/clavulanic acid. A flexible sigmoidoscopy showed pseudomembranous colitis. A CT scan showed diffuse bowel wall edema, and abdominal plain films showed thumbprinting. Stool was positive for Clostridium difficile toxin A. His WBC was 28000, albumin was 1.9. He failed to respond to seven days of intravenous metronidazole and oral vancomycin. A search of relevant medical literature found a few case reports of successful treatment with gamma globulin infusion for severe clostridium difficile colitis. Blood was drawn for immunoelectrophoresis and the patient given an infusion of 400 mg/kg of gamma globulin. Within two days his WBC dropped to 13000. After a week of steady improvement, he was discharged on oral vancomycin and made a full recovery. His immunoelectrophoresis report was returned two days after the infusion and his IgG level was 310 mg/dl, which is significantly lower than the normal range of 700–1600 mg/dl. A subsequent immunoelectrophoresis a month later showed that his IgG level had returned to normal. The postulated cause for the low IgG level and failure to respond to conventional treatment was a protein losing enteropathy due to the severe clostridium colitis which caused him to be immunocompromised. We recommend that patients with clostridium difficile colitis not responding to conventional treatment receive a gamma globulin infusion.

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A Case with Cystic Lesions in Pancreas
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A 32-year-old woman presented with upper abdominal pain radiating to her back, progressively increasing over 3 days associated with a few episodes of vomiting. At the age of 16 years, she had a brain tumor removed, and she also underwent partial nephrectomy for a right sided kidney tumor. Her mother died of a brain tumor at the age of 39 years. Physical examination revealed mild epigastric tenderness. Normal liver enzymes, amylase 41, and lipase 24. A contrast enhanced CT scan of the abdomen demonstrated a large cyst of 3.5 cm at the pancreatic body compressing the stomach anteriorly (Figure 1). The image at level of pancreatic head showed a solid enhancing left renal mass as well as multiple pancreatic head cysts (Figure 2). Following a CT guided aspiration of the largest pancreatic cyst, her symptoms resolved. Aspiration of cystic fluid content showed normal CEA, CA 19.9 and amylase level, and no malignant cells. 

**Diagnosis:** Von Hippel-Lindau Disease (VHL) type I with pancreatic (simple pancreatic cysts) and renal involvement. VHL disease is an autosomal dominant disorder with a high penetrance and a prevalence of 1 in 39000–53000. Overall, pancreatic involvement is seen in 15–77% of patients with VHL disease manifesting as simple cysts (91%), serous cystadenomas (12%), islet cell tumors (7–12%) or combined lesions (11%). 28–45% of patients with VHL develop renal cell carcinomas, which are often multiple and bilateral. It is crucial to diagnose the condition early and patients should be on regular surveillance. A geneticist should be involved in all cases and family members should be screened for the presence of the disease. [figure1][figure2]

Pancreatic calculi are manifestations of chronic pancreatitis. Occasionally, a solitary calcification causes recurrent acute pancreatitis and is a target for therapy. A 50 year-old woman teetotaler was admitted for acute pancreatitis. Serum lipase and amylase were 8545 U/L and 345 U/L. Abdominal CT revealed an 8mm calcification in the mid-portion of the main pancreatic duct with dilatation upstream. ERCP confirmed the presence of an obstructing intraductal calcification in the mid-body of the pancreas, 15 cm from the papilla. Attempts at removal with a basket and ESWL were
unsuccessful. She suffered recurrent pancreatitis and underwent surgery. A distal pancreatectomy removed an 8 mm calcium carbonate calculus. Tissue upstream from the obstruction revealed acute and chronic inflammation with normal tissue downstream. These findings implicate the stone as the primary etiology of her recurrent acute pancreatitis. Ductal hypersecretion of calcium or lithostathine deficiency may have caused the stone. Since pancreatectomy 35 months ago, she developed diabetes mellitus, but has been pain free. Interventionsal endoscopy coupled with ESWL has emerged as an excellent alternative to surgery for symptomatic pancreatic stones. Its success is greater with a single stone < 12 mm in size and located in the head or pre-papillary segment. ESWL alone can be successful as well but requires more repetitive treatments. Stones located in the body or tail, proximal to a stricture, or difficult to reach by retrograde cannulation are candidates for combined interventional endoscopy and ESWL. An immediate reduction in pain is achieved in 75–95% of patients. The best results are seen in patients who have the duct completely cleared of stones and fragments. Surgery can be applied when less invasive therapy is unsuccessful. [figure1][figure2]

Mesenteric Lymphoma Presenting as Mesenteric Panniculitis with a Negative PET Scan
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Mesenteric panniculitis (also known as sclerosing mesenteritis) is a chronic inflammatory disease of the mesentery. It is known to have a wide spectrum of clinical presentations. In general, a biopsy is recommended for diagnosis, although a recent study proposed that a negative PET scan is highly effective in differentiating benign and neoplastic mesenteric processes. The following case report questions the accuracy of a negative PET in this setting. Not applicable.

The patient is a 52 year-old Caucasian female who was found to have milky-appearing ascites during routine vaginal hysterectomy and repair of uterovaginal prolapse. Abdominal CT scan was pursued for further workup of this unexplained ascites; this showed the typical features of mesenteric panniculitis, including strandlike and patchy densities of the mesenteric fat surrounding the mesenteric vasculature in the mid-abdomen. The patient was then referred to our practice for further evaluation and treatment. She described episodes of severe abdominal pain occurring about every 3 months for the past 2–3 years. She also mentioned episodes of bloating and nausea occurring several times a week. Physical examination revealed a soft abdomen which was nondistended and nontender. There was no organomegaly, palpable masses, or localized adenopathy present. Her Mesenteric Panniculitis Symptom Assessment Score (MPASAS) was 24, suggestive of moderately symptomatic disease. ESR and CRP were normal. A PET scan demonstrated no abnormal metabolic activity in the affected mesentery or any lymphadenopathy. Laparoscopy showed a thickened segment of mesenteric fat. Biopsies were obtained which demonstrated a B-cell non-Hodgkin lymphoma of follicular origin. A recent study by Zissin et al* stated that “a negative PET scan has a high diagnostic accuracy in excluding tumoral mesenteric involvement...” This case questions this accuracy and reinforces the need for biopsy even in the setting of negative PET scan to rule out co-existing neoplastic disease.


Refractory Esophageal Stricture in Zollinger-Ellison Syndrome Treated with a Removable Stent
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A 63 year old man with a past medical history significant for gastrinoma resection 15 years prior and Barrett’s esophagus presented with abdominal pain. Upper endoscopy (EGD) revealed grade IV esophagitis and multiple duodenal ulcers. A recurrent gastrina with Zollinger-Ellison Syndrome (ZES) was suspected and the patient was started on high dose proton pump inhibition therapy four times daily. An octreotide scan and liver biopsy confirmed the diagnosis of recurrent gastrinoma in the liver. Gastrin level at this time was 906 pg/mL. On the ninth day of hospitalization the patient developed significant dysphagia and underwent a second EGD. Findings were consistent with a pinpoint stricture at 28 cm. An 8.6 mm diameter 160 Olympus endoscope could not traverse the stricture and esophageal dilation was performed with through-the-scope (TTS) balloons at 6, 7, and 8 mm. A barium esophagram confirmed a 9 cm long stricture. Eight weekly endoscopies were performed for serial dilations of the stricture (some on an outpatient basis). During each session the stricture was severely narrowed and dilation was restarted using an 8 mm balloon. Triamcinolone was injected at 2 of the sessions. The patient’s esophageal stricture remained refractory to all endoscopic and medical treatment. The decision was made to place a removable 12 cm long silicone coated Polyflex® self-expanding esophageal stent (Boston Scientific, Watertown, MA, USA). During the ninth endoscopy the stent was placed after balloon dilation. The stent remained in place for 5 weeks; during that time the patient noted significant improvement in his dysphagia and quality of life. The stent was then removed utilizing standard endoscope and rat tooth forcep techniques. One week after removal the patient remained asymptomatic.

Comments: Esophageal complications of ZES are rare and include Barrett’s esophagus, esophagitis, stricture, and perforation. This case is unique in that it is the first case to document rapid time progression from Barrett’s to severe esophagitis and stricture formation in less than 5 months. Also, severe esophagitis to stricture formation occurred within 9 days. This is also the first case of successful placement of a temporary removable esophageal stent for a refractory stricture due to ZES. We suggest that an esophageal stent is beneficial in patients with ZES and challenging esophageal strictures resistant to conventional treatment.

Smoking Cessation and IBD – When Smoke Obscures the Underlying Fire
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The relationship between smoking and inflammatory bowel disease is well recognised. Characteristically it has been negatively associated with ulcerative colitis but positively associated with Crohn’s disease. This case highlights a paradoxical presentation. A 32 year old female presented with a three month history of alternating cycles of diarrhea and constipation. She had stopped smoking two months prior to the onset of her symptoms and there was a strong family history of inflammatory bowel disease. Sigmoidoscopy and rectal biopsies were consistent with diffuse active chronic proctitis of ulcerative colitis type. She was commenced on treatment but continued to have intermittent mild but worsening symptoms over the following five years, culminating in admission to hospital with an acute severe flare up. During this admission she developed a perianal fistula and repeat colonoscopy revealed macroscopic changes characteristic for Crohn’s disease. This was confirmed histologically and she has subsequently responded well to infliximab therapy. The impact of cigarette smoking cessation as a potential risk factor for ulcerative colitis is well documented. Smoking is usually associated with the development of late onset Crohn’s disease and cessation is known to improve its clinical course. This case highlights a contradiction to orthodox teaching and reveals how initial histology can be misleading. It also emphasises the importance of maintaining an open view to the possibility of an alternate diagnosis in patients who do not respond to initial treatment.
Assessing the Response to Drainage for Biliary Leak: Falsely Positive HIDA Scan

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Case: A 60 yrs old female who initially had open cholecystectomy for ascending cholangitis 2 weeks ago, was readmitted with abdominal pain, fever, leucocytosis and raised LFTs. CT abdomen showed fluid collection in right upper quadrant. Percutaneous drain with pigtail stent placement revealed biloma. HIDA scan suggested bile leak at gallbladder bed. She underwent ERCP with sphincterotomy. After ERCP, the percutaneous drainage continued but decreased. Repeat HIDA scan after clamping the percutaneous drain revealed no leak at gallbladder bed, but a new leak was seen on the left upper abdomen. However, repeat CT abdomen showed resolution of previous fluid collection with no new collection on the left side. The new biliary leak on repeat HIDA scan was actually due to bile reflux into the stomach after ERCP with sphincterotomy. The percutaneous drain was finally removed, and the patient continued to do well.

Discussion: Biliary leak is frequent after open cholecystectomy. US or CT are initial tests of choice for intraperitoneal fluid collection, but can’t differentiate biloma from other fluid collections. HIDA scan is diagnostic for ongoing bile leak. It’s not only a sensitive non-invasive method of investigating possible bile injuries (1), but can also be used to assess the response to drainage (2). However, HIDA scan can be falsely positive (3). This was demonstrated in our patient. This emphasizes the importance of correlating serial HIDA scan results with clinical status and CT findings.

REFERENCES


Lactobacillus GG for the Treatment and Cure of Ulcerative Colitis — A Case Report

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Probiotics have recently been shown to have beneficial effects on patients with Crohn’s disease, pouchitis, and possibly IBS. To date, there is a paucity of data on their role in the treatment of ulcerative colitis. This case report suggests a potential new role for probiotics, indicating its possible ability to treat or even cure ulcerative colitis. The patient is a 65 yo woman with a family history of Crohn’s disease who presented for GI evaluation due to a two week hx of rectal bleeding and crampy abdominal pain. She had soft, non-liquidy stools. There was no hx of chronic diarrhea, recent wgt loss, or previous antibiotic use, and she denied risk factors for ischemic colitis. She was seen in the ER one week after symptom onset and labs revealed a WBC of 5, and Hct of 43. Testing for stool culture, and O & P revealed negative results after 48 hours. The patient was given Ciprofloxacin and Metronidazole upon discharge from the ER but had no response, prompting a GI referral. On exam, she was afebrile and the abdomen was non-tender. She was advised to take Lactobacillus GG (10 billion CFUs) BID and a colonoscopy was scheduled. Colonoscopy revealed ulcersations, erosions and mucosal friability throughout. Bxs showed cryptitis, crypt abscesses. and expansion of the lamina propria by inflammatory cells including lymphocytes, plasma cells, and PMNs, suggesting both acute and chronic inflammation. A second opinion from pathology confirmed a dx of UC. 5-ASA treatment was advised, however the pt reported complete symptom resolution with probiotic use. Sigmoidoscopy was performed 25 days after initiating probiotic treatment, and was totally normal. Bxs revealed no evidence of any inflammation or crypt distortion. This case illustrates the possible role of Lactobacillus GG in the treatment of UC. It is possible, alternatively, that the pt had a self-limited colitis, and not UC. However, the pathologic changes seen on colonoscopy indicated UC and not a self-limited colitis or ischemia. Also, the lack of response to antibiotics, the negative stool culture and the presence of severe inflammatory changes seen endoscopically 18 days after symptom onset argue against an infectious source. Probiotics are emerging as therapy for mucosal inflammatory disorders as well as IBS and thus their potential role in UC should not be overlooked. Large randomized, controlled trials of Lactobacillus GG in the treatment of UC are warranted. Unitl then, empiric adjunctive treatment with Lactobacillus GG appears reasonable.

Laparoscopic Gastropexy for Congenital Organoaxial Gastric Volvulus in an Adult with Severe Intestinal Malabsorption

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A 62 year old male with malabsorption, malnutrition, and multiple comorbidities underwent laparoscopic gastropexy for congenital organoaxial
vovulus, an uncommon lesion. The patient was well until 18 months prior, when he developed non-bloody diarrhea (> 20 stools per day), and progressive weight loss of over 120 lbs (> 1/3 total body weight). Upper endoscopy and colonoscopy with biopsies were nondiagnostic. His cardiac function deteriorated, with dilated cardiomyopathy, and atrial fibrillation requiring pacemaker/defibrillator placement within 1 year. He underwent 72 hour fecal fat (75% absorption), followed by endoscopic retrograde cholangiopancreatography (“normal”), complicated by acute heart failure with collapse. During subsequent admission, work-up showed normal fecal elastase, and negative genotype for Celiac disease, infection, and PCR for Whipple’s disease in blood. Upper GI demonstrated organoaxial gastric volvulus. He was treated empirically for Whipple’s, made NPO with full parenteral nutrition, and referred for surgery. Repeat upper endoscopy and biopsies showed increased intraepithelial lymphocytes, and amyloidosis of duodenal vessels (IgM, IgG, IgD, IgA, α, λ, amyloid A and B negative). At laparoscopy, the liver appeared normal, spleen was slightly enlarged. The stomach was suspended at a normal gastroesophageal junction, but had rotation of the body and fundus with a volvulus that was mostly posterior and a midline pylorus. Liver biopsy, resection of incidental Meckel’s diverticulum, gastropexy, and gastrotomy were accomplished laparoscopically without complication. Postoperatively, the patient was started on peptide feeds, but continued to have malabsorption at discharge one week later. He was re-admitted within 4 weeks for Enterobacter gergoviae sepsis, intraabdominal free air/possible peritonitis. Mesenteric angiogram was normal. Over the 6 week admission, complicated by recurrent ventricular tachycardia, TPN was used until optimal weight achieved, then weaned as continuous peptide feeds increased. These were well tolerated with only 2 stools per day, and negative fecal fat, pH, and reducing substances on full GT feeds/low fat diet, upon discharge. The patient remains well 6 months after discharge.

Rendezvous Procedure for Post-Operative Biliary Disconnect: An Alternative Intervention
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A 70-year-old female was referred for obstructive jaundice. Her past history was significant for right hemicolectomy for colon cancer with a 10 year disease-free period until a recent diagnosis of colon cancer metastasis to the right hepatic lobe. She underwent pre-operative chemotherapy and a recent right hepatic trisegmentectomy. On evaluation, 10 days post-operatively, she was febrile with upper abdominal pain and her total bilirubin was 9.1 mg/dl, direct bilirubin 7.1 mg/dl, AST 55 U/L, ALT 132 U/L and alkaline phosphatase 183 U/L. A CT scan showed a biloma and a HIDA scan confirmed the presence of a bile leak. ERCP revealed extravasation of contrast from the proximal common bile duct (CBD) into a large biloma and failed to demonstrate intra-hepatic ducts (IHDS). Repeat injection with large volume contrast showed IHDS but without any communication with the CBD. Attempts to traverse this disconnect with multiple wires were unsuccessful. In the ensuing weeks the biloma and IHDS were drained percutaneously by interventional radiology although several attempts to internalize the external biliary catheter were unsuccessful. A joint endoscopic and radiologic “rendezvous” technique was undertaken to internalize drainage. A snare was endoscopically introduced over a guide wire into the periportal space of biliary disconnect through the ampulla. Another guide wire introduced transhepatically into the same space was grasped with the snare and internalized into the duodenum. An internal/external transhepatic catheter was then passed over the guide wire and sutured to the skin. Traumatic accidents and iatrogenic injury during laparoscopic biliary surgery are the most common causes of biliary leaks from partial or complete transection of the bile duct. Based on the nature of the injury, timing, and patient characteristics repair can be surgical, radiologic, endoscopic or a combination thereof. We present a case of iatrogenic versus ischemic bile duct transection that was successfully managed with a combined radiologic-endoscopic rendezvous procedure. A multidisciplinary approach to the treatment of complicated bile duct transections remains the cornerstone of therapy. In cases of high surgical risk a combined radiologic-endoscopic approach is a viable and successful alternative.

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Savary Dilatation and Botulinum Injections for a Patient with Refractory Dysphagia after Surgical Myotomy for Achalasia
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Achalasia is an esophageal motility disorder with features of aperistalsis and failure of the Lower Esophageal Sphincter (LES) to relax during swallowing. Treatment options include pneumatic balloon dilatation, botulinum endotoxin injection, and surgical esophagomyotomy. Patients presenting with resistant dysphagia after myotomy pose a unique clinical challenge with limited experience in the literature. We describe a patient who had symptomatic improvement with botulinum injections for persistent dysphagia symptoms after surgical myotomy. A 62-year-old female who underwent myotomy 22 years ago presented with recurrent symptoms of dysphagia to solids. Initial treatment with 3 Maloney dilatations under fluoroscopy every 2 to 4 months for 9 months did not improve symptoms. Endoscopy was revealing for a tortuous esophagus with a focal area of distal narrowing. Botulinum Endotoxin Type A injection of 100 units in 4 quadrants of the distal esophagus was performed with symptomatic improvement for 6 months. A subsequent Savary dilatation for recurrent dysphagia provided minimal improvement of her symptoms. Her last procedure performed 3 months ago combined Savary dilatation and botulinum injections with subsequent improvement of symptoms. The most durable symptomatic response since myotomy was when botulinum toxin was used alone or with mechanical dilatation.

Discussion: Non-operative, endoscopic therapies available for achalasia include botulinum injection or pneumatic balloon dilatation. Randomized prospective studies have demonstrated a superiority of balloon dilatation over botulinum toxin injections in the need for serial, long-term treatment of achalasia, and a cost-benefit of pneumatic balloon dilatation over surgical myotomy. Myotomy remains the most efficacious treatment overall, with reported success rates of 85 percent of patients at 10 years and 65 percent of patients at 20 years. The literature for management of patients with refractory achalasia or continued dysphagia following surgical myotomy is limited, however, with only 2 previous cases of using botulinum endotoxin after myotomy reported. The need for repeated injections of botulinum toxin before myotomy may also translate to the post-myotomy course, as long-term tolerance develops to the toxin. Our case demonstrates the utility of botulinum injections alone and with Savary dilatations in providing a more durable response than Savary or Maloney dilatation alone.

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LKM-Positive Autoimmune Hepatitis: A Novel Complication after Pegylated Interferon and Ribavirin Treatment for Chronic Hepatitis C Infection
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Hepatitis C has been implicated in the development of autoantibodies, specifically LKM antibodies. Treatment of chronic hepatitis C infection in LKM-positive patients can trigger severe autoimmune hepatitis from immunostimulatory effects of pegylated interferon. However, LKM-positive autoimmune hepatitis has not been described after recent completion of treatment in the United States.

Case: A 27 year old female with no prior medical history of autoimmune diseases presented for treatment of chronic hepatitis C, genotype 1a, infection acquired from a blood transfusion while recovering from pre-term
Ischemic Gastritis: A Rare Case of Acute and Chronic Etiology

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The abundant vascular supply of oxygenated blood to the stomach via major arteries and smaller collateral vessels provides resistance to mucosal ischemia. However, mucosal changes can occur in the acute vasculocclusive setting after a major operative procedure, or with chronic mesenteric insufficiency. We present a patient who developed diffuse gastric ischemia one day after coronary bypass surgery during a one month hospitalization for a global ischemic event. A 67 year-old female developed bright red blood output from her oral-gastric tube one day after coronary bypass surgery using a saphenous vein graft. Her bowel movements were loose and without hematochezia. She had no prior history of GI bleeding. She was initially hospitalized one month prior to the surgery for non-ST elevation myocardial infarction and cardiogenic shock with associated elevation of liver transaminases and acute renal failure. She was treated with aspirin, prophylactic esomeprazole, and vasopressors during her hospital course. She had a history of atherosclerotic disease and smoked tobacco regularly. She was intubated and sedated, with mean arterial blood pressure 81 mmHg and central venous pressure 9 cmH2O. Examination demonstrated hypo-active bowel sounds and a soft abdomen. Hemoglobin was 10.6 g/dL, pH 7.46, lactic acid 1.8 mmol/L, and stool was hemoccult negative. EGD revealed severe ulceration and friability throughout the entire gastric mucosa, with a normal esophagus and duodenum. Gastric biopsies demonstrated diffuse mucosal necrosis with preservation of only 1/3 of the mucosa, consistent with ischemia. Colonoscopy was normal. Conservative medical management was provided with an intravenous proton pump inhibitor and TPN. Five days later, she was extubated and began a liquid diet without complication. She was discharged from the hospital one week later. Mesenteric ischemia of the small and large bowel are more commonly investigated than the stomach. Gastric ischemia can be quite severe and in the presence of necrosis causes significant morbidity. A common diagnostic and treatment modality is surgery. Prior reports demonstrate either an acute or chronic etiology. We present a rare patient with ischemic gastritis and mucosal necrosis secondary to both acute and chronic injury, successfully treated with medical therapy. We conclude that certain circumstances are amenable to a conservative treatment approach.
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HEHE is a rare vascular tumor of variable malignant potential. Proposed risk factors have included female gender, use of oral contraceptives, and vinyl chloride; however, there are of reports in the literature of HEHE after solid organ transplantation. We will present two cases of HEHE that occurred in our institution after transplantation, one liver transplant (LTx) and one kidney transplant (RTx).

Case 1: A 45yo male who had LTx 1yr prior for Hepatitis C and hepatocellular carcinoma was noted to have liver lesions on surveillance CT scan. He was otherwise asymptomatic; the serum alpha-fetoprotein level and liver function testing were both normal. His immunosuppression included Neoral and CellCept, and there was no history of rejection. The CT scan demonstrated 2 hyperintense liver lesions on the arterial phase in the right lobe measuring 2cm and 1cm, while three areas of focal hypervascularity were seen on angiography. There was no evidence of metastatic disease. Liver biopsy demonstrated infiltration of the liver parenchyma by primitive-appearing vascular structures that had a positive immunohistochemical stain for CD34 and contained intracytoplasmic vacuolization with red blood cells compatible with HEHE. No surgical intervention or chemotherapy was performed, and there has been no clinical change 1 yr later.

Case 2: A 35yo male was admitted for fatigue, abdominal pain, and jaundice 3 months after RTx. Immunosuppression consisted of Neoral, CellCept, and prednisone; there was no history of rejection. The serum bilirubin and alkaline phosphatase levels were elevated at 6.6 mg/dL and 258 U/L, respectively, while serum PCR for EBV and CMV were both undetectable. Innumerable, diffuse foci with increased T2 signal in the liver and spleen with intraperitoneal lymphadenopathy was evident on abdominal MRI, and numerous nodular, highly vascular lesions with epithelioid cells containing intracytoplasmic vacuolization and red blood cells were seen on the liver biopsy. Immunohistochemical staining was positive for CD31, CD34, and Factor VIII-rAg, consistent with HEHE. There has been no change in his clinical status 1 yr later with conservative management.

Discussion: Patients after solid organ transplantation have a well documented increased risk of malignancy, most notably of the skin, cervix, and lymphoma. These two cases describe the occurrence of HEHE within one year of transplant; an association that has not yet been described in the literature.

Pseudomelanosis Duodeni Diagnosed in a Patient with Upper Gastrointestinal Bleeding and Calciphylaxis
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Pseudomelanosis of the duodenum is a rare benign entity of unknown etiology. We report a case of pseudomelanosis duodeni found incidentally during endoscopy for acute upper gastrointestinal bleeding.

Case Report: A 68 year old African American male with multiple medical problems presented with melena. His past medical history was significant for coronary artery disease, cardiac pacemaker, hypertension, diabetes, end stage renal disease on hemodialysis, and lower extremity ulcerations secondary to calciphylaxis. On physical examination he was noted to have stable vital signs, bilateral lower extremity ulcers, and melena on digital rectal examination. Laboratory evaluation revealed a BUN of 53 mg/dL, creatinine of 7.3 mg/dL, and hematocrit of 22%. Emergent upper endoscopy revealed a bleeding gastric ulcer which was treated. Incidentally, upon intubation of the duodenum, pigmented mucosa of the entire duodenal wall was seen (Figure 1). Biopsies from the duodenum revealed pigment-laden macrophages containing brown-black pigment, consistent with pseudomelanosis duodeni. Pseudomelanosis of the duodenum was first described by Bisorki and Kleinman in 1976. Multiple cases have been reported in the literature with similar characteristics and pathology. It has been described mainly in African Americans, females, and patients in the sixth or seventh decade of life. Common associated conditions include chronic renal insufficiency, hypertension, diabetes, gastrointestinal bleeding, and peptic ulcer disease. Some case series have also reported medications associated with this condition such as hydralazine, propranolol, hydrochlorothiazide, lasix, digoxin, and stimulant laxatives. Our patient shared many of the above associations in addition to calciphylaxis. The histopathology tends to show brown black pigment in the macrophages of the lamina propria. In summary, pseudomelanosis duodeni is a rare, often, incidental finding on endoscopy with characteristic pathology. The condition occurs in patients with similar age, gender, and medical problems. Pseudomelanosis duodeni may also be associated with calciphylaxis. [figure1]

Case Report of a Metastatic Yolk Sack Tumor Involving the Duodenum
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We present a case of metastatic yolk sac tumor, a rare germ cell tumor, involving the duodenum causing obstruction and gastrointestinal bleeding.

Case Report: A 28-year-old male status-post chemotherapy and stem cell transplantation for metastatic mediastinal yolk sac tumor was evaluated by the gastroenterology service for a history of melena. Upper endoscopy revealed a ulcerated mass with yellow exudate and overlying clots in the duodenal bulb (Figure 1). Tissue biopsies were consistent with patient’s previous yolk sac tumor. A repeat upper endoscopy was performed two months later for a history of nausea and recurrent melena. The previously identified mass was now seen extending from the duodenal bulb to the pylorus; obstructing passage of the endoscope to the second portion of duodenum. After the tumor was deemed unresectable by surgical consultation, an upper endoscopy with Yag Laser ablation was performed to debulk the tumor. This was followed by successful deployment of an expandable luminal stent in the duodenum to relieve obstruction. The patient was later discharged tolerating a soft diet with a plan to continue chemotherapy. Yolk sac tumors of varied primary sites have been reported in the literature. Previously reported metastatic sites have included liver, lung, retroperitoneum, peritoneum, portal vein, lymph nodes, spinal cord, bone, brain, and duodenum. Primary yolk sac tumors of the gastrointestinal tract are rare; with only 3 cases of tumors involving the stomach reported in the literature. Schäffler et al. reported the first case of a yolk sac tumor with extensive metastatic disease involving the duodenum.
Our case represents the second case in the literature of a yolk sac tumor involving the duodenum. Complications of the tumor in the patient, including gastrointestinal bleeding and obstruction, were treated with YAG laser ablation and endoluminal stent placement. In summary, yolk sac tumors are rare germ cell tumors that can metastasize to various sites and rarely involve the gastrointestinal tract. [figure1]

**Case Report:** A 41-year-old Hispanic male with a past medical history of AIDS (CD4 < 10), toxoplasmosis, CMV retinitis, HIV wasting syndrome and IV drug abuse presented with a 6 week history of diarrhea and weight loss. Physical findings revealed a cachectic male with oral thrush, tachycardia, and diffuse abdominal tenderness without peritoneal signs. Stool cultures, ova and parasites and C. Difficile studies were normal. Biopsies taken from the third duodenum were acid fast negative and revealed macrophages that were PAS positive after diastase digestion. The specimens were sent for immunohistochemical preparation and review. They revealed intense immunohistochemical staining with many negative foci, the findings were consistent with Whipple’s disease which may have been partially treated.

**Discussion:** Yearly, less than 30 cases of Whipple’s disease are reported world wide. Only one confirmed case of Whipple’s disease among a HIV/AIDS patient has been reported. This case raises the possibility that *Tropheryma whippelli* may have the ability to act as an opportunist pathogen in immunodeficient states and therefore, should be ruled out in patients with negative AFB staining. [figure1][figure2]

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**A Rare Case of Whipple’s Disease in a Patient with AIDS**

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Whipple’s disease is a rare infectious disease caused by the gram positive bacterium *Tropheryma whippelli*. A classic presentation involves arthralgias, weight loss, diarrhea and abdominal pain. The weight loss and diarrhea are a consequence of macrophage-predominant inflammatory cells that infiltrate the small intestine mucosa and cause obstruction of the mesenteric lymph nodes resulting in malabsorption. Endoscopy with small bowel biopsy is the “Gold Standard” for diagnosis. Typical histology reveals villous atrophy and PAS positive inclusions. Treatment consists of two to four weeks of IV penicillin G and streptomycin, followed by a year of trimethoprim-sulfamethoxazole.

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**Spontaneous Fungal Peritonitis (Candida albicans) in Cirrhosis**

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Spontaneous fungal peritonitis in cirrhotic patients remains a very rare entity. We present a case of a 46 years old male with cirrhosis secondary to hepatitis B and C infections and alcohol abuse who came to our hospital with increased abdominal girth and altered mental status. There was no recent antibiotics use or hospital admissions. A diagnostic paracentesis confirmed the portal hypertension etiology with a Serum Albumin Ascites Gradient (SAAG) of 1.5 and elevated polymorphonuclear count consistent with spontaneous bacterial peritonitis. He was started on ceftriaxone. His mental status deteriorated and he was intubated for airway protection. The repeat laboratory values showed worsening of the liver tests and of the coagulopathy. The ascitic fluid culture grew Candida Albicans as a sole germ. Candida Albicans was also found later in the blood and the urine cultures but the culture from the intravenous catheter tip remained negative. At that time his HIV test came back positive. His regimen included liposomal amphotericin B and caspofungin but he deteriorated with onset of disseminated intravascular coagulation and features of multi organ failure followed by death. Candida albicans can affect almost every organ of the human body however, fungal peritonitis remains less frequently reported: we can distinguish three settings that predispose to fungal peritonitis: abdominal surgery, peritoneal dialysis and cirrhosis. According to surgical literature a positive peritoneal culture of Candida meant a worse
oucome in cases of spontaneous perforations and abdominal abscesses. Fungal peritonitis mainly from Candida was also noted to be a significant entity in peritoneal dialysis where it represents 10% of infectious etiologies carrying a 5–53% mortality. Treatment guidelines recommend peritoneal lavage to decrease the fungal mass, catheter removal in case of positive fungal culture and anti fungal agents. In conclusion, fungal peritonitis in cirrhosis remains a rare condition with only a few reports. In our case there was no obvious port of entry for the infection, but the immuno-suppression due to HIV and the underlying liver disease were the culprits. Fungal peritonitis in cirrhosis is associated with a poor prognosis that is secondary to the co-morbidities of the affected patients. A high index of suspicion and early treatment might improve survival.

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Endoscopic Band Ligation of Gastric Arteriovenous Malformations in a Patient with Hereditary Hemorrhagic Telangiectasia

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A 45-year-old man with hereditary hemorrhagic telangiectasia (HHT) was referred for symptomatic anemia related to recurrent brisk GI blood loss form documented arteriovenous malformations (AVMs). Prior upper endoscopy disclosed multiple gastric AVMs. Previous treatment modalities included argon plasma coagulation (APC), heater probe/injection therapy, and endovascular embolization on multiple occasions. Despite this, the patient continued to have episodes of GI blood loss requiring multiple hospital admissions and transfusions. Ultimately, the patient underwent repeat upper endoscopy showing two ulcerated AVMs, one in the cardia and one in the high body. Due to recurrent bleeding and failure of previous treatments, a decision was made to treat the two lesions using band ligation. The procedure was performed in the standard fashion and the patient was discharged from the endoscopy center on the same day. Repeat upper endoscopies at one week, one month, and six months showed obliteration of the AVMs with complete healing and scar formation. In a period of six months follow up, the patient had no further bleeding. Endoscopic band ligation is a routine procedure performed both for variceal and non-variceal upper gastrointestinal tract (GI) hemorrhage. There is no consensus as to the best treatment option for non-variceal, non-ulcer upper GI hemorrhage. Only a few reports have been published pertaining specifically to the treatment of arteriovenous malformations using band ligation. Band ligation provides effective hemostasis in non-variceal upper GI hemorrhage. Furthermore, band ligation should be considered for AVMs that are refractory to traditional therapeutic options such as APC and angiographic embolization.

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Corticosteroids for Treatment of Decompensated Hepatic Sarcoidosis

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Sarcoidosis is a granulomatous disease primarily affecting the lungs, lymph nodes, skin, eyes and CNS. Hepatic granulomas are evident in most patients, but symptomatic liver disease is uncommon. Once clinical symptoms develop, liver disease is usually progressive and may necessitate liver transplantation. Corticosteroids are the mainstay of treatment of sarcoidosis and are indicated in the setting of ocular, cardiac, neurological, or symptomatic pulmonary involvement. The use of corticosteroid therapy in the setting of decompensated liver disease due to sarcoidosis is not widely accepted. We present a case of decompensated hepatic sarcoidosis in which the patient showed marked improvement in symptoms and hepatic synthetic function coincident with corticosteroid treatment.

Case: A 54-year-old African-American female presented with several weeks of jaundice, edema, fatigue and confusion. She had a 20 year history of ophthalmic sarcoidosis and longstanding elevation of alkaline phosphatase, splenomegaly and small nonbleeding esophageal varices. Liver biopsy performed 7 years earlier demonstrated noncaseating granulomas. She had been maintained on long-term, low-dose prednisone for her eye disease but this had been tapered and discontinued approximately 6 months earlier. There were no other recent medication changes or parenteral exposures. Physical examination revealed scleral icterus, tense ascites, bilateral lower extremity edema, palmar erythema and asterixis. Laboratory findings included albumin 2.8 g/dL, INR 1.1, alkaline phosphatase 309 U/L, bilirubin 6.2 mg/dL, AST 71 U/L, ALT 30 U/L, and platelets 92000. There was no serological evidence of viral hepatitis. Doppler ultrasound showed normal portal and hepatic vein blood flow. Prednisone was reintroduced at 20 mg daily. She experienced rapid symptomatic and biochemical improvement and prednisone was tapered to 10 mg daily over six months. Bilirubin has stabilized at approximately 2 mg/dL with resolution of ascites, edema and encephalopathy and she remains well 2 years later.

Discussion: This case report validates the role of corticosteroids as a potential treatment for decompensated hepatic sarcoidosis. The use of corticosteroids may postpone or prevent liver failure and the need for liver transplantation.

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Pigbel of the Stomach – A Rare Cause of Fulminant Gastric Necrosis

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Enteritis necroticans (pigbel) is a segmental necrotizing infection of the jejunum and ileum caused by Clostridium perfingens (C.p) type C. The disease occurs sporadically in developing countries and is extremely rare in the U.S. We present what we believe is the first report in the U.S. of pigbel involving the stomach in a diabetic adult. An 80 year old diabetic man presented with a several hour history of lower chest pain and indigestion. His initial exam was entirely benign without rebound tenderness or guarding. Laboratory values included: WBC 9.8, Hct 31, platelets 257. Cardiac enzymes were normal. A non-contrast CT of the abdomen revealed gas in the wall of the stomach, the gastric veins and the portal vein. A preoperative endoscopic evaluation showed an impressive black discoloration of the mucosa in the proximal half of the stomach. Antrum and duodenum appeared normal. The patient underwent a subtotal gastrectomy with Roux-en-Y gastrojejunostomy. No obvious vascular occlusions were detected at the time of surgery. The histologic evaluation confirmed complete necrosis of the proximal gastric wall and a large number of gram-positive rods with the characteristic appearance of C.p. The patient developed persistent fevers and multiorgan failure. He expired 4 days postoperatively. Enteritis necroticans was first described in Germany in the 1940s as “Darmbrand”
Interferon Induced Reversible Collapsing Focal Segmental Glomerulosclerosis (CFSG) in a Treatment Experienced Patient with HCV

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Interferon-α (IFN-α) causes both dose-dependent and idiosyncratic toxicities. Only two cases of ARF with nephrotic syndrome due to CFSG induced by IFN-α therapy for HCV have been reported in treatment (tx) naïve pts without underlying malignancy. We report the first case of IFNα induced CFSG with full recovery of renal function. 66 y/o. Hispanic male HCV+, HIV-, ex-JVDU & ex-ExTOH presented in ’99 for tx. Labs: genotype 1, HCV RNA 221000 c/mL, ALT 70, AST 54, Cr 0.8, UA nl, liver biopsy grade 1, HIV -, ex-IVDU & ex-EtOH presented in ’99 for tx. Labs: genotype 1, HCV without underlying malignancy. We report the first case of IFN α + ties. Only two cases of ARF with nephrotic syndrome due to CFSG induced Interferon-Pathology, NY Presbyterian Hospital, NY, NY.

Nephrology, St. Barnabas Hospital, Bronx, NY and Department of Medicine – Divisions of Hepatology, Pathology and Nephrology, St. Barnabas Hospital, Bronx, NY and Department of Pathology, NY Presbyterian Hospital, NY, NY.

Interferon-α (IFN-α) causes both dose-dependent and idiosyncratic toxicities. Only two cases of ARF with nephrotic syndrome due to CFSG induced by IFN-α therapy for HCV have been reported in treatment (tx) naïve pts without underlying malignancy. We report the first case of IFNα induced CFSG with full recovery of renal function. 66 y/o. Hispanic male HCV+, HIV-, ex-JVDU & ex-ExTOH presented in ’99 for tx. Labs: genotype 1, HCV RNA 221000 c/mL, ALT 70, AST 54, Cr 0.8, UA nl, liver biopsy grade 1, stage 2. IFNαb 3 x 10⁸ u TIW & ribavirin (RBV) 1200mg qd x 48 wks was given without virologic response (VR) or adverse events (AEs). In 2002 he received PEG-IFNαb 1.5μg/kg q wk & RBV 1200mg qd x 12 wks without VR or AEs. In 2003 he received PEG-IFNα2a 180μg q wk & RBV 1200mg qd x 12 wks without VR or AEs. In 2004 he received IFN alfacon-1 (Consensus IFNa) 15μg qd & RBV 1200mg qd. Pre-tx: Cr 0.9, UA nl. Tx was stopped at wk 10 due to injection site reactions. At wk 12 pt presented with 10kg wt gain, anasarca, BP 150/90, Cr 1.5, alb 1.3, chol 330, TG 590, UA 4+ protein, cryoglobulins-, tox screen-, urine eos-, renal U/S.-, 24 hr urine protein 4.52gm. Renal biopsy done (Fig. 1). 12 mos later: no edema, BP 124/68, Cr 0.9, UA 1+ protein, 24 hr urine protein 403gm. 14 mos later: no edema, BP 130/74, Cr 0.8, UA trace protein. In conclusion, this is the: 1) First case of CFSG in a tx experienced HCV+ pt without an underlying malignancy 2) First case with full recovery of renal function (except for trace proteinuria) without steroid tx 3) Second case of CFSG induced by IFN alfacon-1 for the tx of HCV 4) 3 prior courses of IFNαs supports the idiosyncratic nature if IFN induced renal disease 5) Need for closer monitoring of renal function when using IFN (particularly IFN alfacon-1) for HCV. [figure1]

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Protein-Losing Enteropathy from Eosinophilic Enteritis Solely Diagnosed by Wireless Capsule Endoscopy (WCE) and Double-Balloon Enteroscopy (DBE)

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A 47-year-old woman presented with bilateral lower extremities edema for 1 mo. Past history was significant for pernicious anemia and contact dermatitis. Labs were notable for iron-deficiency anemia (hemoglobin 11.3 g/dL and ferritin 5 mcg/L), eosinophilia (20.7%), and hypoalbuminemia (2.8 g/dL). Ultrasound and CT scan of the abdomen were normal. Urinalysis was negative for proteinuria. Stool exams were negative for parasites. 48-hr stool collection confirmed fat malabsorption (16 g/24 hrs) and markedly increased α-1 antitrypsin clearance (424 mL/24 hrs), indicating protein-losing enteropathy. Extended EGD and colonoscopy with extensive biopsies were normal, as similar to small intestinal series. WCE revealed multiple rounded patches of raised erythema with centrally flattened villi throughout the small intestine (A). DBE confirmed the similar finding (B). Pathology of the targeted biopsies of the lesions was diagnostic for eosinophilic enteritis. Following an initial treatment with oral prednisone 30 mg for 2 wks, serum albumin and eosinophils returned to normal with complete resolution of lower extremities edema. Eosinophilic gastroenteritis is a rare disease characterized by tissue eosinophilic infiltration that can involve any layers of the gut wall. Diagnostic criteria include the presence of GI symptoms, demonstration of eosinophilic infiltration on biopsy, absence of eosinophilic involvement of organs outside the GI tract, and absence of parasitic infection. Clinical presentation varies depending on the layer of involvement. Histologic evaluation from endoscopic biopsies represents the best way to confirm the diagnosis. Because the disease tends to be patchy, it is recommended that multiple biopsies should be obtained from different areas throughout the GI tract. In this report, we present a patient with mucosal eosinophilic enteritis. Despite extensive biopsies from conventional endoscopic procedures, the diagnosis cannot be established because the disease localizes in the small intestine. It emphasized the role of WCE followed with DBE as the method of choice in evaluation for mucosal diseases of the small intestine. [figure1]

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A Case of Non-Hodgkin’s Lymphoma Presenting as a Sister Mary-Joseph’s Node

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Non-Hodgkin’s lymphoma presenting as a Sister Mary Joseph’s Node is a very rare entity and ours is only the fourth case that has been reported. A 55 year old male with a history of B-cell lymphoma treated with CHOP in 1993, squamous cell carcinoma of the upper lip and depression presented with increased abdominal girth, diffuse abdominal pain, bloating, weight loss and anorexia for several months. He had a normal screening colonoscopy five years prior. He was a non-smoker and a social drinker. Physical exam was significant for a mildly distended abdomen, splenomegaly, normal bowel sounds, and a mobile, hard, 3 cm nodule at the umbilicus. Rectal examination showed guaiac negative brown stool. He had low grade fever, but vitals signs were otherwise normal. Laboratory data was significant for mildly elevated AST and ALT and anemia. An EGD was performed which showed erosive gastritis and mild extrinsic compression of the antrum. Biopsies from the stomach were unremarkable. A CT scan of the abdomen and pelvis showed extensive infiltrative changes in the omentum, numerous peritoneal nodules, ascites, a large partially necrotic mass within the mesentery, and a soft tissue mass in the pouch of Douglas. FNA of the umbilical nodule revealed only scant lymphocytes. A CT-guided biopsy of the abdominal mass showed follicular center lymphoma. The patient was subsequently referred to the Oncology service for treatment of recurrent non-Hodgkin’s lymphoma. Sister Mary Joseph’s node (or nodule) is a clinical sign of metastatic cancer involving the umbilicus. The vast majority represent adenocarcinoma arising from an ovarian or gastrointestinal primary. Non-gastrointestinal and non-gynecologic cancers previously reported include renal cell carcinoma, prostate carcinoma, leukemia cutis, multiple myeloma and lymphoma. Follicular center lymphoma usually begins with painless adenopathy in cervical, axillary, inguinal, and femoral regions and metastasis to peri-umbilical nodes is rarely reported.

Hepatorenal Syndrome Following Splenorenal Shunt Thrombosis
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20 year-old Hispanic male known case of idiopathic non-cirrhotic portal hypertension. His primary manifestation of this has been esophageal variceal bleeding. He had three episodes of bleeding within five months, all were treated with endoscopic banding. Due to repeated bleeding he was felt to be a candidate for a distal splenorenal shunt. This was performed ten days after the last episode of bleeding. His shunt was found to be open on two imaging studies. Three days after the procedure the patient became markedly edematous and oliguric. Lab work showed increase in liver and renal markers, coagulopathy and high lactic acid without acidosis. His mental status became intermittently obtunded and he was diagnosed with hepatorenal syndrome. It was felt that he likely had a liver ischemic injury secondary to thromboses seen on ultrasound. He was managed conservatively with IV fluid, packed red blood cells, fresh frozen plasma, proton pump inhibitor and lactulose enemas. This resulted in gradual and significant clinical and laboratory improvement. Patient was discharged home with follow up in liver transplant clinic.

Discussion: Idiopathic portal hypertensive IPH, characterized by gastroesophageal variceal hemorrhage, is not uncommon in young adults. Treatment of variceal hemorrhage in patients with IPH are similar to those in patients who bleed from other causes. Distal splenorenal shunt is a safe, durable, and effective treatment for controlling recurrent variceal hemorrhage in patients with acceptable operative risk and good liver function. It does not compromise future liver transplantation and can be considered delay the time until transplantation is required. Complications of the procedure include thrombosis, pneumonia, recurrent bleeding, pancreatitis, pancreatic pseudocyst and wound infection.

A Rare Thrombotic Complication of IBD
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A 30 year-old Caucasian female with a 12 year history of ileocolonic Crohn’s disease, status post ileo-cecectomy, presented with abdominal pain, distension, nausea, and vomiting despite treatment with azathioprine and infliximab. On presentation, she had a non-tender abdomen with moderate distension and tympany. Colonoscopy found a stricture in the proximal transverse colon. Small bowel radiographs showed proximal colonic and distal small bowel dilation with evidence of a coloenteric fistula. She underwent subtotal colectomy with a side-to-end ileosigmoid anastomosis and repair of the fistula. Pathology revealed moderately active Crohn’s enteritis and severely active Crohn’s coliitis with stricture formation. Thirty hours post-operatively, the patient was noted to have left hand weakness and numbness and a left facial droop. MRI showed a right frontal lobe parenchymal bleed and high signal intensity filling defect centrally within the superior sagittal sinus consistent with cerebral venous sinus thrombosis (CVST) and associated intracranial hemorrhage. She was started on heparin. Thrombophilia work-up was negative for protein C, S and anti-thrombin III deficiencies, hyperhomocysteinemia, Factor V Leiden mutation and antiphospholipid antibody. Her facial droop and hand weakness markedly improved in 7 days. She was started on warfarin and discharged. This case illustrates a rare but serious thrombotic complication of IBD. CVST is more common in UC than CD (87 v 13%). It presents with headache, seizures or focal neurologic signs. Mortality is estimated at 6–10%; long-term neurologic sequelae remain in up to 44%. Hemorrhage complicates CVST in 35–50% of cases. MRI is the most sensitive diagnostic modality. Anticoagulation is the preferred therapy with up to 80% complete recovery without higher rates of hemorrhage. In IBD, there is a 3-fold increased relative risk of thromboembolism especially in patients with active, extensive disease. DVT is most common but uncommon sites like CVST are increasingly reported. The pathophysiology of thrombosis in IBD is incompletely understood but likely is due to initiation of coagulation pathways by inflammatory mediators. Inherited thrombophilias, surgery, prolonged immobilization, steroid therapy and catheaters also contribute to hypercoagulability. Clinicians should have a high index of suspicion for CVST in IBD patients with headaches, seizures or focal neurologic findings, as this uncommon complication carries significant morbidity and mortality but can be effectively treated with anticoagulation.

Duodenal Behçet’s Syndrome Successfully Treated with Azathioprine
Bradford C. Sampson, MD, Richard G. Farmer, MD.∗ Gastroenterology and Hepatology Division, University of Rochester Medical Center, Rochester, NY.

Behçet’s Syndrome is a multisystem inflammatory disorder characterized by recurrent oral and genital ulcers. Ocular, joint, CNS, and GI involvement are all common, but GI lesions are typically resistant to medical therapy. We present a case of deep duodenal ulcers in a 44 year-old female successfully treated with azathioprine. A 44 year-old A.A. female with a history of Behçet’s syndrome presented with 3 months of abdominal pain, nausea, and vomiting unresponsive to treatment with rabeprazole and sucralfate. Her symptoms were worse after eating. She denied any hematemesis, melena, hematochezia, diarrhea, or constipation. Medical history showed Behçet’s diagnosed as a teenager. Family history showed a father with stomach cancer at 38. There was no history of NSAID use. On exam, multiple aphthous ulcers were seen in the oropharynx. Abdomen was soft and obese with moderate epigastric tenderness. Ophthalmologic, joint, and neurologic exam were all normal. Basic labs and CT of the abdomen were all normal. EGD showed multiple superficial erosions in the antrum and proximal esophagus. Two 1.5×3cm ulcers were seen in the D2 portion of the duodenum. Biopsies showed a non-specific “fibrinopurulent exudate consistent with ulcer.” Antral biopsies were negative for H. pylori. Serum gastrin and a SBFT were normal. Over the next 6 months her symptoms worsened despite the continuation of PPI therapy and the addition of hydroxychloroquine by her rheumatologist. She required large doses of narcotic agents in order to tolerate any food and, despite this, she lost 45 pounds and was forced to go on disability. Subsequent EGDs showed persistence of her large duodenal
ulcers and small antral ulcers. Azathioprine 2.5mg/kg was started. Six weeks later, EGD showed resolution of the small antral ulcers and partial resolution of the duodenal ulcers. Subsequently, her symptoms resolved. Four months later, she has gained 20 pounds and no longer requires pain medications.

**Discussion:** GI involvement of Behcet’s is variable (2–50% of cases, largely dependent on geographic area of interest). Ileocecal and colonic involvement is most common, and intestinal lesions are usually resistant to medical treatment. There have been two previous case reports of duodenal involvement, each requiring a surgical intervention. A review of 136 Japanese surgical cases showed duodenal involvement in 2 cases. To our knowledge, this is the first report of duodenal Behcet’s with successful medical treatment.

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**An Unusual Presentation of Henoch-Schonlein Purpura**

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Henoch-Schonlein Purpura (HSP) is a leukocytoclastic vasculitis (LCV) which affects the small blood vessels of the skin, joints, gastrointestinal tract (GI) and kidneys. It is characterized by abdominal pain, arthritis, nephritis and a distinctive purpuric rash most pronounced on the legs and buttocks. We present an unusual case of HSP in which GI manifestations were confused initially with a disseminated infectious process versus Crohn’s disease.

**Case Report:** The patient is a 26 year old woman with a history significant for food allergies associated with urticaria and angioedema. She was admitted with a one week history of colicky abdominal pain, nausea, vomiting and diarrhea. On physical exam she was afebrile. She had facial edema and urticaria to the upper extremities. Diffuse abdominal tenderness on palpation was noted without distention, guarding or rebound tenderness. Her admission laboratory tests revealed gauiac positive stool, WBC count 15.7 and Platelet 521. Hematuria on UA. EGD showed multiple ulcerations in the duodenum. Colonoscopy demonstrated a 4 cm mass with superficial ulcerations at the ileocecal valve. There was patchy inflammation with friability throughout the GI tract. Abdominal CT scan revealed focal bowel-wall thickening in the cecum, duodenum and proximal jejunum. Biopsies of the duodenum, ileocecal area and colon showed acute ulcer only. Crohn’s disease was suspected and treatment initiated. On hospital day five, new skin eruptions appeared on the lower legs which were large, purpuric, palpable and nonblanching. Skin biopsy of leg lesion showed acute LCV. The patient improved clinically and discharged on tapered steroids. Direct immunofluorescence later returned positive for IgA.

**Discussion:** Our patient demonstrated several common features of HSP but also revealed unique findings. While HSP occurs most frequently in children (85%) and in males (2:1), our patient was a 26 year old woman. Furthermore, endoscopy in patients with HSP usually demonstrate an erosive, hemorrhagic mucosa with marked edema but a mass at the ileocecal valve has not been previously reported. Diseases such as Crohn’s disease and infectious ileitis, however, have been described to affect the ileum and the ileocecal valve. Thus, in our patient, the atypical skin rash at initial presentation with the ulcerated mass at the ileocecal valve delayed the diagnosis of HSP.

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**Acute Obscure GI Bleeding from Ileal Varices**

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Portal hypertensive varices are often found in the esophago-gastric region. Rectosigmoid and anal varices are also well described. Portosystemic collaterals in the ileum are less common; reported prevalence among cirrhotic patients is 18%. Correlations include portal gastropathy and abdominal surgery. We report a patient with a history of obesity, alcoholism, and recent abdominal surgery, who developed severe gastrointestinal bleeding from varices in the terminal ileum. A 36 year-old obese alcoholic male presented 3 months after umbilical herniorrhaphy with persistent hematoma. He was hospitalized 3 times over a 4 month period for severe anemia. On the first two admissions, EGD revealed nonbleeding grade I-II esophageal varices and moderate diffuse portal gastropathy. Colonoscopy with intubation of the terminal ileum found hemat in the lumen without an identifiable bleeding source. A small bowel follow through with spot compression views of the terminal ileum was normal. Small bowel enteroscopy to the mid-jejunum did not reveal anomalies. On the third admission, he was hypotensive and tachycardic; initial hemoglobin was 6.2 g/dL, requiring 8 units of blood. He was jaundiced; abdomen was obese, nontender, and without ascites. Laboratory data revealed INR 1.6, bilirubin 7.3 mg/dL, albumin 1.4 g/dL, and normal creatinine. Abdominal ultrasound demonstrated an enlarged liver with heterogeneous nodularity and increased echogenicity. A repeat colonoscopy identified hemat in the right side of the colon. Visceral angiography did not identify a bleeding source, but demonstrated slow hepatofugal blood flow within the superior mesenteric vein. Technetium-labeled red blood cell scintigraphy localized radiotracer within the terminal ileum. Exploratory laparatomy identified actively bleeding ileal varices. He underwent ileocecal resection; histologic analysis demonstrated terminal ileal vascular ectasia consistent with varices. Variceal bleeding in the small bowel is rare, but associated with mortality up to 35%. Endoscopic localization of a source only

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**Primary Hepatic Carcinoid Tumor (PHCT). A Rare Entity. Review of the Literature**

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Carcinoid tumors are rare, but are the most common gastrointestinal (GI) neuroendocrine tumors. Within the GI tract, most carcinoids arise in the small intestine (45%, most commonly in the ileum), followed by rectum (20%), appendix (16%), colon (11%), and stomach (7%). PHCT is a very rare entity. Its description has been limited to case reports. We describe a case of PHCT and a review of the literature.
Appendicular Orifice Inflammation and Hematochezia in an Adolescent
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Appendicular orifice (AO) inflammation has been described as a skip lesion in adults with distal ulcerative colitis (UC). It is important for the clinician to recognize this finding in the pediatric population to avoid confusion with the skip lesions more commonly seen in Crohn disease. A review of a case of an adolescent with AO inflammation and proctitis. A 14 year old Caucasian female presented with a 2-month history of occasional abdominal pain and emesis. She developed hematochezia with the passage of formed to firm stools. The hematochezia persisted in spite of treatment with stool softeners. Hgb, WBC, platelet count, ESR, comprehensive metabolic panel, and small bowel contrast radiography were normal, but a computed tomography (CT) of the abdomen raised the concern for terminal ileitis. Physical examination was normal. A stool sample was negative for occult blood. Esophagogastroduodenoscopy with biopsies were remarkable only for lactase deficiency. Colonoscopy revealed normal terminal ileum (TI) and cecum but the AO was everted, edematous and grossly inflamed [figure]. The rectum had asymmetry edema, erythema and friability. The intervening colon was normal. Biopsies of the AO revealed moderate acute and chronic inflammation, acute cryptitis without granulomas. Rectal biopsies showed mild inflammation with cryptitis in 2 samples, and normal histology in one sample. These biopsies were compatible with inflammatory bowel disease. Because of a concern for appendicitis, a CT was performed following the endoscopy which documented the partially everted appendix without appendicitis. The IBD panel did not reveal elevated ASCA, anti-OmpC and ANCA. She did well on treatment with oral mesalamine and topical rectal mesalamine. Colonoscopy was done 4 months later because of recurrence of the abdominal pain and hematochezia. No gross mucosal abnormalities were seen and biopsies of the AO revealed focal, minimal acute cryptitis. TI, colon and rectal biopsies were normal. The patient has remained asymptomatic on oral mesalamine. Recognition of the occurrence of AO inflammation in conjunction with proctitis in the pediatric age group is essential for initiation of anti-inflammatory therapy and avoidance of appendectomy. This condition behaves similarly to distal UC that may not have the AO inflammation. [figure1]
In conclusion, we present a clinical case and iconography of rectal ulcers. Histology was of chronic proctitis. HIV search in rectal biopsy is in course. The patient told the physician he had lost seven kilograms in the last two months, with four unformed stools per day with fresh blood in the last week. He was discharged at the Philadelphia, PA.

We present the case of a 46 years old Caucasian male, previously healthy, referred to the Gastroenterology unit because of weight loss and diarrhoea. We report the case of an 85 year old woman with a history of hypertension and glaucoma who presented with acute respiratory distress and stridor. She was in good health until the day of admission when she ate dinner and began to notice upper abdominal pain radiating to the back as well as shortness of breath. She called 911 and in the ER was noted to have stridor. She became increasingly hypoxic and bradycardic requiring intubation. Initial chest x-ray showed a large dilated esophagus. The patient’s family reported that she had always been a “slow eater” and occasionally complained of trouble swallowing but had never been evaluated. Her weight had been stable for many years. Her physical exam was notable for mild hypertension and mild obesity. Labs were significant for a white count of 14 thousand/ul with 95% segs, a total protein of 6 g/dl and an albumin of 3 g/dl. Her hemoglobin, electrolytes, creatinine, transaminases, alkaline phosphates and bilirubin were normal. Neck and chest CT demonstrated a gas-filled dilated esophagus causing compression on the trachea, deviating it laterally and to the right. An air fluid level was noted within the esophagus. Endoscopy confirmed a massively dilated, tortuous esophagus with retained food consistent with achalasia. A Botulinum toxin injection was performed. The patient was started on parenteral nutrition. Initial attempts at extubation failed. Subsequently she required tracheostomy. She underwent esophageal myotomy with partial fundoplication as well as placement of a feeding jejunostomy tube. She progressed and was discharged on tube feeds. Eight weeks later an upper GI series continued to show a dilated esophagus but with adequate emptying of barium from the esophagus. Her diet was advanced and she was able to tolerate a regular diet without symptoms. This case demonstrates an extreme presentation of achalasia. Achalasia can be associated with respiratory complications such as aspiration and airway obstruction. In reports of airway obstruction cited in the literature, esophageal decompression led to resolution of symptoms. This case is unique in that the patient sill had compromise despite decompression. Important teaching points highlighted by this case are that achalasia can present in a variety of ways and because of its insidious onset can go undiagnosed for many years.
Mycofenolate Mofetil – Associated Pseudo-Crohn Colitis

Raquel Goncalves, MD, Maria J. Moreira, MD, Carla Rolanda, MD, Pedro Pereira, MD, Mario Marcelino, MD, Fernando Pardal, MD, Guilherme Macedo, PhD, FACG.* Gastroenterology, S. Marcos Hospital, Braga, Portugal and Pathology, S. Marcos Hospital, Braga, Portugal.

Mycofenolate mofetil (MMF) was introduced in the practice of clinical transplantation for more than 10 years. In live transplant patients, its use evolved from toxicity-sparing protocols to the most common regimen of maintenance immunosuppression at hospital discharge. Gastrointestinal toxicity however, usually manifested as chronic diarrhea of unknown origin, is a common side effect, but only recently a pattern of injury described as Crohn’s like changes has been defined. A male Caucasian 20 years old patient was managed conservatively, but during each of her other admissions for anemia, ESR of 100 and hypokalemia. He was admitted for 3 times, when several microbiologic, histologic and endoscopic studies were performed. After finding a Crohn’s like pancolitis with patchy erithema, granularity and longitudinal serpiginous ulcers (with ileal and rectal sparing), several attempts were made to find CMV, tuberculosis or other mycobacteria, without success. Immunosuppression was reduced and developed steroid sensitive rejection. After MMF withdrawal and rejection control, there was a clinical success. Immunosupression was reduced and developed steroid sensitive rejection. Mycofenolate mofetil (MMF) was introduced in the pratice of clinical transplantation for more than 10 years. In live transplant patients, its use evolved from toxicity-sparing protocols to the most common regimen of maintenance immunosuppression at hospital discharge. Gastrointestinal toxicity however, usually manifested as chronic diarrhea of unknown origin, is a common side effect, but only recently a pattern of injury described as Crohn’s like changes has been defined. A male Caucasian 20 years old patient had OLT 6 years ago for isoflurane fulminant liver failure. For five year, on double maintenance regimen of tracholymus and MMF, he was clinically stable through with insulin dependent diabetes mellitus from the 8th month post OLT. On his 5 year postop, he began to experience chronic diarrhea, progressively prolonged, with blood and night fever. We found mycrocytic anemia, ESR of 100 and hipokalemia. He was admitted for 3 times, when several microbiologic, histologic and endoscopic studies were performed. After finding a Crohn’s like pancolitis with patchy erithema, granularity and longitudinal serpiginous ulcers (with ileal and rectal sparing), several attempts were made to find CMV, tuberculosis or other mycobacteria, without success. Immunosuppression was reduced and developed steroid sensitive rejection. After MMF withdrawal and rejection control, there was a clinical success. Immunosupression was reduced and developed steroid sensitive rejection. Mycofenolate mofetil (MMF) was introduced in the pratice of clinical transplantation for more than 10 years. 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Successful Placement of Percutaneous Endoscopic Gastrojejunostomy Tube (PEG/J) Systems in 2 Pregnant Patients

Stacie A.F. Vela, MD, Mark H. Delegge, MD.* Gastroenterology and Hepatology, Medical University of South Carolina, Charleston, SC.

Traditionally, a pregnant patient who is unable to eat has been managed with parenteral nutrition (PN). Enteral nutrition (EN) has become an alternative in pregnant patients who would otherwise require the use of PN. Fewer complications than PN which requires a central venous catheter. We were able to tolerate oral nutrition. Enteral feeding is associated with fewer complications than PN which requires a central venous catheter. We strongly recommend the use of PEG/J tube systems for the delivery of enteral nutrition in pregnant patients who would otherwise require the use of PN.

Successful Placement of Percutaneous Endoscopic Gastrojejunostomy Tube (PEG/J) Systems in 2 Pregnant Patients

Stacie A.F. Vela, MD, Mark H. Delegge, MD.* Gastroenterology and Hepatology, Medical University of South Carolina, Charleston, SC.

Traditionally, a pregnant patient who is unable to eat has been managed with parenteral nutrition (PN). Enteral nutrition (EN) has become an alternative approach in the treatment of some of these patients. Here we report two pregnant patients who were treated with placement of a PEG/J tube feeding systems. A 25-year-old woman presented at 18 weeks gestation with her first of multiple acute pancreatitis episodes during her pregnancy. She originally was managed conservatively, but during each of her other admissions for pancreatitis she required PN. Work up for the etiology of her pancreatitis included an MRI which showed pancreatic head fullness, and sphincter of oddi (SOD) manometry which demonstrated SOD hypertension. Sphincterotomy was performed. At 27 2/7 weeks gestation she developed central line associated bacteremia and the PN catheter was removed. A second central line was placed. Once PN was restarted, the patient developed laboratory evidence of PN-associated cholestasis. The patient still could not tolerate oral intake without abdominal pain. Physical examination carefully outlined the gravid fundus and there appeared to be adequate area to place a PEG/J feeding tube system safely. The patient was sedated for the procedure with propofol administered by an anesthesiologist. Esophagastroduodenoscopy (EGD) revealed erosive esophagitis and a PEG/J tube system was placed without complication. The patient tolerated the feedings well and was discharged home 9 days later. A 25 year-old woman was 23 3/7 weeks gestation and had been admitted 8 times for hyperemesis gravidarum during this pregnancy. She had lost 16% of her body weight since the beginning of her pregnancy. PN was started; however she developed a deep venous thrombosis associated with her central catheter. She did not tolerate nasogastric feedings. Using propofol administered by an anesthesiologist for sedation, a PEG/J tube system was placed in this patient successfully after a normal EGD. She tolerated the feeding well, and was discharged home 3 days later. We present 2 successful cases of PEG/J tube system placement in pregnant women who were not able to tolerate oral nutrition. Enteral feeding is associated with fewer complications than PN which requires a central venous catheter. We strongly recommend the use of PEG/J tube systems for the delivery of enteral nutrition in pregnant patients who would otherwise require the use of PN.
need for repeated endoscopic extractions in PSC. The anatomical changes of the biliary tree and formation of proximal strictures in PSC may preclude sphincterotomy from being an effective treatment for recurrent calculi.

**Rifaximin in the Treatment of Refractory Solitary Rectal Ulcer: A Case Report**

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Solitary rectal ulcer is a chronic condition of multifactorial origin linked with rectal mucosal prolapse and disordered defecation. It is typically refractory to treatment with antibiotics, mesalamine formulations, and fiber. This is the first report of refractory solitary rectal ulcer that responded to treatment with rifaximin. MB is a 52-year-old woman who initially presented 11 years ago with increased constipation, abdominal pain, and bloody mucopus. Physical examination revealed a perianal fistula, and colonoscopy showed an 8-cm ulcer in the rectum. Biopsies taken at that time were significant for granulation tissue and ulcer debris with no architectural distortion. Colonoscopy and biopsies were normal except for rectal ulcer. Barium enema and small-bowel series were also normal. Serologies for antineutrophil cytoplasmic antibody (ANCA), and anti-Saccharomyces cerevisiae antibody (ASCA) were negative, as was RPR. Metronidazole treatment was initiated, and although the fistula closed after 3 months, the constipation and ulcer were refractory to repeated courses of antibiotics as well as oral and topical 5-aminosalicylic acid. Repeat colonoscopies and deep rectal biopsies confirmed granulation tissue and ulceration with no rectal carcinoma. Rifaximin 400 mg b.i.d., was then initiated and the patient experienced marked decrease in abdominal cramping and constipation. After 4 months of rifaximin therapy, colonoscopy showed significant healing with only a residual 1–2 cm rectal ulcer. Biopsy showed granulation tissue and features of mucosal prolapse. Rifaximin is a nonabsorbed (<0.4%), gut-selective, oral antibiotic with broad-spectrum in vitro activity against gram-positive and gram-negative organisms that is currently indicated in the U.S. for treating travelers’ diarrhea. There is increasing evidence of its efficacy in treating Crohn’s disease, ulcerative colitis, small intestinal bacterial overgrowth, irritable bowel syndrome, Clostridium difficile-associated diarrhea, and other intestinal conditions. In this patient with a solitary rectal ulcer, treatment with rifaximin 400 mg b.i.d. was associated with ulcer healing and relief of constipation. Rifaximin-associated symptom improvement may be caused by reduced bacterial adherence to the ulcer and a favorable impact on impaired gastrointestinal motility. Rifaximin use for treatment of solitary rectal ulcer, as well as rectal prolapse and disordered defecation, warrants further study.

**Nevirapine (NVR) Induced Vanishing Bile Duct Syndrome: A Case Report**

David F. Stein, MD,∗ Sean D. Byrne, R.P.A.-C., Patricia Halton, R.P.A.-C., Rose Tirelli, ANP, Jay Meyers, MD, Judith Berger, MD, Richard Hwang, MD, Yechum Kim, MD, Mohdeh Momeni, MD, Andrea N. Culliford, MD. Divisions of Hepatology, Infectious Disease & HIV Care & Pathology, St. Barnabas Hospital, Bronx, NY.

Purpose: A 41yo male with sexually acquired HIV was well controlled on HAART since 1999. He had no history of opportunistic infections or EtOH use. In 2006, CD4 count decreased from 245 to 112 and HIV RNA increased from <50 to 454 c/ml. He had mildly elevated liver enzymes (Table A) that were thought to be due to HAART {Abacavir (ABC), Lamivudine (LAM), Zidovudine (AZT), Tenovir (TFV)}. He had negative hepatitis A,B,C serologies, HBV DNA by PCR, HCV RNA by PCR. ANA-, nl ceruloplasmin, nl AIAT, and iron studies were wnl. Resistance was thought to be causing his decreased CD4 and increased HIV RNA. His HAART regimen was changed to ABC, LAM, and NVR. LFTs just prior to this were within normal limits (Table 1B). After two weeks, LFTs were mildly elevated (Table 1C). There were no symptoms and he was tolerating this regimen well. NVR was increased from 200mg to 400mg q am. Two weeks later, the patient complained of vague abdominal pain and was jaundiced. LFTs were markedly abnormal (Table 1D) and NVR was stopped. An abdominal sonogram showed a contracted gallbladder without stones and no biliary ductal dilation. PT 14.6, INR 1.6, AFP 1.8, repeat Hepatitis A, B, and C serologies were negative, HCV RNA-, HBV DNA-, ANA-, smooth muscle Ab-, LKM-, AMA, ANCA-. Liver biopsies showed the absence of bile ducts involving all portal tracts. Increased numbers of lymphocytes and occasional plasma cells were seen. No eosinophils were present. The histology and clinical presentation are consistent with NVR induced vanishing bile duct syndrome.

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While acute hepatic failure has been reported in the literature with NVR, intrahepatic cholestasis with ductopenia has not been previously described.

Pancreatic Pseudocysts and a Cyst-Duodenal Fistula Complicating Severe Necrotizing Pancreatitis from Pancreatic Divisum
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Gastroenterology and Hepatology Division, University of Rochester Medical Center, Rochester, NY.

A 50 year-old healthy physician was admitted with epigastric pain, nausea, and vomiting and diagnosed with his first attack of acute pancreatitis. Initial history, laboratory and imaging investigations did not reveal an etiology. His condition progressed to severe necrotizing pancreatitis with the development of fever, pleural effusion, and hyperglycemia. He had a prolonged hospital course and required treatment with Total Parenteral Nutrition, insulin, and antibiotics. Albeit a relatively benign outpatient course, four weeks after discharge he developed a 11.2 × 6.2 cm sized pseudocyst. The cyst initially remained stable, but three months later increased in size to 19.6 × 12.2 cm and the patient experienced progressive abdominal pain and anorexia. Endoscopic Ultrasound-guided gastric drainage with tract dilation and placement of two 10 Fr transgastric stents was performed. Fever after one week necessitated cystogastrostomy dilation with placement of a third stent and nasocystic catheter with saline flushes for one week. A subsequent Endoscopic Retrograde Cholangio-Pancreatography revealed thick, milky, purulent discharge through a cyst-duodenal fistula [Figure 1] and pancreas divisum with accessory duct-cyst fistulous communication. The need for accessory pancreatic duct stenting was circumvented as the fistula provided natural drainage and the patient achieved resolution of his pancreatic pseudocyst over several months. This case demonstrates complications of necrotizing pancreatitis; the cyst-duodenal fistula likely helped to decompress and achieve resolution of the pseudocyst.

Secretin-Stimulated MRCP Diagnosis of Annular Pancreas
Easwaran P. Variyam, MD,* Wayne B. Schoettle, DO Internal Medicine, Texas Tech University Health Sciences Center, Lubbock, TX and Radiology, University Medical Center, Lubbock, TX.

Establishing the diagnosis of annular pancreas is often delayed. We describe a case summary of a gentleman 86 years of age with a long history of vomiting in whom the diagnosis of annular pancreas was delayed for over three (perhaps nine) years, magnetic resonance pancreatography after secretin stimulation demonstrated the duct of annular pancreas, and symptoms resolved after operative treatment (initially gastrojejunostomy and later converted to a Roux-en-Y gastrojejunostomy due to persisting severe gastric retention). Annular pancreas is one of the more common congenital anomalies of the pancreas. Most symptomatic patients are discovered early in life. A review of the published literature on annular pancreas revealed this to be the oldest reported patient and the first report of the use of secretin – stimulated MRCP to diagnose annular pancreas.

Statin Induced Cholestatic Hepatitis: Confirmed on Re-Challenge
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Statins are known to occasionally cause abnormal liver chemistries. Frank jaundice after statins, however, is rare. We describe a rare case of cholestatic hepatitis secondary to a statin, confirmed on re-challenge.

Case Report: A 79 year old caucasian female with a history of cholecystectomy and hyperlipididemia presented with painless jaundice and pruritis. She had been on simvastatin for 10 months before the development of pruritis. Simvastatin was changed to atorvastatin. One month later her bilirubin was 2.5 mg/dl, alkaline phosphatase 953 U/L, ALT 307 U/L, AST 124 U/L. All serologies for viral and autoimmune causes were negative. CT scan of the liver and bile ducts were normal. ERCP failed to reveal any obstructive etiology. All liver biochemistries normalized after discontinuation of atorvastatin.

Two months later, atorvastatin was reintroduced. Within a few weeks, she complained of reoccurrence of pruritis. Her alkaline phosphatase was 783 U/L, bilirubin was 0.6 mg/dl, ALT 241 U/L, AST 176 U/L. Repeat imaging studies and ERCP were again normal. All liver biochemistries normalized after discontinuation of atorvastatin. We describe a rare case of cholestatic hepatitis induced by statins, confirmed by re-challenge. There appears to be cross reaction among simvastatin and atorvastatin. Most prior case have not been confirmed by re-challenge. Clinicians should be aware of this rare occurrence.

Disulfiram-Induced Hepatitis and Gallbladder Wall Thickening
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Disulfiram – induced hepatitis is a known complication of the drug. We describe a patient who developed severe fatigue 2 months after initiating disulfiram therapy that was treated with a stimulant drug. It was not until a few weeks later that drug induced hepatitis was appreciated. We present a case of severe disulfiram-induced hepatitis to alert to this possibility.

**Case Report:** A 60 year old female presents with painless jaundice. She had a history of alcohol abuse and depression. She was treated with disulfiram daily by her psychiatrist to encourage alcohol cessation. Over the ensuing 2 months she developed increasing fatigue and weakness, for which she was placed on a stimulant (Modafinil). She failed to improve. Within a few weeks she developed overt jaundice. Bilirubin was 5.1 mg/dl, AST 1695 U/L, ALT 728 U/L, PT, PTT and albumins were normal. Serologies for all viral and autoimmune etiologies were negative. Imaging studies of the liver and biliary tree were normal, and they were no gallstones. However, gallbladder wall was markedly thickened on ultrasound, CT scan and MRCP. The patient was afebrile with a soft non tender abdomen. The white cell count was always normal. Her liver biochemistries and gallbladder imaging studies normalized on discontinuation of disulfiram. We describe a patient with severe disulfiram-induced hepatitis and marked gallbladder wall thickening without other signs of acalculous cholecystitis. Her gallbladder wall thickening was likely a nonspecific finding related to her cholestatic hepatitis, although we cannot exclude a drug induced phenomenon affecting the gallbladder wall. This case emphasizes the need to be aware of disulfiram-induced hepatitis, which can presents with non specific symptoms, and be associated with reversible gallbladder wall thickening shortly after starting the drug.

**PolyFlex Wallstent Used To Close Gastrocutaneous Fistula**

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MM is a 55 yo female who underwent RYGBP(Roux-en-Y gastric bypass) for morbid obesity in 4/02. Post-operatively she developed gastric outlet obstruction requiring balloon dilatation of the G-J anastomosis. She further developed a staple-line disruption, incisional hernia, and a gastrocutaneous fistula. She was placed on TPN via a PICC-line, IV antibiotics and asked to remain NPO. Follow-up endoscopies identified the fistulous opening just below the anastomotic margin (endo picture 1). Attempts were made to inject collagen glue percutaneously by IR and Enteryx endoscopically around the fistulous opening in an effort to close the fistula but both failed. The patient continued to have bilious, serosanguinous drainage mixed with particulate food residue from the fistula site at the base of her surgical scar. FISTulogram documented a communication with the gastric lumen (see radiograph 1). Cultures failed to document an ongoing infection. She elected to undergo a revision and fistulectomy in 8/04. The post-op course was complicated by ARDS, wound dehiscence and persistent drainage from the same fistulous opening. She was again placed NPO and required TPN IV for nutritional support for 3 months. Fistulogram again showed a fistulous communication. Ingestion of blue food coloring mixed with soda was immediately expressed onto the gauze dressing covering the fistula. Reluctant to undergo further surgery, MM agreed to placement of a 21mm-25mm x 120mm PolyFlex Wallstent(Boston Scientific Corp) in 3/05.The proximal end of the stent lay in the distal esophagus with the distal end in the jejunal limb. The covered portion of the stent transversing the gastric pouch, anastomosis, and fistulous opening (see endo pic. 2) Drainage from the fistula diminished immediately post-op. Her diet was advanced to soft mechanically and the PICC line was removed. The stent was removed 5/05. A second surgical opinion was obtained. FISTulogram failed to document a communication with the stomach. Within 1 week of stent removal the fistula was closed and no drainage was observed. Follow up 1 year later documented complete closure of fistula without residual symptoms. PolyFlex Wallstent placement endoscopically should be considered a viable alternative to surgical closure of gastrocutaneous fistulas.

**A Case of Mucosal Bridges Associated with Idiopathic Esophageal Ulcers Treated with Argon Plasma Coagulation**

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Esophageal mucosal bridges associated with idiopathic esophageal ulcers (IEU) have been previously reported in two patients. We report the first case of the use of argon plasma coagulation (APC) to treat esophageal mucosal bridged. The patient is a 32 year old male with history of AIDS with a CD4 count of 30/cmm, off antiretroviral medications, who presented with 2 week history of worsening epigastric pain, odynophagia and dysphagia to solids. He reported weight loss and anorexia. He had an episode of self-limited coffee ground emesis 2 days prior to admission. The patient was febrile and hemodynamically stable. Physical exam was significant for severe tenderness in epigasrium, with normal bowel sounds. Laboratory data was significant for anemia. EGD showed multiple large, deep ulcers in the mid to distal esophagus. Biopsies of the ulcers revealed chronic esophagitis, mucosal ulceration and granulation tissue. No histologic findings suggesting viral or fungal infection were identified. A viral culture was negative. Prednisone was prescribed for IEU. The patient returned several weeks later with dysphagia and odynophagia and reported non-adherence to the medication. Repeat EGD showed numerous white plaques and multiple mucosal bridges at the site of the previously seen ulcers. The mucosal bridges were transected with APC. His symptoms improved and he was discharged on fluconazole, pantoprazole and antiretroviral medications. Esophageal mucosal bridge is a rarely encountered entity. Several conditions have been associated with esophageal mucosal bridge formation. These include candidiasis, Crohn’s disease, nasogastric tube trauma, lupus and variceal sclerotherapy. IEU associated with HIV infection is well recognized as an important cause of esophageal symptoms. Very little is known about the natural history or treatment of esophageal mucosal bridges. We report a case of effective treatment of esophageal mucosal bridges using APC.

**Chylosic Ascites Due to Midgut Carcinoids**

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Chylosic ascites is the accumulation of peritoneal fluid that is rich in triglycerides and is often an indicator of underlying malignancy. The differential diagnosis for this condition is broad. Carcinoids are responsible for ∼1% of cases of chylosic ascites. We report one such case, of which fewer than 30 total cases have been reported in the literature.

**Case Report:** A 74 year old African American male with a past medical history significant for depression presented with abdominal distension and a 20 lb weight loss over 5 months. He denied diarrhea, constipation, flushing, or wheezing. He drank alcohol socially and had no family history of cancer. Abdominal exam was significant for shifting dullness. CT of the abdomen showed massive ascites with a prominence of the superior mesenteric root tissue and a fullness of the pancreatic head and body. Two liters of a milky ascites was drained; triglyceride level was 1624 mg/dL. Laparoscopy was performed and biopsies were taken of the mesenteric mass, small bowel serosa, and pelvic peritoneum. Pathologic examination showed no malignancy. Two weeks later he developed new abdominal pain and a gastroganin enema revealed a perforation near the cecum. Emergent laparotomy with ileocolotomy and ileostomy was performed. Pathology revealed greater than 20 intestinal and mesenteric carcinoid tumors, the largest of which being 1.5 cm and penetrating the small intestinal wall. Additionally, 9 of 23 lymph nodes sampled contained carcinoid. He was not deemed a candidate for chemotherapy, was made DNR, and expired two weeks later.

**Discussion:** Carcinoid tumor is a rare etiology of chylosic ascites, often requiring numerous invasive tests to reach a diagnosis. The proposed
mechanism is serotonin induced fibrosis of mesenteric lymphatic ducts. Classical diarrhea and flushing are typically present when metastases are present in the liver. Prognosis is poor with a mean survival time of 15 months per the largest cohort of cases. Treatment is often directed at symptomatic relief with somatostatin analogs and controlling the ascites with low fat diet, regular large volume paracentesis, spironolactone, and in refractory cases the temporary use of parenteral nutrition as well as surgically placed shunts. Surgical excision is successful in the absence of metastases or lymph node involvement. Unresectable disease has a poor response to multigent chemotherapy.

Pseudomelanosis of Barrett’s Esophagus, the Gastric Antrum, Duodenum, and Jejunum

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First noted on endoscopy in 1976, pseudomelanosis is a rare finding consisting of hyperpigmentation of the duodenal and gastric lamina propria by macrophages laden with vesicles containing mostly iron sulfide. Still thought to be a benign incidental finding, its exact etiology is unknown. The condition typically presents in females in their seventh decade with chronic renal failure on hemodialysis taking antihypertensive medications containing sulfinylurea. Hemoglobin was 5.0 g/dL and stool was guaiac positive. Past medical history was significant for chronic renal failure on hemodialysis and hypertension requiring four medications including hydralazine. She was not on any form or iron replacement and did not use anthracine derived laxatives. Endoscopy revealed an erythematous distal esophagus, moderate gastric antral hyperpigmentation, and extensive hyperpigmentation of the entire duodenum. The affected mucosa had a speckled appearance. Endoscopy two years beforehand had revealed no such abnormalities. Duodenal histology showed dark intracellular granules in the lamina propria negative for iron oxide or melanin. Similar findings were also noted with less density in the gastric antral biopsies. Esophageal specimens showed intestinal metaplasia above the Z-line, and a small amount of intracellular granules (see figure) not seen in the adjacent squamous epithelium. Subsequent push enteroscopy noted a similar hyperpigmentation extending well beyond 50 cm past the ligament of Treitz.

Discussion: We report the first case of pseudomelanosis present in a Barrett’s esophagus and the second case of pseudomelanosis seen in the jejunum. While the condition itself is felt to be benign, its exact pathogenesis and long term significance are unknown. [figure1]

A Semi-Elemental Enteral Formula with Prebiotics Is Associated with Weight Gain in Intestinal Failure Patients Undergoing Intestinal Rehabilitation

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Patients with intestinal failure (IF) not supported by parenteral nutrition (PN) are often unable to gain weight despite intestinal rehabilitation (IR) intervention with use of supplemental enteral nutrition (EN). Newer EN products with prebiotics such as fructooligosaccharides (FOS) and inulin are proposed to help maintain gut mucosal integrity, reduce bacterial overgrowth and improve fluid and electrolyte absorption. This study aims to describe the effect of switching from a polymeric or semi-elemental EN formula (EN1) to an isoosmotic, isotonic, semi-elemental formula with 4 g FOS and inulin per liter (EN2) in IF patients. All IF patients receiving EN1 followed by EN2 and undergoing IR from November 2001 through June 2006 were eligible for the study, excluding those concurrently receiving PN. Eight patients (41–80 y) met study criteria and patient data surrounding oral (N = 5) and enteral via feeding tube (N = 3) use of EN1 and EN2 were extracted from the Cleveland Clinic IR database. Primary diagnoses included radiation enteritis (N = 5), ulcerative colitis (N = 1), small bowel volvulus (N = 1) and mesenteric ischemia (N = 1). Oral diet and medications were maximized through IR in 4 of 8 patients prior to starting EN1. Each patient took EN1 and EN2 in equal amounts with totals differing between patients (250–2000 kcal/d, mean 860 kcal/d) and meeting 15.3% to 93.1% (mean 38.2%) of daily estimated

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Gastric Variceal Band Ligation: A Report of Two Cases

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Gastric varices exist in 20% of patients with portal hypertension and can arise in the cardia or fundus. We report our experience banding gastric varices in two patients. Patient #1 is a 47 year-old male with a history of cirrhosis secondary to hepatitis C. An isolated cardiac varix had been seen on a prior EGD and later confirmed by EUS. Subsequent EGD showed an enlarged varix with a large red spot and was prophylactically ligated with a Wilson Cook 6 shooter band ligator. Nadolol was started, and there were no immediate complications. Three months later, a cardiac varix was again seen around the site of the previous banding. Multiple red spots were again observed, and the varix was banded with two rubber bands. Three weeks later, the patient was admitted with a rapid UGIB. He was emergently sent for TIPS with embolization of the short gastric vein and had no further evidence of bleeding. Six months later, the patient has had no further bleeding episodes. Patient #2 is a 62 year-old male status post an orthotopic liver transplant secondary to hepatitis C with severe recurrence leading to early graft failure. Sixteen months after transplant, an EGD was performed to remove a common bile duct stent. He was noted to have a fundal varix that was oozing blood. There were no esophageal varices or portal hypertensive gastropathy noted. Two rubber bands were applied to the varix with hemostasis achieved. A repeat endoscopy two months later failed to demonstrate any gastric or esophageal varices. The patient was listed for re-transplantation and has had no further bleeding episodes after four months of follow-up.

Discussion: Management of gastric varices remains controversial. Primary prophylaxis of high-risk lesions is frequently performed in many Asian countries but is typically not performed in the U.S. Fundic location, advanced Child’s stage, presence of red spots, and large size all predict an increased likelihood of future bleeding, and lesions considered to be high risk are sometimes treated. Primary prophylaxis of a high risk lesion in our patient with band ligation was unsuccessful. In the U.S, TIPS with embolization remains the standard of care for severe acute hemorrhage from gastric varices. Treatment of actively bleeding cardiac varices with band ligation has been shown to be safe and effective. Our second patient’s actively bleeding varix was treated with band ligation successfully. An algorithm for management of gastric varices in the US needs to be developed and adopted.
nutritional needs (35 kcal/kg base weight). All patients started on EN1 at least 60 days post last abdominal resection leaving ≥100cm SB attached to some part of colon (N = 7) or > 200cm small bowel (SB) with no colon in continuity (N = 1). EN1 (polymeric, n = 6; semi-elemental, n = 2) was taken for a mean of 4.9 months (1.5–12 m) with weight loss (0.6%–9.9%, mean -5.1%) occurring in all patients. Each patient then switched to an equivalent amount of EN2 for a mean of 2.9 months (1.5–7 m) with weight gain (1.2%–10.6%, mean +3.9%) occurring in all patients. Serum albumin levels were intact and remained intact (mean initial and final 4.3 mg/dL) in all but one patient (initial 2.0 mg/dL, final 2.8 mg/dL) through the course of the study. It is concluded that three months of oral or enteral intake of a semi-elemental enteral formula with prebiotics may induce weight gain in patients with IF undergoing IR. Larger, prospective, randomized trials are needed to confirm these results.

Acute Pancreatitis Resulting from Delayed Hemolytic Transfusion Reaction with Hyperhemolysis (DHTR/H): A Rare Complication in a Sickle Cell Patient
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43 year old female with sickle cell anemia was admitted for severe lower extremity pain. The patient gave no history of precipitating factors and her last pain crisis was many years ago. She had been transfused approximately 11 times in the past with the last transfusion being one week ago. On admission, she was afebrile with normal vital signs. Physical examination revealed a woman in mild distress from pain, minimally icteric sclera and unremarkable abdominal examination. Lab results at the time of admission were obtained (Table 1). The patient was treated for acute vaso-occlusive crisis with IV fluids, supplemental oxygen and analgesics. She was improving up to day 7 upon which she developed vague abdominal pain, and her labs indicated severe hemolysis and acute pancreatitis (Table 1). She had a normal calcium and lipid panel. An MRI/MRCP revealed peripancreatic inflammatory changes and no evidence of cholelithiasis or biliary dilation. The patient was diagnosed with delayed hemolytic transfusion reaction complicated with acute pancreatitis. She was treated with intravenous steroids, and intravenous immunoglobulins (IV Ig) with gradual resolution of her pain, and pancreatitis. Alloimmunization occurs in patients with SCD with prior transfusions, and has a reported incidence of 5% to 36%. Delayed hemolytic transfusion reaction/hyperhemolysis (DHTR/H) is one of the serious complications of alloimmunization. It presents with severe hemolysis, usually one week after blood transfusion. Animal studies have suggested that proinflammatory and immunoregulatory cytokines released during hemolysis can cause pancreatitis. Although sickle cell is a risk factor for acute pancreatitis, the temporal relation of the onset of pancreatitis to delayed transfusion reaction implicates the latter in the pathogenesis. Previous studies have suggested some success in using high-dose intravenous immunoglobulins (IVIG) 1g/kg and corticosteroids in preventing additional hemolysis. Recognition of this potential complication is crucial to the supportive treatment of the patient. To our knowledge, this is the first case of acute pancreatitis in the setting of delayed transfusion reaction in a patient with adult sickle cell disease.

Successful Management of Peristomal Variceal Bleeding with Coil Embolization in a Patient with Decompensated Cirrhosis
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Peristomal varices occasionally form in cirrhotic patients who have surgically created anastomoses and stomas. Variceal hemorrhage in this group carries an estimated mortality of 3%–4% per episode, compared to the 30%–40% mortality with esophageal variceal bleeding. We present a 59 year old African American male with Hepatitis C and Child’s B cirrhosis, 5 years s/p colostomy for colon cancer, diabetes, end stage renal disease, peripheral vascular disease with bilateral amputations who presented with recurrent episodes of active bleeding in his colostomy bag over the past year. The patient was hemodynamically stable on presentation but had to be transfused one unit of packed RBC’s. He had a Hb of 8.1 gm/dl with an INR of 1.4. His liver function tests were significant for an albumin of 1.1 gm/dl. An endoscopy done one month ago showed hemorrhagic esophagitis with duodenal polyps and no evidence of esophageal or gastric varices. A Colonoscopy through the colostomy site showed diverticulosis. An abdominal CT revealed a cirrhotic liver, splenomegaly, and moderate ascites with confluent veins around stoma site. The etiology of his bleeding was thought to be due to peristomal varices secondary to portal hypertension. Surgical intervention or Transjugular intrahepatic portosystemic shunt (TIPS) placement were not suitable options in him secondary to multiple co morbidities and the risk of encephalopathy and liver failure. Interventional radiology attempted coil embolization of these peristomal varices. Access into the portal system was obtained using a percutaneous portal transhepatic puncture. Inferior mesenteric venogram demonstrated enlarged IMV with hepatofugal flow into varices around the colostomy site. The main varix was coil embolized with four 8 mm nester coils. The post coil embolization venogram revealed a collateral vessel supplying the varix to the stomal site. Two coils were then

Intussusception as a Complication of Colonoscopy
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A seventy-year-old Caribbean male with history of hypertension presented to a community hospital complaining of intermittent abdominal pain. He had normal appetite and no weight loss. Physical examination and laboratory tests were normal. Air contrast barium enema was done which revealed a four-centimeter (cm) lobular sessile mass in medial aspect of cecum and a one-cm. polyt in lateral aspect of cecum. Colonoscopy with biopsy of the lesions was performed. The procedure was uneventful. One hour later, the patient developed severe, diffuse abdominal pain. Physical examination revealed diffuse abdominal tenderness without rebound or guarding. A right subcostal mass was palpated. Roentgenogram (FUA) of abdomen revealed no air fluid levels and no pneumoperitoneum. CT scan with contrast revealed ileocolic intussusception with a filling defect in the right colon. The patient underwent an emergent exploratory laparotomy with partial small bowel resection and right hemicolectomy. Pathology of the excised specimen revealed ileocolic intussusception with multiple congested polyps. Right colon showed hamartomatous polyps. There was no evidence of perforation. Postoperative course was uneventful and patient was discharged after ten days. Adult intussusception is infrequent and is almost always secondary to a definable lesion. Colonic intussusception in an adult should be resected in total, in view of the high likelihood of malignancy. Small bowel intussusception may be treated initially by reduction if the small bowel is viable. One hypothesis is that intussusception may be induced by hyperperistalsis, which would expel gas and empty the insufflated colon after colonoscopy. Another possibility is that intussusception after colonoscopy is just incidental. There is only one case in literature (Yamazaki et al) reporting intussusception due to colonoscopy. This is the second case reported of an ileocolic intussusception secondary to colonoscopy. Colonoscopy precipitated the intussusception since it occurred just one hour after the procedure.
placed at the origin of this vessel. The catheter was removed with no post procedure complications. The patient had no further episodes of bleeding after the embolization and continues to do well at the 3 month follow up. Stomal variceal hemorrhage has a lower mortality compared to esophageal variceal bleeding. TIPS is another modality to control bleeding from ectopic/stomal varices. Coil embolization with or without TIPS should be considered as a therapeutic option in stomal variceal bleeding especially in high-risk surgical patients.

Metastatic Prostate Cancer Presenting as Occult Gastrointestinal Bleeding
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A 66 year old man presented with increased urinary frequency and was subsequently diagnosed with prostate cancer based on an elevated PSA of 100 and a biopsy consistent with a Gleason score of 9. A bone scan was suggestive of bony metastases, although plain radiograph films were non-confirmatory. Since he was symptomatic with a high PSA and Gleason score, he was placed on depot shots of goserelin, a luteinising hormone-releasing hormone analogue. Three months into therapy, his obstructive symptoms resolved, his PSA decreased to 0.3 and repeat CT scan showed no residual pelvic mass, hydrenephrosis or lymphadenopathy as seen on initial CT scan. The goserelin was continued since he had a good response to hormonal therapy. He remained asymptomatic until seven months later when he presented with lightheadedness, fatigue, and shortness of breath. He was found to be anemic with a hematocrit of 20 and was transfused two units of blood with an appropriate response and discharged with iron supplementation. One month later he presented with fatigue and substernal chest pain at which time he was found to have a hematocrit of 23. His symptoms resolved with blood transfusion and a work up revealed that he was hemoccult positive. Subsequently, he was scheduled for endoscopy. The EGD was unremarkable while the colonoscopy demonstrated a prominent appendiceal orifice with ulceration. Biopsies taken from within the appendix were consistent with prostate adenocarcinoma. A subsequent CT scan demonstrated a 3 × 2 cm soft tissue mass extending from the prostate, a number of enlarged mesenteric lymph nodes and multiple osseous metastases. Specifically, there was a one centimeter lymph node extending directly into the appendix. Common sites of prostate cancer metastases include regional lymph nodes, bone, and lung. This case demonstrates an unusual presentation of intestinal erosion of a metastatic lymph node presenting as symptomatic occult gastrointestinal bleeding leading to the diagnosis of recurrent prostate cancer.

Delayed Lower GI Hemorrhage after Polypectomy
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We present the case of a 72 year old female who presented with acute bleeding per rectum. Vital signs were within normal range and physical exam was unremarkable. Her hemoglobin was 11.2 mg/dl but fell to 10.0 mg/dl within 6 hours of admission. She was transfused with six units of blood while awaiting colonoscopic evaluation. Colonoscopy revealed a visible spurting vessel with overlying clot in the transverse colon. (Figure 1) The vessel and surrounding mucosa were injected with epinephrine, cauterized with Gold probe, and clamped with two hemoclips. The hemorrhage was successfully terminated. Review of records revealed a surveillance colonoscopy performed 27 days earlier that was significant for a 5 mm sessile polypectomy via hot biopsy at the same site. The incidence of postpolypectomy hemorrhage is 1%-6%, and may occur at any time from immediately until 14 days postprocedure. This patient’s presentation is unusual given her delayed bleeding (20 days), acuity of hemorrhage (6 hours), and subsequent need for hospitalization and transfusion. Typical management of hemorrhage consists of ICU observation, transfusion, clipping, and cauterization. If no lesion is found, angiography may be performed. [figure1]
**Discussion:** Disseminated HSV hepatitis is a rare but frequently fulminant disease of pregnancy. The disease is often fatal without early recognition and institution of therapy. Clinical presentation alone and thus clinical suspicion is typically required for diagnosis. The tetrad of high fever, anicteric hepatitis, thrombocytopenia, and leukopenia in the second or third trimester is sufficient for diagnosis. Confirmation with serologic tests and/or liver biopsy can be considered, though treatment should not be delayed. In both cases dramatic clinical improvement was noted on acyclovir.

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**A Rare Case of Primary Amyloidosis Presenting with Massive Gastrointestinal Bleeding**

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Gastrointestinal amyloidosis is implicated more often in secondary or reactive amyloidosis of the AA type than primary amyloidosis of the AL type. We report a rare case of gastric and colonic amyloidosis of the primary type associated with plasma cell dyscrasia.

**Abstract:** A 70 year-old woman with protein C deficiency, factor V Leiden and ischemic colitis with colectomy-confirmed colonic amyloidosis presented with large hematemesis. She had started treatment for plasma cell dyscrasia (MGUS) with melphalan and prednisone recently. Coumadin and lovenox were stopped with FFP infusion given and Greenfield filter placed. However, patient continued to bleed requiring more than 10 units of PRBC over a 7-day period. Multiple endoscopies showed large gastric masses or cystic protrusions. Normal-appearing mucosa also sloughed off easily. Biopsies showed no tumor but amorphous and eosinophilic hyaline material. CT revealed a large bilobed nonenhancing gastric mass, a small hepatic hypodensity and left pleural effusion. Repeat endoscopy five days later revealed multiple large gastric ulcers with some greater than 5cm. EUS showed the stomach wall up to 6mm thick. Total gastrectomy and esophagojejunostomy with Roux-en-Y were then performed. Gastric pathology revealed amyloidosis with diffuse and focal deposits of amyloid in the submucosa, muscle layer and numerous thick-walled, gaping blood vessels. Sulfated alcian blue and Congo red stains revealed moderate staining for amyloid and electron microscopy also confirmed features typical of amyloid. She is doing well 4-months after surgery with hematology follow-up. This is a case of gastric amyloidosis in a patient with plasma cell dyscrasia presenting with massive upper gastrointestinal bleeding from cystic gastric masses and large ulcers with history of colonic amyloidosis. She also has pleural effusions, liver lesion and proteinuria, which may indicate pulmonary, hepatic and renal involvement of her primary amyloidosis. Treatment is to address the cause of her underlying primary amyloidosis or plasma cell dyscrasia with chemotherapy. [figure1]
a migrated PEG tube to the 4th portion of the duodenum (figure 1) and no evidence of cholelithiasis or choledocholithiasis. An ERCP was conducted which visualized a migrated gastrostomy tube into the 4th portion of the duodenum with obstruction of the ampulla and subsequent multiple ulcerations surrounding the papilla and gastrostomy tube (figure 2). The gastrostomy tube was repositioned and the patient clinically defervesced with laboratory markers returning to normal values. The above case demonstrates the importance of maintaining a high index of suspicion of tube migration when surrounding the papilla and gastrostomy tube (figure 2). The gastrostomy tubes and should raise clinical awareness of PEG tube migration leading to pancreatitis. [figure 1][figure 2]

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Diffuse Large B-Cell Lymphoma in a 27 Year-Old Man

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Although primary gastric lymphomas are an uncommon malignancy, their incidence is on the rise with diffuse large B-cell lymphoma as the most common histological type.

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Recurrent Pneumoperitoneum as a Presentation of Refractory Celiac Disease

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Pneumoperitoneum is an alarming radiologic finding that usually signals an acute abdominal catastrophe. Rarely, cases of recurrent pneumoperitoneum represent manifestations of chronic disease processes that affect the intestinal mucosa. Here, we report a case of refractory celiac disease with ulcerative jejunitis presenting as recurrent pneumoperitoneum. In the medical literature, only 12 cases of pneumoperitoneum or pneumatosis cystoides intestinalis presenting as complications of celiac disease are cited.

Case Presentation: A 63 year old man with a 30 year history of celiac disease presented with 3 days of crampy right lower quadrant abdominal pain and bilious vomiting. He also complained of diarrhea despite following a gluten-free diet. His abdominal exam revealed absent bowel sounds, and right lower quadrant rebound tenderness. An abdominal CT scan was remarkable for the finding of retroperitoneal free air along with areas of dilatation in the proximal jejunum. An emergent exploratory laparotomy was then performed. Despite repeated inspections of the bowel, no perforation was found. The abdomen was then closed and a follow-up abdominal x-ray did not show any evidence of pneumoperitoneum. The patient was then discharged when he able to tolerate oral intake. Over the next 6 months, continued complaints of intermittent abdominal pain prompted an x-ray that again showed pneumoperitoneum. The patient was conservatively treated with bowel rest and again discharged. A subsequent capsule endoscopy was notable for failure of the capsule to advance into the jejunum. The capsule was retrieved and the images were significant for bleeding and ulceration in the proximal jejunum. Given these findings, a repeat exploratory laparotomy was performed for a presumed diagnosis of ulcerative jejunitis. Operative findings confirmed the diagnosis as multiple strictures were found every 6–10 cm in the jejunum. A strictureplasty and gastrojejunostomy were then performed.

Discussion: Pneumoperitoneum is a rare complication of celiac disease. Although its presence on abdominal imaging should prompt surgical attention, 27% of exploratory laparotomies performed in celiac patients for this reason are negative for findings of perforation. This case illustrates that ulcerative jejunitis should be included in the differential diagnosis of recurrent pneumoperitoneum in a patient with refractory celiac disease.

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A Patient with Colonic Neurofibroma Causing Iron Deficiency Anemia

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Colonic Neurofibromatosis is an uncommon lesion found during colonoscopy. We report a case of a single colonic neurofibromatous polyp in a patient with recurrent iron deficiency anemia.

Patient Details: A 48 year old white female with Neurofibromatosis I was admitted with syncope, recurrent gastrointestinal bleeding and iron deficiency anemia. Upper endoscopy and small bowel series were normal. After an adequate bowel prep, colonoscopic examination showed a 6 mm ascending
colon polyp. With the resection of the colonic lesion, patient’s anemia resolved. Histopathological examination of the polyp was positive for S100 staining (figure 1) indicative of neural origin and staining for smooth muscle actin was negative (figure 2) consistent with a histological diagnosis of Colonic Neurofibroma.

**Discussion:** Neurofibromatosis I is an autosomal dominant neurocutaneous disease occurring in approximately 1 in 2500 live births. The small intestine and stomach are the usual sites of involvement in the gastrointestinal tract. The clinical picture includes abdominal pain, palpable masses, hemorrhage due to necrosis or ulceration of the mucosa or obstruction due to intussusception. Colonic Neurofibromas are rare. The colonic lesions are often sessile and wide based but also pedunculated polyps have also been observed. Colonic Neurofibromas are rare, usually seen in patients with type 1 Neurofibromatosis. Immunohistochemical stains are positive for vimentin and S-100 protein but negative for desmin, smooth muscle actin, c-kit and CD34. Our patient represents a rare case of colonic neurofibroma causing iron deficiency anemia. [figure1][figure2]

**Black Esophagus: More Common Than We Think?**

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**Case Series:** We present three cases of “black esophagus” that illustrate our experience with this uncommon entity. The first patient, an 81 year old male with cirrhosis and end stage renal disease, presented with three weeks of vomiting, two days of coffee-ground emesis, hypotension, and tachycardia. Urgent endoscopy (EGD) revealed circumferential, confluent ulceration and mucosal necrosis with eschar and exudate, extending along most of the esophagus (figure 1), with a sharp transition to normal mucosa at the gastroesophageal junction (GEJ). Ten hours later he aspirated and died. The second patient, a 72 year old male alcoholic with cerebrovascular disease, presented with two days of hematemesis. He had tachycardia, a tender abdomen, and a marked leukocytosis. EGD revealed an esophagus similar to our first patient, as well as multiple confluent duodenal ulcers with fibrinous exudate. He was treated with pantoprazole and carafate but developed dysphagia, and ultimately an esophageal stricture requiring Savory dilation. The third patient is a 55 year old woman with recent urosepsis, admitted with hypotension and hematemesis. EGD revealed black esophageal mucosa with exudate. Esophagectomy was considered, however diagnostic thoracoscopy showed viable esophagus. Repeat EGD five days later demonstrated significant healing.

**Discussion:** The first endoscopic case of “black esophagus” was described in 1990; since then, fewer than 40 cases have been reported. The diagnosis excludes caustic ingestions, and is recognized on EGD by the classic features described above. The suspected incidence ranges from 0.01–0.2%, but we have seen it in 0.6% of patients undergoing upper endoscopy. The etiology and pathogenesis are unknown, though ischemia and increased gastric acid exposure likely play important roles. 15–25% of patients experience complications such as stricture formation, and the mortality rate in these patients is as high as 50%. Deaths, however, are rarely directly attributable to esophageal complications. By presenting this small case series, we hope to raise awareness of “black esophagus” and remind gastroenterologists that, despite its dramatic appearance, this entity serves more as a marker of a patient’s overall poor health. [figure1]

**A Case of Ileal Dieulafoy’s Lesion in a Patient with Crohn’s Disease**

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A case of recurrent bleed from an ileal Dieulafoy’s lesion in a patient with Crohn’s disease status post multiple bowel resections is reported. After undergoing two prior ileocolonic resections for life threatening lower gastrointestinal hemorrhages, this patient presented with three episodes of transfusion requiring hematochezia. Two initial colonoscopies were non-diagnostic. The third colonoscopy revealed an actively bleeding vessel in a disease free region of the ileum, consistent with Dieulafoy’s lesion. The lesion was treated endoscopically with epinephrine injection and cautery with good hemostasis. This is the first reported case of ilea dieulafoy’s lesion in a patient with Crohn’s disease. Though life threatening hemorrhage is a known complication of Crohn’s disease, we should not omit other causes of lower gastrointestinal bleed.

**Endoscopic Diagnosis of Colo-Colonic Intussusception**

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Colo-colonic intussusception is a rare disorder in the adult population. The diagnosis is typically made radiographically or upon surgical exploration.
We present a case of colo-colonic intussusception diagnosed at endoscopy. A 44 year old man with a history of peptic ulcer disease and diabetes mellitus presented with hematochezia and left lower quadrant pain for one month. The pain was described as sharp, intermittent, radiating to the back and the legs, relieved by bowel movements and aggravated by food ingestion. He denied nausea, vomiting, fever and chills. He denied unusual food intake, travel or sick contacts. On exam the patient was afebrile, mildly hypertensive and tachycardiac at 124 bpm. The abdomen was soft, non-distended, with left lower quadrant tenderness. Rectal exam showed brown guaiac negative stool.

The patient underwent a colonoscopy, which revealed a large mass starting at 15 cm from the anal verge and occupying almost the entire lumen. Although the overlying mucosa of the mass appeared smooth and regular, it had a dusky appearance suggestive of ischemia. The colonoscope was advanced along the mass to a point of luminal twist, after which it could not be passed any further. The diagnosis of colo-colonic intussusception was entertained and as the area could not be passed endoscopically, surgical consultation was requested. An abdominal CT scan showed a region of probable intussusception in the sigmoid colon with associated mesenteric fatty infiltration. The patient underwent a laparoscopic segmental resection of the sigmoid colon. At the time of surgical intervention, no intussusception was noted, although a smooth 5 cm mass was seen. Pathologic assessment of the mass revealed a smooth muscle tumor of uncertain malignant potential, which was CD-117 negative. Three days postoperatively, he was discharged home in stable condition. The incidence of intussusception in the adult population is very low, and in most cases associated with an underlying lesion, such as an adenoma, lipoma or adenocarcinoma. Only 8–19% of cases of intussusception in adults are colo-colonic. The presentation of intussusception can range from symptoms of obstruction to gastrointestinal bleeding. Diagnosis is usually made either radiographically or by surgical exploration. Colonoscopy is rarely the first diagnostic tool and can often miss the intussusception. The treatment is almost always surgical due to the high prevalence of an underlying lesion and the propensity for recurrence.

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Neuroendocrine Tumor of the Pancreas Presenting as Acute Pancreatitis
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Pancreatic neuroendocrine tumors represent less than 10% of all pancreatic tumors and manifest few symptoms unless they are functional with hormone production. Non functional tumors may produce abdominal pain, weight loss or palpable abdominal mass but uncommonly present as acute pancreatitis. We report a case of nonfunctional pancreatic islet cell tumor presenting as acute pancreatitis.

Case Report: A 48 year old Caucasian male presented with a 2 day history of severe epigastric and left upper quadrant abdominal pain radiating to the back associated with nausea. He was afebrile and had tenderness on palpation in the epigastrium and left upper quadrant. Labs revealed elevated amylase (741 U/L) and lipase (2411 U/L), white count of 10000 UL and mildly elevated transaminases and alkaline phosphatase. He was not on any medications and was a social drinker. Abdominal ultrasound revealed a large heterogeneous hypoechoic mass in the tail of the pancreas measuring 10 × 8 × 7 cm and dilatation of the pancreatic duct. These findings were confirmed on contrast enhanced CT scan which additionally demonstrated peripancreatic fat stranding. Endoscopic ultrasound (EUS) demonstrated a hypoechoic mass in the tail of the pancreas with perigastric blood vessels and proliferation of the blood vessels in the splenic hilum. EUS guided fine needle aspiration of the mass showed numerous neuroendocrine type cells in clusters which had strong positivity with pan keratin, synaptophysin and chromogranin and mildly positive staining with neuron specific enolase, cytologically consistent with neuroendocrine tumors. The incidence of nonfunctional islet cell tumors of the pancreas is 0.5 to 2 million/year and only 22 cases (23, including this) have been reported in English literature to present with acute pancreatitis. Only 7 cases had the tumor in the tail of the pancreas. Most patients were young; the mean age at presentation was 48.5 years. Obstruction of the pancreatic duct by the mass appears to be the etiology of pancreatitis. Treatment of these tumors is usually palliative; most have metastases on initial investigation. Surgical resection of the tumor is planned for our patient. Neuroendocrine tumors of the pancreas can be a cause of acute pancreatitis and need to be ruled out in pancreatitis of unknown etiology. Work up involves imaging studies, specifically ultrasound, CT scan, MRI, and EUS with biopsy of the mass for confirmation.

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An Unusual Case of Biliary Colic . . . It’s Not Always a Stone!
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Case: We describe a case of a 67 year old woman visiting from Mexico who presented to the ER with epigastric pain, nausea and vomiting for 3 days. Physical exam revealed an overweight afebrile woman with stable vitals. She was jaundiced and had mild epigastric tenderness. Labs revealed WBC 15.4, TB 5.2, LD 1.3, ALP 321, GGT 846, AST 529, ALT 430 and lipase 200. Eosinophil count was normal. Viral serology for Hep A, B and C were negative. CT abdomen showed a dilated CBD to 11 mm and Cholelithiasis. Patient underwent an ERCP which confirmed the dilated CBD and cholelithiasis. There was a small filling defect in the right hepatic duct.Biliary sphincterotomy and balloon sweeps of the CBD and CHD was performed. The balloon sweeps resulted in extraction of two adult worms, which were later identified by the CDC as Fasciola hepatica.

Discussion: Human fascioliasis is a huge public health concern worldwide. Clinical presentations are typically are of 3 types -1) An acute/Liver phase lasts about 6 weeks and typically presents with fever, hepatomegaly, and eosinophilia. 2) Chronic/biliary phase, which is usually asymptomatic but may present with biliary colic, cholangitis, cholelithiasis and obstructive jaundice.3) Ectopic Fascioliasis. Methods of diagnosis include identification of ova and parasite in stool studies, duodenal aspirates, bile specimens. Serological diagnostic tests are also available. CT scan may show dense nodules, tracts, subcapsular hematoma, thickened capsule, parenchymal calcifications. Treatment with antiparasitic agents is effective with high cure rates. Due to increasing migration of people from endemic areas, we should expect to see more such cases in the USA.

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Giardiasis Presenting as Duodenal Nodules in a Patient with Dyspepsia
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Giardia Lambia is the most common protozoan isolated from the GI tract worldwide. Patients with Giardiasis typically present with diarrhea but a significant number of patients present with upper GI symptoms only. Histology of the small bowel mucosa is generally inconspicuous though peculiar histopathological feature associated with Giardiasis has been reported in one study. We report a patient presenting with dyspepsia having significant number of descending duodenal nodules which showed Giardiasis associated with chronic inflammation on pathology. A 45 year-old male with morbid obesity and no other medical problems presented with dyspepsia for 3–4 years. He underwent EGD which showed several erythematous descending duodenal nodules with whitish borders ranging from 2mm to 5mm in size (picture 1). The descending duodenal biopsy showed giardiasis associated with chronic active mucosal inflammation. He was treated with oral metronidazole for 2 weeks. He had significant improvement of his symptoms after the treatment. Pre and post treatment stool ova and parasites were negative.
Giardiasis duodenitis presenting as “whitish nodular puncture with a focus or diffuse pattern” endoscopically has been described in one study. Histology in these patients is usually inconspicuous and search for the parasite is suggested in all biopsy specimens obtained from the duodenum. Our patient had unique finding of significant erythematous descending duodenal nodules showing Giardiasis with microscopic changes on pathology. This case highlights the importance of considering Giardiasis as an important differential in a patient even in the absence of diarrhea and showing focal or diffuse pattern of descending duodenal nodules and negative stool studies.

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Community Acquired MRSA Liver Abscess in a Patient with Primary Sclerosing Cholangitis and Cirrhosis
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Community acquired Methicillin-resistant *Staphylococcus aureus* (MRSA) constitutes an exceedingly rare cause of liver abscess in adults with liver disease. A 49-year old male with history of Ulcerative colitis and primary sclerosing Cholangitis (PSC) presented to the GI clinic with two days of fever and left sided abdominal pain. The patient reported intermittent bloody diarrhea for over two months prior to admission. He had never been hospitalized before. He had no history of surgeries or vascular interventions. Outpatient medications were Mesalamine and Prednisone. He has history of alcohol abuse, but quit drinking 2 years ago. He denied ever using intravenous drugs. He was diagnosed of PSC by ERCP five months prior to admission. On admission, he was febrile (102.1F) and Tachycardic(104). His physical exam was remarkable for mild left-sided tenderness. Significant initial laboratory findings were WBC: 18.5 k/cmm, AST: 54IU/L, ALT: 84IU/L, Alk phos: 239IU/L, and Bilirubin: 1.5mg/dL consistent with prior results. The patient was admitted, blood and stool cultures were obtained, he was treated with intravenous antibiotics, and bowel rest. CT scan of the abdomen performed which revealed new large (4.6 × 2.8cm) thick enhancing rim lesion in the liver which has and central necrosis; There were also findings of cirrhosis and intrahepatic ductal dilation similar to the prior study. Blood culture grew MRSA. The patient was begun on vancomycin and oral Clindamycin. He remained febrile during outpatient follow-up, his follow up CT scan 2 months after discharge very small hypo density consistent with resolving abscess. This case illustrates how predisposing clinical factors for both MRSA bacteremia and abnormal liver parenchyma might come together to cause such a rare liver abscess. An extensive literature review revealed only 11 reported cases in adults. Most of these cases included risk factors such as an immunosuppressed host, a history of instrumentation affecting the liver, or predisposing hepatic lesions such as prior *Schistosoma* granulomas. In our patient we think, PSC and cirrhosis made him susceptible to developing a liver abscess; this association has not been reported before in the literature.

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Duodenal Myxolipoma Presenting as a GI Bleed
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A 74 year old caucasian male presents with complaints of intermittent weakness, fatigue, back pain, generalized abdominal pain, increased abdominal distension, melena, and bloody stools for the past 3–4 years, requiring frequent blood transfusions and hospitalizations. Previous EGD and colonoscopies show small bowel and colon angioectasias. Abdominal xray, CT scans, and upper GI series were unremarkable. An EGD showed multiple small, non-bleeding angioectasias in the duodenal bulb and the 2nd part of the duodenum, and a 1.5 cm non-bleeding, ulcerated, infiltrative, malignant-appearing mass in the 2nd part of the duodenum. Biopsies came back as “granulation tissue with acute and chronic inflammation,” without any malignancy or neoplasia. The colonoscopy showed a few small angioectasias with no bleeding and no other sources of bleed. The patient then underwent an exploratory laparotomy with resection of the 5–6 cm long x 2 cm wide duodenal mass. Pathology report returned with the diagnosis of “myxolipoma with ulceration, and acute and chronic inflammation with changes of pro lapsed, and normal cytogenic studies.” Patient did well post-operatively and was discharged home in stable condition. To this date, he has not had any more hospitalizations for GI bleed. There is very little literature on duodenal myxolipomas presenting as gastrointestinal bleeds. Lipomas in the small bowel usually do not bleed, but may cause intermittent bowel obstruction and intussusception. Gastrointestinal angiolipomas are exceedingly rare, however, a few case reports in the literature have shown that duodenal angiolipomas do exist and may lead to substantial GI bleed. Ulcerated lipomas, with exposed bleeding vessels, would account for the GI bleed/hemorrhaging of a usually avascular lipoma. Interestingly, the 5–6 × 2 cm mass found in this patient was not detected on CT scan or upper GI series. We are presenting this interesting case to support the fact that there are rare occurrences of duodenal myxolipomas that may be missed on CT scans and upper GI series, but found on endoscopy, and present itself as a GI bleed.

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A Rare Case of Acute Symptomatic Gastric Torsion Caused by Gastrostomy Tube Placement
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Gastrostomy tube is used as an adjunct to gastropexy for treatment of gastric volvulus. Gastric volvulus or torsion caused by gastrostomy tube placement has only been reported as a rare long-term complication in neurologically impaired children with chronic gastric distension. This is the first case report of an acute symptomatic gastric torsion caused by G-tube placement.

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Gastrostomy tube is used as an adjunct to gastropexy for treatment of gastric volvulus. Gastric volvulus or torsion caused by gastrostomy tube placement has only been reported as a rare long-term complication in neurologically impaired children with chronic gastric distension. This is the first case report of an acute symptomatic gastric torsion caused by G-tube placement.

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Abstract: A 64-year-old woman with history of stage III poorly-differentiated endometrial adenocarcinoma with prior hysterectomy, bilateral oophorectomy and extended radiation treatments presents with nausea and vomiting for one week. CT scan showed distal small bowel obstruction with dilation of the stomach and proximal small bowel. Exploratory laparotomy and decompensation was performed with extensive lysis of adhesions, segmental resection of ileum and cecum, and G-tube placement. Patient was doing well until about one week later when she developed increased G-tube output. After starting clear liquid trial, patient also developed persistent emesis. Upper endoscopy showed a J-shaped stomach with narrowing of the lumen in mid stomach created by large twisted folds. G-tube was also seen in mid upper stomach at the twisted folds. Barium upper GI with small bowel series showed torsion in mid stomach at the G-tube site. The G-tube had been placed for 30 days and was removed. Patient’s nausea and vomiting then began to improve significantly. Patient started eating regular solid food without difficulty. She was discharged home and still doing well 5 months later. Gastrostomy tube placement can cause acute gastric torsion, as seen in our patient, even though it is ironically used for treatment of gastric torsion along with gastropexy. After surgical decompensation, our patient’s previously distended stomach may have reshaped, creating twisting along the axis of the G-tube. Nevertheless, gastric torsion should be suspected in patients who present with nausea and vomiting after G-tube placement. [figure1]

possible gastric angiodysplasia lesions, which were once again ablated with APC. Patient’s rectal bleeding subsided and hemoglobin remained stable after 4 units of PRBC. Two months later, rectal bleeding recurred requiring another 4 units of PRBC transfusion. Repeat examinations were performed, including Meckel’s scan which was normal, a tagged-RBC scan showing bleeding in right lower quadrant of the abdomen and capsule endoscopy which showed blood in the terminal ileum. A total of at least 4 endoscopies, 5 colonoscopies, 3 capsule endoscopies, 2 tagged-RBC scans, and 2 Meckel’s scan were performed at multiple institutions. The source of bleeding was finally localized to an area near the terminal ileum. We then referred the patient to Cedar Sinai Medical Center for double-balloon enteroscopy from below, which revealed a bleeding Meckel’s diverticulum. The area was cauterized and a clip was placed. At one-year follow-up, patient’s bleeding had not recurred and hemoglobin is stable. Double-balloon enteroscopy can identify a Meckel’s diverticulum not seen by any other modality and offers effective treatment for bleeding from it thus avoiding an operation.

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Conservative Management of Grade IV Liver Laceration with Hepatic and Bile Duct Injury in Pediatric Patient Using ERCP Stenting and Percutaneous Drainage
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This is a 10 year old Hispanic male who presented with a Grade IV liver laceration with bleeding, hemoperitoneum, and pulmonary contusions secondary to a MVA. A week later a 7-French drain was placed to help drain the excess fluid. Over the next few days, he started developing nausea, vomiting, and abdominal pain. The drain showed increased bilirubin and labs showed elevated total bilirubin, direct bilirubin, alkaline phosphatase, and mildly elevated lipase. There was a concern of a possible bile leak due to damage to the hepatic duct and/or the common bile duct. An ERCP was performed to better visualize and evaluate the pancreatic, hepatic, and biliary ductal systems. Dye was injected into the common bile duct and a leak extending from the right main hepatic duct to the dome of the liver was noted. A 1cm sphincterotomy was performed and a 7 French x 7cm stent was placed. The patient tolerated the procedure well without complications or blood loss. His symptoms of nausea, vomiting, and abdominal pain quickly resolved and the drain showed decreased bilirubin and labs showed normal bilirubin and alkaline phosphatase levels quickly returned to normal within the next two days. The patient was discharged in stable condition and has had no complications. Currently, nonoperative management of blunt pediatric liver injuries is generally the standard of care in the absence of hemodynamic instability. However, associated bile duct injuries remain difficult challenges and there are few case reports in the literature documenting techniques and methods of conservative approaches. We are presenting this case to further validate and confirm the success of using conservative interventional endoscopic and radiologic management, such as ERCP stenting with percutaneous drainage, of hepatic and bile duct injuries caused by blunt trauma in the pediatric population.

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A Case of Eosinophilic Esophagitis Missed with Multiple Endoscopic Biopsies
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Walsh et al. (J Surg Path 1999; 23:390–396) reported that patients with eosinophilic esophagitis had proximal and distal eosinophilia with a uniform distribution of eosinophils in the mucosa. We report a patient eosinophilic
esophagitis that was diagnosed only after surgical resection. A twenty-nine-year-old male with a history of asthma presented to our medical center with a history of solid food dysphagia since the age of 4 requiring dilation every 2 months despite high dose PPI therapy. The patient was adopted so family history was not available. An initial endoscopy at our medical center revealed a long distal stricture and biopsies distally were consistent with reflux esophagitis. The patient had a second esophagus 2 months later and a distal esophageal stricture was again identified but linear furrowing and mucosal rings were described. On this endoscopy, proximal biopsies were obtained and again only revealed rare eosinophils. A barium esophagogram was performed and revealed a distal stricture with delayed passage of a 13 mm barium tablet. The patient was seen by the surgical team and underwent a segmental resection of 7 cm of distal esophagus and 5 cm of proximal stomach. Numerous eosinophils were seen in the resection specimen consistent with the diagnosis of eosinophilic esophagitis. Review of the pathology shows an average of 80 eosinophils per hpf. Retrospective review of the initial biopsies only revealed rare eosinophils. This case represents a classic eosinophilic esophagitis case that went undiagnosed despite clinical recognition of typical features including asthma and dysphagia unresponsive to high dose PPI therapy with endoscopic mucosal rings and furrows. We, therefore, recommend a trial of empiric topical steroid therapy in patients with suggested eosinophilic esophagitis in the absence of eosinophils on mucosal biopsy.
Requests for feeding tube placement, in those newly diagnosed with dysphagia, is a common request of the gastrointestinal medicine service. We describe the case of an adult patient with severe mental retardation who developed substantial oropharyngeal dysphagia and aspiration pneumonia after an unknown foreign body ingestion. A 43-year-old Mentally Retarded White Male resident of a state mental institution was transferred to our Emergency Department due to new onset fever and dyspnea. His nurse reported a two day history of non productive cough and no history of pneumonia. The patient was non-verbal secondary to severe intellectual disability and presented with increased oral secretions. The patient was admitted, diagnosed with aspiration pneumonia, and placed on antibiotics. Due to suspected aspiration pneumonia, a bedside swallow evaluation was performed which was significant for impaired swallowing. Modified Barium Swallow Study revealed severe aspiration risk for aspiration and foreign body ingestion who present with new onset respiratory symptoms. [figure1][figure2]

The endoscope was passed without difficulty to the hypopharynx where a foreign body was discovered and removed by rat tooth forceps. The foreign body was identified as a chicken bone (see below). The remainder of the specimen was opened that the problem became evident, which consisted of an iatrogenic creation of a 3cm. SA pseudoaneurysm caused by the non absorbable suture used two years prior during the bariatric procedure, which eroded into the proximal stomach. Patient does not have any history of pancreatitis or abdominal trauma. One week prior to this surgery patient presented to the ER with a sentinel upper GI bleed that was worked up with an EGD and colonoscopy which were both unremarkable. Splenic artery pseudoaneurysm is a very rare entity caused by pancreatitis, blunt abdominal trauma and very rarely by an iatrogenic intervention. To our knowledge, this is the first report of a SA pseudoaneurysm probably caused as a result of injury to the vessel during the bariatric procedure. It should be suspected in a patient with history of previous bariatric surgery whenever they present with massive upper GI bleed. If EGD is inconclusive, angiography and early intervention is recommended to reduce the high mortality associated with conservative management.
story was unremarkable. His vitals were stable and he appeared comfortable. He had no stigmata of chronic liver disease. Auscultation of the right lung base revealed minimal rales. His abdomen had tense ascites without obvious organomegaly. Labs were normal except for an elevated alk phos of 143 U/L. Diagnostic paracentesis revealed cloudy ascites with SAAG less than 1.1 and WBC of 3000/microlitre with lymphocytic dominance. Gram stain, AFB stain, and cultures of the fluid were unremarkable. Cytology suggested a non-small cell neoplasm. Chest x-ray showed no pleural plaques and CT of the abdomen showed thickening of the omentum. PET scan showed hypermetabolic regions throughout the omentum. Omental biopsies revealed atypical cells, consistent with mesothelioma.

**Discussion:** Malignant mesothelioma with metastases to the omentum can occur, but primary mesothelioma of the omentum is rare. To the best of our knowledge, this is the third case in the English literature of primary peritoneal mesothelioma occurring in the absence of known asbestos exposure. Prior to the 1970s, asbestos was an ubiquitous insulation material, and the patient may have unknowingly been exposed. Mesothelioma of the omentum is postulated to be secondary to asbestos ingestion. Histopathologically, mesothelioma appears similar to metastatic adenocarcinoma, thus immunohistochemical staining (sensitivity and specificity 80 to 90%) can aid diagnosis. Our patient’s sample was positive for WT-1, CK 5/6, HBME-1, and negative for CEA and TTF-1. Prognosis is poor with median survival at 12 months. [figure1][figure2]

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**Endoscopic Management of Duodenal Obstruction Due to Migrated Biliary Stents**

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Distal migration of self-expandable metal stents (SEMS) from the bile duct could potentially result in ulceration, bleeding and duodenal obstruction. We describe endoscopic management of two patients with duodenal obstruction from migrated SEMS. Endoscopic argon plasma coagulation (APC) and cap-assisted stent fracture techniques were used to recanalize the lumen.

**Case 1:** A 64 year-old Hispanic male with unresectable pancreatic head carcinoma presented with obstructive jaundice and ascites. Two overlapping SEMS biliary stents and an internal-external drain was placed. Subsequently, the patient developed symptomatic duodenal obstruction as confirmed by Upper GI series (see figure).

Endoscopic transection of the migrated segment of the stent with APC was unsuccessful due to the narrow lumen. Using cap assisted endoscopy, the distal end of the stent was brought in the bulb by using an endoloop. The migrated segment of the stent was fractured against the cap of the endoscope by grasping and pulling pieces of the stent with a Pelican forceps, until the stent segment in the lumen was completely cleared. Barium study 2 days later showed a patent C-loop of duodenum, with excellent flow. Patient tolerated oral diet and was discharged from the hospital 24 hrs later.

**Case 2:** A 66 yr-old male with unresectable ampullary cancer treated with SEMS presented with obstructive jaundice and UGI bleeding. Endoscopy revealed a migrated biliary stent impinging against the posterior wall of the duodenum causing ulceration, bleeding and gastric stasis. Endoscopic retrieval of the stent resulted in hemorrhage, which was controlled by embolization of the gastro-duodenal artery. Subsequently, endoscopic transection of the distally migrated segment with APC was performed along with retrieval of the stent wires in piecemeal fashion with a grasping forceps. Patient was able to resume oral diet and was discharged from the hospital 24 hrs later. We conclude that endoscopic removal of migrated biliary stent can be performed safely. [figure1]

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**Multi-Focal Colonic Follicular Lymphoma: A Rare Case Discovered on Screening Colonoscopy**

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The gastrointestinal tract is the most common site of primary extranodal involvement of non-Hodgkin’s lymphoma (NHL). However, follicular lymphoma, the most common form of low-grade NHL, rarely involves the colon. This case describes a rare occurrence of an uncommon type of follicular lymphoma discovered in the colon on screening colonoscopy.

**Case:** An apparently healthy 61-year-old male who presented to the endoscopy center for screening colonoscopy. The patient was asymptomatic upon presentation. Family history revealed a grandfather who was diagnosed with colon carcinoma. Physical exam was normal. The colonoscopy showed a 2.5-cm flat colon polyp in the proximal ascending colon, which was removed with snare electrocautery; a 4-mm sessile colon polyp in the sigmoid colon; and five 3–5-mm submucosal polyps at the rectosigmoid junction and rectum, which were biopsied with cold biopsy forceps. Biopsies at each site revealed multi-focal colonic follicular lymphoma, grade II/III. Immunohistochemical staining revealed a CD5+, CD10+, and BCL2+ neoplasm. Heme profile with differential and basic metabolic panel were normal. The patient underwent a CT of the abdomen which showed thickening of the small bowel with saccular dilation suspicious for small bowel lymphoma, numerous mesenteric and para-aortic lymph nodes, and a 1.3-cm splenic granuloma. A capsule enteroscopy was performed and revealed polyps in the proximal jejenum, and erythematous areas of uncertain etiology in the distal small bowel. A PET scan revealed a focal area of increased uptake in the rectum. Bilateral bone marrow aspirations and biopsies were obtained which revealed no evidence of disease. The patient is currently under the care of an oncologist.

**Discussion:** The most common site of primary extranodal involvement of non-Hodgkin’s lymphoma is the gastrointestinal tract, with the stomach being the usual site and the colon comprising only 10%. Of this subset of neoplasms, follicular lymphomas, or follicle center lymphomas, represent a mere 1–3%. Pathology of these neoplasms are most commonly CD5-, non-Hodgkin’s lymphoma is the gastrointestinal tract, with the stomach being the most common site of primary extranodal involvement of non-Hodgkin’s lymphoma. However, follicular lymphoma, the most common form of low-grade NHL, rarely involves the colon. Involvement of non-Hodgkin’s lymphoma (NHL). However, follicular lymphoma, the most common form of low-grade NHL, rarely involves the colon. This case describes a rare occurrence of an uncommon type of follicular lymphoma, the most common form of low-grade NHL, rarely involves the colon.

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Methylnaltrexone Reverses Opioid-Induced Bowel Dysfunction (OBD) in a Critically Ill Burn Patient; a Case Report

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To investigate the effect of methylnaltrexone (MNTX) on OBD in the critical care setting, MNTX is a peripheral opioid receptor antagonist that does not cross the blood-brain-barrier in humans. In phase 2 and 3 clinical trials with the SC formulation, methylnaltrexone has been demonstrating to reverse OBD in patients with advanced illness without reversal of analgesia or withdrawal. In a phase 2 post-operative bowel dysfunction study with IV MNTX, bowel recovery was accelerated by 20 hours without reversal of analgesia or withdrawal. We hypothesized that MNTX might benefit critically ill patients with OBD by resolving GI dysmotility and improving enteral feeding. A 21-year-old male had been admitted to the ICU for a 30% burn injury incurred by a fire and explosion. He underwent excision and skin grafting and was receiving 60–100 mg/kg morphine via continuous infusion and intermittent boluses. He was extubated but was unable to effectively feed enteral, due to high gastric residuals and a lack of bowel sounds over 4 days. Average enteral feeds of 1200 cc/day resulted in gastric residuals of 750 cc/day. With approval from the University of Chicago IRB, he received 8 doses of MNTX (0.3 mg/kg, IV over 10 minutes, q6 hours) over 48 hours. He continued receiving morphine via bolus and continuous infusion. MNTX was well tolerated and did not elicit pain or withdrawal symptoms at any time. Flatus occurred immediately during the first dose of MNTX. Over the subsequent 48 hours, gastric residuals decreased to 0 cc/day. The patient was able to tolerate enteral feeds and averaged over 2400 cc/day during this time (below). By day 5 he was tolerating solid food by mouth. Although prophyaxis of ileus has been described using peripheral opioid antagonists in elective surgical patients, treatment of OBD in critically ill patients has not been previously reported. The immediate improvement in feeding, gastric residuals,
and gut function in this patient suggests a role for methylaltrexone in the
critical care setting. [figure1]

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Leukemic Ascites: A Rare Cause of Acute Ascites
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The purpose of this abstract is to review the presentation of an extremely rare cause of acute ascites. This 30 year old caucasian man presented with one week of abdominal pain, distention, anorexia, fever, chills and sweats. Physical examination was notable for fever, distention of the abdominal wall with tenderness in the upper quadrants and marked organomegaly. There was no rebound or guarding. An initial complete blood count revealed marked leukocytosis with fifty percent blast forms. Liver function tests were normal. A preliminary diagnosis of acute myeloid leukemia was made based upon a review of the peripheral smear. Additional diagnostics were performed including computed tomogram of the abdomen which demonstrated organomegaly, ascites and excluded vascular thrombosis as a contributor. Diagnostic paracentesis proved the presence of numerous blast forms with the same cytometric markers as earlier samples from the serum had shown. The SAAG was 1. Cultures were sterile. Bone marrow biopsy with cytogenetic analysis confirmed the preliminary diagnosis. The patient was begun on induction chemotherapy with cytarabine and daunorubicin and within one week of completion demonstrated regression of organomegaly and ascites. In the unusual patient with acute myelogenous leukemia the incidence of acute ascites is extremely low with only a few cases reported in the literature. When evaluating these patients common causes must be excluded. The possibility of ascites as an inflammatory reaction to the primary disease must be considered. The treatment is directed at the primary disease. The presence of leukemic ascites is a poor prognostic sign.

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Spontaneous Perforation of the Duodenum by a Migrated Ureteral Stent
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Iatrogenic duodenal perforation is a rare occurrence, typically related to endoscopic procedures such as ERCP. We report a unique case of a previously undescribed cause of duodenal perforation: a migrated ureteral stent. An 84 year old female presented to the emergency department with complaints of right-sided abdominal pain. The sharp pain began 5 hours prior. She reported a chronic discomfort in the right upper quadrant over the past year. There was no melena, hematochezia, or weight loss. Her past medical history was significant for a right-sided ureteral stent placed for nephrolithiasis 10 years prior. On physical exam, she was afibrile with normal vital signs. The abdomen was soft, non-distended, and tender to palpation of the right upper quadrant. There was right flank tenderness. Laboratory studies revealed a leukocytosis. Liver and renal function testing were normal. Urinalysis showed significant pyuria and hematuria. Computed tomography (CT) scan of the abdomen was performed to further evaluate the patient's abdominal pain. A heavily calcified stent was identified and appeared to have migrated outside the urinary drainage system, lying near to and potentially within the duodenum. Pneumoperitoneum was not present, but there was pneumocystitis. Upper endoscopy was performed to clarify the findings of the CT scan. Upper endoscopy revealed a stent that had perforated the third part of the duodenum, with roughly 10cm of the stent lying within the duodenum. The patient underwent open nephrectomy and duodenal repair. She has recovered and remains well. Iatrogenic duodenal perforation is rare, typically managed conservatively. Ureteral stents have a long history of complications but our patient represents the first reported instance of a migrated stent causing duodenal perforation. Our patient also represents the longest reported indwelling ureteral stent, which was a contributing factor to her ultimate perforation. This case demonstrates the importance of discussing the need for follow-up when ureteral stents are placed. Duodenal perforation should be considered as a potential complication of long standing ureteral stents.

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A Young Woman with Liver Disease?
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As advances are made in medicine, new syndromes are introduced by man's tinkering with nature. As women undergo fertility treatments with increasing frequency, new complications arise. One of the complications of these treatments is the ovarian hyperstimulation syndrome (OHSS). The ascites associated with this syndrome is well described in the fertility literature. However, there is a paucity of literature describing the liver test abnormalities in this syndrome. We recently encountered a young woman who underwent in vitro fertilization and presented with ascites and a moderate elevation of her transaminases. She was diagnosed with and treated for severe OHSS. Her ascites and liver test abnormalities resolved within weeks of onset. A 34 year-old woman presented with increasing abdominal girth, a 5-pound weight gain and shortness of breath over a one-week period. She had a history of asthma, endometriosis and infertility. Eight days prior to admission, she had undergone in vitro fertilization. She took only a prenatal vitamin and progesterone. She did not drink alcohol, nor use illicit drugs. She denied a family history of liver disease, abdominal malignancies and other complaints. The only positive findings on her examination were: decreased breath sounds and dullness to percussion in the bases of the lungs and a moderately distended abdomen with a protruding umbilicus. Her CBC showed a WBC of 12.8, Hb of 16.4 and Hct of 47. The platelet count, MCV, basic metabolic panel and coagulation studies were all within normal limits. Liver function tests showed a low albumin of 2.9, but were otherwise normal. The patient was diagnosed with severe OHSS and admitted to the gynecology service of our institution. She had an ultrasound of the chest, abdomen and pelvis, which confirmed pleural effusions, ascites and enlarged ovaries. On the fourth hospital day, her transaminases started to rise (maximum elevation of 7-8x normal). An acute viral hepatitis panel and other markers of liver disease were negative. Her symptoms resolved with paracentesis and sodium restriction. She was discharged home on the seventh hospital day. Her transaminases normalized 28 days after admission. OHSS is a rare cause of ascites and abnormal liver tests. Liver function test abnormalities accompany this syndrome in 30% of cases. The mechanism for liver abnormalities is not yet known. Gastroenterologists should be aware of OHSS as a cause of ascites and abnormal liver tests with potentially lethal consequences in its most severe form.

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Acute Pancreatitis Secondary to Migrated Gastrostomy Tube
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The aim of our study is to evaluate the pattern of acute pancreatitis due to the migration of Gastrostomy tube (GT). There were four cases of acute pancreatitis with a possible relation to migration of feeding tube. The diagnosis of acute pancreatitis was confirmed by significant elevation of serum Amylase and Lipase and CT scan findings of peri-pancreatic inflammatory changes. Clinical presentation, laboratory values, radiological findings and outcome of these patients were recorded. Initial symptoms were vomiting in two cases and abdominal pain and vomiting in another two cases. All four cases had a migrated GT balloon through the pylorus confirmed clinically or radiographically. Amylase and Lipase values were more than 10 times normal and values declined significantly within 24 hours of repositioning.
the feeding tube by pulling the balloon back into the stomach. Complete resolution of symptoms occurred within 48 hours after repositioning of the GT and intravenous hydration. Liver chemistries were within normal limits and there was no CT or sonographic evidence of intra or extra hepatic bile duct dilatation. Pancreas related complications were not observed in the four patients. However, two cases were complicated by pneumonia and urinary tract infection. All gastrostomy tubes were balloon type. In all cases, the initial physical exam done by the gastroenterologist revealed a migrated tube. Migration of gastrostomy tube through the pyloric channel may lead to acute pancreatitis. In this series, all cases were mild and responded to intravenous hydration and relocation of the balloon out of the duodenum and into the stomach. The cause for the development of acute pancreatitis can be the obstruction of ampulla of Vater or pancreatic duct by direct pressure of the migrated balloon. These cases could have been prevented by proper awareness of health care professionals or caretakers of physical signs of migrated feeding tube.

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Avoid Excessive Elevator Angulation When Placing a Biliary Wallstent® with the New Olympus V-Scope®
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The new Olympus V-Series duodenoscopes represent an advance in duodenoscope design by incorporating an elevator with a v-groove that allows a greater degree of angulation, allowing a guidewire to be held securely by the endoscopist. We describe a patient in which excessive elevator angulation may have contributed to malfunction and fracture of the stent delivery system. Placement of a 60 mm long covered biliary Wallstent® was planned in a patient with metastatic Ampullary Carcinoma who had biliary obstruction. A JF-260V duodenoscope was used for what turned out to be a difficult procedure due to space constraints within the duodenal C-loop imposed by the large ampullary tumor. After placement of the stent delivery catheter over a guidewire across the ampulla, the delivery system catheter was seen to form a 60-degree upward kink just beyond the duodenal end of the un-deployed Wallstent. This was straightened out with endoscope & catheter manipulation, and the Wallstent deployed in good position with good immediate stent expansion. When the delivery system catheter was removed it was found that the stent delivery system inner catheter bearing the radio-opaque markers had fractured, and was retained in the stent lumen within the bile duct. The decision was taken not to attempt removal of the retained catheter at this time to avoid the risk of stent migration. The patient's LFTs improved markedly following stent placement, and he received palliative chemotherapy subsequently. The retained delivery system catheter was removed endoscopically a month later without incident. We believe that excessive elevator angulation during Wallstent deployment contributed to fracture and retention of part of the Wallstent delivery catheter. The V-scope facility of increased elevator control by the endoscopist, but we caution that excessive up-angulation of the elevator should be avoided when deploying a Wallstent.

We present 2 cases of sinusoidal obstruction syndrome (S.O.S) also described as hepatic veno occlusive disease. Both female patients (with myeloblastic acute leukemia, 32 and 36 years old) had progressive jaundice and liver function deterioration 4 to 7 days after HCT. They also had conditioning with Bu/Cy regimen. Diagnosis was made after transjugular liver biopsy on the 7th and 10th day after HCT with severe impairment of coagulation and low platelet count (< 30,000). They were uneventful and showed hepatic congestion, sinusoidal dilatation and centrilobular hepatic injury and death, without significant inflammation. Specific treatment was promptly initiated after diagnostic confirmation, with infusion of defibrotide, a novel polynucleotido-biocloetide with adenosine receptor agonist activity. Clinical and biological improvement was immediate, with normal liver function tests at discharge 20 days after. We conclude that the transjugular liver biopsy is extremely useful in defining liver abnormalities after hematopoetic cell transplants.

815
An Uncommon Endoscopic Presentation of Primary Follicular Lymphoma in the Duodenum
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Primary Follicular Lymphoma (FL) of duodenum is rare. We here describe a case of primary duodenal lymphoma with unique endoscopic findings. 45 year old Caucasian woman presented with one month history of nausea, vomiting, and epigastric abdominal pain. There was no history of melena and weight loss. An upper endoscopy with biopsy revealed an abnormal ulcerated and thickened fold in the second portion of the duodenum. Histology noted for dense infiltrate of atypical lymphocytes suspicious for lymphoma. Four weeks later a repeat endoscopy with a side viewing duodenoscope was done which showed an abnormal thickened fold with erythema and ulceration, away from ampulla of VATER. Histology noted for infiltrate of small mature lymphocytes forming a follicle. An immunophenotypic analysis revealed monoclonal B-cells that were positive for CD45, CD19, CD20, and CD5 but negative for CD10. These findings were consistent with follicular B-cell lymphoma. Serologies for Helicobacter pylori, HIV, hepatitis C and celiac sparge were all negative. A computed tomography of chest, abdomen and pelvis did not reveal any abnormality including lymphadenopathy. A bone marrow biopsy with flow cytometry and cytogenetics were normal. Patient was treated for stage I, grade 1 follicular lymphoma (FL) of the duodenum with 3 cycles of rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone (R-CHOP) and radiation. After one year of follow up, patient remains asymptomatic with complete regression noted on a repeat endoscopy. Follicular lymphoma arising in the duodenum with nodularity and polyposis has been reported. This case is unique as it is presented with abnormal erythematous and ulcerated fold in the duodenum. Primary duodenal lymphoma if diagnosed early carries a favorable outcome with currently available treatment modalities.

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The Key Role of Transjugular Liver Biopsy in the Management of Liver Complications of Hematopoietic Cell Transplantation
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A patient undergoing hematopoietic cell transplant (HCT) is at risk for toxic, infectious and immunologic liver injury with a time span of 10–90 days. Myeloablative conditioning regimens may damage hepatic sinusoids, leading to hepatomegaly, right upper quadrant pain, fluid retention jaundice and a range of laboratory findings such as high transaminases and cholestasis.

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Diffuse Small Bowel Inflammation: A Case of Idiopathic Ulcerative Jejunitis
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Diffuse small intestinal inflammation is a rare finding which presents a diagnostic conundrum for most physicians. Its differential diagnosis includes conditions ranging from gastroenteritis to lymphoma. Ulcerative jejunitis (UJ) is a poorly understood disorder, which usually presents in the setting of celiac disease, and often is a harbinger of small bowel lymphoma. We present...
one of the few cases in medical literature of a patient, who developed UJ with a modest response to treatment with corticosteroids. The patient is a healthy 50-year old African American female who presented with a history of nausea, vomiting, and abdominal pain of one day's duration. The pain, described as tightness, was localized to the periumbilical and epigastric regions. The pain was quickly followed by vomiting and watery diarrhea. There was no obvious bleeding. These symptoms were followed by chills and low-grade fever. CT scan of the abdomen on admission revealed diffuse small bowel inflammation from the ligament of Treitz to the proximal ileum. Routine stool studies were negative. Anti-transglutaminase antibodies were negative. A push enteroscopy revealed severe ulceration and edema from the distal duodenum to the extent of the enteroscope. Biopsies revealed edema, abundant exudation, and some lymphocytic infiltration, compatible with chronic jejunitis. There were no granulomas, giant cells, vasculitis, or lymphoma. After a prolonged hospital stay marked by persistent symptoms, parental nutrition, a repeat enteroscopy, and a laparoscopic exploration, she was started on corticosteroids, which resulted in slow improvement but progressive improvement. UJ is a rare condition characterized by small bowel ulcerations, edema, abdominal pain, and malabsorption in the absence of any other etiology. Severe malabsorption leads to malnutrition and wasting. Malignant transformation into T-cell lymphoma is more common in the setting of celiac sprue. Early diagnosis, based on characteristic clinical, endoscopic, and histologic findings leads to early institution of corticosteroids. Corticosteroids are the mainstay of treatment, but are at best only moderately effective. Untreated, the prognosis is extremely poor, thus early recognition is imperative. Small bowel edema portends a different differential diagnosis to investigate. Ulcerative jejunitis may lead to malnutrition and T cell lymphoma. Early recognition and treatment with corticosteroids is imperative to attempt to minimize risk of these complications.

817
New Portable Enteral Pump Technology Allows Normal Toddler Activity
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A 2-year-old female with severe reflux, hypercholesterolemia, hypertriglyceridemia, and failure to thrive underwent a Nissen procedure at 17-months of age. A gastrostomy was placed, and tube feedings were started via a first generation portable pump (FGPP). The patient did not adapt well to two different models of FGPPs. The first FGPP did not allow for variable dose feeding, forcing the caregiver to fill the feeding bag every 3 hours to prevent overfeeding and resulting in missed feedings. The patient switched to a different FGPP which was too large for the patient to carry and had to remain in an upright position, limiting ambulatory benefits. Both FGPPs required frequent recharging, resulting in missed feedings and limited mobility. Gravity feedings were attempted; these were easier for the caregiver than the FGPPs, but the patient did not tolerate them. Retrospective Case Study: After the first 3 months of tube feeding, caregivers switched to a new generation portable pump (Infinity, ZEVEX Inc, Utah). The patient now reliably receives 120 ml every 3 hours and an overnight feeding of 50 ml/hr for 10 hours. The daytime feedings are performed with the patient carrying the pump in a backpack. Caregivers report no missed feedings and complete ambulatory mobility with the pump. After switching to the new pump, within 98 days, the patient gained 1.8 pounds and grew 1.25 inches. This case study illustrates how new technology facilitates the delivery of enteral feedings, leading to improved feeding plan compliance that supports growth and mobility.

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Metastatic Esophageal Adenocarcinoma Presenting as a Nasal Cutaneous Lesion
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Cutaneous metastasis of gastrointestinal cancers occur uncommonly, and those of esophageal origin even rarer. We present a case of a patient with no GI symptoms who was diagnosed with esophageal adenocarcinoma after biopsy of a cutaneous lesion on the nose. A 59 year old female presented for workup of an infiltrating, violaceous cutaneous lesion on the tip of her nose. The lesion was initially seen 6 months prior, but she had refused diagnostic evaluation until it grew to approximately 2 cm. Biopsy of the lesion revealed adenocarcinoma, likely of gastrointestinal origin. Past medical history consisted of hypertension and depression. She was an 80 pack-year smoker, and drank 2 glasses of wine per night. Her father had esophageal carcinoma of unknown type. She denied any gastrointestinal symptoms including dysphagia, pyrosis, abdominal pain, nausea, change in bowel habit and weight loss. The patient underwent EGD showing irregular, nodular, salmon-colored mucosa starting at 28 cm from the gums, extending to the gastroesophageal junction. Upon retroflexion, the irregular, ulcerated mucosa extended to the cardia. Biopsies showed invasive moderately well-differentiated adenocarcinoma. Staging evaluation included a CT scan of the chest and abdomen showing pulmonary and hepatic lesions consistent with metastasis (staged IVb). She underwent two courses of chemotherapy and received palliative radiation. She expired two months after the diagnosis was established. Metastatic lesions to the skin occur rarely with less than 0.5% involving the face. Most cases of cutaneous metastasis arise from malignant melanoma, breast and pulmonary carcinoma. Much rarer are cases of gastric or colonic adenocarcinoma that metastasize to the skin. We present a very rare case of a nasal cutaneous lesion as the initial symptom presentation of a metastatic esophageal adenocarcinoma. Three cases of cutaneous metastasis of esophageal carcinoma have been published, two of which were located on the scalp. The cutaneous lesions can present as nodules, cellulitis, bullous lesions or ulceration. As in this case, most instances of cutaneous metastases of GI origin are diagnosed at a late stage and confer a poor prognosis. The aim of treatment in most of cases is palliative only.

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Hemobilia with Gallbladder Necrosis: Report of Two Cases
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Intracholecystic hemorrhage associated with hemobilia and fulminant gallbladder (GB) disease is rare. We report 2 cases of major GB bleeding complicated by wall necrosis and catastrophic sequelae requiring urgent laparotomy.

Case 1: A 72 y.o. male presented with a 2 day hx. of severe, diffuse, sharp abdominal pain. Past medical history: atrial fibrillation. Medications included aspirin, clopidogrel, and warfarin. On exam, temp. = 38.5C; pulse = 100/min.; BP = 85/48 (sitting); heart rhythm was irregularly irregular; abdomen: epigastric tenderness without guarding or peritoneal irritation. Hgb. = 7.4 gm/dl. WBC = 10900 (12% bands). Platelets = 133000; INR = 2.2. PT = 22.8. PTT = 29.8 sec.; abdominal ultrasound = echogenic densities in the GB suspicious for blood clots. CT = hyperdensity of the GB lumen and ascitic fluid with density consistent with blood. Laparotomy with cholecystectomy revealed perforated GB, hemoperitoneum, and clots in the GB lumen; acalculous cholecystitis; full-thickness wall congestion, hemorrhage, thrombosis; and perforation at the fundus.

Case 2: A 69 y.o. man with recent chemotherapy for non-small cell lung cancer complained of severe upper abdominal pain for 2–3 days. He had a history of diabetes. Medications included 1 aspirin daily. On exam, temp. = 35.9C; pulse = 80 beats/min.; BP = 100/60(sitting). Cardio-respiratory exam was normal. The abdomen was distended, tympanic and diffusely tender with guarding. WBC = 21, 500; platelets = 110000. AST elevated at 171. Alkaline phosphate elevated at 422. Bilirubin(D/T) = 0.9/1.6. Abdominal ultrasound: biliary sludge, thickened GB wall. Abdominal CT: large GB with 3 units of blood in the lumen; biliary hamartomas were present.

Discussion: Intracholecystic hemorrhage not due to gallstones is rare. In each case, multiple mechanisms may have contributed, including atrial fibrillation and anti-coagulation in case 1, the effect of immunosuppression
Cytomegalovirus (CMV) infection of the stomach is rare even in immunocompromised patients. We report an unusual case of CMV infection presenting as gastritis in an immunocompetent patient. A 78-year-old black female with a history of hypertension, dyslipidemia, peripheral vascular disease and stroke, presented with history of abdominal pain, weight loss, persistent nausea and vomiting for 2 weeks. The pain was described as dull, aching and localized to the epigastric region. There was no associated fever or change in bowel habits. She denied hematemesis, hematochezia or melena. She denied any unusual food intake or travel. Pertinent medication included clopidogrel. On examination, the patient was afibrile with normal vital signs. Abdominal examination was significant for mild epigastric tenderness, active bowel sounds and no organomegaly. She underwent a workup including a CT scan of the abdomen and pelvis which showed mild thickening of the distal stomach. Subsequent EGD showed friable, erythematous and edematous antral mucosa. Biopsies of the antrum showed gastritis with viral inclusions consistent with CMV gastritis. The patient was treated with valganciclovir 450 mg PO BID. HIV testing was negative and CD4 count was 550/μL. She had a follow up endoscopy showing resolution of the gastritis. Repeat biopsies showed no morphological evidence of CMV infection. The patient reported resolution of her symptoms. She also had a colonoscopy to look for any CMV changes in the colon, which was not present. There are few reported cases of CMV gastritis in immunocompromised patients, such as HIV infected patients, and bone marrow and solid organ transplant recipients. CMV infection of the stomach is rare even in immunocompetent patients.}

A Case of Gastric Sarcoidosis Presenting as Linitis Plastica
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Sarcoidosis is a systemic granulomatous disease frequently involving the lungs, lymph nodes, eyes and skin. Gastric sarcoidosis, though the most commonly involved portion of the gastrointestinal tract, is rarely seen. We describe a case of gastric sarcoidosis which presented as linitis plastica. A 35-year-old black female with history of pulmonary sarcoidosis diagnosed three years prior presented with abdominal pain and persistent vomiting for two weeks. The pain was described as burning, located in the epigastrum, and worsened postprandially. She also reported nausea, vomiting and weight loss. She denied diarrhea, fever or any other gastrointestinal symptoms. She tried esomeprazole without any relief. On examination, the abdomen was soft, with moderate tenderness in the epigastrum and left upper quadrant. Bowel sounds were active. Rectal examination showed brown guaiac negative stool. The patient underwent EGD, which revealed a diffuse inflammatory lesion involving approximately 50% of the circumference of the gastric body, with the appearance of linitis plastica. Multiple biopsies from the lesion were obtained. The pathology revealed multiple noncaseating epithelioid granulomas suggestive of gastric sarcoidosis. No malignant cells were noted. CT scan of the abdomen and pelvis showed thickening of the body of the stomach. She was started on prednisone 40mg once daily, then gradually tapered to a maintenance dose of 10mg once daily, with complete resolution of symptoms. A repeat upper endoscopy showed disappearance of the previously noted lesions. Gastric sarcoidosis is rare, with only 60 cases described in the literature. Patients may present with epigastric pain, pyrosis, and nausea and vomiting secondary to narrowing of the gastric lumen due to granulomatous inflammation and fibrosis of the stomach wall. Weight loss can be severe, often raising a suspicion for malignancy. There have been a few reported cases of upper GI bleed, which may be massive and fatal. Endoscopic and radiographic findings may be nonspecific. Diagnosis rests upon histological evidence of noncaseating granulomas in a patient with clinical evidence of sarcoidosis. We report a case of gastric sarcoidosis that had an appearance of linitis plastica, giving the false impression of malignancy. There was complete resolution of symptoms and endoscopic findings with corticosteroid therapy.

HCV-Associated Lymphoma Presenting as Splenic Vein Thrombosis
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Malignancy, most commonly pancreatic, may compress, erode or inflame the splenic vein resulting in splenic vein thrombosis (SVT). Isolated gastric varices may develop due to retrograde flow into short gastric veins from collaterals of the bypassed vessel. Lymphoma is an exceptional cause of this potentially catastrophic complication. To alert clinicians to its spectrum and potential for misdiagnosis, we report a case of SVT and gastric varices due to hepatitis C virus (HCV)-associated lymphoma.

Case Report: A 44 y.o. male with known HCV and sustained virologic response to treatment presented with 2 wks. of dyspepsia. Physical exam:
unremarkable. Stool was occult blood positive. Hemoglobin = 14.0 gm%, platelet count = 290000, AST = 18, ALT = 15. Normal hepatic synthetic function. UGI endoscopy: non-bleeding gastric varices without esophageal varices. CT scan: gastric wall thickening and lymphadenopathy of the celiac axis, with compression of the portal-splenic vein junction. The splenic vein was not visualized, and assessed as occluded. Mesenteric lymph node biopsy: diffuse large B-cell lymphoma. One year after chemotherapy–induced remission, SVT persisted on imaging. At that time, the patient had 1 episode of coffee-ground emesis and a decrease in hemoglobin to 7.0 gm%. UGI endoscopy: no active bleeding or stigmata of recent bleed from gastric varices. He underwent splenectomy to eliminate gastric varices.

Discussion: Because of the anatomic proximity of the pancreatic tail and splenic vein, most cases of SVT and isolated gastric varices are due to acute and chronic pancreatitis or pancreatic cancer. Non-pancreatic metastatic malignancy is a rare etiology. Misdiagnosis of the underlying disorder may occur due to (1) low index of suspicion (2) absence of clinical or biochemical evidence of portal hypertension (3) absence of associated esophageal varices (4) gastric varices may be mistaken endoscopically for hypertrophied or inflamed fundal folds (5) gastric varices may be decompressed by hypotension secondary to acute bleeding. Delayed diagnosis of lymphoma may have occurred if gastric varices were assumed to be due to HCV, especially if evidence of cirrhosis or portal hypertension were present. This case illustrates a rare etiology of SVT and an unusual extrapleural manifestation of HCV. Isolated gastric varices on endoscopy should alert physicians to possible SVT. Lymphoma involving the splenic vein must be considered in selected cases of unexpected or unexplained SVT, gastric varices, or GI bleeding.

Bleeding from an Ulcer within a Multi-Septated Periampullary Duodenal Diverticulum Successfully Treated with Endoscopic Therapy
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Although colonic diverticulae frequently cause lower GI hemorrhage, bleeding from duodenal diverticulae is rare. The literature describes endoscopic approaches to obtaining hemostasis with vascular lesions within colonic diverticulae, including injection, cautery, and clipping, but the endoscopic management of duodenal diverticular hemorrhage is not well-described. We report a case of GI bleeding due to an ulcer within a periampullary duodenal diverticulum (PADD).

Case Report: A 58-year-old man with a history of hemochromatosis, gout, and obscure gastrointestinal bleeding presented to our ER with melena, dizziness, and weakness. He had been admitted nine months earlier to an outside hospital for similar reasons, where he underwent upper endoscopy (EGD), colonoscopy, and capsule endoscopy without a clear source identified. He was readmitted to the outside hospital one week earlier, presenting with recurrent melena, and was found to have bleeding from within a PADD. Injection sclerotherapy was performed, and he was stabilized and discharged. When the bleeding recurred, he was advised to come to our institution for further management. On admission, he had stable vital signs and an unremarkable abdominal examination. He denied the use of aspirin or NSAIDs. His hemoglobin on admission was 7.0 mg/dL. EGD confirmed bleeding from a PADD. Side-view duodenoscopy revealed a PADD with multiple septations. An ulcer with a visible vessel but no active bleeding was seen on the apex of one of the septae. The papilla was not clearly visualized. Attempts at clipping were unsuccessful through the side-viewing endoscope. Bipolar electrocautery with 30 W was performed to obliterate the vessel and prevent further bleeding. The patient experienced no complications from the treatment. Follow-up EGD at 72 hours documented vessel obliteration. Serology for H. pylori was negative. Follow-up endoscopy has revealed nearly complete re-epithelialization of the ulceration. The patient has been maintained on high-dose pantoprazole and sucralfate, and has had no recurrent episodes of overt bleeding. This case documents the ability to use bipolar cautery to manage bleeding from a PADD, without inducing pancreatic or biliary complications. Further refinements in technology may be warranted to permit endoscopic clips to be deployed more easily through a side-viewing duodenoscope.

Eosinophilic Esophagitis Complicated by Microperforation and Pneumomediastinitis Missed by an Esophagogram
Navakaonth Gorrepati, MD, MPH, Sung Yang, MD, MD, Sung Yang, MD. IM, William Beaumont Hospital, Royal Oak, MI and GI, William Beaumont Hospital, Royal Oak, MI.

Eosinophilic Esophagitis (EE) is being increasingly recognized as a cause of intermittent dysphagia, atypical chest pain and food impaction. One study noted that patients with EE maybe at increased risk of perforation during an EGD. Diagnosis of a perforation is usually made by an esophagogram. Case: A 39-year-old woman presented to the emergency room with an esophageal food impaction of two hours duration. She had several similar episodes in the past (around 3–4 per year), which resolved spontaneously on their own. She was otherwise healthy. Upper GI endoscopy showed food impaction at the GEJ on a Schatzki’s ring. Food was gently pushed into the stomach and there was a mild tear of the Schatzki’s ring with minimal bleeding. There were features of feline esophagus. A single esophageal ulcer was also noted at the site of food impaction. Four hours later patient developed severe mid sternal chest pain, nausea, vomiting, fever and tachycardia. An esophagogram showed no evidence of extravasation. Radiographs of the neck and chest did not show any acute process. A CT scan of the chest done five hours later showed extensive pneumomediastinitis with air visualized from the base of the neck dissecting inferiorly to the wall of the stomach. [figure1]Patient was kept NPO and was started on intravenous piperacillin tazobactam. Proton pump inhibitors were also given. After a period of seven
Chronic Gastrointestinal Infections/Parasitosis in Clinical Practice  
William P. Stappy, MD,* Private Practice, Los Angeles, CA.

Patients seen in consultation for non-specific gastrointestinal complaints (foregut, midgut, and hindgut) with 'negative' endoscopies, stool for O&P, and abdominal ultrasound are often dismissed as 'functional' disorders. The purpose of this report is disclose the presence of chronic gastrointestinal infection/parasitosis in such a population over ten years of practice. Patients (672) referred for non-specific gastrointestinal dysfunction were tested for the presence of infection/parasitosis. A combination of saliva (IgA and IgG), stool (microscopic and antigen detection by florescence microscopy) by Diagnos-Techs, Inc. are the subjects of this report. Patients with chronic gastrointestinal complaints without demonstrable pathology by endoscopic or radiographic examination are likely to have infections/parasitosis. A third of these have more than one pathogen. A third of patients are spouses, 'significant others', children. This indicates person to person transmission is the primary path for these disorders and these conditions are grossly underestimated.

NUMBER OF PATIENTS = 672

Cryptosporidium parvum 243
Ameoba histolytica 213
Helicobacter pylori 212
Giardia lambium 163
C. difficile 114
Blastoctysis hominis 41
Ascaris lumbricoides 64
Tinea solium 32
Trichinella spiralis 23

NUMBER OF INFECTIONS/PARASITES = 2210

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Metastatic B-Cell Lymphoma Resulting in Biliary Strictures  
Gopal Narasimhan, MD, Amir Awad, MD, Franklin E. Kasmin, MD, Seth A. Cohen, MD, Jerome H. Siegel, MD.* Division of Digestive Diseases, Beth Israel Medical Center, New York, NY.

Strictureing of the biliary tree resulting in jaundice and pancreatitis is an uncommon manifestation of B cell lymphoma. Diagnosing malignant spread with ERCP using brush cytology has been only rarely reported. A 27 year old male presented with a 1 week history of mid-epigastric pain radiating to his flanks bilaterally. The pain was sharp in nature, worse after eating causing nausea and vomiting for 3 days. For several days prior to presentation, he noticed yellowing of his sclera and jaundice. He had no significant past medical history and denied excessive alcohol use. Initial amylase was 194 u/l (28–100 u/l) and lipase 493 u/l (10–60 u/l) with normal serum chemistries and blood count. Total bilirubin was elevated to 11.4 mg/dl (0.1–1.2 mg/dl) as was serum alkaline phosphatase – 161 u/l (30–125 u/l). CT of the abdomen and pelvis showed findings consistent with acute pancreatitis and diffusely enlarged mesenteric lymph nodes. Ultrasound was negative for gallstones, however there was mild dilatation of the common bile duct (CBD) to 7mm. MRI & MRCP were unrevealing for the cause of his jaundice. Upper endoscopy was performed (GIF-140, Olympus America) and showed an ulcerated gastric nodule of which biopsies were taken revealing diffuse large B cell lymphoma. ERCP was performed at an outside institution, and despite multiple attempts, the CBD could not be visualized or cannulated. An ERCP was repeated at our institution several days later which revealed a pancreatic duct (PD) stricture distal to the genu with dilatation of the proximal PD. Additionally, a stricture was seen affecting the distal third of the CBD with proximal dilatation to 2 cm. A sphincterotomy was performed and brushings of the CBD & PD were obtained before placing stents into these ducts. The brushings revealed clusters of neoplastic cells positive for CD-20, diagnosing metastatic spread of B-Cell lymphoma to the biliary tree. Jaundice with stricturing of both the CBD and PD causing ductal dilatation and a double duct sign on ERCP is infrequently seen as the presenting complaint in malignant B cell lymphoma. In addition, it is extremely uncommon to diagnose spread of B-cell lymphoma by brush cytology making this case very unique.

828

A Rare Cause of Iron Deficiency Anaemia  
Ravi Madhotra, FRCP, MD,* Chris Akubuine, MD, Vijay Deasai, FRCPath, MD, Andrew Mitchell, FRCS, MD Gastroenterology, Milton Keynes General Hospital, Milton Keynes, United Kingdom; Pathology, Milton Keynes General Hospital, Milton Keynes, United Kingdom and Surgery, BMI Saxon Clinic, Milton Keynes, United Kingdom.

We present a rare case of iron deficiency anaemia due to metastatic malignant melanoma of small bowel that occurred 9 years after curative resection of melanoma from right foot. A 48 yr old white lady presented with IDA, and abdominal pain for 4 weeks. A malignant melanoma was removed from her right foot in 1995 and a local recurrence was excised 2 yrs later. she was discharged from surveillance follow up 5 years later. On examination she looked pale but systemic exam was otherwise normal. Laboratory results showed Hb 9.9 g/dL with MCV 67 fl. CRP was 67.6 mg/L. Liver and renal profiles, EMA and tumour markers were normal. Stool tests (x 3) were negative for occult blood. Upper endoscopy and colonoscopy were normal. Abdominal and pelvic ultrasound exam was normal. Two weeks later her Hb dropped to 5.7g/dL with CRP rising to 170 mg/L. As the stool tests were negative for occult blood we requested a CT scan rather than small bowel enema. CT scan showed a large (16mm) jejunal mass (Figure 2) and liver lesions suggestive of metastasis deposits. A small bowel enema confirmed a large mass in mid-jejunum. The jejunal tumour was excised. Liver lesions were biopsied. The resected jejunal mass and liver biopsies confirmed metastatic melanoma (Figure 1). Patient is currently undergoing chemotherapy 6 months post surgery. Metastatic melanoma to GI tract is a relatively uncommon cause of iron deficiency anaemia. Metastasis of melanoma to GI tract is particularly rare after nearly a decade of curative resection. It is
important for clinicians to bear in mind the importance of past history of melanoma, however remote it may be. [figure1][figure2]
vomiting. She denied shortness of breath, palpitations, and dizziness. Patient also had been in stress because of job change and she was also moving. She had no prior cardiac history and had no previous cardiac workup. Otherwise she was physically active. She had a history of 25-pack year smoking and was a current smoker. Her vitals were stable and her exam was unremarkable. Her EKG admission showed ST segment elevation in leads V2, V3 and V4 and her initial Troponin was 14. She was taken for emergent catheterization, which showed normal coronaries and anteroparial hypokinesis. The echo done following day showed apical hypokinesis; her EF was normal. She was started on beta blockers. She had a CT scan of abdomen, which was normal. Follow up echocardiogram done 4 weeks later was normal with resolution of apical hypokinesis. This case illustrates an unusual complication of colonic surgery. The cause of this syndrome is not entirely known but may be related to microvascular dysfunction. Despite the initial presentation these patients usually do very well and wall motion abnormalities typically resolve. The diagnosis is based on characteristic ventriculography with normal coronaries. They may also have higher levels of catecholamines in their blood, which this patient had. The long-term treatment is not clearly defined.

**Non-Cirrhotic Portal Hypertension (Banti Syndrome) in a Liver Transplant Patient**

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To make physicians aware that portal hypertension can develop after liver transplantation in the absence of cirrhosis. The diagnosis was confirmed by detailed portal pressure assessment angiographically, multiple liver biopsies and the patient’s response to splenectomy. A 39 y.o. woman developed fulminant hepatic failure of unknown etiology in January 2001 and required liver transplantation. Her post-operative course was unremarkable until late 2004 when she developed left-sided abdominal fullness and splenomegaly on exam. An MRI/MRA showed patent portal, superior mesenteric and splenic veins with scant ascites. Liver biopsy showed chronic hepatitis with rare septal fibrosis (F-I). An EGD revealed grade 1 varices. Over the next year, her abdominal discomfort worsened. Repeat liver biopsy revealed focal portal and periportal fibrosis (F-I-H) but no cirrhosis. EGD revealed 5 columns of grade 4 varices with red wale signs and severe portal gastropathy. Labs: Hgb 8.7, plt 64000, normal PT/PTT, and albumin of 3.3. Ultrasound with doppler documented normal blood flow in the portal and hepatic veins. The patient was admitted to the hospital for banding of her esophageal varices. MRI/MRA of the abdomen revealed massive splenomegaly and small ascites, but patent vasculature. Blood cultures (including fungal and viral), sputum cultures and urine cultures were negative. Banti Syndrome was confirmed by a hepatic venogram with measurement of hepatic venous wedge pressure and hepatic venous pressure gradient. Splenectomy was recommended and the operation went well. Her spleen was 21 cm long and weighed 882 g. Her abdominal discomfort completely resolved and her cell counts rose dramatically. Six months later, the patient is doing well, with repeat EGD showing grade 1 varices and resolution of her portal gastropathy. The pathogenesis of Banti syndrome, also called non-cirrhotic portal hypertension, is not known. Transplant hepatologists should be aware that abdominal pain, anorexia, anemia and thrombocytopenia may be caused by this disorder. This is the first documented case of Banti Syndrome in a post-transplant patient.

**Esophagogastric Fistula: A Case of Esophagogastric Fistula in an HIV Patient with Previous Esophageal Ulceration**

Andrew N. Pearson, MD, Subbaramiah Sridhar.* Gastroenterology and Hepatology, Medical College of Georgia, Augusta, GA.

Esophagogastric (EG) fistula is a rare entity, described following Nissen surgery, Crohn’s disease and chronic reflux with ulceration.

Case Report: A 44-year-old male pt. with a history of end stage HIV presented with profound weakness, odynophagia, coughing and wt loss of 40 lbs. over 4 months. His CD4 count was 3. An upper endoscopy performed one year earlier showed 2 ulcers spanning the esophagus 30–39 cm. A repeat EGD on this admission revealed a large defect in the esophagus at 30 cm opening into a friable, granular, ulcerated tract that led into the cardia of the stomach. A wire was passed into the stomach via the false lumen. The scope was then passed through the true lumen of the esophagus and on retroflexed view the wire was visualized exiting the false lumen. The two orifices were
separated by normal appearing gastric mucosa. Brushings and biopsies obtained from the fistulous tract showed only non-specific inflammation. A barium swallow and contrast enhanced CT scan confirmed the ulcerated false lumen communicating with the stomach with no other abnormality. A polyflex-covered stent (18–23mm wide and 9cm length) was used to cross the opening of the fistula, thus closing the EG fistula tract. A subsequent barium study confirmed that the stent was bridging the fistula and no barium entering the fistula. Following placement of the stent the patient’s symptoms resolved completely and he was discharged from the hospital.

**Discussion:** This is the first case of esophagogastric fistula described in an HIV patient. Although esophagogastric (EG) fistula is described rarely in other conditions, it should be considered in the differential diagnosis of odynophagia in HIV disease. Endoscopically placed covered esophageal stent is a practical, minimally-invasive option to close such fistula. [Figure 1]

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**835**

**Combined Utility of Capsule Endoscopy and Directed Push Enteroscopy for Identifying Small Bowel Lymphoma**

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A 75-year-old male with a history of gastroesophageal reflux disease presented to an outside hospital after a syncopal episode. Prior to arrival, he had three months of vague epigastric discomfort unrelated to eating, one month of progressive fatigue and dyspnea, and one week history of melena. On exam, his abdomen was soft and non-tender with guaiac positive stools. Laboratory values revealed Hgb of 6.9 g/dL (MCV 85 fL, RDW 25%). Esophagogastroduodenoscopy (EGD) and colonoscopy were normal without a bleeding source identified. Small bowel follow through was also normal. He was discharged on pantoprazole after symptomatic improvement with blood transfusions. One month later, he was admitted to our hospital with worsened fatigue, dyspnea on exertion, and recurrent melena. Laboratory assessment revealed a Hgb of 6.0 g/dL (MCV 83 fl, RDW 24%). Repeat EGD and colonoscopy as well as enteroscopy were all normal. A video capsule endoscopy was performed revealing several ulcerated masses in the proximal jejunum including one with a fresh blood clot. As these lesions were within reach, push enteroscopy was repeated and the ulcerations visualized. Biopsies were consistent with large B-cell lymphoma resulting in proximal jejunal resection with primary anastomosis.

**Discussion:** Gastrointestinal (GI) bleeding with its point of origin outside the reach of EGD and colonoscopy represents an extraordinary diagnostic and therapeutic challenge. In approximately 5% of cases, the bleeding source is located in the small bowel. Optimal diagnostic approach to identify small bowel lesions is unknown. After a non-diagnostic EGD and colonoscopy, push-enteroscopy is often considered the next intervention. However, the procedure can be technically difficult, limited by intestinal motility and looping, with potential complications of post-procedure abdominal pain, intussusception, and pancreatitis. Also, only a limited portion of the proximal jejunum can be examined. Several randomized, controlled trials have shown capsule endoscopy (CE) to have a higher diagnostic yield for obscure GI bleeding compared to enteroscopy. In our patient, the malignancy was initially missed by enteroscopy but successfully visualized once guided by CE findings. Targeted enteroscopy then led to tissue diagnosis and assisted in operative planning. Given its higher diagnostic sensitivity, it should be considered before push enteroscopy for diagnostic work-up of patients with obscure blood loss.

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**836**

**Gastric Outlet Obstruction Secondary to Breast Cancer Metastasis**

Gopal Narasimhan, MD, Petros C. Bonias, MD, Amir Awad, MD, Elpidio Jimenez, MD, David H. Robbins, MD, Henry C. Bodenheimer, Jr, MD, Albert D. Min, MD.∗ Division of Digestive Diseases, Beth Israel Medical Center, New York, NY and Neurology, Pathology & Laboratory Medicine, Beth Israel Medical Center, New York, NY.

A 40 year old woman presented to the emergency department complaining of sharp, intermittent epigastric pain and vomiting for two days. The patient had a history of metastatic invasive ductal carcinoma of the breast. A CT Scan of the abdomen and pelvis with contrast revealed moderate pelvic ascites and a markedly distended stomach – consistent with gastric outlet obstruction. On EGD, an ultra-thin (5.9 mm – GIF XP-160, Olympus America) videoscope was unable to be passed beyond the duodenal sweep. Multiple biopsies were performed revealing marked lymphatic tumor embolism by metastatic carcinoma (Figure 1). The capillaries within the duodenal mucosa were severely distended and showed multiple clusters of malignant epithelial cells with features consistent with metastatic lesions from her primary ductal breast carcinoma. The true incidence of breast cancer metastatic to the gastrointestinal tract is unclear. Few clinical series have described this entity, and specific instances have been described only as case reports. Studies have shown preferential involvement of gastrointestinal metastases by infiltrating lobular carcinomas, despite the increased prevalence of ductal carcinomas in breast cancer in general. Ductal carcinoma of the breast in one study accounted for only 0.2% of metastasis to the GI system. Our patient had metastatic disease secondary to invasive ductal carcinoma of the breast causing a gastric outlet obstruction, a complication rarely reported in the literature, making this case unique. [Figure 1]
Collagenous Sprue Masquerading as Crohn’s Disease
Neeraj Sharma, MD, Amit Agrawal, MD, Bright Williamson, MD, Brenda Hoffman, MD, FACG,* Department of Gastroenterology and Hepatology, Medical University of South Carolina, Charleston, SC.

Collagenous sprue has been recognized as a refractory form of celiac sprue. Though both disorders may share clinical and pathological features, we report a case of collagenous sprue that was completely unresponsive to a gluten-free diet and had been previously treated as Crohn’s disease.

Case: 58 year old white female with no past medical history presented with six months of diarrhea and weight loss. She had 5–10 watery, non-bloody bowel movements per 24 hours including a nocturnal component. During this time, she lost 30 pounds. At previous institutions, upper and lower endoscopy, as well as capsule endoscopy, were interpreted as enteritis and colitis. Biopsies were interpreted as consistent with Crohn’s disease. Despite negative serologies for sprue, she was treated for sprue with no improvement in symptoms after a two month gluten-free diet. At our institution, stool studies were negative for infectious etiologies. Serologic tests for inflammatory bowel disease were also negative. Enteroscopy showed patches of nodular, denuded small bowel. [figure1]Biopsy showed villous atrophy with collagen deposits consistent with collagenous sprue. [figure2] Her symptoms improved significantly with complete bowel rest and hyperalimentation. The patient was treated with azathioprine and prednisone. At 6-week follow up, the patient had azathioprine-related hepatitis; she then received infliximab to keep her in remission and to avoid long-term prednisone. Collagenous sprue is a histopathologically distinctive lesion of the small bowel that is associated with chronic diarrhea and malabsorption. It may mimic inflammatory bowel disease or celiac disease. Collagenous sprue could represent a separate entity that is likely immune-mediated.

Gastric Trichobezoar Presenting as Acute Pancreatitis during Pregnancy
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Trichobezoars are rare occurrences, seen primarily in young females with trichophagia. Reported complications include obstruction, bleeding, perforation, and pancreatitis. Our patient, a 23 y/o female 18 weeks pregnant, was admitted for two days of epigastric pain. Postprandial vomiting had been present for two months. There was no history of alcohol use or pancreatitis. She appeared depressed with flat affect. A 10 cm firm mass was palpable in the epigastrium. Initial serum lipase was 3672 IU/L, liver enzymes were normal. Ultrasound revealed an intraluminal gastric mass; the gallbladder and bile ducts were normal. MRI study confirmed the presence of a large gastric mass suspicious for bezoar. Separate intraluminal matter was present throughout the duodenal sweep. The pancreas appeared normal. On further questioning, the patient admitted to twirling, pulling and ingesting her hair. Upper endoscopy revealed a large, hard foreign body with obvious hair, diagnostic of trichobezoar (Fig. 1). Small ulcerations were present in the stomach, and separate hair accumulations were seen in the duodenum. Endoscopic removal was not feasible. Total parental nutrition was begun; serum lipase decreased to normal after four days. At exploratory laparotomy, the trichobezoar contoured the stomach outline, and was removed through an anterior gastrotomy (Fig. 2). An enterotomy was performed to remove the duodenal bezoar. Pathology showed the gastric bezoar composed primarily of hair; small fragments of decorative tinsel, paper and plastic were also present. The patient recovered uneventfully and fluoxetine was administered for trichotillomania and trichophagia. This is the first reported case...
of gastric trichobezoar presenting as acute pancreatitis during pregnancy.

839
Schwannoma of the Descending Colon: A Rare Tumor Mimicking Carcinoma
Natalya Belova, MD,* Nicholas Triantafillou, MD. Gastroenterology, New York Hospital Queens, Flushing, NY.

A 75 year old male presented to a gastroenterologist for the work-up of an accidentally found descending colon mass. CT scan of the abdomen performed for evaluation of hematuria revealed non-obstructing 4.2 cm mass involving distal descending colon, highly suspicious for adenocarcinoma, small lymph nodes in adjacent mesentery and borderline enlarged retroperitoneal lymph nodes. Patient denied abdominal pain, change in bowel habits or hematochezia. His previous history included hypertension, atrial fibrillation and benign prostate hypertrophy. Previous colonoscopy was performed 7 years ago and did not reveal any lesions. There was no family history of benign or malignant tumors, or neurofibromatosis. Results of a physical examination of the abdomen and other systems were unremarkable. Laboratory tests (CBC, chemistry, LFTs) were within normal limits. During colonoscopy a large protruding mass was found in the distal descending colon, 40 cm from anal verge. It appeared submucosal with normal overlying mucosa, hard in consistency. [figure1]Biopsy of the mass was unrevealing, except for melanosis coli. Resection of the left and sigmoid colon was performed with findings of 3.1 × 3.8 cm submucosal mass, well circumscribed, orange-tan in color, extending into serosal fat. Histology was consistent with cellular schwannoma. Immune stains confirmed the diagnosis (positive for S-100 protein; negative for CD117, CD34 and smooth muscle actin). Seven resected lymph nodes were without significant pathology. We reported a very unusual neoplasm of the colon. Schwannomas are mostly benign tumors deriving from the cells of Schwann that form the neural sheath. The gastrointestinal autonomic nerve tumors are uncommon stromal tumors, representing 2–6% of GIST, with most common location in the stomach and small intestine. Schwannomas of the colon are very rare. The diagnosis of GI schwannoma is difficult preoperatively; lesions appear as subepithelial tumors and biopsy specimens are likely to be normal. Immunohistochemical studies are required to distinguish schwannoma from other GIST. Surgical resection with wide margins is the cornerstone of treatment.

840
Definitive Diagnosis by EUS FNA of Multiple Intra-Abdominal Lymphoid Lesions
Kaumudi Somnay, MD,* Natalya Belova, MD. Gastroenterology, New York Hospital Queens, Flushing, NY.

A 44 year old male with history of AIDS presents with fever, dysphagia, occasional vomiting and weight loss of four months’ duration. On physical exam his temperature is 102°F, blood pressure is 130/80 mm Hg, heart rate is 115 beats per minute. He appears chronically-ill. Chest is clear to auscultation; abdomen is soft, non-tender, non-distended, without hepatosplenomegaly or palpable masses; on rectal exam stool is hem negative. There are no palpable lymph nodes. Labs show a Hgb of 7 g/dL and Hct of 21%, MCV of 71 fl.; CD4 cell count is 5 cells/µL. LFTs reveal: AST 230 U/L, ALT 167 IU/L, Alkaline Phosphatase 383 U/L, total bilirubin 1 mg/dL. EGD performed for evaluation of patient’s dysphagia reveals significant extrinsic compression of the stomach. [figure1]A CT scan of the abdomen is done which reveals a 6.1 × 4.1 cm low density mass in the splenic hilum, indenting the posterior aspect of the stomach, smaller mass in the paragastric region, and possible microabscesses throughout the spleen. The working diagnosis is lymphoma. An EUS with both transgastric FNA and Trucut biopsies is performed for tissue diagnosis before starting treatment. [figure2]Fine needle aspiration reveals both purulent material and necrotic tissue. Patient tolerates procedure without complications. Histological analysis shows necrotic tissue mixed with lymphoid cells, histiocytes, caseating granuloma and presence of acid-fast bacilli. Further analysis identifies acid fast bacilli as Mycobacterium tuberculosis. Patient is treated with four drug regimen of isoniazide, rifampin, pyrazinamide and ethambutol. He improves with treatment and is discharged. This case demonstrates that EUS with FNA is a safe and valuable tool for providing a definitive diagnosis of intra-abdominal lymphoid lesions.
Impaction of a biliary basket or fracture of the traction wire during mechanical lithotripsy with a trapped stone is a rare, but well-known complication. We present here a novel method for retrieval of an entrapped Dormia basket. A 65 Y.O. female patient presented initially to another institution and had an open cholecystectomy for symptomatic gallstones. The patient had multiple ERCPs with mechanical lithotripsy for retained CBD stones, which failed to clear the bile duct. The patient was referred to our institution for further management of her difficult CBD stones. At the time of presentation, the patient had intermittent right hypochondrial pain, serum alkaline phosphatase 180 IU/L (normal 50 to 125 IU/L) and normal bilirubin. The ERCP revealed biliary sphincterotony and dilated CBD with a 1.5 Cm stone. The biliary orifice was dilated with a 15 mm balloon; the stone was engaged with a mechanical lithotriptor (Duralith lithotripsy; ConMed). However, upon trying to crush the stone the lithotriptor traction wire broke in the shaft. The scope was then removed and only 20 Cm of the bare wire was left outside of the patient’s mouth. The stone was entrapped in the basket and could not be disengaged. This wire was too short to place a Soehendra lithotriptor orifice was dilated with a 15 mm balloon; the stone was engaged with a mechanical lithotriptor (Duralith lithotripsy; ConMed). However, upon trying to crush the stone the lithotriptor traction wire broke in the shaft. The scope was then removed and only 20 Cm of the bare wire was left outside of the patient’s mouth. The stone was entrapped in the basket and could not be disengaged. This wire was too short to place a Soehendra lithotriptor. The endoscope was advanced carefully and we were able to break the web leaving a mucosal tear. The scope was then advanced through the esophagus with mild resistance showing several small dimples that represented the small orifices of the pseudodiverticula. Biopsies from the stricture area and randomly from the esophagus revealed moderate chronic inflammation of the squamous epithelium. Based on these characteristic findings, we diagnosed her illness as EIPD. After the procedure the patient recovered uneventfully and was discharged home. Telephone follow ups at 4 and 10 weeks revealed complete resolution of her dysphagia.

Esophageal intramural pseudodiverticulosis (EIPD) is a rare benign disorder characterized by a typical radiological appearance of multiple, small, flask-shaped outpouchings in the esophageal wall. EIPD is mainly a disease of the elderly. It presents with progressive dysphagia that is related to esophageal stenosis or strictures in most patients. Its etiology and pathogenesis are largely unknown. A 78 Y.O. woman presented with a few months history of dysphagia, which had gradually become worse in recent months. Her main complaint was of the recurrent sensation of solid food getting stuck in her throat for few seconds, after which the food would proceed normally. Her symptoms became worse before her presentation. The swallowing of fluids was unaffected. There was no weight loss, hematemesis, gastroesophageal reflux symptoms, or accidental ingestion of corrosives. Her physical examination was normal and laboratory findings were within normal limits. A barium esophagogram was performed. This showed a nonobstructing cervical web with limited distensibility of the esophagus. In addition, there were numerous small barium-filled outpouchings through out the esophagus. An esophagogastroduodenoscopy was subsequently performed with a GIF 160 esophagogastroscope, 8.6 mm outer diameter (Olympus Optical, Tokyo, Japan). A crescent shaped web about 15 cm from the incisors was seen. The endoscope was advanced carefully and we were able to break the web leaving a mucosal tear. The scope was then advanced through the esophagus with mild resistance showing several small dimples that represented the small orifices of the pseudodiverticula. Biopsies from the stricture area and randomly from the esophagus revealed moderate chronic inflammation of the squamous epithelium. Based on these characteristic findings, we diagnosed her illness as EIPD. After the procedure the patient recovered uneventfully and was discharged home. Telephone follow ups at 4 and 10 weeks revealed complete resolution of her dysphagia.

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Retrieval of an Impacted Biliary Basket with a Trapped Stone. A Novel Technique
Amir Awad, MD, Jerome Siegel, MD, MACG, Franklin Kasmin, MD, Seth Cohen, MD, * Department of Medicine, Beth Israel Medical Center, New York, NY.

Impaction of a biliary basket or fracture of the traction wire during mechanical lithotripsy with a trapped stone is a rare, but well-known complication. We present here a novel method for retrieval of an entrapped Dormia basket. A 65 Y.O. female patient presented initially to another institution and had an open cholecystectomy for symptomatic gallstones. The patient had multiple ERCPs with mechanical lithotripsy for retained CBD stones, which failed to clear the bile duct. The patient was referred to our institution for further management of her difficult CBD stones. At the time of presentation, the patient had intermittent right hypochondrial pain, serum alkaline phosphatase 180 IU/L (normal 50 to 125 IU/L) and normal bilirubin. The ERCP revealed biliary sphincterotony and dilated CBD with a 1.5 Cm stone. The biliary orifice was dilated with a 15 mm balloon; the stone was engaged with a mechanical lithotriptor (Duralith lithotripsy; ConMed). However, upon trying to crush the stone the lithotriptor traction wire broke in the shaft. The scope was then removed and only 20 Cm of the bare wire was left outside of the patient’s mouth. The stone was entrapped in the basket and could not be disengaged. This wire was too short to place a Soehendra lithotriptor orifice was dilated with a 15 mm balloon; the stone was engaged with a mechanical lithotriptor (Duralith lithotripsy; ConMed). However, upon trying to crush the stone the lithotriptor traction wire broke in the shaft. The scope was then removed and only 20 Cm of the bare wire was left outside of the patient’s mouth. The stone was entrapped in the basket and could not be disengaged. This wire was too short to place a Soehendra lithotriptor. The endoscope was advanced carefully and we were able to break the web leaving a mucosal tear. The scope was then advanced through the esophagus with mild resistance showing several small dimples that represented the small orifices of the pseudodiverticula. Biopsies from the stricture area and randomly from the esophagus revealed moderate chronic inflammation of the squamous epithelium. Based on these characteristic findings, we diagnosed her illness as EIPD. After the procedure the patient recovered uneventfully and was discharged home. Telephone follow ups at 4 and 10 weeks revealed complete resolution of her dysphagia.

Sarcoidosis is a multi-system granulomatous disease of unknown etiology primarily involving the pulmonary and lymphatic systems. Clinically recognizable gastrointestinal involvement occurs in 0.1 to 0.9 percent of patients with sarcoidosis, although the incidence of subclinical involvement may be much higher. A 50 yr old African American woman with a 15 year history of inactive pulmonary and cutaneous sarcoidosis was referred for colorectal cancer screening colonoscopy. Past medical history included sickle cell trait, hypothyroidism, retinal tear and uterine fibroids. Physical examination was unaffected. There was no weight loss, hematemesis, gastroesophageal reflux symptoms, or accidental ingestion of corrosives. Her physical examination was normal and laboratory findings were within normal limits. A barium esophagogram was performed. This showed a nonobstructing cervical web with limited distensibility of the esophagus. In addition, there were numerous small barium-filled outpouchings through out the esophagus. An esophagogastroduodenoscopy was subsequently performed with a GIF 160 esophagogastroscope, 8.6 mm outer diameter (Olympus Optical, Tokyo, Japan). A crescent shaped web about 15 cm from the incisors was seen. The endoscope was advanced carefully and we were able to break the web leaving a mucosal tear. The scope was then advanced through the esophagus with mild resistance showing several small dimples that represented the small orifices of the pseudodiverticula. Biopsies from the stricture area and randomly from the esophagus revealed moderate chronic inflammation of the squamous epithelium. Based on these characteristic findings, we diagnosed her illness as EIPD. After the procedure the patient recovered uneventfully and was discharged home. Telephone follow ups at 4 and 10 weeks revealed complete resolution of her dysphagia.
Colonic involvement in sarcoidosis occurs rarely and has been reported to present with obstructive symptoms. Extensive literature review revealed only one previous report of colonic sarcoidosis presenting as colonic polyposis.

Rapid Progression of Liver Fibrosis in a Patient with HCV and Crohn’s Disease Treated with Infliximab
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To examine the relationship between chronic hepatitis disease progression in a patient with Crohn’s disease on infliximab therapy. We present a 52 year old non-alcoholic caucasian male with Crohn’s disease (CD). He was diagnosed in 1972, and maintained in remission on Azulfidine. Twenty years later he was diagnosed with HCV genotype 1. The patient was started on infliximab infusions, dosage 5mg/kg body weight, to concomitantly treat a worsening symmetrical arthritis and relapse of CD. As part of his HCV workup a liver biopsy (Biopsy A) revealed mildly active chronic hepatitis, no bridging fibrosis and mild steatosis. Upon re-evaluation 5 years later, a repeat biopsy (Biopsy B) was performed. Although normal transaminases there was a significant progression of disease to moderately active cirrhosis and moderate steatosis. This case shows rapid disease progression from mild fibrosis to cirrhosis in an HCV genotype 1 patient on infliximab. Previous case reports have examined viral load and liver function tests for up to a 12 month period and concluded that use of infliximab in Crohn’s patients with concomitant HCV is not detrimental. In contrast our case uses liver biopsy rather than surrogate markers and has a 5 year followup. The development of cirrhosis during this observation period suggests that infliximab may potentiate progression of fibrosis due to HCV and increase the amount of steatosis. Rapidly progressive liver fibrosis and steatosis in this setting is multifactorial. Infliximab might potentiate disease progression by interfering with a protective host immune response to infection. However, a confounding variable in the current case is the presence of significant steatosis. It is possible that the impact of infliximab is related to the steatosis and it is the steatosis rather than the infliximab that acts synergistically with HCV and results in more rapidly progressive disease. We have shown rapid development of cirrhosis in a CD patient after five years of infliximab therapy. We recommend further examination of the association of infliximab with both hepatic steatosis and progression to cirrhosis in the setting of HCV infection.

Underlying Hemochromatosis Unmasked by Propafenone Hepatotoxicity
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A 23 year old Caucasian male with a 3 year history of paroxysmal atrial fibrillation (AF), without any known underlying cause, was found to have isolated transaminase elevation on routine laboratory screening. He denied nausea, abdominal pain, pruritus or change in urine and stool color. He had no personal or family history of liver disease and denied excessive alcohol intake or illicit drug use. Propafenone 250 mg three times per day was started 5 months prior for recurrent AF. Physical examination was unremarkable with no stigmata of chronic liver disease. Laboratory data showed, aspartate aminotransferase 168 U/L, alanine aminotransferase 537 U/L, total bilirubin 1.1
mg/dL, alkaline phosphatase 120 U/L, albumin 4.3 g/dL, hemoglobin 15.3 g/dL, ceruloplasmin 26.5 mg/dL, and alpha1-antitrypsin 160 mg/dL. Viral hepatitis serologies, anti-nuclear antibodies, serum protein electrophoresis, anti-smooth muscle antibodies, and anti-mitochondrial antibodies were negative. Iron studies revealed total serum iron 255 mcg/dL, total iron-binding capacity 280 mcg/dL, ferritin 760 mcg/dL and transferrin saturation > 80%. A Doppler ultrasound of the liver showed normal hepatic echotexture with patent vasculature and normal caliber bile ducts. Liver biopsy showed lymphocytic portal and perportal hepatitis with acinar zone 3 periportal necrosis consistent with a drug reaction. Quantitative analysis showed hepatic iron concentration of 2498 mcg/g dry weight with iron index of 2 mmol/g/year. Gene testing revealed genotype C282/H63D. Propafenone was discontinued and transaminases gradually normalized. Therapeutic phlebotomy was initiated to maintain serum ferritin < 50 mcg/L. During 2 years of follow-up intermittent break-through AF was observed despite an ablation procedure and flecainide therapy. Clinical manifestations of iron overload are rare in hemochromatosis compound heterozygotes (C282/H63D). AF has never been reported as a phenotypic expression of the hereditary hemochromatosis compound heterozygote status. In this case, we speculate that excess iron overload is due to a concomitant defect in one or more of the novel proteins (eg, hepcidin, hemojuvelin, or transferrin receptor 2) involved in iron metabolism. It is plausible that increased hepatic iron concentration might have predisposed to an otherwise exceedingly rare propafenone hepatotoxicity as well. Awareness of unusual systemic effects of chronic iron overload can lead to appropriate genetic testing and diagnosis.

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Intestinal Spirochetosis: Treatment with Single Dose Penicillin

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Intestinal Spirochetosis is characterized by spirochetes attached to the apical cell membrane of the colorectal epithelium. Clinical manifestations include abdominal pain, diarrhea and fatigue. It is infrequent in the western world, but prevalence rates are high in homosexuals and HIV-infected individuals. Treatment options have been reported ranging from wait-and-see policy to the use of antibiotics. A 47-year-old HIV-positive male presented with a 2-month history of progressively worsening diarrhea, abdominal pain, bloating and fatigue. Physical examination was unremarkable; laboratory tests including stool studies, did not reveal any cause for his diarrhea. No mucosal abnormality was found on colonoscopy; however, biopsy of colonic mucosa showed intestinal spirochetosis. He was treated with a single injection of 2.4 million units of benzathine penicillin intramuscularly, a treatment regimen for primary and secondary syphilis. His symptoms resolved within 2 days and he remained asymptomatic at 4-month follow-up. Additionally, he reported subjective fever for 1 day immediately following the treatment. This case demonstrates that a single injection of benzathine penicillin can be used successfully in the treatment of intestinal spirochetosis. This has obvious implication regarding compliance. Furthermore, we believe this may be the first report of a Jarisch-Herxheimer reaction following treatment of intestinal spirochetosis. [figure1][figure2]
A Case of Pancreatic Tuberculosis Mimicking Malignancy
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We present a rare case of isolated pancreatic TB masquerading as a malignant neoplasm. A 21-year-old Somali female, with unremarkable past medical history, presented with a 2 months history of progressively worsening right-sided flank pain. She denied any fever, chills, night-sweats, weight-loss, and adverse gastrointestinal or urinary symptoms. An abdomen/pelvis CT showed multiple enhancing masses (largest mass size: 2.2 × 2.7 cm) within the body and tail of the pancreas, splenic-vein thromboses and isolated gastric varices. The superior mesenteric vein (SMV) and portal vein were patent. A low-density mass/ fluid collection (4.5 × 6.3 cm) was noted within the right psoas muscle. Multiple enhancing low-density lesions were noted along the iliac lymph-node chain. The CT findings were highly suspicious of metastatic mucinous cystadenocarcinoma of the pancreas. Laboratory data was significant for WBC 8.5 × 10^9/L, hemoglobin 12.3 g/dL, ESR 86 mm/1 h, CRP 5.3 mg/dL, CA-125 66 U/mL, normal amylase/lipase and liver function test. Esophagogastroduodenoscopy with endoscopic ultrasound (EUS) showed a diffusely enlarged lobular pancreas with a hypoechoic appearance. A complex, partially cystic mass was noted in the posterior wall of pancreatic body. There was loss of echoplane between the pancreatic mass and the SMV. Adjacent to stomach, there were multiple large nodes (> 2 cm), most of which had cystic spaces within them. No mediastinal adenopathy was seen. Fine needle aspiration (FNA) from perigastric lymph nodes and tru-cut biopsy from the pancreatic mass showed reactive lymphoid hyperplasia and acutely inflamed pancreatic parenchyma negative for malignancy. A CT-guided drainage of the right psoas fluid collection was performed. The cultures from the right psoas abscess fluid and the peri-gastric lymph node aspirate returned positive for Mycobacterium tuberculosis complex (MTB). A CT Chest and multiple induced sputum samples remained negative for acid-fast bacilli smear, MTB probe, and culture. Resistance to isoniazid and rifampin was noted. Pancreatic mass lesion resolved on a 24 months course of five anti-tuberculous drug therapy including amikacin, levofloxacin, pyrazinamide, ethambutol, and cycloserine. This case highlights the fact that TB should be considered in the differentials of complex pancreatic cystic lesion even in the immunocompetent individuals. EUS FNA culture can help confirm the diagnosis.

Familial Adenomatous Polyposis and Factor VII Deficiency in a Young Man: A Rare Coincidence
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To report a case of Familial adenomatous polyposis in a young man with concomitant Factor VII deficiency. A 29 y/o African American male presented with complaints of weakness and recent shortness of breath. He attributed the symptoms to several nosebleeds in the past six months. He denied any trauma or other medical history. Patient reported frequent nose bleeds for last six months though denied any vomiting, malena, hematochezia or other sources of bleeding. His father died at age of 42 with colon cancer and uncle also had colon cancer but denied any bleeding disorders in family. He was a smoker, occasional alcohol user but denied illicit drug abuse. On examination, he was tachycardic with blood pressure of 110/50. Rest of the exam was remarkable only for heme positive brown stool on rectal exam. Lab data showed hematocrit 11 with MCV 67, Platelet 473K, TIBC 431, Serum Iron 9 and Ferritin 3 ng/mL. His coagulation profile showed PT elevated to 20.7 seconds and INR elevated to 1.8. He was admitted and received 3 units of packed red blood cells. With profound iron deficiency anemia and strong familial history of colon cancer, gastrointestinal consultation was sought. Panendoscopy was remarkable for innumerable polyps in colon. FAP was most plausible diagnosis. Biopsies revealed adenomatous polyposis without high-grade dysplasia or malignancy. Coagulation parameters did not correct after transfusions. Mixing study showed correction of prothrombin time. Coagulation factor deficiency seemed possible cause. Factor VIII and IX were normal. Factor VII levels was drawn later, after hematology consultation, it was 12 (reference 70–130). A diagnosis of factor VII deficiency was made. He underwent colectomy and received recombinant factor VII perioperatively. Patient was counseled and genetic counseling was advised along with surveillance in other family members. This is an interesting presentation of two rare familial disorders in same patient. Familial adenomatous polyposis is autosomal dominant diseases caused by mutations in the adenomatous polyposis coli on chromosome 5q21. FAP occurs in approximately 1/10000–30000 live births, and accounts for less than 1 percent of the total colon cancer risk in the USA. With estimated prevalence of 1 : 500 000, inherited FVII deficiency is also a rare, autosomal recessive coagulation disorder. The FVII gene (F7) is located on chromosome 13. There has been no reported link between these two relatively rare disorders and this might be just a coincidence or not!
A Large Gastric Polyp Causing Iron Deficiency Anemia and Intermittent Gastric Outlet Obstruction

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Purpose: Case: A 71 y/o female with history of hypertension was evaluated for iron deficiency anemia. Patient denied bright red blood per rectum, melena, or hematemesis. She had no change in her diet or weight loss. There was no family history of gastrointestinal cancers. Physical examination was normal. A colonoscopy was unremarkable. Upper gastrointestinal endoscopy revealed a 30 mm multi-cystic pedunculated polyp in the fundus (Figure 1). Multiple biopsies suggested a hyperplastic polyp, helicobacter pylori negative. Repeat endoscopy for polypectomy found the polyp intussuscepting into the pyloric channel causing gastric outlet obstruction (Figure 2). The stalk was dusky in appearance. The polyp was pulled up into the antrum using a snare and resected in a piecemeal fashion; however, complete resection was not accomplished due to severe bleeding. Histopathology examination showed a tubular adenoma. A third endoscopy for complete resection of the polyp was performed. A spreading/infiltrative appearance was noted at the base of the polyp while bulk of the lesion was removed, revealing a tubular adenoma with focal high grade dysplasia. She was referred for surgical evaluation.

Discussion: Most gastric polyps are small; however, larger polyps may seldom be encountered on endoscopic examination. Larger the polyp size, higher is the risk of complications such as obstruction, bleeding and iron deficiency anemia. Intussusception of gastric polyps has been rarely reported. Lastly, multiple biopsies should be taken to ensure there is no underlying malignancy.
A 50 year old Hispanic male with hypertension, urticaria pigmentosa, vitamin B12 deficiency and anemia was evaluated for chronic diarrhea and was diagnosed to have celiac sprue with positive antigliadin antibodies. He also complained of having a foamy urine but did not undergo formal evaluation of kidney function initially. He was started on a gluten free diet with resolution of diarrheal symptoms but kept having proteinuria and soon developed swelling of both his lower extremities. Subsequent evaluation revealed the presence of nephrotic syndrome with a 24 hour urine protein of 4.7 gms. He had a serum creatinine of 1.2 mg/dL, Hemoglobin of 10.5 g/dL, low C3 and normal C4 levels. A kidney biopsy performed diagnosed him to have membranoproliferative glomerulonephritis (MPGN). He was started on PO steroids (without any cytotoxic agents) which he received for 6 months. He responded to treatment after six months of therapy and has stayed in disease remission. Celiac sprue is a common cause of malabsorption in Caucasians, and the etiology of the disease is suspected to involve environmental, immunologic and genetic factors. The immunologic components suspected are the IgA antibodies (IgA antigliadin, IgA antiamyloid and IgA anti-tissue transglutaminase). Circulating immune complexes have been noted to be deposited in the kidney and are occasionally implicated in causing IgA nephropathy. But the occurrence of MPGN in the setting of Celiac disease is more infrequent. We report this rare occurrence of MPGN in a patient with celiac disease. The potential significance of identifying patients with celiac disease to have MPGN may have important implications to understanding the etiology of these diseases. This case suggests that the possible source of antigen in celiac disease with MPGN may be of a dietary origin which required treatment with steroids to maintain remission of disease.

**Discussion:** Peg-IFN may cause neurological symptoms including acute demyelinating polyneuropathy. This may be due to an autoimmune reaction resulting from cytokine-induced immune dysregulation during peg-IFN therapy. It is very important that gastroenterologists and/or hepatologists recognize this neurological problem during Peg-IFN therapy as it may require prompt discontinuation of Peg-IFN and an immediate referral to a neurologist for further diagnosis and treatment in order to prevent long-term neurological deficits.

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**Bisacodyl Induced Ischemic Colitis**

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Ischemic colitis represents the most common form of gastrointestinal ischemia and can be classified as gangrenous or non-gangrenous. Non-gangrenous ischemic colitis is further subdivided into chronic and transient. The transient form of ischemic colitis may be seen in otherwise healthy individuals and can be attributed to a variety of factors including estrogen, severe hypovolemia and laxative use. We present several cases of bisacodyl induced ischemic colitis in previously healthy individuals undergoing bowel prep for outpatient colonoscopy.

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**A Case of Acute Inflammatory Demyelinating Polyneuropathy Associated with Pegylated Interferon (Peg-IFN) Therapy for Chronic Hepatitis C (HCV)**

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The combination of Peg-IFN and Ribavirin is the standard of care for chronic HCV treatment. There are several well known side effects including flu like symptoms, depression, weight loss, fatigue, arthralgia, myalgia and autoimmune phenomena including peripheral neuropathy associated with Peg-IFN therapy. However, peripheral neuropathy including demyelinating polyneuropathy related to Peg-IFN therapy is extremely rare and its pathophysiology has not been well described in the literature. We present a case of acute demyelinating polyneuropathy associated with Peg-IFN (Pegasys) therapy for chronic HCV.

**Case:** A 65 year old woman with chronic HCV was treated with the combination of pegasys and ribavirin. She had a significant reduction in HCV RNA with early viral response after 12 weeks of therapy. However, her treatment course was complicated with pneumonia, which required antibiotic treatment and a temporary discontinuation of Pegasys. After resolution of the pneumonia, she continued HCV treatment and subsequently developed tingling, numbness, and weakness of her lower extremities that led her to becoming wheelchair bound. She was hospitalized for a possible post-infectious Guillain-Barre syndrome (GBS), and Pegasys/Ribavirin was discontinued. Lumbar puncture was unremarkable, but an electromyogram (EMG) and sural nerve biopsy were consistent with acute demyelinating polyneuropathy. She was treated with four courses of Intravenous Immunoglobulin therapy as well as rehabilitation. After several months, her muscle weakness resolved without having any residual neurological deficit.

**Discussion:** Peg-IFN may cause neurological symptoms including acute demyelinating polyneuropathy. This may be due to an autoimmune reaction resulting from cytokine-induced immune dysregulation during peg-IFN therapy. It is very important that gastroenterologists and/or hepatologists recognize this neurological problem during Peg-IFN therapy as it may require prompt discontinuation of Peg-IFN and an immediate referral to a neurologist for further diagnosis and treatment in order to prevent long-term neurological deficits.

**Test Results**

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<tr>
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read as normal, there was no sonographic evidence of acute cholecystitis or cholelithiasis. The common bile duct was not dilated. Viral hepatitis panel was negative. A thorough history on past medication use was unrevealing. Despite the ultrasound report, biliary obstruction from gallstones remained the most likely diagnosis and additional radiographic imaging was ordered. MRCP was performed which showed numerous stones in the gallbladder (arrowhead) with an abrupt cutoff at the distal segment of the cystic duct (thin arrow). Cholangiogram taken during ERCP showed a normal common bile duct (thin arrow) and a large stone lodged in the cystic duct (asterisk). Direct external compression by the cystic duct gallstone on the common hepatic duct resulted in intrahepatic biliary dilatation (thick arrow) and obstructive jaundice, a clinical entity known as Mirizzi syndrome. Upon re-evaluation, what was initially identified as the gallbladder on ultrasound was actually the cystic duct which was dilated from stone obstruction. This misinterpretation coupled with a normal caliber common bile duct resulted in a delay in making the correct diagnosis of Mirizzi syndrome. Patient was subsequently referred for surgery where she underwent successful laparoscopic cholecystectomy with intraoperative stone extraction. [figure1][figure2]

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Metallic Artifact on CT Scan Due to Antacid Ingestion in a Patient with a Perforated Duodenal Ulcer
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A 48 year old mentally retarded male was brought to the ER with a 2-week history of intermittent epigastric abdominal pain. Abdominal CT with PO and IV contrast performed in the ER showed a collection of hyperdense material with streak artifact in the body of the stomach (Figure 1) and scattered throughout the small bowel. GI was consulted for possible foreign body ingestion. While in the ER, patient had an episode of hematemesis and emesis. EGD showed no evidence of any metallic objects in the stomach. Within the duodenal bulb, a giant 5-cm ulcer was seen in the posterior wall with a visible vessel. Active hemorrhage developed during the procedure which could not be controlled endoscopically. The patient was immediately taken to the OR where he underwent surgical hemostasis and repair of the duodenal ulcer which had perforated. No metallic object was found during surgical exploration. Upon further questioning prior to discharge, the patient admitted taking a large quantity of calcium carbonate over the counter antacid. [figure1]

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Gastrojejunocolic Fistula, a Rare Complication of Prior Gastroenterostomy
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Patient is a 48 yo male with history of bleeding peptic ulcer disease, s/p Billroth II gastrectomy with subsequent conversion to roux-en-y gastrojejunostomy, presents with dyspnea, abdominal pain and chronic diarrhea. In the emergency room patient was afebrile, with BP 124/57, heart rate 67, respiratory rate 18. On abdominal exam patient had normal active bowel sounds, mild tenderness to palpation in LLQ and LUQ. Laboratory data revealed a Hgb 6.9, WBC 3.9, albumin 3.5, lipase 7. CT-abdomen revealed pneumatisis in the colon. Initial management consisted of bowel rest, transfusion of PRBC, IV fluids, and IV antibiotics. Overnight patient did well with resolution of abdominal pain, and patient underwent a colonoscopy to evaluate for possible mesenteric ischemia. Colonoscopy at 45 cm from the anus (around the splenic flexure) revealed a fistulous connection, opening into two different lumens. One lumen opened into the stomach, while the other opened into small bowel. At the juncture where the small bowel, colon, and stomach meet, there was a small clean base ulcer. Preoperatively the patients nutritional status was optimized. Patient subsequently underwent a one-stage repair, with revision of the gastrojejunostomy, removal of the fistula, colocolic anastomosis, and truncal vagotomy. Postoperatively the diarrhea resolved, with patient now having 2-3 formed bowel movements per day. Gastrojejunocolic fistulas are a rare complication of previous gastroenterostomy. It is thought to occur secondary to a marginal ulcer, which occurs due to incomplete gastric resection or incomplete vagotomy for peptic ulcer disease. Clinical presentation consists of chronic diarrhea, fecal vomiting/breath, and weight loss. Diagnosis is made by barium enema. Initially surgical repair for gastrojejunocolic fistula entailed a 3-stage operation involving a preliminary diverting colostomy to optimize nutritional status, resection of fistula, and then closure of colostomy. However, with advances in TPN over the past 20 years, operative morbidity and mortality has been minimized with one-stage surgical repair.

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Successful Treatment of Valproate Induced Acute Liver Failure with Intravenous L-Carnitine
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A 75 year old man with bipolar disease, hyperlipidemia, diabetes, and hypertension, presented with fatigue and a marked elevated ALT and bilirubin. Liver function worsened despite discontinuing valproate, fenofibrate, and metformin. There was no evidence for viral hepatitis. ANA, ASMA, AMA, iron studies, ceruloplasmin, alpha-1 antitrypsin level, and serum lactate were negative or normal. Hepatobiliary ultrasound was normal; and vessels were patent. Liver biopsy showed macrovesicular steatosis, steatohepatitis, and stage 3 fibrosis. The biopsy was felt to represent chronic changes of nonalcoholic steatohepatitis due to metabolic syndrome. There were no signs of acute hepatic injury. We postulated a clinical diagnosis of valproate-induced hepatotoxicity superimposed on NASH. Treatment was started with intravenous L-carnitine, 50 mg/kg/day, in two divided doses. Liver function improved rapidly over the next 5 days. Dose was halved on day 6 and stopped on day 8. Liver function continued to improve over the next 2 weeks. [figure1] Carnitine helps to maintain a normal ratio of acyl to free coenzyme A within mitochondria. Valproate is believed to deplete carnitine levels within mitochondria. Disruption of mitochondrial metabolism may explain valproate-induced microvesicular steatosis and hepatotoxicity. Notably, patients can exhibit severe valproate-induced hepatotoxicity without abnormalities on liver biopsy. We believe that this was the case in our patient who exhibited signs of NASH, only, on liver biopsy. Valproate-induced acute liver failure is often fatal. Bohan et al (Neurology 2001;56:1405) retrospectively studied 92 pediatric patients with severe valproate-induced acute liver failure. 48% of the L-carnitine-treated patients survived, as opposed to 10% of the 50 patients who received supportive care, only [P<0.001]. Intravenous L-carnitine appeared to be more effective than the oral agent, on account of improved bioavailability. Our search revealed no literature on L-carnitine therapy in adults with valproate hepatotoxicity. Our case illustrates the potential benefit of L-carnitine in adults with valproate-induced acute liver failure.

Complications from Percutaneous Endoscopic Gastrostomy (PEG) are rare (2–6%). Our case is a 71 year obese lady who was transferred to our facility from a specialty hospital secondary to leukocytosis and excessive drainage from a recent Coronary Artery Bypass Graft wound. She had a PEG tube placed three months earlier because of poor food intake. On arrival, the patient was found to have BP of 79/42, pulse of 120/min. and Temp of 101.5 F. Body weight was 240 pounds. The patient was unresponsive with purulent rhinitis. The wound on the neck was purulent. There was body odor. She had a history of RCC nephrectomy 18 months previously, presented to the hospital with weakness. During the initial evaluation, the hematocrit was 15.7. He did not have any overt symptoms of GIB. He also denied using any aspirin or NSAIDs. However, on further questioning, the patient admitted to taking some ibuprofen for pain. The initial upper endoscopy (EGD) revealed multiple 2–3 mm shallow ulcers and erosions in the duodenal bulb without any stigmata of active bleeding. These lesions were believed to be NSAID induced and the patient was transfused and treated with a proton pump inhibitor. Twenty-three days later, the patient was again hospitalized for weakness and anemia. His hematocrit fell from 32.4 to 25.4. Repeat EGD showed a 1 cm duodenal bulb ulcer with an adherent clot. The tissue around the lesion was edematous and protuberant. Because of the ulcer position and the patient’s debility, no endoscopic or surgical therapies were performed. He was again transfused and medically managed. As the bleeding continued, a third EGD was performed on day 25. At this time, the duodenal clot was no longer present. However, a bleeding fungating mass was seen in the duodenal bulb extending into the second portion of the duodenum. Biopsies taken from this lesion were consistent with RCC. A follow-up CT scan also demonstrated the duodenal lesion. The patient subsequently underwent arterial embolization to achieve hemostasis. This case illustrates the rapid extension of a metastatic RCC eroding into the duodenum. Although prior reports discuss duodenal metastases, we document the ulceration to penetration time in just over 25 days.

discharge from the sternotomy wound. The abdomen was grossly obese and soft with good bowel sounds. PEG tube site was clean. The patient was resuscitated with iv fluids and iv vancomycin together with sternal wound care. She improved significantly and PEG tube feeding was resumed. She initially tolerated tube feeding well. Three days later she became hypotensive with BP of 81/58, pulse of 110/minute and temp. of 102 F. The abdomen became tense and distended with pitting edema of the abdominal wall. The PEG tube site showed leakage of tube feeding formula and serosanguinous fluid. No bowel sounds could be heard. EsophagoGastroDuodenoscopy was done which showed a fistulous opening at the PEG tube site with no bumper seen. Abdominal CT showed 7 × 15 × 3 cm left anterior abdominal wall phlegmon around the PEG-tube tract which containe the bumper. Surgically, 500 ml of the feeding formula were removed from the abdominal wall anterior to the rectus sheath. The PEG tube was also removed and a Nasojejunal tube was placed for long-term feeding. Percutaneous Endoscopic Gastrostomy has been performed regularly without any significant complications. The complication rate can be diminished by post-endoscopic care of the PEG tube site. Successful Treatment of a Benign Anastomotic Colon Stricture with Colocutaneous and Coloenteric Fistulae Using Overlapping Self-Expandable Metal Stents (SEMS) Emelie E Helou, MD, Aaron J Small, Mark D. Sawyer, MD, Todd H. Baron, MD. * Gastroenterology, Mayo Clinic College of Medicine, Rochester, MN. Colonic SEMS are typically used for palliation of malignant obstruction. Covered stent placement within an uncovered stent has been described for the management of malignant strictures and fistulae. SEMS are uncommonly used for benign strictures and fistulae because of potential migration and complications. Covered and uncovered SEMS have been used as a bridge to surgery in diverticulitis, as an alternative to surgery for inoperable disease. We report a case of a benign anastomatic colon stricture complicated by colocutaneous and colorectal fistulization successfully treated with the stent within stent method. A covered stent was placed within an uncovered stent. A 43 year-old man underwent sigmoid resection with colostomy following perforated diverticulitis. After one year, the colostomy was taken down. One month later, he developed an abscess related to an anastomotic leak. This was drained percutaneously, but complicated by development of a cutaneous fistula. Imaging demonstrated obstruction at the anastomosis with a colocutaneous fistula arising proximal to the stricture. A colocutaneous fistula was also identified. The patient declined surgery with stoma formation. After
Histoplasmosis Presenting as a Colonic Mass in an Immunocompromised Patient
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Gastrointestinal histoplasmosis typically occurs in severely immunocompromised individuals, generally AIDS patients with a median CD4 count less than 40. Even though almost 70% of the AIDS patients with disseminated histoplasmosis have colonic involvement only about 10–45% are symptomatic. We describe a case of a 44 year old white male recently diagnosed with HIV and HCV co-infection, not on HAART, presenting with 1 month history of fever, night sweats, diarrhea and weight loss and a 2 week history of right lower quadrant abdominal pain. On physical exam he was febrile, tachycardic, had a pruritic papular rash on the trunk and extremities and oropharyngeal thrush. He had moderate tenderness in the right lower quadrant, mild splenomegaly but no hepatomegaly. His labs showed Hb of 9.7 g/dl, WBC count 3500 cells/ul, elevated ALT, AST and LDH, albumin of 2.8 mg/dl, and a CD4 count of 67 cells/ul. Stool examination was negative for ova and parasites. Lungs were clear on X-ray. CT scan of the abdomen/pelvis showed thickened wall of the ascending colon, multiple liver nodules, splenomegaly with mesenteric and retroperitoneal lymphadenopathy. Colonoscopy showed a circumferential non-obstructing mass in the ascending colon suggestive of malignancy. Biopsy showed transmural lymphoplasmacytic infiltration with granulomas suggestive of histoplasmosis. Serology for histoplasmosis was positive. Serology for other fungal and viral infections was negative. The patient was treated with 2 weeks of amphotericin B with improvement in his symptoms and was discharged on itraconazole and HAART. After a symptom free interval of 4 months he presented with colon perforation as a result of an ascending colon stricture causing large bowel obstruction. He underwent a hemicolectomy. Histopathological examination of the resected colon showed old fibrosis without inflammation. Histoplasmosis can initially present as colonic mass or perforation and mimic colon cancer in AIDS patients and should always be part of the differential diagnosis particularly when there are multiple colonic lesions, associated retroperitoneal lymphadenopathy and the patient comes from an endemic area. [figure1]
ductal obstruction due to a skeletal muscle bezoar without the development of pancreatitis.

REFERENCES

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Spontaneous Umbilical Hernia Rupture in a Cirrhotic with Ascites: Importance of Patient Education
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Spontaneous rupture of umbilical hernias due to ascites is a rare but potentially life threatening complication. The author will describe a patient who was proactive in his own care and averted any serious morbidity following a spontaneous rupture of his umbilical hernia. The patient is a 57 year old gentleman with cirrhosis from hemochromatosis awaiting transplant who was seen in our liver clinic for almost a year. He had type II hepatorenal syndrome and refractory ascites with a protuberant umbilical hernia. His creatinine level fluctuated between 1.3 and 1.7 mg/dL depending on diuretic dosage. Eventually, for fear of worsening renal function, all diuretics were stopped. Not surprisingly, he required elective paracentesis procedures monthly, then more frequently. During this period, his umbilical hernia became indurated and ulcerated. Four days after an elective paracentesis, the patient was at home when his umbilical hernia spontaneously burst. Approximately 7–8 L was lost from the hernia defect and the patient had lost about 20 lbs of fluid. He presented to the hospital for emergent evaluation that evening. At the hospital, the area was cleansed with betadine, dermabond and steristrips were placed and the patient was sent home given stable vital signs. No albumin was infused, no antibiotics were given and he was told to return if he had recurrent or worsening symptoms. The following morning, he contacted our transplant Nurse Practitioner. He expressed concern over not receiving albumin in the emergency room (as he had for all of his prior paracentesis procedures). He was instructed to return to the hospital for readmission. At that time, he underwent a transjugular intrahepatic portosystemic shunt (TIPS) procedure to control his ascites. He was sent home with a pressure dressing at the umbilical site and a MELD score that placed him high on the transplant list. Five days later, he was transplanted and had repair of the hernia defect. He is currently doing well post operatively. Patient education in being proactive is especially vital for those with liver disease. This patient’s knowledge of albumin’s role prompted him to seek our advice. Cirrhotics should be instructed to inform their doctors of any outside medical encounters. Hernia ulceration may predispose to rupture, thus these patients should also be told what to do should this occur. Minimizing high morbidity in this setting is key to survival.

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Snare Papillectomy Utilizing a Wire Guided Technique
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Tumors arising from the major duodenal papilla account for up to 5% of GI neoplasms. ERCP guided papillectomy provides a nonsurgical approach to removal of these tumors. Post ERCP pancreatitis is a major complication after papillectomy. Pancreatic duct stent placement may provide a way to prevent procedure related pancreatitis. At times this may be difficult because of edema around the papilla after papillectomy. We report on a new wire guided technique for papillectomy with immediate pancreatic duct stent placement. Our patient is a 30-year-old male who has a diagnosis of familial adenomatous polyposis. On a recent surveillance upper endoscopy he was found to have an ampullary adenoma. He returned to us for subsequent ERCP and snare papillectomy. A side viewing duodenoscope was introduced and advanced to the second portion of the duodenum. After identifying the adenoma, the ampulla was engaged and a Dash 480 sphincterotome. Contrast imaging of the common bile duct and pancreatic duct appeared normal. Through the sphincterotome, a guidewire was advanced into the distal pancreatic duct. The sphincterotome was removed, leaving the guidewire in place. The proximal end of the guide wire was placed in the distal end of a Wilson Cook Hexagonal Snare sheath opening. The guidewire was then back loaded through the snare sheath and removed through a hole in the proximal end of the sheath (the hole cut into the sheath prior to endoscopy; see picture 1). The sheath was advanced (with the guide wire inside of the snare sheath) to the prominent ampulla. With the guidewire in the pancreatic duct, snare papillectomy was performed. The sheath was removed (leaving the wire in the pancreatic duct). The entire adenoma was suctioned into a trap. A 5Fr, 3cm Geenan Pancreatic Stent was placed inside of the pancreatic duct over the guidewire. The patient tolerated the procedure well and no post procedure complications occurred. He was discharged home directly from the GI lab. Our case provides a practical approach to snare papillectomy, while at the same time providing easy access to the pancreatic duct allowing for immediate pancreatic stent placement and reduce incidence of procedure related pancreatitis. [figure1]

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A Case of Colon Carcinoid with Carcinoid Syndrome
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A 63 year old female presented with 3 months of watery diarrhea, 10 lb weight loss and intermittent facial erythema. A CT scan of abdomen revealed a large mass inferior to the head of the pancreas extending into to the ascending colon with encasement of the SMA and metastatic liver lesions. Colonoscopy revealed a 5 cm, irregular, ulcerated mass in the ascending colon; biopsy showed characteristics of a carcinoid tumor (figure 1,2). 24-hour urine collection for 5-HIAA was elevated at 84mg/24hrs. Serum gastrin and histamine levels were normal. Octreotide scan showed increased uptake in the pancreatic mass, ascending colon and metastatic liver lesions. ECHO showed no evidence of cardiac tumor involvement. CEA and Ca 19–9 levels were not elevated. Surgical debulking was not considered because of the SMA involvement. The patient was started on Sandostatin LAR 30mg which controlled her diarrhea. Most carcinoid tumors arise from the gastrointestinal tract (74%) and the bulk of these carcinoid tumors are found in the appendix, small intestines and rectum. Colonic carcinoid tumors comprise of about 7.8% of all GI carcinoids and are mainly found in the ascending colon (75%). When found they are frequently large and metastatic but rarely present with frank Carcinoid Syndrome (<5%). Colonic carcinoid tumors
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exhibit the worst prognosis of all GI carcinoid tumors, with an overall 5-year survival rate of 33–42%. When clinically suspected a 24 hour urine collection for 5-HIAA is 73% sensitive and 100% specific for identifying patients with carcinoid syndrome. The treatment for carcinoid tumors is usually surgical resection if <2cm and no evidence of metastatic disease. If patients with carcinoid disease are not eligible for resection, somatostatin therapy may be used to reduce 5-HIAA levels, control the diarrhea and flushing symptoms.

[figure1][figure2]

Doxylamine Induced Acute Fulminant Hepatic Failure
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We report the first case of acute fulminant hepatic failure requiring liver transplantation caused by chronic ingestion of over the counter medication “Unisom” containing doxylamine. Drug induced acute fulminant hepatic failure is one of the medical conditions which warrants an exhaustive history taking. Chart review and review of available literature. A 19 year old healthy male was admitted with anorexia, nausea, vomiting, jaundice, dark urine and steatorrhea of one week duration. Physical exam revealed icterus without signs of chronic liver disease. Laboratory results on admission showed AST 2313, ALT 1689, albumin 3.3, total bilirubin 26.9 with direct fraction 16.5. Acute fulminant hepatitis workup revealed negative acute and chronic hepatitis serologies with negative viral loads, iron and copper studies, autoimmune panel, p- ANCA, c- ANCA, TTG, CPK and aldolase. Alpha-1 antitrypsin levels were normal. No KF Rings were noted. CT Scan showed normal liver and gall bladder with patent hepatic and portal veins. Liver biopsy revealed acute on chronic portal inflammation, centrilobular necrosis, endotheliitis, cholestasis, acute central venular vasculitis with striking eosinophilia and hepatic lobular necrosis suggestive of toxin or drug induced liver failure. Iron and copper stains were negative. MELD score increased from 20 to 40 in a month with epistaxis, asterexis and hepatorenal syndrome. Patient finally underwent liver transplantation. Detailed history elicited recent use of doxylamine for insomnia for two months. Extensive literature search revealed that doxylamine is metabolized and excreted through the liver. Studies in mice suggested increased hepatocellular and thyroid follicular-cell adenomas along with cholestasis and significant liver damage. [figure1] This case strongly illustrates the importance of detailed medicinal intake history taking in any case of acute fulminant hepatitis. We hereby, report the first case of acute fulminant hepatic failure requiring liver transplantation secondary to chronic doxylamine ingestion.

Endoscopic Ultrasound Guided Fine Needle Aspiration Diagnosis of Primary Peritoneal Mesothelioma
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69-year-old male presented with a three-month history of new-onset ascites and lower extremity edema. The patient reported marked weight loss, decreased appetite and night sweats. The patient had no known history of asbestos exposure. Physical examination was remarkable for distended abdomen and tense ascites. There were no organomegaly or physical findings
suggestive of chronic liver disease. Laboratory tests were within normal limits. CT scan of chest and abdomen revealed massive ascites. The mesentery showed anterior omental caking suspicious for disseminated occult malignancy. Endoscopic ultrasound (EUS) showed extensive mesenteric inflammation and moderate amount of ascites. No intra-abdominal lymphadenopathy was present. EUS guided fine needle aspiration of ascitic fluid was performed. Cytology revealed atypical mesothelial cells with malignant morphology. Immunostains for keratin 7, keratin 5/6, and P53 were positive confirming the diagnosis of mesothelioma. Fiberoptic bronchoscopy with transbronchial biopsy and bronchoalveolar lavage showed no evidence of pleural mesothelioma. Primary peritoneal mesothelioma diagnosis was established. To our knowledge this is the first case of primary peritoneal mesothelioma to be diagnosed with EUS Guided Fine Needle Aspiration.

Discussion: Malignant peritoneal mesothelioma is a rare, locally aggressive neoplasm arising from the abdominal serosal lining. Exposure to asbestos fibers has been recognized as a risk factor for pleural mesothelioma. However, the implication of asbestos in the causation of peritoneal mesothelioma is less evident. The definite diagnosis of peritoneal mesothelioma can only be established by histological examination. CT-guided percutaneous core-needle biopsy of the omentum is a safe, and highly accurate procedure for the diagnosis. In our patient, EUS guided fine needle aspiration was an easy and safe technique for diagnosis. There are no uniformly accepted approaches for treatment. Cytoreductive surgery followed by intraperitoneal chemotherapy with cisplatin and paclitaxel has been effective in a number of cases. Favorable prognostic factors for long-term survival include epithelioid tumor subtype, comparatively young age, and female gender.

Primary Aortoenteric Fistula — An Uncommon Cause for GI Bleeding
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A 68-year-old white male presented to an emergency room with acute onset of abdominal pain and hematochezia. The patient’s pain had subsided upon reaching the ER. Physical exam revealed stable vital signs and a tender abdomen without masses or bruits. Diagnostic testing included a tagged red blood cell scan suggesting bleeding within the sigmoid colon, followed by endoscopy which did not identify a culprit lesion. Within 24 hours of hospitalization the abdominal discomfort and bleeding returned. Further imaging with CT angiogram visualized an infrarenal aneurysm with a subtle leak of contrast into the duodenum. He was transferred to a tertiary care center and became hemodynamically unstable with persistent hematochezia upon arrival. Upper endoscopy was repeated but was limited by active pooling of blood. Angiography immediately followed this procedure and confirmed an aortoduodenal fistula (figures 1 and 2). The patient was taken emergently to the operating room for surgical repair and died intraoperatively from massive exsanguination. A primary aortoenteric fistula (PAEF) is a rare diagnosis. Unlike a secondary aortoenteric fistula, a PAEF is an abnormal communication between the aorta and enteric system that develops without prior history of aortic graft placement. The natural history is self-limited bleeding which can escalate to massive exsanguination within 24 hours. For this reason, early suspicion, diagnosis, and treatment are paramount to patient survival. Unfortunately, the bleeding pattern in a PAEF can make diagnostic studies misleading, and current technology may preclude a perfect diagnostic tool. The experience of this case suggests the need for heightened physician awareness of PAEFS and a lower threshold for surgical intervention.

Massive Gastrointestinal Bleeding as a Result of a Dieulafoy’s Lesion in the Jejunum
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Dieulafoy’s lesions may be an unrecognized cause of small-bowel hemorrhage especially in young patients. We report a case of a jejunal Dieulafoy’s lesion that caused massive gastrointestinal hemorrhage ultimately discovered at laparotomy.
Case Report: A 25 year old Hispanic woman presented with a third episode of hematochezia that started ten days earlier. She was hospitalized twice at different facilities requiring multiple blood transfusions. An extensive workup including upper and lower endoscopies, a tagged red blood cell scan, small bowel follow through and a Meckel’s scan were all reported as normal. In our hospital, repeat endoscopies and a video capsule endoscopy were all unremarkable. The patient had an angiogram which revealed extravasation of contrast from a mid jejunal branch of the superior mesenteric artery. This did not respond to angiographic intervention. The patient was subsequently taken to surgery. An intraoperative enteroscopy revealed a 4mm Dieulafoy’s lesion in the jejenum located 60 cm from the ligament of Treitz. The affected area was resected and pathology confirmed a Dieulafoy’s lesion. The patient had an uneventful recovery and was discharged home.

Discussion: Dieulafoy’s lesion is an important cause of obscure gastrointestinal hemorrhage. The underlying cause is of an abnormal, submucosal artery that protrudes through a minute 2–5 mm mucosal defect. These lesions most commonly occur in the proximal stomach, within 6 cm of the gastroesophageal junction. The second most common site is the bulb of the duodenum. Dieulafoy’s lesions of the jejunum, ileum and colon are rare accounting for only 1% (1). Mino et al (2) reviewed 41 cases of small intestinal Dieulafoy’s lesions over a 30 year period and found that 2/3 of the patients were below the age of 40. Furthermore, the disease often occurred in patients in their teens and twenties. This emphasizes the importance of Dieulafoy’s lesions as a cause of bleeding in young patients with GI bleeding of obscure origin. Poster presentation with pictures. Dieulafoy’s lesions may be an unrecognized cause of small-bowel hemorrhage in young patients. A high index of suspicion is necessary when the source of bleeding can’t be identified despite multiple interventions.

Hemorrhage from Cystgastrostomy – Atypical Presentation of Hemosuccus pancreaticus
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In patients with chronic pancreatitis and pseudocysts with cystgastrostomy Hemosuccus pancreaticus (HP) can present as bleeding from cystgastrostomy rather than ampulla.

Case report: We present a case of 22 year-old woman with history of relapsing pancreatitis secondary to alcohol abuse and development of pseudocysts associated with stricture formation in the main pancreatic duct requiring pancreatitis secondary to alcohol abuse and development of pseudocysts. The patient underwent splenectomy.

Discussion: Acute gastrointestinal (GI) bleeding of pancreatic origin is an infrequent but well appreciated complication of chronic pancreatitis. Possible sites of hemorrhage include intraductal hemorrhage termed as hemosuccus pancreaticus (HP), gastric varices secondary to splenic vein thrombosis and intracystic hemorrhage. HP is more common in men with mean age of 50–60 years. The majority of cases are associated with development of fistula between pseudoaneurysm of splenic artery and pancreatic duct. Duodenopancreatectomy is indicated for lesions in the head of pancreas and distal pancreatic resection with splenectomy for lesions in the body and tail. Because of rarity and consequent unfamiliarity with the condition, the diagnosis is often overlooked. Our case is unique as the patient was a young female who presented with massive gastrointestinal bleed. We suspect that erosions of small arteries in the wall of the communicating pseudocyst and blood from pancreatic duct were the cause of bleeding from the cystgastrostomy. She responded to splenectomy.

An Unusual Complication of Percutaneous Liver Biopsy (PLB)
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Percutaneous liver biopsy (PLB) is indicated for the diagnosis and monitoring of therapy in liver disease. Gallbladder puncture is a rare complication (less than 0.1%) with only a few reports in the literature. The addition of ultrasound for site selection is thought to increase the safety of the procedure. A 58 year old man with a history of chronic Hepatitis C was scheduled for a PLB for recurrent viremia following interferon and ribavirin therapy. He had no symptoms of chronic liver disease. His surgical history was significant for a laparoscopic liver biopsy four years prior. His pre-procedure laboratories included a platelet count of 148000, INR 1, APTT 30, ALT 130, AST 94, total bilirubin 1.2 and albumin 4.6. Informed consent was obtained and an ultrasound was performed for the PLB site selection wherein position of the gallbladder was noted. The overlying skin was prepared in a sterile fashion and local anesthesia was achieved. The aspiration biopsy needle was introduced at the preselected site in the right upper quadrant at the mid axillary line by an experienced operator. Clear yellow fluid was obtained upon aspiration and the biopsy needle was withdrawn. Over the next two hours the patient developed increasing right upper quadrant pain and a temperature of 38.4 C was recorded. He remained hemodynamically stable but physical examination was significant for increasing right upper quadrant tenderness and voluntary guarding. Morphine sulfate and ampicillin/subactam were initiated. Laparoscopy was performed. Upon entry into the abdomen the right hepatic lobe was nodular and found to be rotated to the right, elevating the gallbladder further into the right upper quadrant. Mild peritoneal bile staining and inflammatory changes around the gallbladder with adherent omentum were noted. The patient underwent a laparoscopic cholecystectomy and liver biopsy. The patient tolerated the surgery well, had an uneventful post-operative course and was discharged home on post-operative day 2. The liver biopsy confirmed chronic hepatitis with grade 3, stage 3 inflammation/fibrosis and gallbladder pathology revealed chronic cholecystitis. Despite a pre-procedure ultrasound and adhering to the proper techniques, rare complications of PLB such as gallbladder puncture can occur. Early recognition and prompt management, including surgical exploration if indicated, are essential.

Hepatic Sarcoidosis: An Unusual Cause of Pediatric Liver Dysfunction
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Sarcoidosis is a chronic multisystem disease of unknown etiology characterized by the presence of noncaseating granulomas. We report its unusual presentation in a young child whose hepatic dysfunction raised a diagnostic dilemma.

Case Report: A 5-year-old male from Mexico was admitted to the ICU with a hepatitis. He had a 3-week history of daily high fevers, malaise and rash. Exam revealed an ill-appearing, pale child with mildly icteric sclerae, hepatosplenomegaly, ascites and a hyperpigmented, papular truncal rash. Diagnostic tests revealed: AST 259 U/L, ALT 332 U/L, ALP 1110 U/L, T.bili 2.5 mg/dL, Alb 1.7 g/dL, GGT 400 U/L, ESR 47 mm/hr, PT 15 sec, INR 1.43, PTT 53 sec and IgG 2470 mg/dL. Hgb was 7.8K/mm3; WBC and
platelets were normal. Infectious evaluation was negative for viral, bacterial, mycobacterial, fungal and parasitic etiologies, including viral hepatitis A/B/C/E. No toxic, autoimmune, or metabolic causes of liver disease were identified. Chest CT revealed interstitial lung disease and enlarged mediastinal lymph nodes. Tuberculin skin testing and BAL culture/stains for acid fast bacilli were negative. Skin and bone marrow biopsies contained granulomatous foci. Liver biopsy showed necrosis, hepatocyte loss, giant cell transformation and noncaseating, non-necrotizing granulomas. Immunostaining ruled out histiocytosis and NBT testing was negative for chronic granulomatous disease. Elevated serum levels of ACE and aldolase were found. A final diagnosis of sarcoidosis was made and the patient was treated with oral prednisone with prompt resolution of the fever, rash and hepatopathy.

Discussion: Recognizing sarcoidosis is challenging due to its nonspecific presentation. Diagnosis hinges on clinicoradiologic features, histologic proof of noncaseating granulomas, and exclusion of alternate disease processes. Up to 40% of patients with sarcoidosis can present with hepatomegaly and 4–7% with hepatitis. Clinically significant hepatic dysfunction is rare. Oral steroids can result in symptomatic and biochemical improvement, although relapse is common upon discontinuation. Ursodeoxycholic acid has been used as adjunctive therapy. [figure1]

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Retrograde Esophageal Stent Placement Via a Gastrostomy Site as a Treatment for Boerhaave’s Syndrome
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We present a case of a 40 year old male active duty soldier who came to a troop medical clinic complaining of emesis and chest pain. He was found to have a pneumothorax and left pleural effusion. An esophagram showed free communication of the esophagus with the left pleural cavity consistent with Boerhaave’s Syndrome. He underwent left thoracotomy with decontamination, thoracotomy tube placements, and exploratory laparotomy with draining gastrostomy and feeding jejunostomy tube placement. Later, a loop esophagostomy was placed in his neck for diversion of his saliva stream. During a repeat left thoracotomy for decortication of a fungal empyema, the esophageal rupture was identified and repair attempted. A subsequent esophagram showed persistent contrast extravasation at the distal esophagus. After dilation of the gastrostomy site to allow introduction of the delivery system, a 9cm/16mm Polyflex stent (Boston Scientific) was placed over the distal esophagus via a retrograde approach under fluoroscopic guidance. The stent migrated into the stomach within minutes and was removed. Another attempt was successfully made 3 days later with a larger 15cm/25mm stent, confirmed by an immediate gastrograffin contrast study. Following the procedure, the patient recovered quickly. A chest film 8 days later showed the stent to be in unchanged position. He was discharged after thoracostomy tube removal. He returned several weeks later much improved. Repeat esophagram showed no extravasation, but the stent had migrated into the stomach. He is now scheduled for re-anastomosis of the esophagus, with possible intestinal interposition or gastric pull-through approach, in the next few weeks. The stent will be removed at that time. This case represents an unorthodox retrograde approach to stent placement not commonly seen in the literature. While surgical correction remains the gold standard, stent placement has enjoyed increasing popularity though the number of reported cases is still relatively small, especially so with respect to a retrograde approach. As seen in our case, finding the correct site for stent placement may be a commonly encountered problem. In general, Polyflex stents are more economical and more pliable than metallic stents. The pliable nature of this stent may minimize complications previously seen upon stent removal.

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Henoch Schonlein Purpura in the Adult
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Henoch Schonlein purpura (HSP) is a vasculitic disease characterized by IgA deposition within the small vessels of the skin, gut, and glomeruli, and is often associated with arthritis and arthralgias. It is relatively common among children, occurring with an incidence of 14 cases per 100000, but is rare among adults. A 46-year-old man presented with a two-week history of rash and a two-day history of bloody diarrhea and severe abdominal pain. On physical examination, he had purpuric and petechial lesions on the extremitities and trunk, as well as diffuse abdominal tenderness with rebound and guarding. The patient was afebrile and denied any recent illness. On routine laboratory testing the hemoglobin level was 13.7g per deciliter, and the white-cell count was 12700 per cubic millimeter with neutrophilia (73.9 percent neutrophils, 3.0 percent eosinophils, 0.7 percent basophils, 6.5 percent monocytes, and 15.8 percent lymphocytes). A computed tomography scan of the abdomen revealed bowel wall edema in both the distal duodenum and proximal jejunum. On esophageal-gastric-duodenoscopy, purpuric lesions were identified in the 2nd portion of the duodenum. Further laboratory testing revealed elevated serum IgA and decreased complement 4 protein. The diagnosis of Henoch Schonlein purpura was confirmed by biopsy of the duodenal lesions showing deposition of IgA in the vasculature. The patient was treated with mederol (1 mg per kilogram of body weight per day). Early in his treatment he developed hyperkalemia, a decreased creatinine clearance, and a 24 hour urine protein of 6g. At discharge on day 13, he had resolution of his skin lesions, hematochezia, and abdominal pain. HSP typically runs a benign course in children; however, it is important to note that adults are at increased risk of severe disease and the development of chronic renal sequelae. In adults with HSP, proteinuria greater than 1g per day and serum creatinine greater than 1.2 mg per deciliter are prognostic factors that correlate with poor renal outcomes. Among adults with HSP that have had renal biopsies early in the disease, approximately one-third develop chronic renal functional impairment and 11–16% develop end-stage renal disease. To date there have been no prospective controlled clinical trials evaluating pharmacotherapies for adult HSP; but retrospective studies have shown success with corticosteroids, methylprednisolone pulse therapy, immunosuppressive agents, plasmapheresis, and immunoglobulin therapy.

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Celiac Disease Causing NASH with Complete Resolution Following a Gluten-Free Diet
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A healthy 57 year old white female was noted to have elevated liver enzymes (ALT 61, AST 74, AKP 190, T. Bili 0.4) on several occasions. Initial work up revealed a negative viral hepatitis panel, negative ANA, ASMA, AMA, and anti-LKM antibodies. The patient displayed the MPZ phenotype for alpha-1 antitrypsin, and her ferritin was 24. She was 62 inches tall and weighed 102 pounds. She denied current and past alcohol use. A liver biopsy was then performed and revealed antigliadin IgA 1780, antigliadin IgG 123, and t-Transglutaminase IgA 152 (all nl <20). Due to the patient’s mild but chronic complaints of bloating and fatigue, screening for celiac disease was performed and revealed antigliadin IgA 1780, antigliadin IgG 123, and t-Transglutaminase IgA 152 (all nl <20). An EGD with duodenal biopsies confirmed the diagnosis of celiac disease (MARSH IIIb) and the patient was advised to follow a gluten-free diet. She returned after 3 months reporting resolution of dyspepsia, an improved appetite, and a noted weight gain of 24 pounds (BMI up to 23 kg/m2). Repeat liver enzymes revealed complete normalization of ALT, AST, and AKP. The liver enzymes remained normal at 6 months despite further weight gain (BMI up to 25.1 kg/m2). In response to the patient’s request, a repeat liver biopsy was performed to confirm improvement of liver pathology. It revealed <10% steatosis with resolution of NASH and of fibrosis. This case represents the unusual finding of elevated liver enzymes and NASH in a patient with celiac disease; with resolution of both following a gluten-free diet and despite marked weight gain. Elevated liver enzymes have been well described in the presence of celiac disease, however histological changes in the liver, in this context, have been described as “non-specific” or “reactive” changes. NAFLD has also been described in these patients, presumably due to malnutrition, but is typically steatosis without inflammation or fibrosis. To our knowledge, this is the first case in the medical literature to describe NASH in a celiac disease patient with complete resolution following a gluten-free diet. We suggest that screening for celiac disease should be considered in patients with NASH, especially in the absence of a suspected etiology.

Liver Abscess after Transcatheter Arterial Embolization of an Hepatocellular Carcinoma: A Case Report
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Transcatheter arterial embolization (TAE) is used as definitive treatment for unresectable hepatocellular carcinoma (HCC) as well as for downsizing large lesions for the purpose of potential resection or liver transplant. Liver abscess after TAE for HCC is very rare and the incidence varies from 0% to 1.1%, but carries a significant mortality ranging from 14% to 50%. We report a patient with HCC who developed a liver abscess post TAE with successful response to IV antibiotics and percutaneous aspiration. A 65 year-old male with well compensated Leanneec’s cirrhosis was found to have a liver lesion on CT done for follow up of his head and neck tumor in remission. Though initially felt to be a metastatic lesion, HCC diagnosis was made by liver biopsy. In view of the large size of lesion (10 cm) he underwent bland portal vein embolization to induce hypertrophy of the remaining liver prior to surgical resection which was unsuccessful. He then underwent bland embolization of the hepatic artery. He developed right upper quadrant pain shortly after the procedure with a benign abdominal exam and was hospitalized for pain control. On the fourth day post-procedure, he had a fever spike of 101.2 F. He was started on IV piperacillin/tazobactum. His WBC increased to 13000. His urine and blood cultures and chest X-ray were negative. CT abdomen revealed interval development of small focus of air in a portion of the mass. CT guided aspiration yielded 3cc of pus; cavity was too small to leave behind an indwelling drain. Patient deferreded shortly afterwards with resolution of his abdominal pain. Patient was discharged home after receiving 10 days of IV antibiotics. The rarity of infarction and subsequent formation of an abscess after TAE has been mainly attributed to the abundant blood supply in the liver. The partial embolization of the portal vein prior and the large tumor size increased the risk of an abscess in our patient. At present, routine use of prophylactic antibiotics in TAE patients is not generally recommended. Early diagnosis and treatment including parenteral antibiotics and percutaneous aspiration/catheter drainage are highly effective in the management of post TAE liver abscess as seen in our case.
A 78-year-old male with a history of hypertension and recently diagnosed iron deficiency anemia was transferred to our facility after massive post-polypectomy bleeding. In the past six months, he experienced occasional episodes of hematochezia. Colonoscopy at another facility noted multiple polyps. Snare polypectomy was performed, resulting in immediate bleeding and submucosal hemorrhage. The procedure was terminated and the patient was transferred to our facility for further care. His vital signs were stable on presentation. Pertinent physical exam findings included two discrete 2 mm lesions seen on his lower abdomen described as dark blue and protuberant. Laboratory assessment included a Hgb of 12.7 g/dL (MCV 92 fl, RDW 25%). Colonoscopy was repeated revealing multiple raised polypoïd, bluish purple lesions throughout the colon (see pictures). There was no active bleeding and no intervention was done.

Discussion: This patient has Blue Rubber Bleb Nevus Syndrome (BRBNS), a rare disorder with approximately 200 cases reported in the literature. This syndrome is characterized by distinctive cutaneous vascular malformations and gastrointestinal (GI) hemangiomas. Case reports show that the central nervous system, thyroid, eyes, lungs, and bladder may also be affected. A patient may have a few to hundreds of lesions measuring up to 2 cm each. Most cases are sporadic but autosomal dominant inheritance has been reported. Affected individuals can initially present with iron deficiency anemia from occult GI bleeding or even massive GI bleeding, which can be fatal. Endoscopic recognition is important as attempts to biopsy or remove these lesions can result in significant complications. Serial transfusions and lifelong iron replacement have been used to manage this disease. Optimal management remains unclear due to its rarity and anecdotal reporting.

Budd-Chiari Syndrome Due to Inferior Vena Cava Obstruction by Leiomyosarcoma

Leiomyosarcoma (LMS) of vascular origin is rare. Similarly, inferior vena cava (IVC) sarcoma is an unusual cause of Budd-Chiari syndrome. We describe a patient with newly diagnosed LMS who subsequently presented with marked hepatomegaly as the initial manifestation of acute Budd-Chiari syndrome. We report this case to alert clinicians to the spectrum of this rare association.

Case Report: A previously healthy 53 year old man was seen for bilateral lower leg edema. He had no hepatomegaly or ascites on physical exam. Liver function was normal biochemically. Abdominal CT revealed a heterogeneous, enhancing retroperitoneal mass above the right kidney and tumor or clot along the length of the IVC. No ascites was present. Imaging-guided biopsy documented a spindle-cell tumor consistent with leiomyosarcoma.
Discussion:

IVC. He underwent TIPS. 885/704; alkaline phosphatase = 885 previously occult IVC leiomyosarcoma. that abdominal distention and hepatomegaly may be the initial features of a common disorders. Budd-Chiari syndrome, in our patient, occurred acutely symptoms, (2) fulminate, acute, sub-acute or chronic onset suggesting more ble state. Delay in diagnosis may occur due to (1) atypical or non-specific of non-vascular origin may also compress or infiltrate the IVC, cause intimal clot caused hepatic venous obstruction. Contiguous or metastatic neoplasm of non-vascular origin may also compress or infiltrate the IVC, cause intimal damage resulting in clot formation, or be associated with a hypercoagulable state. Delay in diagnosis may occur due to (1) atypical or non-specific symptoms, (2) fulminate, acute, sub-acute or chronic onset suggesting more common disorders. Budd-Chiari syndrome, in our patient, occurred acutely one week after presentation and diagnosis of LMS. Clinicians must be aware that abdominal distention and hepatomegaly may be the initial features of a previously occult IVC leiomyosarcoma.

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Hemobilia after Laparoscopic Cholecystectomy: A Case Report
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Hemobilia is a rare complication of laparoscopic cholecystectomy. We present a case of hemobilia seven days after laparoscopic cholecystectomy. Clinical presentation, radiologic findings, outcome, and management are discussed. A review of the literature is also performed. Case Report: A 50 y.o. female underwent an uncomplicated laparoscopic cholecystectomy for symptomatic cholelithiasis. One week after surgery, she was admitted to the hospital with a three-day history of RUQ pain, nausea, vomiting, and abnormal liver function tests (bilirubin = 2.1 mg/dl, alkaline phosphatase = 138 IU/L, AST – 645 IU/L, and ALT – 273 IU/L). HIDA scan was normal, and CT scan described a possible hematoma in the gallbladder fossa. Three days after admission, the bilirubin increased to 4.9 mg/dl and the hematocrit decreased from 42% to 34.8%. The patient underwent an ERCP which showed active bleeding from the major ampulla. A cholangiogram demonstrated multiple filling defects in the common bile duct and common hepatic duct with no ductal dilatation. Sphincterotomy was performed and a balloon was dragged through the common bile duct. A few blood clots were obtained. An arteriogram was done which showed a thrombus at the base of the right hepatic artery with possible dissection. There was no pseudoaneurysm. No active bleeding was found nor was embolization done. The patient remained clinically stable with eventual normalization of liver function tests.

Discussion: Hemobilia is a rare complication which is mostly caused by either blunt or penetrating trauma (up to 48% of cases). It is also described in cases of infection, gallstones, tumor, pancreatitis, and aneurysms. Only a few cases have been reported as a complication from laparoscopic cholecystectomy. Imaging studies that may help in the diagnosis are CT scan, RUQ ultrasound, and HIDA scan. ERCP confirms the diagnosis, after which an arteriogram should be done as it is the most accurate test to locate the lesion; it can also be therapeutic with embolization of the bleeding vessel. The patient presented in this case remained clinically stable without further surgical or medical intervention. Hemobilia should be considered in a patient presenting with abdominal pain and abnormal liver function tests after laparoscopic cholecystectomy.

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A Novel Indication for Transjugular Intrahepatic Portosystemic Shunt (TIPS): Porta hypertension enteropathy
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A 64 yr/old male was transferred for management of gastrointestinal bleeding and ascites. The patient had been hospitalized twice in the past 11 days secondary to weakness, intermittent melena and profound anemia. He received a total of 9 units of RBCs. Concurrently, the patient was having difficulties with asites refractory to diuretics requiring paracentesis. His past medical history included Laennec’s cirrhosis and rectal adenocarcinoma stage IIIb. A rectosigmoid resection and colostomy was performed in 2004 followed by treatment with adjuvant chemotherpay and radiation. Esophagogastroduodenoscopy and colonoscopy revealed diverticulosis and duodenopathy without ulcerations or varices. A capsule endoscopy showed mucosal changes consisting of multiple areas of patchy erythematous and edematous small bowel mucosa and numerous telengectasias, petechiae and white varices. These findings were visualized from duodenum to terminal ileum and felt to represent extensive portal hypertension enteropathy. He was started on nadolol and discharged. The patient continued to have intermittent melena and required blood transfusions every 7–14 days in order to maintain his Hgb > 8.0 g/dL. He required paracentesis to manage his ascites. A TIPS was placed with reduction of his portosystemic gradient from 16 mmHg to 6 mmHg. The patient did well after TIPS placement with decreased transfusion requirements and resolution of ascites. He experienced one episode of encephalopathy which responded to lactulose. Three months post TIPS his hemoglobin was stable and he no longer required blood transfusions. A repeat capsule endoscopy noted significant improvement of his portal hypertensive enteropathy. The endoscopic findings of portal hypertension are well recognized in the esophagus, stomach and colon. The emergence of capsule endoscopy has allowed better visualization of the small bowel and characterization of portal hypertension enteropathy. The treatment and management of portal hypertension enteropathy has yet to be defined. A TIPS is a well recognized treatment of portal hypertension complications such as rescue therapy for variceal bleeding, refractory ascites, and hepatic hydrothorax. Indications are expanding and include Budd-Chiari syndrome, veno-occlusive disease, hepatorenal syndrome, and hepatopulmonary syndrome to name a few. Portal hypertension enteropathy represents an additional arena for a TIPS placement.

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A Giant Ischemic Ulcer in the Transverse Colon: A Unique Complication of a Benign Post-Radiation Sigmoid Stricture
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We present an unusual case of a Giant Ischemic Ulcer in the transverse colon resulting from a benign Postradiation sigmoid stricture. To our knowledge there is only one case reported of Idiopathic ulceration and stricture of colon with unusual vascular changes (1).

Case Report: 75-year-old Hispanic male with history of prostate cancer, status post radiation therapy three years ago, presented with obstructive symptoms. Barium enema revealed a 16 cm sigmoid stricture with 17 cm dilation of the transverse colon. Subsequent decompression colonoscopy revealed a 5 cm ischemic ulcer in the transverse colon. The patient did not improve with conservative management and required a surgical resection.

Discussion: Our patient presented with a severe sigmoid stricture that over time has lead to a massive transverse colon distention and vascular compromise. Local ischemia eventually resulted in a formation of a giant ischemic ulcer. Multiple stage resection is preferred: first stage is diversion of colon, followed by resection of the stricture with adequate margins of healthy tis-
Primary Hepatic Actinomycosis
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We present a case of a 60-year-old male with actinomycosis in the liver, which is a rare site to be primarily affected with actinomycosis. Primary hepatic actinomycosis is a rare infection that can clinically be confused with hepatic pyogenic abscesses or neoproliferative processes. So far, about 75 cases of primary hepatic actinomycosis have been reported in the literature. It is usually cryptogenic and is more common among immunocompetent individuals and male subjects. Chart review, review of available literature using medline and relevant bibliographies of published articles. A 60-year-old male presented with complaints of 6 weeks of generalized weakness, anorexia and a 12-pound weight loss. On admission, he had a temperature of 101 °F, pallor and mild right upper quadrant tenderness. Past medical history was pertinent for a normal colonoscopy one month ago. Laboratory studies revealed a normocytic normochromic anemia and mild elevations in AST, ALT and alkaline phosphatase. During his hospitalization, he continued to spike daily fevers for over 3 days despite broad-spectrum antibiotics. An Abdominal Ultrasound and CT both suggested a complex mass measuring 10 cm x 8 cm in the right lobe of the liver with mild dilatation of intrahepatic biliary tree. These findings were consistent with an abscess or a tumor. Serum alpha-fetoprotein was normal. Subsequent CT-guided aspiration biopsy revealed findings of infiltration of neutrophils and characteristic sulfur granules by light microscopy. Actinomyces species was also cultured from aspirated pus. Patient was successfully treated with percutaneous catheter drainage and extended courses of intravenous and oral penicillin treatment. This relatively rare case illustrates the need for high index of suspicion, early diagnosis and appropriate management as the infection can be cured with long term antibiotic therapy.

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Autoimmune Pancreatitis (AIP) Mimicking Pancreatic Cancer
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69-year-old man of Greek descent with PMH of dyslipidemia and HTN initially presented with fatigue, malaise, cough and fever of short duration. His primary care physician treated patient with azithromycin for upper respiratory tract infection. Patient returned in 7 days with yellowish discoloration of eyes and skin, dark yellowish urine and pale colored stools. His medications at that time were atorvastatin and terazosin. Family history was negative for GI malignancies. Patient was a former smoker and never abused alcohol. On physical exam patient was visibly icteric with no lymphadenopathy, palpable masses or enlarged organs. Pertinent labs: Total Bilirubin 8.4 mg/dL, direct bilirubin 5.1 mg/dL, Alkphos 671 IU/L, AST 313 IU/L, ALT 393 IU/L, INR 1.1, viral hepatitis panel negative. Drug induced cholestasis was suspected and azithromycin and atorvastatin were discontinued. Patient returned in 7 days with worsening of jaundice, dyspepsia and weight loss of 8 lb. Pertinent labs at that point included: total bilirubin 17 mg/dL, GGTP 1379 IU/L, Alkphos 1680 IU/L, AST 308 IU/L, ALT 358 IU/L, albumin 3.8 g/dL and globulin 4 g/dL. Abdominal CT scan showed a mass in the head of the pancreas with extrapancreatic biliary obstruction, highly suspicious of pancreatic cancer. ERCP showed double duct sign, characteristic of pancreatic cancer. Patient underwent a pancreaticoduodenectomy. However, pathologic diagnosis was autoimmune pancreatitis. Postoperative course was complicated by gastric dysfunction, which later resolved. Pertinent labs obtained at this time included: IgG subclass 4: 471 (7–89 mg/dl), ANA negative, anti-mitochondrial antibody negative, Rheumatoid factor 744 (< 20), CRP 0.5 (< 1mg/dl). Patient was started on oral corticosteroids and pancreatic enyzme supplements. Currently he is totally asymptomatic six months post surgery.

Discussion: AIP or Lymphoplasmacytic sclerosing pancreatitis is a genuine clinical entity with very few case-reports. Hallmarks of AIP are: periductal inflammation and fibrosis, reactive fibroinflammatory pseudotumor...
and venulitis and periphlebitis. Diagnosis should be considered in patients with pancreatic mass in patients with autoimmune disorders. High IgG4 levels are very specific for AIP. Endoscopic ultrasound biopsy is recommended prior to surgery. However it is rarely recognized preoperatively, most of the patients end up getting surgery. Corticosteroids have been tried with some success and recurrences are common.

**Sebaceous Gland Carcinoma as the Initial Clue to Occult Colon Carcinoma (Muir-Torre Syndrome)**

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Muir-Torre syndrome is a rare disease characterized by sebaceous gland tumors associated with internal malignancies, especially colorectal cancer. To alert clinicians to this rare syndrome, we report a case of facial sebaceous carcinoma leading to diagnosis of an occult colon cancer.

**Case report:** A 48-year-old man presented with a 2 month history of facial skin lesions. Past medical history included a childhood history of blistering sunburns. Family history was positive for colon cancer in both his father and brother, each diagnosed in their early 40’s. Neither had documented skin lesions. The patient had recent negative fecal occult blood testing and a normal colonoscopy 5 years previously. He denied weight loss, change in bowel habits or rectal bleeding. Physical exam was unremarkable except for the skin exam which revealed 3 smooth, round, firm flesh-colored papules located on his forehead, nose, and cheek. Biopsy revealed that 2 of the lesions were sebaceous carcinomas. He underwent Mohs surgery for complete removal. Because of the association of sebaceous carcinoma with visceral malignancy, the patient was referred for colonoscopy, which demonstrated a 2 cm polyp with high-grade dysplasia. A right colectomy was performed; pathology documented an invasive mucinous adenocarcinoma. Immunohistochemistry showed evidence of microsatellite instability in the tumor with MSH2-2 antibody, supporting the diagnosis of Muir-Torre syndrome.

**Discussion:** Recognition of these rare sebaceous skin lesions warrants investigation for associated visceral malignancy, most commonly colonic, but also uterine (15% of women with Muir-Torre), bladder, and UGI tract. Nearly 50% of these patients develop 2 or more visceral malignancies. In as many as 20% of cases, skin lesions are the initial manifestation. Colonoscopy surveillance is mandatory as is evaluation of other potential sites. This syndrome is inherited in an autosomal dominant pattern; defects in mismatch repair genes, especially in MSH2 and MLH1, result in microsatellite instability in both cutaneous lesions and internal tumors in Muir-Torre. Analysis of microsatellites or immunohistochemistry testing for MSH2 and MLH1 in skin and visceral tumors is an important diagnostic tool. Physicians must be aware of the Muir-Torre syndrome, its genetics, and the high risk of associated malignancy.

**Severe Necrotizing Pancreatitis and Pseudocyst Development in a Patient on Peritoneal Dialysis**

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In recent years renal dialysis, especially peritoneal dialysis (PD), has become increasingly considered a risk factor for acute pancreatitis (AP). The mechanism of pathogenesis of AP in PD is unclear, however PD appears to have at least a 3-fold higher risk of AP when compared with hemodialysis (HD). Most reported cases of AP in PD are mild or moderate in severity. In this case we report on the development of severe necrotizing pancreatitis and subsequent pseudocyst development with steatorrhea in a patient on PD.

**Case Report:** A 42 y/o black woman with end-stage renal disease from focal segmental glomerulosclerosis, on PD for 22 months, presented to our institution with 2 weeks of abdominal pain, nausea and vomiting. She had no jaundice or fever, and reported no history of alcohol use. She was not taking medications associated with pancreatitis. On admission her lipase was >4000 and liver enzymes were normal. Her WBC count was 23K but rapidly climbed to >50K by the following day. Blood and peritoneal fluid cultures and Gram stains were negative, however she had over 13000 WBC’s in the peritoneal fluid. She had no prior episodes of peritonitis, and was not hyperalacemic or hyperlipidemic. She was placed into the ICU and started on empiric imipenem. PD was ceased and she was changed to HD. CT scan showed necrosis of approximately 30% of the pancreas. She had no apparent complications while in the hospital and was discharged after 12 days. 2 weeks later, she was noted to have steatorrhea, intermittent bouts of pain, and epigastric fullness. She was placed on pancreatic enzyme replacement with resolution of her steatorrhea. MRI/MRCP showed a 6–8 cm cystic lesion in the body of the pancreas. CT guided drainage could not be performed because of an inadequate percutaneous window. She is currently being considered for endoscopic cystgastrostomy.

**Discussion:** This case demonstrates an important, newly recognized risk factor (PD) for AP, and is one of the first reported cases of severe necrotizing pancreatitis with pseudocyst formation and residual exocrine insufficiency associated with PD. Gastroenterologists and nephrologists should recognize PD as an emerging risk factor for AP, including severe cases. Although a complete workup needs to be performed to rule out anatomical causes for AP, these patients may require conversion from PD to HD.

**Endoscopic Clips as Markers To Target Angiographic Therapy of Massive GI Bleeding**

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Metallic endoscopic clips may be useful in identifying the sources of bleeding during angiography. We have used this concept of "Endoscopic Clips as Markers" to help identify a pseudoaneurysm of the gastroduodenal artery (GDA) stump that showed no active extravasation on angiography. Rebleeding was prevented by the placement of an endovascular stent-graft.

**Case Report:** A 43-year old male presented with massive hematemesis 1 month after pylorus preserving Whipple procedure for chronic alcoholic pancreatitis. Emergent endoscopy after resuscitation using a cap assisted pediatric colonoscope demonstrated arterial bleeding from the pancreatic
anastomosis to the jejunum. The bleeding recurred after initial control with application of the first clip. Despite application of multiple clips and dilute epinephrine injection, bleeding continued. Emergent angiography with selective cannulation of celiac trunk was performed. A pseudoaneurysm of the GDA stump was seen in intimate relation to the metallic endoscopic clips (Features: the visualized stump was irregular and larger than the native artery, along with delayed washout of contrast), as shown in figure 1. A 6mm x 40mm Fluency Stent-Graft (Bard, Tempe AZ; Tracheobronchial stent) was deployed in the common hepatic artery to exclude the mouth of the pseudoaneurysm as shown in figure 2. The patient recovered well without any further bleeding episodes. Our case demonstrates the value of endoscopic clips in focusing angiography for effective hemostasis. They are useful in identifying pathology and offering therapy, especially when there is no active bleeding during angiography. [figure1][figure2]

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Use of Polylef® Stent in Conjunction with Infliximab for Refractory Crohn’s Esophageal Stricture

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We report a novel experience with the management of refractory Crohn’s esophageal stricture Case Report: A 59 year old female with history of intestinal and extraintestinal Crohn’s disease was evaluated for dysphagia secondary to esophageal stricture. Endoscopy showed membranous and ulcerative esophagitis. At 25 cm there was significant luminal narrowing. Biopsy revealed ulcerated squamous epithelium, active esophagitis, absence of dysplasia, microorganisms and granuloma formation. The combination of clinical, endoscopic, and histologic information suggested a diagnosis of esophageal Crohn’s disease. Repeat endoscopic balloon dilatations yielded no symptomatic improvement. She returned complaining of persistent dysphagia, weight loss, chest discomfort, and pyrosis. She was started on Infli- ximab and received two infusions 6 weeks apart. Infliximab was continued of clinical, endoscopic, and histologic information suggested a diagnosis of esophageal Crohn’s disease. The bleeding recurred after initial control with application of the first clip. Despite application of multiple clips and dilute epinephrine injection, bleeding continued. Emergent angiography with selective cannulation of celiac trunk was performed. A pseudoaneurysm of the GDA stump was seen in intimate relation to the metallic endoscopic clips (Features: the visualized stump was irregular and larger than the native artery, along with delayed washout of contrast), as shown in figure 1. A 6mm x 40mm Fluency Stent-Graft (Bard, Tempe AZ; Tracheobronchial stent) was deployed in the common hepatic artery to exclude the mouth of the pseudoaneurysm as shown in figure 2. The patient recovered well without any further bleeding episodes. Our case demonstrates the value of endoscopic clips in focusing angiography for effective hemostasis. They are useful in identifying pathology and offering therapy, especially when there is no active bleeding during angiography. [figure1][figure2]

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A Rare Presentation of Gastric Adenocarcinoma with Acute Pulmonary Embolism and Fatal Acute Disseminated Intravascular Coagulation

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Acute disseminated intravascular coagulation (DIC) is a rare but serious complication of malignancies. There are no standard treatment protocols to treat acute DIC in a setting of malignancy. However, there are some reports of using various combinations of chemotherapy with successful results. We report a rare case of poorly differentiated gastric adenocarcinoma initially complicated by deep vein thrombosis and pulmonary embolism (PE) with subsequent fatal acute DIC.

Case report: A 57 year-old African American male presented with dysphagia, weight loss and left upper extremity swelling. His medical history included hypertension, chronic renal insufficiency and remote history of Billroth-type I gastrectomy for duodenal ulcer. Physical exam was significant for thin and malnourished male with an enlarged left supraclavicular lymph node. A bilateral upper extremity venous doppler ultrasonography showed thrombosis of the left internal jugular, left subclavian, and left bra-chiocephalic veins. The ventilation perfusion (VQ) scan was performed and confirmed abnormal ventilation and perfusion defect with high probability of PE involving the right middle lobe. Esophagogastroduodenoscopy (EGD) was subsequently performed and revealed distal esophageal ulceration along with marked thickening and erythema of the gastric mucosa. Gastric biopsies revealed poorly differentiated adenocarcinoma with signet cell features. He was started on coumadin treated symptomatically. Two months after initiation of oral anticoagulation, the patient developed hematemesis. His laboratory findings were significant for coagulopathy with elevated prothrombin time and partial thromboplastin time along with thrombocytopenia and marked hemolytic anemia. Acute DIC was confirmed on subsequent hematologic analyses. Anticoagulant was stopped and he was treated with blood and blood product transfusions. Moreover, high dose 5-fluorouracil (5-FU) and leucovorin was initiated to control DIC. Despite intensive medical interventions patient’s expired eighth days after the onset of DIC. Our case illustrates the extremely rare presentation of gastric adenocarcinoma with both hypercoagulable state and subsequent acute DIC. Although high doses of 5-FU and leucovorin have previously been reported to successfully treat malignancy related acute DIC leading to prolong survival, the treatment was not helpful in our patient.

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Novel Use of Hemoclips in Control of Profuse Rectal Bleeding after Transrectal Prostate Biopsy

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Case Report: A 59-yr male with elevated PSA underwent transrectal prostate biopsy. The procedure was uneventful, however, over the next two days, the patient had intermittent episodes of small volume hematochezia. On the third day post-biopsy day, successive episodes of hematochezia prompted ER visit. Initial evaluation revealed persistent hematochezia on rectal examination. The hemoglobin decreased from 12.2 g/dL to 10.5 g/dL within two hours, necessitating admission to the MICU. An emergent flexible endoscopy (Olympus® GIF-Q160, Olympus, Japan) was performed. Upon advancing into the rectum, fresh blood and blood clots were encountered. After washing and suctioning, a single actively bleeding site, in the anterior rectal wall...
approximately 20 mm from the dentate line was identified, presumed to be the recent transrectal biopsy. Hemostasis was achieved by successful application of three hemoclips (OlympusTM America Corp, Melville, NY). The patient did not have any further episodes of rectal bleeding, tolerated regular diet, and was subsequently discharged within two days.

Discussion: In a large prospective study, the incidence of rectal bleeding after prostate biopsy was reported to range from 17% to 27%, however severe rectal bleeding requiring hospitalization is a rare and uncommon complication. Several methods were reported to be effective in achieving hemostasis after transrectal prostate biopsy. Use of vasoconstricting and sclerosing agents; placement of a 3-way balloon catheter in the rectum; and deployment of rubber bands over actively bleeding sites, were all described to be effective in achieving hemostasis. The potential therapeutic applications of endoscopic hemoclips has rapidly expanded. Technical improvements in hemoclip deployment has significantly enhanced its ease of use. Similarly, hemoclips have been reported to result in a high rate of primary hemostasis (85–100%), and has been shown to be as effective as combination therapy (epinephrine and electrocoagulation) in the therapy of non-variceal upper GI bleeding. Our case demonstrated the novel use of hemoclips in a rare case of post-transrectal prostate biopsy. Mechanical hemostasis was effectively achieved, which resulted in rapid clinical improvement. We demonstrate the potential value of endoscopic hemoclip application in the therapy of overt lower GI bleeding.

Elevated Serum Gastrin: Cases of Mistaken Identity
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Case 1: A 69 year old woman was referred for evaluation of suspected gastrinoma. She had experienced 10 years of intermittent hot flashes, loose stools, and near syncope. Outside workup included serum chromogranin A 54 (ULN 51), VIP normal, gastrin 1661 (ULN 114), and an EUS reportedly with a hypodense lesion in the pancreatic neck. Fine needle aspiration of this lesion revealed gastric cancer. The patient was subsequently treated with aogastric bypass. Our patient demonstrated the novel use of hemoclips in a rare case of post-transrectal prostate biopsy. Mechanical hemostasis was effectively achieved, which resulted in rapid clinical improvement. We demonstrate the potential value of endoscopic hemoclip application in the therapy of overt lower GI bleeding.

Myxedema Coma from Administration of Replacement Thyroid Therapy Directly to the Colon Via a Malpositioned Replacement Percutaneous Endoscopic Gastrostomy Tube
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An unusual case of myxedema coma is reported in a patient receiving thyroid replacement therapy for hypothyroidism, delivered via a replacement percutaneous endoscopic gastrostomy (PEG) tube inadvertently placed in the colon.

Case Report: An 82-year-old male nursing home patient was admitted with an acute change in mental status. At the nursing home the patient had been administered an oral form of levothyroxine delivered via a PEG. This Ponsky-Gauderer type PEG tube was reportedly placed without complications and was revised 6 months prior to admission with a replacement PEG tube ( Foley-type catheter). Laboratory tests on admission revealed elevated serum levels of lactate (59.5 mg/dL) and TSH (77 IU/mL), as well as a depressed serum level of thyroxine (0.7 mg/dL), findings compatible with myxedema coma. The patient was successfully treated with IV levothyroxine and corticosteroids. Abdominal CT scan revealed an unidentified foreign body in the stomach and the replacement catheter balloon in the colon. Upper gastrointestinal endoscopy demonstrated the gastric foreign body to be the bumper of the original PEG tube, which was removed via an endoscopic snare. The intracolonic replacement PEG tube was removed percutaneously after balloon deflation. The colocolonic fistula rapidly healed. During placement of the original PEG, the colon was evidently perforated en route to the stomach thereby creating a gastrocolocutaneous fistula. When the PEG was replaced, the catheter was advanced through the original fistula into the colon without reaching the stomach. Consequently, thyroid replacement therapy was delivered directly into the colon. PEG provides enteral nutrition and medications to patients who cannot take food orally. PEG placement is successful in about 98%, with major complications in about 2% of patients. In this case PEG tube replacement resulted in a colocolocutaneous fistula. This fistula may occur by perforation of intervening bowel during PEG placement or by gradual erosion of the bumper from the stomach into adjacent colon over time. This complication clinically presents with stool leakage around the PEG site, diarrhea, weight loss, acute peritonitis or fasciitis, or gastrointestinal obstruction. The clinical presentation as myxedema coma due to improper site of delivery of medication from faulty PEG placement is unique and novel.

Isolated Angioedema of the Bowel Due to C1 Esterase Inhibitor Deficiency
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Angioedema usually involves the cutaneous and respiratory systems and very rarely is limited to the gastrointestinal tract.

Case Report: Our patient is a 66 yr old Caucasian male with no significant PMH presented with episodic abdominal pain and watery diarrhea for 10 months. He had no h/o urticaria, laryngeal edema, no h/o of use of ACE inhibitors, and no family h/o angioedema. Work up with colonoscopies, exploratory laparotomy with celiac biopsies were nondiagnostic. During the episodes, CT scans revealed thickened small bowel and ascending colon and free fluid in the abdomen. Small bowel series showed mucosal irregularities and intramural edema of the distal ileum. CT scans in between attacks did not show any mucosal edema. Lab studies revealed decreased complement C4, CH50 < 10 U/mL, C1 esterase inhibitor < 4 mg/dL and leukocytosis. His ANA, stool analysis, methemoglobin, ANCA, ASCA, porphyrin levels were within normal limits. Patient was diagnosed with isolated angioedema
VIPomas are rare neuroendocrine tumors that secrete Vasoactive Intestinal Polypeptide. Most VIPomas arise within the body or tail of the pancreas. VIPomas are usually isolated tumors but can occur as part of MEN I syndrome in 5% of cases. Most patients present with VIPoma syndrome (Verner-Morrison syndrome) or the Watery Diarrhea Hypokalemia and Achlorhydria (WDHA) syndrome.

Case report: A 55 year old Hispanic female with past medical history significant for hepatitis C and hypertension presented with a one-year history of large volume watery diarrhea. She denied abdominal pain, fever/chills, recent travel or antibiotic use. Laboratory studies showed dehydration, metabolic acidosis, hypokalemia, hyperglycemia and hypercalcemia. VIP level was 1317. The patient was started on octreotide which helped control her symptoms. MRI showed a large heterogeneously enhancing mass in the tail of the pancreas which measured $7.7 \times 5 \times 7.7$ cm and extended to the hilum of the spleen. Octreotide imaging revealed a large focal area of hot uptake within the region of the tail of the pancreas. The patient was referred for surgery and subsequently received a distal pancreatectomy and splenectomy. Pathology revealed a well differentiated endocrine tumor positive for VIP immunostain with free margins of resection. Post operative course was uneventful.

Discussion: The incidence of VIPoma is approximately 1 in 10 million with up to 60 – 80% having metastasized by the time of diagnosis. Subcutaneous octreotide controls diarrhea by decreasing VIP secretion. Surgery is the treatment of choice if there is no metastasis. We present an extremely rare case of solitary pancreatic VIPoma with excellent response to current standard of care.
Young Patient with Gastric Adenocarcinoma with Lymphatic Spread to Lungs
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History: A 20-year old Hispanic female presented with diffuse severe abdominal pain. Two months earlier she had projectile vomiting. She also had fatigue, nausea and intermittent melena two weeks earlier. ROS revealed an 8-pound weight loss over the past two months. Physical Exam: Cachexia (< 50% ile weight), non-specific abdominal tenderness. No palpable mass. Hemoglobin 4.6 gm/dl, MCV 62 fl, T1 36 mcg/dl, TIBC 400 mcg/dl. EGD demonstrated a bleeding ulcer with elevated rim. Biopsy showed infiltrating poorly differentiating adenocarcinoma and was positive for H.pylori. Chest x-ray demonstrated lymphangitis spread to the lungs and lytic lesion of ribs. Abdominal CT scan was unremarkable. v Nuclear bone scan showed multiple focal areas of abnormal uptake. v CEA level was 30 mg/ml. v Genetic testing Tissue specimen stained normal by in-situ hybridization (ISH) for E cadherin and Beta Catenin gene. Microsatellite instability was absent. Atypical (decreased) p53 gene expression was noted. Course in Hospital: Embolization of the left gastric artery that primarily supplied the tumor was successful. She was started on palliative radiotherapy and chemotherapy.

Discussion: Gastric cancer is very rare before 20 years of age. Since 1960, only 20 cases in patients younger than 20 years of age have been reported. Only 8 of these cases had lymphangitic spread of tumor to lungs. Most of these cases are diagnosed at stage 3 or 4. On histopathology, young patients have more undifferentiated adenocarcinoma and mucinous cell type with signet ring cells. In contrast to our patient who did not have any significant family history, majority of patients present with a strong family history. E cadherin gene mutation is common but microsatellite instability is uncommon in young age gastric cancers. Tumor biopsy in our patient stained positive for E cadherin and Beta catenin gene and also for APC and MSH/MLH – HNPPC meaning that she does not have either a germline or somatic mutation in those genes. ISH for p53 mutation study was positive. This raises a suspicion for Li Fraumeni Syndrome but the clinical scenario does not correlate. H pylori cagA positive strain is strongly associated with gastric cancer although its role in young patients is debatable as in our patient. Atypical (decreased) p53 gene expression was noted. Course in Hospital: Embolization of the left gastric artery that primarily supplied the tumor was successful. She was started on palliative radiotherapy and chemotherapy.

Treatment modalities mostly comprise of chemotherapy and radiotherapy. Prognosis in young patients is meager due to the poor differentiation and the late stage of presentation.

ERCP in Thoracocephalopagus Conjoined Twins
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Conjoined twins are said to occur about 1 in 200000 live births, with a female preponderance of 3:1. Only 5-25% of these live births survive. It is generally accepted that conjoined twins arise from a uniovular gestation that fails to undergo complete separation of the embryonic disc at the 13th-14th day stage. We report a 4 month old pair of female thoracocephalopagus conjoined twins referred for separation in whom ERCP was an important investigation. Computed Tomography of the abdomen and pelvis (Figure 1 to be shown if accepted) revealed a fused liver with a replaced hepatic artery arising from an enlarged SMA. The liver was perfused by both infants. There was also a shared portal vein. There were two gallbladders. There were multiple loops of bowel; the extent of the sharing was unknown. There were two separate distal colons and rectum. Subsequent abdominal ultrasound confirmed findings of the CT. CT Cholangiogram performed a few days later revealed a confluence of bile ducts draining both livers in the midline. The bile ducts drained into a shared common bile duct which then drained into a shared duodenum. The dominant bile duct in the RUQ in one twin joined in the midline with the dominant duct draining the liver in the other twin's RU and LU abdomen. Again seen was a common shared duodenum. ERCP was requested four weeks later to help to further delineate the biliary anatomy in preparation for anticipated separation. The ERCP (figure 2 to be shown if accepted) revealed a shared postbulbar duodenum. Cannulation of a shared ampulla of vater confirmed a shared CBD which bifurcated into separate cystic ducts, gallbladders and intra-hepatic biliary trees. The pancreas in the two twins was also discrete. The surgical separation approximately 3 weeks later was successful. This operation revealed that the twins shared liver, 90 cm small bowel starting at the post-bulbar duodenum, a common ampulla of vater and CBD. The intra-abdominal anatomy of thoracocephalopagus or omphalopagus conjoined twins is usually investigated by ultrasonography, contrast radiology, angiography, computed tomography and MRI. In this case ERCP was helpful in delineating amambiguous biliary anatomy in what is now a successful separation. After performing a literature search, we believe to have reported the first case of ERCP in a thoracocephalopagus conjoined twin. We believe that this procedure is useful in assisting a multidisciplinary team in planning surgical separation.

An Adjunctive Role for Intravenous Steroids in Refractory C. Difficile Colitis
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The clinical spectrum of Clostridium Difficile infection often includes severe and refractory forms of pseudomembranous colitis. Definitive antibiotic treatment of the infection is the mainstay of management rather than treatment of the colitis as a separate inflammatory entity. We report a case that highlights the potential utility of intravenous steroids in the management of refractory C. Diff colitis. A 77 year old female with significant comorbidities presented with recurrent abdominal pains, nausea, vomiting, diarrhea and fevers. She had been treated for recurrent C. Difficile infection and proven pseudomembranous colitis over the preceding 5 months with multiple agents including Flagyl PO and IV. Vancomycin PO at doses ranging from 125 mg qid to 500 mg qid, vancomycin retention enemas, Bactrim 25000 units qid, rifampin 600 mg daily, cholesteryramine up to 16 grams daily, and Sacccharomyces boulardii. Intravenous gamma globulin (300 mg/kg) was also used without improvement. Despite these interventions, she had persistent and refractory severe pseudomembranous colitis with stool toxin assays positive for C. Difficile. Her clinical course was complicated by sepsis, profound hypoalbuminemia, ascites, leukomoid reaction with a WBC count over 63000, and peritonitis requiring laparoscopy to rule out non-colitis pathology including ischemia. She was deemed to ill to tolerate a total colectomy. TPN was instituted with continued use of vancomycin and multimodality therapy. The patient had serial toxin assays which eventually came back negative as did a stool culture for C. Difficile. Despite this, the patient had continued clinical complications due a persistent and severe pseudomembranous colitis. She was placed on intravenous Solum-drol 40 mg bid with a significant clinical and endoscopic improvement in as short as 6 days and near resolution of the colitis by total colonoscopy within two weeks. She has remained stable following discharge. This case illustrates and highlights the potential utility of IV steroids in treating the colitis associated with Clostridium Difficile infection. It is postulated that some patients may develop a UC-like immune response triggered by C. Difficile, even after clearance of the toxin. The clinician should consider IV steroids as an adjunctive option for refractory colitis after aggressive antimicrobial treatments have not lead to optimal clinical resolution, especially if the patient is not an optimal surgical candidate.

A Man with Recurrent Upper Gastrointestinal (UGI) Bleeding Due to an Uncommon Parasitic Infection

Upper gastrointestinal bleeding is a common medical condition that can be associated with morbidity and mortality. Rarely a heightened clinical suspicion and specific testing are needed for diagnosis. We present an unusual case of a patient with recurrent massive UGI bleeding in whom the correct diagnosis was achieved three years after the initial presentation.

**Case:** A 78 year-old male from Puerto Rico presented with three episodes of coffee ground emesis. He had a past medical history of three episodes of hematemesis. A diagnosis of gastritis was made by repeated endoscopies and gastric biopsies. His past medical history also included hypertension, DM, COPD and CAD. His medications included aspirin, plavix and prednisone which was started for a recent COPD exacerbation. Physical examination was unremarkable except for hypotension and hemoccult positive brown stool. Laboratory results showed; WBCs : 9400/uL with 3% esinophils, Hb:8.8 mg/dL, platelets: 435000/uL, normal chemistry, normal LFTs and normal coagulation profile. After the initial resuscitation, EGD was performed and showed gastritis and mild duodenitis. Gastric biopsies were taken. On the third hospitalization day, the patient had another episode of severe hematemesis and epigastric pain. EGD was repeated and showed moderate gastritis and diffuse duodenitis. One day later, gastric biopsy results showed strongyloids stercoralis larva. Given the history of steroid use and the presence of strongyloids stercoralis larva in gastric biopsy the patient was diagnosed with strongyloids stercoralis hyperinfection. He was treated with Ivermectin for one week. The patient had no further bleeding and the symptoms which were attributed to COPD improved. Strongyloides stercoralis infection, although uncommon, is not rare. Hyperinfection is often the result of alteration in the immune status. Strongyloides stercoralis rarely causes UGI bleeding. A few cases have been reported where UGI bleeding complicated a hyperinfection state. The diagnosis is confirmed by demonstration of the parasite in duodenal aspirate and biopsies. Gastric biopsy rarely reveals the diagnosis because the parasite almost always infect small intestinal mucosa. The low index of suspicion and the common practice of not obtaining duodenal biopsies delayed the diagnosis in this case. Patients with obscure gastrointestinal bleeding who lived in or traveled to endemic areas should have duodenal biopsies at esophagogastroduodenoscopy.

**Laparoscopic Assisted Transgastric ERCP: The Yale Experience**

Uzma D. Siddiqui, MD, Kurt E. Roberts, MD, Andrew J. Duffy, MD, Robert L. Bell, MD, Aslanian A. Harry, MD, Priya A. Jamidar, MD.

Transgastric ERCP is passage of a duodenoscope through a gastric wall stoma, rather than by a traditional oral route. The gastrotomy site can be either a mature site previously placed for nutrition, or a surgically created site made intra-operatively at time of ERCP. Transgastric ERCP is used when there is obstruction due to tumor or stricture, or in cases of surgically altered anatomy. Our institution has performed 3 successful transgastric ERCP procedures with intra-operative, laparoscopically created gastrotomy sites.

**Case #1:** 30 y.o. female s/p roux-en-y gastric bypass and cholecystectomy with biliary colic, elevated liver tests, and imaging shows new CBD dilation. She has elective, intra-operative transgastric ERCP. The surgeons attach excluded stomach to the abdominal wall and a tract is created using a needle and dilating catheter. The sterilized duodenoscope is passed directly into the excluded stomach. ERCP confirmed a 12mm CBD, patient presumed to have ampullary stenosis, and biliary sphincterotomy performed.

**Case #2:** 58 y.o. female with non-Hodgkin’s lymphoma s/p bone marrow transplant. Patient has gallstone pancreatitis with ALK PHOS 1300, but no biliary dilation on imaging. At laparoscopic cholecystectomy, intra-operative cholangiogram reveals a CBD stone. Endoscope cannot be passed due to high-grade esophageal stricture which could not be dilated. Intra-operative gastrotomy site created with insertion of a port catheter to create a tract from the abdominal wall and into the distal stomach. Transgastric ERCP performed with sterilized duodenoscope passed through the port and into the stomach. A CBD stone is seen, biliary sphincterotomy performed, and stone removed.

**Case #3:** 38 y.o. female s/p roux-en-y gastric bypass and cholecystectomy. Patient with right upper quadrant pain, persistently elevated ALK PHOS, and MRCP with dilated CBD. The patient has elective, intra-operative transgastric ERCP. The laparoscopically created gastrotomy site is used to pass a sterilized duodenoscope directly into the excluded stomach. ERCP shows a 15mm CBD and biliary sphincterotomy performed for ampullary stenosis. None of our transgastric ERCP patients had any adverse events related to either intra-operative anesthesia, laparoscopic creation of the gastrotomy site, or the ERCP itself. Laparoscopic assisted transgastric ERCP should be considered in those patients with altered anatomy who require therapeutic biliary endoscopy.

**Ascites and Edema Associated with the Use of Sirolimus in Liver Transplant Recipients Can Mimic Complications of Cirrhosis with Portal Hypertension**

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Sirolimus is often used as an immunosuppressive agent in liver transplant recipients. We report here that sirolimus can produce side-effects in liver transplant recipients that mimic changes that occur with cirrhosis with portal hypertension. Four male liver transplant recipients received sirolimus and developed transudative ascites and/or edema in the lower extremities – two common findings of cirrhosis and portal hypertension. Three patients underwent transplant for end-stage liver disease caused by hepatitis C and one patient had alcoholic cirrhosis. At the time ascites and edema developed, two patients had normal hepatic vein pressure gradient. One of these two patients had no fibrosis in the liver; the other had fibrosing cholestatic hepatitis C with cirrhosis. After sirolimus was discontinued in one of these patients, ascites improved. It was not possible to discontinue sirolimus in the other patient because of neuro- or nephrotoxicity to other drugs. Two other patients with edema of the lower extremities did not have hepatic vein pressure gradient measured, but they did not have splenomegaly. One of these patients had no fibrosis in the liver and the other had biliary cirrhosis. After sirolimus was discontinued in these two patients, edema improved or disappeared. Two patients also had bilateral pulmonary infiltrates with dyspnea. When sirolimus was discontinued, dyspnea resolved and pulmonary infiltrates markedly improved or disappeared. Thus, sirolimus can cause side-effects of ascites and edema that can mimic cirrhosis with portal hypertension. Assessment of the severity of liver disease and hepatic vein pressure gradient should be performed in these patients. The drug should be withdrawn, whenever possible, to resolve these complications.

**Atrial Septal Defect Confounding the Diagnosis of Caroli’s Syndrome: An Unusual Presentation**

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A 24 y/o Puerto Rican male with autosomal recessive polycystic kidney disease (ARPKD) and arterial hypertension presented with watery diarrhea, fever, chills and abdominal pain after ingestion of “fast-food” in Mexico, where he was studying Medicine. Patient was started in oral antibiotics with improvement in diarrhea. Upon arrival, the patient was hospitalized and found with splenomegaly and a heart murmur. Further workup revealed the presence of pancytopenia, _E. faecalis_ bacteremia, and...
a cholestatic pattern in liver function tests. Workup was negative for urinary tract infection, infectious diarrhea, or hepatitis. A transthoracic echocardiogram showed a suspicion of a tricuspid valve vegetation. In view of these findings, the patient was transferred to Puerto Rico Cardiovascular Center, where a transesophageal echocardiogram revealed an atrial septic defect secondary to a patent foramen ovale. No vegetations were identified. Abdominopelvic ultrasound and CT scan showed the presence of low density lesions throughout both liver lobes. There was no evidence of common bile duct dilatation or cholecithiasis. A bone marrow biopsy was done for persistent pancytopenia revealing a normocellular bone marrow. A liver biopsy was consistent with Caroli’s syndrome along with the presence of an acute suppurative cholangitis. Patient was discharged home after completion of intravenous antibiotics. After this hospitalization, patient had another episode of cholangitis with bacteremia. He is under evaluation for possible liver transplantation. His liver synthetic function has remained normal. Caroli’s syndrome is a rare congenital disorder characterized by multifocal, segmental dilatation of large intrahepatic ducts and hepatic fibrosis. Most cases are associated with ARPKD. Initial clinical presentation is usually related to biliary abnormalities and portal hypertension. Hepatic synthetic function is usually preserved initially, but liver dysfunction may result from recurrent cholangitis episodes at which time liver transplantation referral is indicated. The presence of a congenital heart defect in this patient further complicated the diagnostic workup of this rare entity. To our knowledge, the association of Caroli’s syndrome with the presence of an atrial septal defect has not been previously reported.

**REFERENCES**

A Rapidly Developing Adenocarcinoma in Cronkite-Canada Syndrome
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A 68 yo male with 4 month history of nausea and loss of appetite. He also sustained a 30 pound weight loss with watery, nonbloody diarrhea. Previous colonoscopy showed diverticulosis. He appeared well developed with normal vitals. He had patchy alopecia over his scalp. Abdomen was benign and rectal revealed brown stool which was heme positive. Fingernails and toenails showed onchodystrophy. Pertinent laboratory revealed hypokalemia and zinc deficiency. EGD showed many polypoid lesions in the stomach and duodenum. Colonoscopy revealed multiple polypoid lesions in TI and colon (Figure 1,2). Pathology showed juvenile polypoid lesions throughout the GI tract consistent with Cronkite-Canada syndrome (CCS). He was started on Prednisone, Rifaximin, and antihistamines. Repeat colonoscopy completed 6 weeks after treatment showed improvement in polypoid lesions. Biopsies of a 2 cm rectal polyp confirmed a well-differentiated, adenocarcinoma with focus of submucosal invasion arising in juvenile polyp. He was referred to surgery and had a low anterior resection with margins of resection showing no residual invasive carcinoma. He was seen three weeks postop with improvement of all his symptoms. CCS is an extremely rare syndrome of unknown etiology. Cardinal manifestations are GI polyposis, skin hyperpigmentation, alopecia, and nail dystrophy as were seen in our patient. GI lesions are hamartomatous polyps. Adenomatous changes and carcinoma occur in, or in close proximity to, hamartomatous polyps in about 15% of affected patients. Our patient developed a colorectal carcinoma within 2 years of a prior negative colonoscopy. Histology showed the carcinoma immediately adjacent to a benign juvenile type polyp. The serrated adenoma-carcinoma sequence in CCS with microsatellite instability and p53 overexpression is a potential explanation for this rapidly developing cancer. [figure1][figure2]
Appendicitis Presenting as Acute Lower Gastrointestinal Bleeding
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Introduction: Appendicitis is the most common acute surgical condition of the abdomen; however, gastrointestinal bleeding is not a complication that is often seen. We report an unusual case of lower gastrointestinal bleeding with active bleeding from the appendix identified on colonoscopy from appendicitis.

Case Report: A 63-year-old woman with history of diverticulosis was admitted with one-day duration of hematochezia. She described a right lower quadrant abdominal pain a week prior to the bleeding which had resolved spontaneously. She had a screening colonoscopy 3 months prior which revealed pandiverticulosis. She was not on any anticoagulants and did not have any nausea, vomiting, fevers, or abdominal pain on presentation. In the ED, the patient was orthostatic and NG lavage was negative for blood. She was afibrile and there were no signs of an acute abdomen. A rectal exam revealed fresh blood. On admission the Hgb was 11.5 g/dl and no evidence of leukocytosis. A bleeding scan showed active bleeding in the cecum/ascending colon. Angiography showed no evidence of active bleeding. A colonoscopy performed after a rapid purge revealed left sided diverticulosis without active bleeding. The cecum and the appendiceal orifice was identified with the appearance of an adherent clot and active oozing of blood from the appendix (fig 1). There was abnormal polypoid appearance of the tissue surrounding the appendix (fig 2). Surgery was consulted and a right hemicolectomy was performed. The pathology revealed a pericecal/per-appendiceal abscess. Bleeding from the appendix is a rare cause of lower GI bleeding. Unless there is massive bleeding, an urgent colonoscopy after a rapid purge can be effective in identifying and managing an acute LGIB. The cause of an isolated appendiceal bleed will determine management and surgical outcome.[figure1][figure2]

An Unusual Cause of Upper GI Bleeding: A Case Report
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A 74 yo female was admitted to the hospital after being found down in her nursing home bedroom. The patient with a known hx significant for DM, CHF, and HTN reported falling to the ground on her way back from the bathroom after feeling weak. An accu-check by EMS revealed a blood sugar of 30 and the pt was treated with D50 on route and D51/2 NS in the emergency room. She eventually reported seeing blood on toilet paper and black tarry stools over the past two days. Vital signs were normal including a pulse of 70. Testing revealed BUN of 82, Hb of 11 with an MCV of 83, and INR of 5. Coumadin was found among the patients daily medicine list from the nursing home. Review of symptoms was negative for abdominal complaints and physical findings revealed external hemorrhoids and melanotic stool without evidence of gross blood. Over the next several days the patients INR was corrected by SQ vitamin K and withholding coumadin. VS remained stable but Hb fell to a low of 8.8 with hydration. On day 3 of hospitalization an upper endoscopy was performed which revealed a 4 cm in length bone embedded into the incisura with surrounding granulation tissue, edema, and fresh blood. A decision was made not to attempt endoscopic removal, as there was concern over the possibility of a contained perforation. After discussion with the surgical team, an exploratory laparotomy with removal of the embedded chicken bone was performed without incident. There was no evidence of free perforation. Further questioning revealed that chicken is served on a regular basis at the patient’s nursing home but she denied any knowledge of swallowing a bone and denied esophageal or abdominal discomfort. It is therefore unknown how long the bone had been embedded in the stomach or in what way it would have presented itself if not for the coumadin toxicity and GI bleeding. While gastroenterologists are often consulted following ingestion of foreign bodies, typically they either pass readily through the GI tract or will become impacted at an area of physiologic or pathological narrowing. This case was unique on several fronts. The patient’s only presenting symptom was melana in conjunction with her coumadin toxicity. In addition to the unusual site of impaction, she neither recalled swallowing the chicken bone nor had any discomfort while the bone was embedded in the incisura.

Anaphylaxis to Polyethylene Glycol (PEG) Solution during Bowel Preparation for Screening Colonoscopy
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A 60-year-old male with a history of gastroesophageal reflux disease, hypertension, and myocardial infarction was instructed to take a four liter PEG solution in preparation for a screening colonoscopy scheduled the next morning. Within thirty minutes of drinking half of a liter, he developed severe itching and hives involving his neck, chest, and back with subsequent swelling of his lips and tongue. Review of systems was positive for sudden onset of nausea, emesis, joint pains, chills, and persistent loose watery diarrhea, but negative for respiratory distress. He had no history of asthma or other allergic diseases, no known drug allergies, and was not recently started on any new medications. Paramedic examination documented tachycardia (100), hypotension (100/palp), swelling of the tongue and lips, and a diffuse urticarial rash. They immediately administered diphenhydramine 50 mg intravenously, relieving his symptoms prior to presentation to the hospital. In the emergency room, laboratory assessment was unremarkable without evidence of eosinophilia. The patient was given methylprednisolone 125 mg intravenously, and after a period of observation without recurrent symptoms, was discharged to home. Rescheduling of colonoscopy was planned with an alternative preparation.

Discussion: Polyethylene glycol (PEG) solution is a commonly used bowel preparation for colonoscopic examinations. In general, it is considered a remarkably safe, well tolerated, and highly effective bowel cleansing agent. Commonly reported adverse effects include disagreeable taste, nausea and vomiting, abdominal fullness, bloating, and cramping. Although product information contains warnings of possible urticaria and delayed eczematous reactions, such incidents have been extremely rare. According to Medwatch of FDA and the 2006 Physicians Desk Reference, there have been only a few isolated cases of urticaria, rhinorrhea, and dermatitis reported suggestive of an allergic reaction. To date, there is only one prior case of probable anaphylaxis to PEG solution published in the literature. Immediate generalized reactions can occur either through an IgE mediated (anaphylaxis) or an IgE independent (anaphylactoid) mechanism. These reactions are clinically indistinguishable. Physicians should be aware of this possible adverse effect and respond immediately with appropriate treatment.
Esophageal Intramural Pseudodiverticulosis in a Patient with Dysphagia

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Esophageal intramural pseudodiverticulosis is a rare condition manifested by multiple, flask-shaped outpouchings in the wall of the esophagus, which represent dilated excretory ducts of esophageal mucous glands. We describe a patient with esophageal pseudodiverticulosis presenting with dysphagia. A 63-year-old male with h/o hypertension, diabetes, ESRD on hemodialysis, coronary artery disease and chronic pancreatitis due to chronic alcohol abuse presented with dysphagia to solids only for about 1 year. No history of heartburn or reflux symptoms. He had lost 10 pounds in one year but denied any loss of appetite. Physical exam was unremarkable. Esophagram showed small outpouchings filled with barium throughout the esophagus representing esophageal pseudodiverticulosis. EGD showed scattered pseudodiverticula in the mid and the distal esophagus with distal esophageal stricture and esophagitis. Biopsy of the stricture revealed non-neoplastic/hyperplastic gastric mucosa with severe active and chronic inflammation with occasional eosinophils. Dilatation of the stricture with 38F Maloney dilator lead to the cessation of symptoms. Esophageal pseudodiverticulosis involves only part of the esophageal wall and the pseudodiverticula correspond to dilated ducts of esophageal glands. It can occur at any age but is seen mostly between 50 and 70 years. The cause remains unclear but in 80–90% of patients there is endoscopic and histologic evidence of chronic esophagitis. In most cases the pseudodiverticulosis is an accidental finding without symptoms but in symptomatic patient’s dysphagia is the most common symptom with 76–90% of patients having an associated stricture, most frequently in the upper third of the esophagus. Endoscopic bougienage is quite effective with response rates of over 96%.

Plasmacytoma of the Colon as Cause of Rectal Bleeding in Patient with Refractory Multiple Myeloma

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Extramedullary plasmacytomas are rare neoplasms. The clinical presentation of plasmacytoma of the colon can mimic colon cancer. We present the case of an extramedullary plasmacytoma (EMP) of the left colon which presented with rectal bleeding. We present the case of a 54-year-old white male with history of multiple myeloma diagnosed in 1998, who was admitted to the hospital with rectal bleeding. He was treated with allogeneic bone marrow transplant in the past, with recurrence of his disease. Subsequent therapy included donor lymphocyte transfusion achieving short-lived partial remission, bortezomib and prednisone with no significant benefit. Current drug regimen was melphalan and prednisone. His disease course had been complicated by cutaneous plasmacytoma, as well as pancytopenia and renal failure requiring renal supplementation therapy. Patient was admitted with bright red blood admixed with stools for the eight-to-nine days prior to his admission. His physical exam was significant for pallor. Abdominal examination revealed no mass. Patient’s blood work included hemoglobin of 7.9 gm/dL, platelets of 35000/μL, and Cr 3.2 mg/dL; INR was 1.1. Colonoscopy was done which revealed an infiltrative and ulcerated, large, near-complete obstructing mass, extending from 40 cm to 35 cm proximal to the anus. Biopsies were consistent with plasmacytoma. The patient was started on radiation therapy due to ongoing bleeding. His rectal bleeding stopped over the next few days and the hemoglobin stabilized. Multiple myeloma (MM) represents the neoplastic proliferation of a single clone of plasma cells engaged in the production of a monoclonal immunoglobulin. Proliferation usually occurs in the bone marrow, but EMP have been found in the lymph nodes, skin, liver, spleen, and other organs. Approximately 10% of MM (solitary or in the setting of MM) occur in the gastrointestinal tract, and most of these cases are in the small bowel or stomach. Less than a quarter of these occur in association with multiple myeloma. There are no established guidelines for the treatment of EMP. Surgery can be curative in cases of solitary EMP. In cases of EMP associated with MM, radiation therapy is usually the preferred treatment modality. This case emphasizes the need to keep plasmacytoma in the differential in patients presenting with rectal bleeding, and especially in those with existing multiple myeloma.

Endoscopic Diagnosis of Primary Amyloidosis

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Non-Microscopic Microscopic Colitis: A Call for Change in Nomenclature
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Microscopic colitis is an uncommon disorder characterized by chronic, watery diarrhea and histologic evidence of chronic mucosal inflammation in the absence of endoscopic or radiologic abnormalities. It is classified into lymphocytic and collagenous colitis based on distinct histopathological findings. An 80-year-old female was evaluated for chronic watery diarrhea. Her history and physical examination were non-contributory except for a history of a gram-negative infection affecting the upper and lower extremities and arthritis. Initial laboratory studies revealed a serum albumin of 3.1 g/dL, but were otherwise normal. Abdominal radiograph was normal and small bowel series demonstrated slow transit time. Esophagogastroduodenoscopy revealed erythematous gastropathy confined to the antrum. After Congo red staining, antral biopsy specimens demonstrated amyloid deposits that showed green birefringence under polarization microscopy. Subsequently, the diagnosis of primary (AL) amyloidosis was confirmed on bone marrow biopsy. Primary amyloidosis most commonly involves the cardiac and renal organs, however, the gastrointestinal tract is involved in up to 70% of patients. Amyloid has been described in the entire gastrointestinal tract. Gastrointestinal biopsies have been shown to be more sensitive than abdominal fat pad biopsies. Rectal biopsies are positive in 50–70% of patients while gastroduodenal biopsies have been shown to have an even higher diagnostic yield. Gastrointestinal symptoms are varied, non-specific and may be related to direct involvement of the GI tract versus infiltration of the autonomic nervous system. Patients may present with symptoms related to intestinal motility (reflux, dysphagia, gastroparesis, constipation or chronic pseudo-obstruction), malabsorption (related to bacterial overgrowth or mucosal infiltration), protein-losing enteropathy, or bleeding (erosions, ulcers). However, only the minority of patients with primary amyloidosis have gastrointestinal symptoms. In patients with known primary amyloidosis and positive gastric biopsies, only 1% had GI symptoms (other than weight loss) (Mayo Clinical Proceedings 1993;68(8):763). The diagnosis of systemic amyloidosis in patients previously undiagnosed remains a clinical challenge, especially in those without known predisposing conditions (e.g. multiple myeloma, rheumatoid arthritis, and end stage renal disease). Thus, in patients such as ours with a clinical suspicion of amyloidosis and gastrointestinal symptoms warranting endoscopic evaluation, mucosal biopsies should be performed as the diagnostic yield is high.  

Sirolimus-Associated Pulmonary Toxicity in a Liver Transplant Patient
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Sirolimus-Associated Pulmonary Toxicity was first described in renal transplant patients. It has also been described in heart and liver transplant patient. Case Report: A 55 year old male underwent uncomplicated orthotopic liver transplantation for cirrhosis secondary to chronic hepatitis C. The immunosuppressive regimen was adjusted to include Sirolimus. After eight months he was admitted to the hospital with dyspnea, cough, chest heaviness, and fevers. Chest radiograph and CT scan showed bilateral air space disease. He was started on broad spectrum antibiotics for bilateral bacterial pneumonia. In the absence of improvement antimicrobial and antifungal medications were added. BAL was performed. Evaluation for bacteria, fungi, viruses, Pneumocystis carinii, acid-fast bacilli and malignancy were negative. Transbronchial biopsies showed lymphocytic interstitial infiltrate with occasional plasma cells and rare neutrophils. Clinical history, failure of response to antibiotic treatment, imaging findings, and bronchial biopsies oriented to Sirolimus-associated pulmonary toxicity. Sirolimus was discontinued and the patient showed immediate clinical improvement. Radiographs performed two months after discharge revealed marked radiologic improvement. Sirolimus is used with increasing frequency in solid organ transplantation to avoid nephrotoxicity associated with calcineurin inhibitors. Pulmonary toxicity has been recognized as an adverse effect most often observed in renal transplant patients. Sirolimus associated pulmonary toxicity is actually a range of syndromes represented clinically by dyspnea, cough, fever, fatigue, or hypotension and histologically by organizing pneumonia, BOOP, interstitial pneumonitis, focal fibrosis or alveolar hemorrhage. The diagnosis of Sirolimus-associated pulmonary toxicity requires careful exclusion of other possible diagnoses. Imaging often reveals bilateral asymmetric pulmonary infiltrates. Clinical improvement and resolution of pulmonary findings is often rapid once the drug is discontinued. Follow-up chest radiograph or CT scan often shows complete resolution within 2–4 months. Sirolimus-Associated Pulmonary Toxicity can complicate solid organ transplant recipients. Treatment is withdrawal of the drug. Pulmonary toxicity may be reduced by avoiding loading doses and monitoring plasma levels. Reports have suggested that steroids may assist with pulmonary recovery.

The Association of Gastric Fundal Polyps and Long Term PPI Therapy – A Case Report
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To determine an association between long term acid suppression therapy with PPI treatment and the development of gastric fundal polyps. 44 year old female who had an EGD 12 years earlier which showed mild antral gastritis. Afterwards she was placed on omeprazole 20 mg daily and remained on it for the next 10 years and a follow-up EGD was performed. Repeat EGD revealed numerous polyps of varying sizes and shapes in the fundus and body of the stomach (figure 1). The largest one was removed and was a “fundal polyp.” Omeprazole was then discontinued and to be used only on an “as needed” basis. She returned 14 months later for a follow-up EGD. She reported only an occasional use of omeprazole. The follow-up EGD showed almost complete resolution of the polyps (figure 2). No biopsy was taken. Fundic gastric polyps may develop after sustained acid suppression by daily use of a PPI. Discontinuation results in resolution of the polyps. Patients with chronic atrophic gastritis also may develop gastric polyps and are at an increased risk of gastric carcinoma. This may be related to chronic H. Pylori infection. One study reported the development of multiple gastric polyps one of which harbored atypia while on chronic esomeprazole treatment (1). Further studies are needed to determine if PPI-induced gastric...
The association between radiation therapy for prostate cancer and a subsequent increased risk of pelvic organ malignancies such as bladder cancer and sarcoma is well established. However, it is not well established if radiation therapy for prostate cancer may also increase the risk of rectal carcinoma. We present a case as illustration of such a phenomenon. The patient is a 75-year-old man who presented with a five-year history, since 2000, of intermittent rectal bleeding associated with bowel movements. He denied any weight loss, heartburn, nausea, vomiting or diarrhea. His past medical history included prostate adenocarcinoma, Gleason Grade 9 (diagnosed in 2000 for which he received radiation and hormonal therapy), nephrolithiasis, hyperlipidemia, and glucose intolerance. A prior colonoscopy in 1997 was normal. Physical examination on presentation was unremarkable. The abdomen was soft and nontender, with normal bowel sounds and no palpable masses or organomegaly. Laboratory data revealed a WBC of 9.8 K/cmm, hematocrit 31.0%, and platelet count of 162 K/cmm. BUN was 27 mg/dL, creatinine 1.0 mg/dL, albumin 3.7 g/dL, total bilirubin 0.5 mg/dL, alkaline phosphatase 80 U/L, ALT 41 U/L, AST 22 U/L. He subsequently underwent repeat colonoscopy which showed a large 5 cm ulcerated mass present at 10 cm from the anal verge with a doughnut shaped configuration. Biopsy of the ulcerated rectal mass confirmed an adenocarcinoma. Abdominal CT scan was negative for lymph node involvement; and his CEA was normal. The patient underwent abdominal perineal resection of the mass. Final stage of the tumor was T3, A/B, N0, MX. On presentation, the patient had intermittent rectal bleeding associated with bowel movements. He denied any weight loss, heartburn, nausea, vomiting or diarrhea. His past medical history included prostate adenocarcinoma, Gleason Grade 9. The differential diagnosis includes pemphigus vulgaris, bullous pemphigoid, and drug-induced injury such as with bisphosphonates. Characteristic findings on endoscopy consist of sloughed fragments of esophageal mucosa and strictures, potentially at multiple levels. Histologically, this entity is notable for intraepithelial cleavage within the superficial esophageal layers. Interestingly, treatment of our patient with swallowed fluticasone resulted in both symptomatic and endoscopic improvement.
Hepatic Actinomycosis after: 59 Year Old with Multiple Liver Lesions after Dental Cleaning
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Case: A 59-year-old man presented with fever, chills, nausea, and right upper quadrant abdominal pain of 4 days duration. He admits to recent dental cleaning two weeks prior to admission. Physical examination revealed an ill appearing patient with T102° F. Abdominal exam revealed mild right upper quadrant tenderness with an increased liver span. Laboratory demonstrated a WBC count of 12000, total bilirubin 1.4, ALT 80, AST 52, and alkaline phosphatase 191. Abdominal CT showed multiple hypodense hepatic lesions. CT guided aspiration demonstrated purulent aspirate containing gram-positive organisms. Histology showed multiple abscesses with evidence of sulfur granules consistent with Actinomycosis. [figure1]The patient was treated with IV ampicillin + sulbactam with complete resolution of lesions.

Discussion: Actinomycosis is caused by filamentous gram positive, anaerobic bacteria. It is a commensal inhabitant of the oral cavity, within gingival crevices and tonsillar crypts. The bacteria acquire pathogenicity via a breach in tissue. The bacterium usually affects middle-aged individuals and is 2 to 4 times more likely in men. The most common areas of involvement are the cervicofacial area (50%) and the abdomen (20% appendix and ileocecal region). Hepatic Actinomycosis is easily confused with metastatic disease in cases of multiple lesions and hepatoma in cases with a single lesion. Majority of cases are diagnosed by FNA, with histology showing actinomycotic sulfur granules. Anaerobic collection and culture is a requirement for isolation, making a diagnosis by culture less than 50%. Penicillin or amoxicillin are used as 1st line therapy. Recession is usually required in cases not responding to antibiotic therapy. One report in the literature identified hepatic actinomycosis with a dental abscess as a source. Dental procedures are usually the cause of cervicofacial involvement. It is hypothesized that this patient developed transient bacteremia after dental cleaning with invasion of the liver by the anaerobic bacteria.

“Steroids and Statins Induced Myopathy” and “Statins Induced Cranial Nerve Dysfunction” an under Recognized Cause of Dysphagia
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A 77-year-old white female has a sudden onset of difficulty in swallowing for solids and liquids. Symptoms started with a feeling of lump in the throat that progressed to total dysphagia. The patient was treated initially with antibiotics and antifungal as outpatient, which did not give any relief. She had multiple other co-morbidities including RA, rheumatoid pneumonitis on high dose steroids, hypertension, hypothyroidism but euthyroid on supplementation, hyperlipidemia on high dose of simvastatin, GERD and developed pre-renal azotemia secondary to dehydration. In the past the patient had negative workup for other connective tissue diseases. The dose of prednisone was gradually reduced but she could not be taken off steroids and also simvastatin was discontinued since sh was malnourished secondary to poor oral intake and the rest of work up was started. The CAT scan of the neck did not show any obvious abnormalities, the esophagram however, showed evidence of immediate subglottic aspiration with only minimal barium traversing the thoracic esophagus into the stomach. On upper endoscopy no obvious source for the dysphagia was found, biopsies obtained showed reactive epithelial changes with chronic inflammation and areas of fibrosis. The video swallow showed considerable esophageal dysmotility with associated retrograde flow of opaque material into the pharynx with several episodes of laryngeal aspiration. On modified barium swallow there was lack of any observable peristalsis in the cervical and thoracic esophagus and persistent pooling of material in these areas was noted. Additional small amount of fluid resulted in pooling in the larynx and aspiration. Esophageal dilatation was done without significant benefit. MRI brain was negative for new onset infarcts or tumor. A peg tube was inserted endoscopically for feeding but the patient continued to aspirate even the stomach contents despite proper feed precautions and then ultimately a Jejunostomy tube was placed and was discharged to a rehabilitation center after two weeks of extensive workup and treatment with diagnosis of idiopathic dysphagia. Both steroids and simvastatin are known to cause myopathy and simvastatin is also known to affect the cranial nerves causing facial paresis, alteration of taste and can also cause peripheral neuropathy. More studies and observation is needed and these medications are needed to be included in the etiology of dysphagia.

An Unusual Neoplasm of Pancreas
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Primary pancreatic lymphoma (PPL) is rare, comprising less than 0.5% of pancreatic tumors. Only fewer than 150 cases have been reported in English literature. Prompt diagnosis with cytopathology is needed to differentiate it from the more common pancreatic adenocarcinoma to determine the modality of treatment.

Case report: The patient for discussion is an 81-year-old Caucasian gentleman who was admitted for upper abdominal pain, anorexia and weight loss going on for about six months. Physical exam was evident for significant icterus and abdominal tenderness. There was no palpable lymphadenopathy. Laboratory data showed an unremarkable hemogram, elevated liver enzymes and a bilirubin of 17.8 mg/dl. Subsequent CT scan of his abdomen showed a soft tissue mass in the region of the pancreatic head measuring 5.5 by 5.5 cm in size consistent with a probable pancreatic head mass. He underwent a CT guided biopsy of the mass, which favored a diagnosis of diffuse large B cell lymphoma on immunohistochemical testing. An extrinsic common hepatic stricture was seen on ERCP, which was successfully stented. Further follow up showed a downtrending of bilirubin and enzyme levels. He is currently undergoing chemotherapy with Cyclophosphamide, Vincristine and Prednisone regimen along with the monoclonal antibody Rituximab.
A 55 y/o male presented to GI clinic because of hematochezia for 6 months, associated with constipation and difficulty defecating. He also had abdominal cramps which were relieved by bowel movements. The patient complained of a “lump on the bottom,” which was painful when sitting. One year prior to this visit, a physician performed a rectal exam and told him that this was a hemorrhoid. Despite seeing several physicians over the intervening year, with complaints of hemorrhodia, repeat rectal examination was not performed. Our rectal examination revealed a large ulcerated lesion protruding from the anus posteriorly (Fig. 1.) The lesion was tender and firm with extension into the rectum. Pathology, from a shave biopsy, revealed squamous cell carcinoma in situ with focal microinvasion. Fine needle aspiration with flow cytometry has been advocated to be the most accurate diagnostic tool. The primary modality of treatment consists of chemotherapy and radiotherapy. The prognosis is much better than pancreatic adenocarcinoma.

Diagnosis criteria for PPL

1. No lymphadenopathy either superficial or mediastinal
2. A normal leukocyte count in peripheral blood
3. Main mass in the pancreas with only peripancreatic lymph node involvement if any
4. No hepatic or splenic involvement

Derived from from Dawson et al Studies have shown a strong male predominance with a male to female ratio of 7:1. The mean age at diagnosis is 68 years. The gastrointestinal tract is the most commonly involved extranodal site for non-Hodgkin’s lymphoma. Secondary involvement of pancreas from contiguous lymph node disease is more common than primary pancreatic lymphoma, which is a rare entity. These tumors are highly chemo and radioresistant with no role for surgery. Prognosis is better than the 5% 5-year survival rate in pancreatic adenocarcinoma and survival ranges from 2 to 6.5 years. Primary lymphoma of the pancreas is a rare disease. The majority of them display a B-cell phenotype. Fine needle aspiration with flow cytometry has been advocated to be the most accurate diagnostic tool. The primary modality of treatment consists of chemotherapy and radiotherapy. The prognosis is much better than pancreatic adenocarcinoma.

Discussion:

Diagnostic criteria for PPL

1. No lymphadenopathy either superficial or mediastinal
2. A normal leukocyte count in peripheral blood
3. Main mass in the pancreas with only peripancreatic lymph node involvement if any
4. No hepatic or splenic involvement

Steroid-Sensitive Cholestatic Syndrome – A Case for a Return to the Basics
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Cholestasis can be defined as the arrested flow of bile. Laboratory, imaging, and histological studies are central to reach a diagnosis. However, a thorough history and physical examination remain the cornerstone to the diagnostic process. We present a case which highlights this point. Mrs. C. M. is a 58 year-old white female who was admitted for evaluation of cholestasis, limb pain, and weakness of 4 weeks duration. Neurological evaluation, which included imaging studies, EMG, and nerve conduction studies, was not diagnostic. Extensive serologic testing was negative except for significantly elevated ESR and CRP. A small hepatic hemangioma and gallstones were found on abdominal imaging. A liver biopsy was not diagnostic, showing minimal sinusoid dilation without hepatocyte atrophy or biliary ductal dilation. It was negative for hemosiderin, copper deposits, α1 anti-trypsin inclusions, or findings of primary biliary cirrhosis, chronic hepatitis, or an infiltrative process. She was diagnosed with polymyalgia rheumatica (PMR) and started on prednisone. Her symptoms promptly improved, along with a progressive decrease of her ESR, CRP, and liver enzymes. At outpatient follow up, her symptoms had resolved and her liver tests were normal. We believe that our patient’s cholestatic syndrome was secondary to PMR. An over reliance on extensive and expensive evaluations would have failed to make the diagnosis. The diagnosis was reached by the basics of the medical method: a good history and physical exam.
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A 28 yr old male with history of hypertension, presented with acute onset, severe and progressive epigastric pain associated with nausea and vomiting. Patient was non-compliant with medications, never consumed alcohol nor smoked and with no such previous episode or gallstone disease. At admission his BP was 240/140 mm Hg and there was tenderness with guarding in the epigastrium with absent bowel sounds. Lab results showed elevated amylase (213 IU/L) and lipase (2756 IU/L) and normal renal and liver functions.

Initial CT scan of abdomen and a HIDA scan were negative. Echocardiogram revealed concentric left ventricular hypertrophy (LVH) with LV diastolic dysfunction. Secondary causes of severe hypertension, including work up for vasculitis were negative. Repeat CT scan of abdomen showed multiple areas of low attenuation in the pancreas, consistent with pancreatic necrosis and edema (Figure 1). Magnetic resonance imaging of abdomen showed normal biliary (A) and pancreatic duct (B) without any filling defects, stricture or anomaly (Figure 2). A diagnosis of acute pancreatitis secondary to malignant hypertension was made and patient was managed on multiple intravenous and transdermal antihypertensive medications, kept nothing per oral and started on total parenteral nutrition. After control of blood pressure his symptoms gradually improved with steady decline in serum amylase, lipase and a follow up CT scan of the abdomen showed resolving areas of pancreatic necrosis and edema. Pancreatic parenchymal lesions in malignant hypertension are well recognized. Clinically significant acute pancreatitis evolving from malignant hypertension is extremely rare. This case is an excellent demonstration that malignant hypertension even though a rare is an important risk factor for acute pancreatitis.

Ascitic Fluid Strongyloidiasis as the First Manifestation of AIDS

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Strongyloides Stercoralis is an intestinal parasite that frequently found in the tropics. Autoinfection is a unique process for strongyloides stercoralis that permits reappearance of the disease. Most of these patients are asymptomatic. Overwhelming autoinfection may lead to hyperinfection and disseminated Strongyloidiasis immunosuppression. We present a 49 y/o Liberian male who migrated to USA10 years ago, presented with 2 weeks history of huge ascites. He was a truck driver and consumed 2–3 cans of beer per week. He admitted to sexual promiscuity. Admission vitals T 98.2 F, P 74/min BP 130/71 mmHg. On physical examination he was cachectic, in no distress, with pale conjunctiva and abdominal distension with ascites. Laboratory findings were WBC 9,000, GR-72%, L-12%, E-1.2%, HB-7.2gm/dl, HCT-19.1%, PLt-215, 000, MCV-94fl, Eosinophils 1.2%, PT-16.6 sec, PTT-47.1 sec, AST-129MU/ml, ALT-85, T.Bili-1.4, ALK.phos-372, Total protein 7.2, Albumin 1.7. Electrolytes and renal functions, amylase and lipase were normal. CT scan of the abdomen fatty infiltration of the liver and huge ascitis. EGD showed linear gastritis and duodenitis. His ascites was rapidly accumulating after abdominal paracentesis. Ascitic fluid showed WBC-39, PMn-25%, RBC-0gm/dl, Alb-0gm/dl, T.prot-0.4gm/dl. AFB smears with no elevation of WBC count or triglycerides. Initial CT scan of abdomen and a HIDA scan were negative. Echocardiogram revealed concentric left ventricular hypertrophy (LVH) with LV diastolic dysfunction. Secondary causes of severe hypertension, including work up for vasculitis were negative. Repeat CT scan of abdomen showed multiple areas of low attenuation in the pancreas, consistent with pancreatic necrosis and edema (Figure 1). Magnetic resonance imaging of abdomen showed normal biliary (A) and pancreatic duct (B) without any filling defects, stricture or anomaly (Figure 2). A diagnosis of acute pancreatitis secondary to malignant hypertension was made and patient was managed on multiple intravenous and transdermal antihypertensive medications, kept nothing per oral and started on total parenteral nutrition. After control of blood pressure his symptoms gradually improved with steady decline in serum amylase, lipase and a follow up CT scan of the abdomen showed resolving areas of pancreatic necrosis and edema. Pancreatic parenchymal lesions in malignant hypertension are well recognized. Clinically significant acute pancreatitis evolving from malignant hypertension is extremely rare. This case is an excellent demonstration that malignant hypertension even though a rare is an important risk factor for acute pancreatitis.

[figure1]

[figure2]
were negative. Cytology showed no malignant cells. Ascitic fluid microscopy revealed many filariform larvae of strongyloidiasis. Stool examination for ova and parasites also confirmed Strongyloidiasis. HIV test was positive. Patient was diagnosed as disseminated strongyloides and was treated with Thiapendazole for 2 week. Repeat ascitic fluid and stool examination showed no Strongyloidiasis 2 weeks after treatment. Strongyloides stercoralis infections are rare but have increased in incidence in immunocompromised patients. Disseminated infection is associated with increased mortality. Physicians caring for persons who may have been in areas endemic for strongyloides and who may be at risk for HIV infection should be aware of this unusual presentation of disseminated strongyloidiasis. [figure1]

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Diagnosis of Hepatocellular Carcinoma. Going beyond the Algorithm
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Hepatocellular carcinoma (HCC) is one of the most common cancers worldwide with a five year survival of less than 5%. The incidence of HCC is on the rise and is affecting a younger population. HCC is commonly associated with liver cirrhosis in up to 80% of cases. There is a high association of HCC with chronic hepatitis C and chronic hepatitis B. Unfortunately, HCC is often clinically silent until it is well advanced and should be considered in patients whose clinical status indicates sudden decompensation. The diagnosis of HCC can be made without biopsy in patients with liver cirrhosis and a mass showing characteristic arterial vascularization that is seen on two different imaging modalities along with elevated serum alpha-feto protein (AFP) levels. The positive predictive value of the clinical and radiological findings exceeds 95 percent. Several imaging modalities have been used in the diagnosis of HCC. The sensitivity of helical CT and magnetic resonance imaging (MRI) for detecting HCC is reported to be as high as 90 percent. Several studies have also suggested the use fluoro-deoxy-glucose (FDG) PET in the detection of HCC. However, the diagnosis of HCC can sometimes present a particularly challenging scenario to the clinician. herein we describe a case of a 56 year old African-American male with history of cirrhosis secondary to long standing primary sclerosing cholangitis, who was found to have an elevated AFP level. As part of the work-up for HCC, the patient initially underwent ultrasound and CT scan followed by an MRI of the abdomen. All the imaging studies including a FDG-PET scan were negative for malignancy. Ultrasound of the scrotum was negative for testicular tumors. In view of the rising levels of AFP in the presence liver cirrhosis, the diagnosis of HCC was strongly suspected despite the negative work up. An exploratory laparotomy with intra-operative ultrasonography was performed by surgery upon our recommendation, which revealed a very large hepatic mass, occupying most of the right and left lobe of the liver. Open biopsy was performed which was consistent with primary HCC. Patient was not considered to be a good candidate for chemotherapy and Oncology and he expired two months later. This case underscores the importance of the clinical sense, and illustrates a unique scenario in the diagnosis of HCC despite the completely negative radiological workup.

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Mixed Connective Tissue Disease Causing Gastroparesis with Ulcerating Gastritis and Pyloric Stricture
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Case: A 74 year-old female presented with heartburn, epigastric pain, bloating, and 15 lb. weight loss. She denied dysphagia. She has hypertension and dyslipidemia but no diabetes. She had a colectomy 20 years ago for ulcerative colitis. She has no family history of gastric cancer or autoimmune disease. She was 120 lbs. Her abdomen was soft with mild epigastric tenderness and intact ostomy. EGD revealed superficial antral ulcers. Biopsies showed gastritis without h. pylori. Gastrin was normal. She continued PPIs with improvement, but six months later symptoms progressed to early satiety with postprandial vomiting. She only tolerated soft foods and weighed 100 lbs. Small bowel follow through was normal. CT revealed gastric wall thickening. [figure1] EGD showed severe, nodular, gastritis with ulceration. EUS confirmed gastric thickening and jumbo biopsies were negative for adenocarcinoma, amyloidosis, or lymphoma. Her weight loss and symptoms persisted, and a gastric emptying study was abnormal. EGD again showed severe gastritis, now with pyloric stricture requiring dilation. [figure2] Autoimmune panel resulted in high ANA, 1/640 speckled. Anti-Scl 70 was negative for scleroderma. High Anti-U1 RNP titer diagnosed mixed connective tissue disease (MCTD).

Discussion: MCTD, or overlap syndrome, is an autoimmune disorder with features of lupus, scleroderma, and myositis with high anti-U1 RNP. MCTD primarily affects females aged 20 to 40, and Raynaud’s phenomenon with arthralgias is common. The pathophysiology is unclear, but B lymphocytosis and tissue plasmocyte infiltration occurs. Scleroderma GI disorders such as esophageal dysmotility, gastroparesis, malabsorption, and bacterial overgrowth can occur. Acid stasis led to gastritis and pyloric stricture in our patient. MCTD treatment requires supportive care, rheumatology evaluation, and consideration for corticosteroids.

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Ameboma: An Unusual Finding in an Asymptomatic Patient
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61 Hispanic male with a history of hypercholesterolemia was referred to our clinic for a screening colonoscopy. He denied any complaints of weight loss, diarrhea, abdominal pain, hematochezia, melena fever, chills or fatigue. He was originally from South America, but had been in the U.S. for over five years. Our patient had no abnormal laboratory findings. On colonoscopy he was found to have a 2 cm ulcerated, friable flat mass with exudate in the ascending colon just outside the cecum. Histology revealed an ameboma which was described as severe active chronic inflammation with an exudate fragment showing trophozoites with erythrophagocytosis. The patient was treated with 10 days of metronidazole followed by 10 days of paromomycin. Intestinal amebiasis is caused by the protozoan Entamoeba histolytica. Worldwide 30–50 million symptomatic infections occur. It is the third most common parasitic cause of death. In the United states most of the cases are seen in immigrants from developing countries and travelers. Infection begins with ingestion of cysts from fecally contaminated water or food. Excystation occurs in the small bowel where trophozoites emerge. Ninety percent of patients colonized by E. histolytica spontaneously clear the infection by one year. Most patients are asymptomatic, however invasive intestinal amebiasis may mimic inflammatory bowel disease, malignancy and malabsorptive illnesses. Extraintestinal manifestations are uncommon. They include liver abscesses, pleuropulmonary disease, cerebritis and peri-carditis. Diagnosis is made by serologic and stool examinations. Microscopic examination of the stool has a low sensitivity 30–60%. A high false positive rate exists secondary to non pathogenic entamoebas which are morphologically identical to and more common then entamoeba histolytica. ELISA stool antigen test which detects adherence lectin antigen has a sensitivity of 87% and a specificity of greater than than 90%. Serum antibody tests are most useful for extraintestinal disease when organisms are not found in the stool. Antibodies are detectable by the first week of infection and may persist for years. Up to 25% of uninfected patients in endemic regions are positive. An Ameboma is an unusual manifestation of entamoeba histolytica. In immigrants from developing countries with atypical colonic masses one must consider entamoeba histolytica as part of their differential diagnosis.

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Unique Case of Klatskin Tumor Treated with Whipple Procedure
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We report a 77 year old white female who was admitted with jaundice and 20 lb weight loss. CT scan of the abdomen revealed dilation of the intrahepatic and extrahepatic bile ducts. MRCP revealed similar results in addition to a stone in the extrahepatic ducts with a questionable distal common bile duct stricture and a normal pancreatic duct. ERCP performed in a community hospital reported a questionable distal common bile duct stone, dilated intrahepatic and extrahepatic ducts and questionable extravasation of contrast from the biliary tree, for which the procedure was aborted. The patient was transferred to our institution for repeat ERCP and further management. Her past medical history included cholecystectomy, CVA and atrial fibrillation. Her medications included protonix, warfarin, and multivitamins. She had no known drug allergies. She smokes one pack of cigarettes a day and denies alcohol use. Family history was negative for malignancies. Her physical examination was unremarkable except for jaundice and an irregular heart rhythm. LFT’s revealed a total bilirubin of 20.8 mg/dL, alkaline phosphatase of 468 IU/L, AST 139 IU/L and an ALT of 115 IU/L. ERCP was performed at our center and revealed distal bile duct stricture at the head of the pancreas with a very low “intrapancreatic” biliary hiliar, a markedly dilated right main extrahepatic duct (25 mm) and a left main extrahepatic duct (15 mm) with a stone in the left extrahepatic duct. Brushing of the distal common bile duct and biliary hiliar at the level of the pancreatic head was performed followed by placement of right and left hepatic duct stents (10 Fr x 10 cm in the right duct and 7 Fr x 10 cm in the left duct). The cytology result were suggestive of cholangiocarcinoma. Subsequently the patient underwent pylorus-preserving Whipple’s procedure (pancreatecoduodenectomy with separate choledochoenterostomy anastomosis of right and left extrahepatic ducts). The surgical pathology confirmed the diagnosis of cholangiocarcinoma involving the common bile duct 1 cm below the biliary hiliar (Klatskin tumor) which was located at the head of the pancreas. Despite the complex and unusual anatomical variation of the biliary-pancreatic system in this patient, the combination of MRCP and ERCP was very useful in making the pre-surgical diagnosis and facilitated the surgical plan. This is a unique case of Klatskin tumor treated with a Whipple procedure due to the location of the biliary hilum within the head of the pancreas.

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An Unusual Case of Upper Gastrointestinal Bleeding
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Upper gastrointestinal bleeding is a common medical problem associated with significant morbidity. We present an unusual case of upper gastrointestinal bleeding. A 26 year old African American male presented to the Emergency Department with hematemesis. He also reported having four episodes of melena over the previous 24 hours. His past medical history is significant for HIV infection, chronic Hepatitis B, ESRD on hemodialysis, and IV drug use. He has no prior history of gastrointestinal bleeding. Physical exam was significant for a puffy face, and a left subclavian hemodialysis catheter. Abdominal exam revealed a soft abdomen with tenderness to palpation in the lower quadrants. Rectal exam revealed red blood. Laboratory data was significant for the following: Hematocrit 24, INR 1.1, platelets 172, and normal LFT’S. In the emergency room, he was started on an Octreotide drip and underwent urgent upper endoscopy. EGD revealed red blood in the esophagus, but no evidence of distal esophageal varices. Coffee grounds were present in the stomach, but no clear etiology of the bleeding was identified. The octreotide drip was discontinued and the patient started on an intravenous PPI. Over the next 12 hours, he had ongoing bleeding, and a failing hematocrit, despite packed red blood cell transfusion. Repeat EGD revealed varices in the upper third of the esophagus and no other abnormality. A diagnosis of bleeding downhill varices related to the hemodialysis catheter was made. The patient underwent a venogram which confirmed stenosis of the left brachiocephalic vein and SVC. Subsequent venoplasty resulted in improved flow and a decrease in the prominence of venous collaterals. The patient had no further bleeding in 7 months of followup. Downhill varices are a rare cause of upper gastrointestinal bleeding that results from SVC obstruction and flow reversal in the azygous-hemiazygous system. This entity has been associated with mediastinal tumors, subternal goiter, and central line placement. Patients commonly present with swelling of the upper extremities, face, and head. Gastrointestinal bleeding is reported in less than 10% of cases. Endoscopic treatment of downhill varices carries a high risk of bleeding and perforation. Clinicians should consider this diagnosis in patients with upper gastrointestinal bleeding and history of central line placement.

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Acute Esophageal Necrosis: Black Esophagus and a History of Renal Transplant
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The black esophagus is a finding rarely seen in upper endoscopy. We report two patients who were found to have black esophagus secondary to acute esophageal necrosis on upper endoscopy with a similar clinical history of renal transplantation. The first of these patients had undergone renal transplant 8 days prior to admission for end stage renal disease secondary to hypertensive nephropathy. His operation and postoperative course were uneventful and he was discharged home soon after his surgery. He was then readmitted with increasing creatinine from 0.9 mg/dL to 1.3 mg/dL concerning for
acute rejection. The second patient was admitted with severe nausea, vomiting, and diarrhea two years after his renal transplant for diabetic nephropathy. Both patients complained of new onset severe odynophagia. On exam the patients were noted to be afebrile and normotensive. Neither patient was septic in appearance. With the exception of the transplanted kidney palpated on abdominal exam, the physical exams were normal. Both patients had a slight increase in their white blood cell counts associated with a left shift. To evaluate for an infectious cause of their odynophagia, both patients underwent EGD. During endoscopy black debris was noted on a white exudate extending from the upper 1/3 of the esophagus to the GE junction. At the GE junction there was a sharp transition to normal appearing gastric mucosa. Esophageal biopsies showed acute necrotizing esophagitis, while cultures found no evidence of bacterial or viral infections. The patients were placed on IV PPI therapy and were not allowed oral intake for 24 hours. Antivirals as well as antibiotics were started until culture results were known. Within ten days both patients were back to their normal states of health. Neither developed dysphagia or had recurrence of their symptoms. Acute esophageal necrosis resulting in a black esophagus has been estimated to occur in 0.2% of all patients undergoing endoscopy. Although frequently self limited it may lead to severe strictures. There is a high mortality associated with this disease, as up to 35% of patients succumb to an underlying illness. Many different disease processes have been described in relation to acute esophageal necrosis. Although both of these patients had other risk factors for developing acute esophageal necrosis, the relative rarity of this finding suggests that renal transplantation and its associated immunosuppression requirements may be risk factors for the development of acute esophageal necrosis.

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Acute Liver Failure of Unclear Etiology
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This is a case of a 48 y/o male with a history of mental retardation, seizure disorder, and depression brought to the ED by his caretaker with the complaint of jaundice and disorientation. He had recently lost 10 pounds but had otherwise been in his usual state of health until 2 weeks prior when he complained of feeling unwell. Four days prior, he developed jaundice, intermittent nausea and vomiting, and RUQ discomfort. Finally, 24 hours prior, he became lethargic. There is no history of liver disease in the patient or family. He does not use alcohol or drugs and medications include paroxetine, valproate, and risperidone. He takes no OTC meds or herbal remedies. His exam is significant for a thin man who is agitated and uncooperative. Pertinent findings included jaundice, RUQ tenderness to palpation, hepatomegaly, and no evidence of chronic liver disease. Initial laboratory results included a total bilirubin of 15.7, ALT 3281, AST 7700, alkaline phosphatase 560, and INR 3.8. His WBC is 21.5, HgB 9.4 (MCV 74), and platelets 110. Acetaminophen level is undetectable. U/S demonstrates markedly abnormal architecture most prominent in the right hepatic lobe and patent hepatic veins. Further evaluation included a negative work up for acute viral hepatitis. Ceruloplasmin, ANA, and anti smooth muscle Ab were negative. The patient developed hyponatremia and multi organ failure requiring broad spectrum antibiotics and vasopressor support. He was not considered for transplantation. His family withdrew care and he expired after 48 hours in the hospital. Autopsy revealed gastric adenocarcinoma with linitis plastica growth pattern and a liver with confluent areas of necrosis, microvascular carcinomatosis and sinusoidal infiltration with adenocarcinoma. This is a case of acute liver failure (ALF) from a rare cause, malignant infiltration with gastric adenocarcinoma. Recognition of ALF is vital to guide the diagnostic evaluation and treatment including triage to an institution capable of transplantation. Highlighted are the differential of ALF in the range of diagnostic tests sent as well as the clinical manifestations of ALF which deserve special consideration in terms of treatment options. One should consider liver biopsy with ALF of unclear etiology, especially with clinical clues of a diagnosis that would exclude transplantation. Finally, also demonstrated is the obstructive nature of the infiltrating tumor and resulting ischemic injury to the liver.

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A Dual Forceps-Snare Technique for Removal of a Covered Metal Stent
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ERCP is the procedure of choice in the management of obstructive jaundice. However, cancer and surgery can alter anatomy preventing biliary access with a duodenoscope. We report an endoscopic technique used to remove a distally migrated covered SEMS using a dual channel gastroscope with simultaneous insertion of endoscopic accessories where duodenoscopy and other methods of retrieval failed.

Case report: A 48yr male with a diagnosis of pancreatic cancer was hospitalized for cholangitis despite recent placement of a 6cm x 10mm covered SEMS over a malignant stricture four months ago. Using a duodenoscope, pycoric intubation was difficult and duodenal positioning by shortening the scope to achieve paradoxical advancement was not possible. In constrast, a gastroscopic view of the covered SEMS within the narrowed and tortuous duodenum. Over half of the covered stent had migrated distally into the narrowed 2nd duodenum. [figure1]Use of a snare alone could not be manipulated to retrieve the stent. After several failed attempts by various other methods, successful retrieval of the covered SEMS was achieved by simultaneous insertion of the snare and biopsy forceps through a dual channel gastroscope. The two accessories were then conjoined by grasping the snare loop with the forceps. [figure2]With this method, the snare could be maneuvered in a greater range that enabled the stent to be successfully looped and removed with the snare. Additional stenting was recommended by transhepatic route. The patient fully recovered and was discharged. Distal stent migration is a recognized event that can have serious complications. Here, we report a novel endoscopic technique used to remove a covered SEMS and should be considered in the armamentarium of retrieval methods.
Anabolic Steroid Induced Cholestasis Secondary to a Dietary Supplement

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Dietary supplement consumption has become increasingly popular over the last decade, both through internet sales and retail stores globally. Although the U.S Food and Drug Administration (FDA) prohibits the marketing of synthetic compounds as dietary supplements, the agency has limited role in the enforcement of safety testing, marketing, and regulation of health food supplements. We present a case of prolonged drug-induced jaundice resulting from the use of a body-building supplement that was purchased from a local nutrition store.

Case report: A previously healthy 22-year-old Caucasian man presented with a two-week history of progressive jaundice, dark urine, and pruritus. He had no risk factors for viral hepatitis and he did not abuse alcohol. Physical exam showed a well developed and deeply jaundiced young man without hepatomegaly. Laboratory studies showed AST/ALT, 57/91 U/L, alkaline phosphatase, 203 U/L, total bilirubin, 33 mg/dL, albumin, 4.7 g/dL, INR, 0.99. Viral hepatitis serologies were negative and ceruloplasmin was normal. Abdominal ultrasound showed a normal liver without biliary dilatation. Over the next 11 weeks, his symptoms abated and the jaundice resolved. Additional questioning revealed that he started taking an over-the-counter muscle building supplement (Anabolic Xtreme Superdrol® one tablet daily) four weeks before the onset of jaundice. The active ingredient of this compound is 2a-17a-dimethyl-5a-androst-3-one.

Discussion: Anabolic steroid induced cholestasis has been well documented. All of these steroids are synthetic agents with an alkyl group in the C17 position, including the product in this case. The distribution/sale of a presumed dietary supplement that was later revealed as a known hepatotoxin represented an FDA regulatory violation. On March 8, 2006, the FDA sent a letter to the product manufacturer (http://www.fda.gov/foi/warning-letters/g5736d.pdf) ordering the discontinuation of further interstate commerce involving this product. Given the widespread distribution of this compound, clinicians should be aware that a dietary supplement whose active ingredient contains an anabolic steroid may remain in circulation and may cause protracted cholestasis.
reveal any microorganisms and Congo red stain was negative for amyloid. Colonoscopy demonstrated normal terminal ileal and colonic mucosa. Capsule endoscopy was significant for edematous, scalloped duodenal mucosa, and significant lymphoid hyperplasia of the ileum. [Figure 1]

**Discussion:** Malabsorption and diarrhea can occur in up to 40% of patients with CVID. Small intestinal biopsies may show sprue-like histologic features and nodular lymphoid hyperplasia of the gastrointestinal tract can be detected in a high proportion of patients. The sprue-like syndrome in CVID is a distinct entity which is referred to as hypogammaglobulinemic sprue. Patients do not respond to a gluten-free diet and most require glucocorticoids or immunoglobulins.

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**Hepatic Portal Venous Gas in Presence of Pneumatosis Intestinalis**

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Hepatic portal venous gas (HPVG) and pneumatosis intestinalis (PI) are rare conditions characterized by formation of gas in portal venous system and within the walls of small or large intestine respectively. We report a case of HPVG in association with PI in a patient with transmural bowel infarction. A 54 year old male with history of severe atherosclerotic disease was admitted to the hospital for workup of non-sustained ventricular tachycardia. Two days post left heart catheterization, patient developed worsening non-bloody diarrhea and abdominal pain. Physical examination was significant for distended tender abdomen with absence of bowel sounds. Laboratory workup revealed white cell count of 33500 (cmm, lactic acid of 5.4 mmol/L and pH of 7.18. A computed tomography (CT) of abdomen showed widespread diffuse air in hepatic portal venous system (figure 1) with air in small and large bowel wall (figure 2). Patient underwent immediate exploratory laparotomy, which showed transmural infarction of complete small bowel and right colon consistent with complete occlusion of superior mesenteric artery. In adults, HPVG is associated with a variety of pathological conditions including intestinal ischemia and necrosis (70%-75%), ulcerative colitis (8%), intra-abdominal abscess (6%), and idiopathic causes (15%). PI is idiopathic (15%) or secondary (85%) to bowel ischemia, inflammatory bowel disease, *clostridium difficile* infection, scleroderma, COPD, and drug therapy. CT provides conclusive diagnosis in most cases. Findings of HPVG or PI by itself at CT should be carefully evaluated in the context of clinical findings. However, the combination of two in adults is suggestive of a life threatening bowel ischemia. Physicians should recognize that HPVG in combination with PI is an ominous sign of transmural bowel infarction and needs emergent intervention. [Figure 1][Figure 2]

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**Gastroduodenal Artery Aneurysm Presenting as Jaundice and Abdominal Pain**

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D-Lactic Acidosis

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To present 2 cases of D-Lactic Acidosis with different presentation.

Case 1: 47 year old male with history of vertigo and jejunoileal bypass surgery in 1975 presented with mental status changes, vertigo – unrespon- sive to meclizine, irritability, gait ataxia, and slurred speech. Physical exam was unremarkable. Laboratory values showed: anion gap 22, bicarbonate 11, ABG showing pH 7.15, pCO2 19, and O2 saturation 93%. Lactic acid, salicylate levels, urine and serum toxicology screen, urine and serum ketones, methanol, and ethylene glycol were all normal. Serum creatinine 1.3, and serum ammonia level 65 and normal LFTs while D-lactic acid level of 2.46 mmol/L. Metronidazole, vancomycin, sodium bicarbonate infusion and a low carbohydrate diet improved patient’s condition. D-lactic acid levels of 1.09 mmol/L at discharge.

Case 2: 35 year old male had orchiectomy in 1997 for testicular teratoma treated with chemotherapy. In 2003, he presented with symptoms of small bowel obstruction secondary to retroperitoneal recurrence of teratoma, lead- ing to surgical resection. On post-operative day 21, obstruction lead to re- exploration and gastrojejunostomy with enterosomy. His subsequent hospi- tal course was uneventful and he was discharged on regular diet. In 2006, he presented with early satiety and abdominal discomfort. He was started on ciprofloxacain by his surgeon with some improvement. This raised the possibility of D-lactic acidosis, confirmed by an anion gap of 13.5, serum bicarbonate 14.5 and D-lactic acid level of 1.31 mm/L. He improved with low carbohydrate diet and flagyl. D-Lactic acidosis, is a rare entity associ- ated with short bowel syndrome, short bowel surgery, or jejuno-ileal bypass. Mechanisms include overgrowth of gram-positive anaerobes that produce D-lactate, and malabsorption in the proximal small bowel leading to car- bohydrate fermentation. Symptoms are mainly neurological, but may be insidious. Diagnosis is by history, anion gap acidosis, normal lactate levels but increased D-lactate levels, and sometimes an elevated urine anion gap. Acute treatment is a low carbohydrate diet, antibiotics, sodium bicarbonate, and rehydration. Extreme cases may require hemodialysis or surgical in- tervention such as reversal of jejuno-ileal bypass, intestinal lengthening, or colon resection. Any patient with a history of short bowel surgery or bypass presenting with neurological symptoms or unexplained anion gap acidosis should be a candidate for workup of D-lactic acidosis.

Amiodarone, an iodinated benzofuranic derivative, is often used in the treat- ment of cardiac arrhythmias. A number of side effects have been reported in up to 74% of patients at 1 year, including pulmonary fibrosis, thyroid disease, corneal deposits and neurologic disorders. Transient asymptomatic elevation of transaminases can occur in ~25% of patients on chronic oral therapy, how- ever acute hepatitis, severe cholestasis and cirrhosis are rarely documented. We present a case of acute fulminant hepatic failure following initiation of amiodarone with rapid resolution on its discontinuation. The patient is a 67 year old gentleman with a past medical history significant for coro- nary artery disease and end stage renal disease on hemodialysis. He initially presented to an outside facility with a ventricular arrhythmia that required defibrillator placement and intravenous loading of amiodarone followed by oral therapy. Shortly after discharge, the patient developed increasing con- fusion and profound weakness and was readmitted. On this hospitalization, he was noted to have a profound hypoglycemia with a dramatic elevation in aminotransferases, as well as total bilirubin, alkaline phosphatase and pro- thrombin time (ast 999, alt 1375, alkaline phosphatase 191, total bilirubin 6.8). With increasing lethargy and confusion, the patient was transferred to the intensive care unit for closer monitoring. A CAT scan of the head was unrevealing, toxicology screen and acetaminophen level negative, acute viral hepatitis panel negative. Further questioning of the patient’s family did not indicate any history of heavy alcohol consumption nor the use of any herbs or other potential hepatotoxins. Amiodarone was promptly discontinued and the patient was empirically treated with n-acetylcysteine and lactulose. Over the next 5 days, the patient’s liver function panel and synthetic function improved considerably with notable clearing of the patient’s mentation. He was subsequently discharged to a skilled nursing facility, with almost normal- ization of liver tests. The absence of other causes of liver disease and the clinical course suggest that amiodarone was responsible for the development of acute hepatitis in this patient. The exact mechanism of amiodarone-related toxicity remains unknown.
Discussion: Both Boerhaave’s syndrome and Benign Pneumomediastinum have been described in hyperemesis gravidarum. Excluding Boorhave’s syndrome is of critical importance. The mechanism of pneumomediastinum in our patient may be either rupture of a mediastinal emphysematous bleb into the mediastinum or air dissection through an esophageal mucosal tear. We describe a patient with severe hyperemesis gravidarum who developed benign pneumomediastinum. Once Boerhaave’s syndrome has been excluded, patients can respond well to conservative therapy.

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Normal Uptake of Technetium 99m in Gastric Mucosa Mimicking Active GI Bleeding

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Lower gastrointestinal bleeding (LGIB) is a common clinical problem that varies in severity, location, and work-up. The evaluation of LGIB depends on the clinical status of the patient (pt) and the suspected source. Diagnostic tools include colonoscopy, enteroscopy, scintigraphy and angiography. Technetium-99m (99Tcm) erythrocyte (RBC) scans are used to localize bleeding and to determine if angiography should be utilized, as well as to direct angiographic or endoscopic treatments.

Case: 63 y/o man with history of NSAID use presented to ER with melena. After volume resuscitation, EGD and colonoscopy failed to identify bleeding source. During his hospitalization, the pt had another episode of bleeding with hemodynamic instability. He underwent 99Tcm RBC scintigraphy, which revealed accumulation of RBCs in the topography of the stomach. Repeat EGD revealed normal gastric mucosa and no blood in the stomach. Angiography was negative. Wireless capsule endoscopy revealed the site of bleeding to be a small bowel lymphoma.

Discussion: 99Tcm, one of the most widely used radionuclides, is derived from sodium tetraoxogeten. It is used to label RBCs in vitro, which are re-injected into the pt, and act as a blood pool scan. Of concern, bleeding scans may be normal in up to 70% of pts later documented to have a LGB source. Second, a positive scan may identify the wrong area in 30% to 50% of bleeding colonic lesions. Depending on the time between images, it may be impossible to tell exactly where in the GI tract the radionuclide entered. Lastly, it is important to know that 99Tcm is found to concentrate in the gastric mucosa. In 1962 it was shown that gastric mucosa was able to take up and secrete 99Tcm. The mechanism is not well understood. Theories postulate that 99Tcm is concentrated by the gastric mucous epithelial cells but the degree of concentration is influenced by surface area, blood flow, and health of gastric mucosa. The pH of the gastric contents may influence the secrertion or mucosal retention of 99Tcm, implicating a role of the parietal cell.

Summary: Regardless of the mechanism, gastric uptake of 99Tcm occurs, and represents normal activity. With new scanning methods, gastric activity on a bleeding scan should represent a pathologic gastric process; however, normal gastric uptake must be considered in pts reported to have a gastric bleeding source. Second, a positive scan may identify the wrong area in 30% to 50% of bleeding colonic lesions. Depending on the time between images, it may be impossible to tell exactly where in the GI tract the radionuclide entered. Lastly, it is important to know that 99Tcm is found to concentrate in the gastric mucosa. In 1962 it was shown that gastric mucosa was able to take up and secrete 99Tcm. The mechanism is not well understood. Theories postulate that 99Tcm is concentrated by the gastric mucous epithelial cells but the degree of concentration is influenced by surface area, blood flow, and health of gastric mucosa. The pH of the gastric contents may influence the secretion or mucosal retention of 99Tcm, implicating a role of the parietal cell.

Intestinal Ganglioneuromatosis Polyposis: A Rare Cause of Abdominal Pain

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Ganglioneuromatosis (GNM) polyposis is an unusual intestinal disease entity generally described in children, rarely in adults. It is characterized by a proliferation of mature ganglion cells, Schwann cells and nerve fiber bundles in the lamina propria and submucosa of the bowel wall. It may affect any portion of the gastrointestinal tract, but ileum, colon and appendix are most frequently involved.

Case Report: A 53-year-old male with no significant medical or surgical history, presented with a 2-months abdominal pain, occasional vomiting, a 10-pound weight loss, decreased appetite and constipation. He was not on any medications. On physical examination he was afibrile and had peri-umbilical and lower abdominal tenderness, without guarding or rebound. Rectal exam was normal. Abdominal CT demonstrated thickening of the cecal and appendiceal wall without masses or lymphadenopathy. Colonoscopy showed a few small polyps in the descending and transverse colon and diverticula in the transverse and ascending colon. The polyps were intramuscosal neuromas on biopsy. However, due to persistent abdominal pain, an exploratory laparotomy was performed and a mass measuring 1.5 cm was palpated above the cecum. Subsequently, a right hemicolectomy was done. Pathology of the right colon revealed multiple small neuromas in the superficial submucosa with projections extending into the lamina propria, causing a polypoid arrangement. The neuromas consist of subtle proliferation of spindle cells with few interspersed ganglion cells consistent with ganglioneuromatosis polyposis. Post-operative course was uncomplicated. At one-month follow-up, the patient had no abdominal pain and had normal bowel movements.

Discussion: GNM polyposis can be associated with von Recklinghausen’s disease, multiple endocrine neoplasia (MEN) type 2B, Cowdens disease, nonfamilial adenomatous polyposis and colonic adenocarcinoma. Patients may present with abdominal pain, constipation or diarrhea. Although the pathophysiology is poorly understood GNM polyposis is known to cause motor abnormalities of the alimentary tract, including defective peristalsis in the esophagus and poor contractility of the colon. Diagnosis is by histology. Though rare, this condition should be considered in patients presenting with nonspecific gastrointestinal symptoms. Gastroenterologists must be aware of the increased risk of obstruction, intestinal and endocrine neoplasia in GNM polyposis patients.

Hepatic Fascioliasis Complicated by Hepatic Cyst in Communication with the Biliary Tree and Secondary Sclerosing Cholangitis

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To review a case of Fasciola hepatica with the complications of secondary sclerosing cholangitis (SSC) and hepatic cyst in communication with the biliary tree. Infection with the liver fluke Fasciola hepatica is rarely reported in both Canada and the United States. A 27 year-old Caucasian female presented with right upper quadrant pain, hypodense hepatic lesions, and eosinophilia two months after returning from Mexico, where she had adventurous eating habits and recalled watercress ingestion. A diagnosis of hepatic fascioliasis was made on the basis of clinical and radiologic presentation in conjunction with serum antibody testing. After treatment, with triclabendazole, her pain did not fully resolve. Percutaneous drainage of one of the hepatic cysts was performed yielding bilious fluid. ERCP revealed direct communication of the hepatic cyst with a branch of the right intrahepatic duct and sclerosing cholangitis. A literature review did not identify any other cases of communicating hepatobiliary cyst secondary to Fasciola infection. There have been several reports SSC after years of chronic Fasciola infection, but none with the patient this close to the acute phase of infection. The hepatobiliary cyst was treated with endoscopic stenting resulting in incremental shrinkage in the size of the cyst as well as improvement in pain. The SSC is asymptomatic, with preserved synthetic function. As the implicated cause of the sclerosis has been identified and corrected it is felt that the patient has a good prognosis and that further progression of the sclerosis is unlikely. There is unlikely to be an increased risk of cholangiocarcinoma in this patient as neither Fasciola infection nor SSC is associated with heightened incidence of malignancy.
Intraepithelial Cholestasis (IHC) is a rare complication of sickle cell disease (SCD). While diagnosis is challenging given the overlap of IHC with other conditions of SCD – hepatitis, cholecystitis, hepatic crisis, early recognition of this entity is essential for avoiding fatal outcome.

**Case Report:** A 41 year old black man was brought to ED for blurred vision, productive cough and right upper quadrant (RUQ) abdominal pain. Past medical history: SCD, hypertension, end-stage renal disease on hemodialysis. Vital signs: BP 90/50, HR 98, T 99 F, SpO2 95%. RA and physical exam was remarkable for icteric sclera and skin, RUQ tenderness, hepatomegaly. He was treated with IV hydration and narcotics for acute sickling crisis. On the 2nd hospital day he remained hypotensive, became lethargic & febrile with worsening abdominal pain. Labs: leukocytosis, hyperbilirubinemia (total bilirubin 7.14mg/dL, 13.8mg/dL, 23/21, 39/39) and a cholestatic pattern on liver panel, coagulopathy, and elevated BUN/creatinine. Serologic tests for viral hepatitis and HIV: negative and abdominal ultrasound was unremarkable except for a single gall stone. CT scan showed normal biliary duct. Subsequently, he developed worsening coagulopathy with bleeding from his oral cavity, increasing abdominal pain and worsening mental status (ammonia: 59). These findings led us to the clinical diagnosis of IHC. He was transferred to a tertiary care center for exchange transfusion. However, he underwent exploratory laparotomy for suspected abdominal compartment syndrome. But no evidence of bowel ischemia was noted on fluorescein injection. Despite maximal supportive care, his condition continued to deteriorate and life support was discontinued as requested by his family.

**Discussion:** IHC is due to widespread sickling within the hepatic sinusoids leading to ischemia & ballooning of hepatocytes- intranuclear cholestasis. Estimated mortality: 37%. It is characterised by striking jaundice, renal impairment, coagulopathy, and encephalopathy with RUQ pain, fever, tender hepatomegaly and leukocytosis. Surgery in IHC has been reported to be associated with a poor outcome and all survivors have been treated with exchange transfusion and intensive supportive care. IHC must be considered in the differential diagnosis of SCD patients who present with very severe hepatic crisis and go on to develop the characteristic features mentioned above. Vigorous exchange transfusion and correction of coagulopathy appears to be the best therapeutic approach in these cases.

**A 37-Year-Old Man with Rash and Abdominal Pain**

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A 37 year-old man was admitted to the trauma service following a rollover ATV accident. Prior to the accident he was in good health. Injuries included a L1 burst fracture which required spinal cord decompression. Post-surgical hospital course was uneventful. He was transferred to the rehabilitation unit on post-operative day #5 with persistent incomplete paraplegia. On post-operative day #15 the patient developed a painful purpuric rash on his lower extremities. Punch biopsies were obtained. Several hours later he complained of nausea accompanied by nonbilious emesis and severe generalized abdominal pain. Physical examination revealed a non-rigid abdomen without peritoneal signs. Complete metabolic panel, complete blood count, liver function tests and pancreatic enzymes were normal. Abdominal computed tomography revealed marked bowel wall thickening involving the distal duodenum and proximal jejunum. Push enteroscopy demonstrated contiguous ulcerations throughout the distal duodenum and proximal jejunum. This was biopsied. The esophagus and stomach were normal. Dermatopathology demonstrated dermal blood vessels with positive IgA vascular staining, consistent with IgA vasculitis. Small bowel pathology demonstrated acutely inflamed and focally ulcerated mucosa. There was no evidence of neoplasia or infection. The diagnosis of Henoch-Schönlein purpura was made. Henoch-Schönlein purpura is a small-vessel vasculitis which commonly affects the skin, kidneys, and gastrointestinal tract. The disease is often heralded by antecedent infections, but may also occur following other physical stressors including trauma. Gastrointestinal manifestations occur in most persons with Henoch-Schönlein purpura and most commonly affect the duodenum and small intestine. Diagnosis may be difficult as the characteristic purpuric rash may be preceded by gastrointestinal symptoms leading to a delay in diagnosis or even unnecessary surgical exploration. Disease may vary from isolated duodenal mucosal ulcerations to a more severe presentation such as intussusception, obstruction, or bowel perforation. Diagnosis should be considered in patients presenting with gastrointestinal complaints accompanied by rash or new onset kidney disease. The disease is usually self-limited, but the duration of disease may be truncated by immunosuppressive therapy. Duration of therapy is variable and relapse is common if immunosuppressive therapy is tapered too rapidly. Most patients have no residual sequelae or recurrence of disease upon resolution.

**Elevated Intra-Abdominal Pressure and Organ Failure in Abdominal Lymphoma**

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**Introduction:** Increased intra-abdominal pressure (IAP) associated with single or multorgan failure characterizes the abdominal compartment syndrome (ACS), most commonly seen post-operatively or in the setting of massive fluid resuscitation. Malignancy with ascites is a very unusual etiology. To alert clinicians to the spectrum and clinical relevance of this potentially catastrophic disorder, we report the rare association of diffuse abdominal lymphoma complicated by IAP, respiratory failure and sepsis.

**Case Report:** A 71 y.o. woman was admitted with a 1 week history of abdominal discomfort and increasing abdominal girth. Past medical history included atrial fibrillation and type 1 diabetes mellitus. On exam, temp = 98.6F; BP = 141/50. Mild diffuse tenderness without signs of peritoneal irritation was present on abdominal exam. Asites with shifting dullness was found. Pertinent lab values: Hgb = 10.4gm% with normochromic, normocytic RBC indices; WBC = 7300; glucose = 135mg%; BUN/creatinine = 36/1.5. Abdominal CT scan :ascites, multiple low intensity soft tissue densities, suspicious for diffuse carcinomatosis of possible ovarian or GI primary site. Ultrasound-guided paracentesis : WBC = 46000 (lymphs = 96%); RBCs = 64 per cubic cm; albumin = 2.7gm%; LDH = 3420 IU; serum albumin-ascites albumin(SAAAG) = 0.6. Cytology demonstrated large nucleated, basophilic lymphoid cells with irregular cytoplasm consistent with lymphoma. Over 48 hours, she developed a marked increase in both distention and asites, then respiratory failure requiring intubation. Indirect measurement of abdominal pressure was done by instilling 50 cc of saline into the urinary bladder with measured pressure elevated at 44 mm Hg (normal to 5, elevated > 20). Her course was complicated by Staph aureus bacteremia, Candidemia and hospital death.

**Discussion:** Current understanding of the contribution of intra-abdominal hypertension and abdominal compartment syndrome to the complex problems of acutely ill medical patients is incomplete, as in our patient. Existing data indicates that IAP developing after ICU admission is a risk factor for multi-organ failure and may contribute to increased morbidity and mortality. Abdominal pressure should be monitored in high-risk patients, including patients such as ours, who have intra-peritoneal malignancy and experience acute deterioration.
Hepatocellular carcinoma (HCC) has a poor prognosis and for an unresectable tumor the course is rapidly fatal. Spontaneous regression of HCC has been described but appears to be a rare phenomenon. We report a patient with a large multifocal HCC with portal vein invasion, who had a complete spontaneous resolution of the tumor.

**Case:** A 56 years old man was referred for abdominal pain and feeling a lump in his abdomen in Nov 05. He was diagnosed with HCV two years ago. His PMH was significant for COPD and HTN. Current meds included diltiazem, propanolol and oral inhalers. His HCV risks included a tattoo. He smokes 4 cig and drinks 5 beers/day. He had no cutaneous stigma of liver disease. A firm mass was palpable in the epigastric area. His AFP levels were markedly elevated at 2854 ng/ml. A CBC and synthetic functions were normal. ALT slightly elevated to 44 IU/ml. HIV was negative, HBSAb positive, HBSAg negative and HBeAb (total) positive. HCV RNA was 14500000 IU/ml (2b).

An US showed a solid mass encompassing the entire L. lobe and PV thrombosis. A CT noted a 7.5 cm mass at the anterior aspect of the L. hepatic lobe extending to the R. hepatic lobe, a 3.6 cm mass within the PV and several small lesions. A CT biopsy confirmed a mod. diff HCC. In Feb, 2006, he presented with chills, sweats and abd. distension, no ascites was appreciated. The previously palpated mass was not felt. He had leukocytosis with a left shift. AFP normalized to 6.6 ng/mL. He denied using OTC/herbal medicine. An MRI, a CT and an US failed to show the tumor. PV was patent. His HBSAg turned positive in April 06 but two months later is negative again. Current LFT’s are normal, HBeAb-M is negative, HBeAg and HBV-DNA are pending.

**Discussion:** Among 28 cases of HCC undergoing a complete spontaneous regression our patient is the first reported case in the setting of chronic infection with both HCV and HBV, with a suspected HBV reactivation and subsequent clearance. In our patient HBV could have been responsible for tumor production. A clear mechanism for spontaneous regression is not well understood. A variety of proposed theories include; immune, genetic and hormonal mechanisms; withdrawal from estrogen, alcohol and carcinogens; local or systemic infections and tumor infarction due to a compromised blood supply. In our case, the last two mechanisms might be responsible for the tumor disappearance. More in depth analysis is needed to find the common characteristics among this group of unique individuals.

Six months later the patient returned to the hospital with 6 days of progressive dysphagia to solids. In the interval period he had gained over 25 pounds with good appetite and no limitation of daily activities. Repeat upper endoscopy under general anesthesia revealed distal displacement of the Polyflex stent and proximal tumor overgrowth causing high-grade obstruction. The stent was removed under manual traction uncovering a 4cm by 1cm tracheoesophageal fistula. The endotracheal tube and carina were clearly visible through the large fistula. A 120 mm long, 18 mm Ultraflex stent was then placed under fluoroscopic guidance but did not cover the entire length of the fistula. Therefore, a 90 mm long, 21 mm Polyflex stent was placed within the previously placed Ultraflex stent. The fistula appeared fully covered with the proximal end of the stent just below the UES. The patient was extubated and able to tolerate full liquid diet 24 hours later. This case illustrates management of one of the major complications that may occur with advanced esophageal cancer. New technical devices such as the Polyflex and Ultraflex esophageal stents allow occlusion of tracheoesophageal fistulas with improved quality of life in patients who otherwise may suffer early demise from respiratory complications related to these fistulas.
We report a case of a 2 month old male presenting with edema and hypoalbuminemia who was found to have a Wilms tumor. This is the first reported case of Wilms tumor presenting as protein losing enteropathy.

**History:** The patient presented to his primary care physician with fever and irritability. On exam he was noted to have pitting edema of the bilateral lower extremities and periorbital swelling. This was long standing, as parents did not consider this a change in his baseline. Labs on admission were remarkable for a total protein of 3.8 g/dL and albumin of 2.3 g/dL. CBC with differential was unremarkable and ALC was slightly low at 2.97k/uL. Urine was negative for protein. US of the abdominal vasculature was negative for thrombosed vessel and no mass was appreciated at that time. He was treated with albumin infusions and IV furosemide. His feeds were switched to hydrolysate and then elemental formula with no significant improvement in his clinical or lab status. Cardiac ECHO was normal. The patient had an EGD and flexible sigmoidoscopy with biopsy. These were vi- sually normal, and pathology was negative for any inflammatory changes or evidence of dilated lacteals. MR of the lower extremities and pelvis were negative for evidence of lymphangiectasia. Stool for α-1-antitrypsin was markedly elevated. A tagged albumin scan was done hoping to localize the source of protein loss. The study was non-diagnostic, however a lack of perfusion was described in the upper pole of the right kidney. Subsequent imaging confirmed the mass. He underwent right radical nephrectomy with lymph node sampling. Intraoperatively dilated lymphatics of the mesentery and a small amount of chyloous ascites were noted. Pathology showed Wilms tumor with invasion of the renal capsule and no lymph node involvement. Post-operatively the patient has successfully maintained albumin levels above 3.5g/dL with no infusions and his ALC has been increasing. Clinically he is less edematous and his growth has been good.

**Discussion:** Protein losing enteropathy is a clinical entity multiple potential etiologies. Typically it is caused by mucosal inflammation or lymphatic obstruction. Severe infections or inflammatory states may also increase intestinal permeability leading to protein loss. One potential mechanism for our patient's presentation is mass effect with impingement of the effenter lymphatics. Also possible is a paraneoplastic syndrome or humoral effects of substances secreted by the tumor.

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**Laparoscopic Highly Selective Vagotomy for Recurrent Duodenal Ulceration with or without Gastric Outlet Obstruction**

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Medical treatment heals ulcers in 90% of the cases but they recur in 50–70% of the patients. We present a proposal of laparoscopic treatment for patients with recurrent ulcer after a long-term medical treatment or with gastric outlet obstruction. Four patients underwent laparoscopic highly selective vagotomy (HSV) with or without pyloroplasty between 1998 and 2006. There were 4 male patients aged 19–45 years (mean age: 30 years). All patients were operated electively. For patients with a chronic peptic ulcer disease, pre-operative assessment involved a recent gastroscopy, isotope gastric study and mandatory 24-hour pH measurement. HSV proved feasible in 100% of the cases in spite of a history of previous surgery and peritonitis in patients with a perforated ulcer. There were neither conversions nor intra-operative complications. There was no mortality or morbidity except one patient with transient esophageal stricture following vagotomy around abdominal esophagus. All patients were rated Visick I and II. The acid output had significantly decreased 6.3 to 0.8 in BAO, 26.9 to 3.4 in MAO, respectively. No patient had recurrence in follow-up periods without medication. The treatment of choice for recurrent duodenal ulcer is laparoscopic highly selective vagotomy. The laparoscopic approach shortens the hospital stay and improves patient's comfort.

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**Felt’s Syndrome: An Unusual Cause of Idiopathic Portal Hypertension**

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Felt's syndrome is defined by the triad of rheumatoid arthritis (RA), splenomegaly, and neutropenia. Liver function abnormalities and portal hypertension are not typical features of felt's syndrome. Nodular regenerative hyperplasia (NRH) has been associated with portal hypertension in both RA and Felt's syndrome. Only three prior case reports have described patients with Felt’s syndrome and portal hypertension in the absence of NRH. We present two additional cases of Felt's syndrome and portal hypertension without NRH on liver biopsy or imaging studies. A 35 year old Morrocan female and a 44 year old white male were referred for evaluation of splenomegaly and portal hypertension. Both patients were noted to be leukopenic and neutropenic but had normal liver enzymes. Serum bilirubin and INR were normal. On further clinical evaluation, both patients had symptoms and signs consistent with RA. In addition, both patients had high anti-Citrulline-Containing Protein antibody titers. Both had soro- graphic evidence of portal hypertension. In the female patient, EGD showed three columns of grade 3 esophageal varices and liver biopsy showed mild parenchymal hepatitis but no evidence of fibrosis, NRH, or schistosomiasis. In the male patient, liver biopsy showed mild steatohepatitis and collagen plate thickening of central veins with chicken wire fibrosis but no evidence of cirrhosis or NRH. Tests for viral hepatitis, Wilson's Disease, smooth muscle antibody and iron overload were negative. Felt's syndrome is an uncommon entity. There are only 12 reported cases of Felt's syndrome and idiopathic portal hypertension, 9 of which were associated with NRH. NRH may lead to oblitative portal venopathy, which has been considered a cause of idio- pathic portal hypertension in patients with Felt’s syndrome and RA. Both of our patients had Felt’s syndrome and portal hypertension in the absence of NRH. This argues against NRH as the sole cause of portal hypertension in this entity. Regardless, prior case reports including ours have documented development of esophageal varices and hemorrhage. EGD should be performed for variceal screening in these patients. Overall prognosis is generally fa- vorable. Further complications of portal hypertension such as ascites and encephalopathy have not been described with Felt’s syndrome.

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**Cutaneous Metastasis to the Neck from Colon Adenocarcinoma**

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Cutaneous metastases are infrequently a first sign of internal malignancy. Head and neck metastases from colorectal cancer are extremely rare. Most of these lesions appear years after resection of the primary colorectal tumor, as metastatic recurrences. However, we report a man who initially presented with a large posterior neck mass diagnosed to be mucinous adenocarcinoma and eventually discovered to be a metastatic lesion from a primary colon cancer. Upon review of the literature, there have been no known reports of cutaneous metastases to the neck region from colorectal cancer.

**Case Presentation:** This is a 53-year-old, Caucasian male who presented with a slowly enlarging right posterior neck mass treated with multiple courses of antibiotics for a presumed abscess over the course of 6 months. Eventually the mass enlarged to a size of 12 × 5cm, ulcerated, resulting in significant discomfort to the patient, a biopsy was obtained which revealed a mucinous adenocarcinoma. The patient was noted to have iron deficiency anemia. Upon colonoscopy, a nearly obstructing ascending colon mass was noted. Biopsy confirmed the primary tumor as mucinous adenocarcinoma of the colon. Palliative chemoradiation was chosen as treatment. Lung and breast cancer are the most common malignancies metastasizing to the skin.
in men and women respectively. Clinically, cutaneous metastases manifest as nodules, ulceration, cellulitis like lesions, bullae or fibrinous processes. The pathogenesis is from direct spread from the initial tumor or dissemination via lymphatics. Cutaneous metastases rarely occur with colorectal adenocarcinoma, accounting for approximately 5 percent of all cutaneous metastases. Most frequently, cutaneous metastases from colonic cancer result from a recurrence of the carcinoma at the abdominal skin from prior surgical incisions. Thus, early recognition of tumour relapse from a suspicious skin lesion may lead to initiation of treatment before widespread metastases occur. In our case, the cutaneous metastasis went undetected for six months until an accurate diagnosis was made. The case we describe here is unusual because colorectal adenocarcinoma rarely metastasizes to the head and neck region. In the head and neck region only fifteen cases of cutaneous metastases have been reported. And to our knowledge this is the first reported case of metastases to the neck region from colon cancer.

A 4-year-old female with failure to thrive, metabolic acidosis, ketosis, and motility disorder was diagnosed at 14 months with a mitochondrial, multi-systemic disorder. Born via emergency C-section at 32 weeks, she was then not expected to survive beyond 24 hours. Patient received NG feedings via a pump until she learned to suckle; then she was breastfed from 6 to 23 months. Because of insufficient nutrient absorption from dumping syndrome and cyclic vomiting, she was fed every 2 hours, resulting in little sleep for patient and caregiver. A gastrostomy was placed at 23 months and pump feedings to resume. Patient required feedings over 22 hours at 40 ml/hr. and was now walking.

Retrospective Case Study: Her pediatric gastroenterologist advised the caregiver not to restrict patient’s mobility, since she would be more likely to retain mobility and experience improved levels of energy as she grew. He prescribed a new generation portable pump (NGPP – Infinity, ZEVEX Inc, Utah), which has a small backpack the patient can wear and operates in any orientation, consistent with any type of physical activity. A first generation portable pump (FGPP) containing a drip chamber was used until insurance approval for the NGPP was obtained. Size and orientation requirements restricted mobility, confining patient to a wheelchair 95% of the day. Use of the NGPP has significantly improved patient’s quality of life. She now enjoys activities typical for a young child, without restriction. Her first month using the NGPP, she gained 4 ounces. Pumping, constipation, and cyclic vomiting have all decreased. The positive changes noted demonstrated how new technology improves health by maintaining unrestricted physical activity along with continuous enteral feedings.

Patients Treated With Nitoxazanide (254)

<table>
<thead>
<tr>
<th>ORGANISM/PATHOGEN</th>
<th>CASES</th>
<th>ERADICATION</th>
<th>SUCCESS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cryptosporidium parvum</td>
<td>243</td>
<td>240</td>
<td>99%</td>
</tr>
<tr>
<td>Amoeba histolytica</td>
<td>112</td>
<td>112</td>
<td>100%</td>
</tr>
<tr>
<td>Giardia lambia</td>
<td>120</td>
<td>118</td>
<td>98%</td>
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<tr>
<td>Blastocystis hominis</td>
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<td>Ascaris lumbricoides</td>
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<td>C. difficile</td>
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<td>100%</td>
</tr>
<tr>
<td>T. solium</td>
<td>22</td>
<td>22</td>
<td>100%</td>
</tr>
<tr>
<td>T. spiralis</td>
<td>11</td>
<td>11</td>
<td>100%</td>
</tr>
</tbody>
</table>

Nitoxazanide is highly effective in treating/eradicating gastrointestinal pathogens; this includes parasites, helminths, protozoa, and pathologic bacteria.

Probiotics and Colostrum in the Treatment of C. difficile Colitis

Clostridium difficile colitis (Toxins A&B) is a major pathogen in both in- and out-patient settings. Allopatic therapy is equally dangerous. The purpose of this study is to share the experience of treatment of C. difficile with probiotics and colostrum. One hundred and fourteen patients with C. difficile were seen. Eighty seven were treated with a 'probiotic', Saccharomyces boulardii (250 mgm) and colostrum (960 mgm), PO, BID for two weeks. Eighty five of eighty seven patients were found free of C. difficile toxins A&B after two weeks of the probiotic S. boulardii and colostrum. Treatment of C. difficile toxins should begin with probiotics and colostrum, not antibiotics. Most cases of C. difficile are caused by antibiotics. Fight fire with fire.

Myocarditis Associated with Campylobacter jejuni Infection: A Case Report

Hundreds of patients (672) with thousands (2210) of gastrointestinal infections/parasites have been treated over the past ten years. A third of these have more than one parasite making treatment a challenge. Two hundred and fifty four (254) were treated with one drug, Nitoxazanide 1 GM., PO, BID. The purpose of this report is to suggest that ‘one drug’ therapy will eradicate chronic gastrointestinal infection (bacteria, amoeba, helminth) in most patients. Of 672 patients 2210 were found to have gastrointestinal infection/parasitis. A third had more than one parasite. Those with more than one (254) were prescribed one drug, Nitoxazanide (1 gram, PO, BID, for two weeks).

The pathogenesis includes parasites, helminths, protozoa, and pathologic bacteria.
negative. Patient was given a diagnosis of myocarditis and was treated supportively. Due to the unresolving diarrhea, colonoscopy was performed. The colonoscopy revealed erythematous, friable mucosa with multiple deep ulcers in the sigmoid colon (Figure 1). The pathology specimen revealed acute colitis with cryptitis and crypt abscesses. Stool culture of an aspirate obtained during colonoscopy revealed *C. jejuni*. Within one week of hospitalization patient improved. At 30 days follow up, the patient was symptom free, without further diarrhea or chest pain. Review of the literature reveals 14 case reports worldwide of myocarditis associated with *C jejuni* infection. The pathogenesis is unknown; however, it has been suggested that myocarditis develops either as a result of bacteremia or as a result of a secondary immune reaction. Myocarditis can present as sequelae of *C jejuni* infection. *C jejuni* should be considered as a culprit whenever there is a presentation of diarrhea in conjunction with myocarditis-like symptoms. [figure1]

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A Case Presentation of Gastric Cryptosporidiosis in an HIV Patient
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A 24 yo female, with a history of sexually acquired HIV on no medication, presented complaining of epigastric abdominal pain associated with nausea and non-bloody vomiting for 7 days. She reported wetary, non-bloody diarrhea for 3 months with a 10 pound weight loss, but denied any fever, chills, or change in appetite. On exam, she was afebrile with generalized wasting. Laboratory studies revealed 12.9 mg/dl Hgb, with the base line Hgb of 12–13 mg/dl, WBC = 1.7 with 61.6% neutrophils, 18.8% lymphocytes and a low CD4 count (< 20). Stool work up was negative for ova and parasites x 3, including Cryptosporidium parvum, wright stain and stool cultures were negative for WBCs and bacteria. Upper endoscopy and colonoscopy were performed. The antral mucosa was markedly erythematous, edematous and the mucosal surface was markedly friable. Thickened gastric folds were seen. Biopsies were taken of these areas. The colonic mucosa appeared normal. Histopathologic examination of antral and duodenal mucosal biopsies showed chronic active gastritis with extensive cryptosporidiosis and *H. pylori* organisms. Biopsies from the colonic mucosa were positive for Cryptosporidium parvum as well. In view of these findings, therapy with Alinia 500 mg twice daily was started. After 2 weeks, clinical improvement was observed with reduction of both epigastric pain and diarrhea. Repeat endoscopy 8 weeks later showed normal gastric mucosa. No organisms were identified on repeat antral and duodenal biopsies. Cryptosporidium parvum is a common protozoal infection that has been recognized as a human pathogen since 1976. It causes self-limited diarrhea in immunocompetent hosts, but severe and prolonged diarrhea in immunocompromised individuals, particularly those with HIV infection. Cryptosporidium parvum has been detected with increasing frequency in the gastrointestinal tract but involvement of the stomach is rarely reported. This case report presents the clinical, pathologic and endoscopic features of Cryptosporidium associated erosive gastritis and highlights the importance of upper endoscopy and biopsy in diagnosis of this entity. [figure1]
Liver Abscess Following Botulinum Toxin Injection for Achalasia
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Achalasia is an idiopathic neuromuscular disorder of the esophagus associated with the absence of distal esophageal peristalsis and incomplete relaxation of a normal or hypertensive lower esophageal sphincter. Intraspincteric injection of botulinum toxin has been used as an alternative to balloon dilation and surgical myotomy in selected patients. This therapy has been reported to be as safe and effective as other therapies for achalasia, with only mild, self-limiting side effects reported. We report a case of a pyogenic liver abscess three days following a therapeutic injection of botulinum toxin for treatment of esophageal achalasia. A 77 year old white male with a history of GERD and achalasia underwent therapeutic injection with 100 units of botulinum toxin for achalasia. Seven days prior, an abdominal ultrasound was performed to investigate mildly elevated transaminases and revealed only mild steatosis without any focal hepatic abnormality. The patient then presented to the ER three days after the injection complaining of right upper quadrant abdominal pain, nausea, fever of 101–102°F, and chills for one day. Initial labwork revealed WBC 25,800(μL with 20% bands, total bilirubin 1.5mg/dL, alkaline phosphatase 153mg/dL, and SGOT 202mg/dL, and SGPT 219mg/dL. CT scan of the abdomen revealed an 8.0 × 7.5cm ill-defined mass in the upper portion of the right hepatic lobe with multiple loculated fluid pockets and numerous air bubbles consistent with a hepatic abscess. The patient underwent percutaneous drainage of the liver abscess, and results of the abscess material, including Gram stain and bacterial culture, mycobacterial and fungal smears and cultures, and E. hystolytica serology, all remained negative. Botulinum toxin has become a widely accepted therapy for esophageal achalasia, and its adverse effect profile has primarily been limited to mild, self-limiting side effects. However, more serious adverse effects, including urinary retention, pneumothorax, fatal heart block and myasthenic crisis, have been reported. We report the development of a liver abscess three days after intraspincteric botulinum toxin injection. The adverse effect profile of botulinum toxin needs ongoing surveillance and will become apparent with increasing utilization of botulinum toxin injection therapy.

Tumour Blush or a Radiological Artefact?
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Mesentric angiogram is a crucial investigation in patients with occult GI bleeding. Tumour blush is seen on angiogram is usually seen in tumours like leiomyosarcoma. We present a case where tumour blush finally disappeared – was it an artefact? A 72 year old lady presented with recurrent Iron Deficiency Anaemia needing repeated blood transfusions. She had lost about 1kg in weight. She required frequent blood transfusions. Gastroscopy, colonoscopy, small bowel enema and CT scan of abdomen were normal. Her Hb dropped to 6gm/dL. Colonoscopy was repeated and revealed scanty fresh blood in proximal colon. An urgent superior mesenteric angiography showed a tumour blush (see picture 1) in mid-jejunal area suggesting a hypervascular tumour. A push enteroscopy up to distal jejunum was however normal. A mini-laparotomy plus intra-operative enteroscopy also did not reveal any pathology. A repeat mesenteric angiography was arranged with view to embolisation, but tumour blush was not found this time (see Picture 2). Mesentric angiogram generally provides a reliable diagnostic information. In this case mini-laparotomy and intra-operative did not corroborate the findings of angiogram. The apparent tumour blush was probably an artefact in this particular case? This patient with occult GI bleed remains diagnostic challenge but her transfusion requirement has reduced. [figure 1] [figure 2]

Atypical Cocaine Induced-Enterocolitis: A Case Report
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Purpose: We present a case of a 46 year-old African-American male with past medical history of GERD who presented with sudden onset of abdominal pain that woke him up from sleep. The pain was described as severe,
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Diffuse Intestinal Multiple Lymphomatous Polyposis: A Rare Presentation
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Primary non-Hodgkin’s lymphomas of GI tract are rare accounting for 1–4% of malignancies. Multiple lymphomatous polyposis (MLP) is characterized by involvement of long segments of GI tract by polyoid tumors originating from mantle zone of lymphoid follicle. Hence, it is considered a subtype of lymphoma called Mantle Cell Lymphoma (MCL). These account for 20% of Non-Hodgkin’s lymphomas of GI tract. Since 1961 no more than 70 cases have been published. Even rarer is the diffuse involvement of GI tract. The case we report is only second published case of diffuse GI lymphomatous polyposis involving esophagus as well as the rest of GI tract. Other cases involved most of the GI tract but not the esophagus except for one case which involved esophagus as well. A 65-year-old man was referred for screening colonoscopy. Other than occasional constipation patient denied abdominal pain, GI bleeding, fever or weight loss. He had 35 pack years of smoking but no family history of cancers. Labs: normal chemistry and liver enzymes, mild anemia with hematocrit of 34 and elevated ESR of 31. Colonoscopy revealed multiple polyoid tumors ranging in size from 4mm to 5cm from rectum to cecum. A small bowel enteroscopy showed polyoid lesions of esophagus (Fig), stomach, duodenum and jejunum some of which were ulcerated. Histologically lesions were composed of diffuse infiltration of mucosa and submucosa of medium sized atypical lymphocytes with irregular cleaved nuclei and scant cytoplasm. Immunohistochemical studies were positive for CD20 and bcl-2 protein supporting the diagnosis of MCL. Whole body CT and PET scans revealed a paratracheal and few small retroperitoneal lymph nodes, normal liver and spleen and a 4.5×5cm lesion in the terminal ileum. Bone marrow biopsy was normocellular. HIV test was negative. Prognosis of MCL is generally reported to be poor with mean survival of 20–30 months without treatment. Being asymptomatic our patient refused chemotherapy and still remains well and alive after 24 months of diagnosis.

Interferon Therapy Induced Sub-Fulminant Steatohepatitis
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43-year-old Caucasian female with end stage renal disease requiring hemodialysis, being evaluated for renal transplant presented for treatment of Chronic Hepatitis C. Her medications included Midodrine, Fludrocortisone, and Phoslo. She was anicteric without stigma of chronic liver disease. Laboratory tests revealed Hb 10.1g/dl, platelets of 520000, PT/INR 16/1.2. Creatinine 4.5mg/dl, Bilirubin 0.3mg/dl, albumin of 3.7g/dl. AST 741 U/l, ALT 49 U/l, ALkaline phosphatase 479 U/l. ANA, AMA, SMA negative. HCV RNA 14460000 IU/ml. CT scan showed hepatomegaly. Liver biopsy showed chronic hepatitis with dense portal chronic inflammatory infiltrate, portal fibrosis, focal interface inflammation and moderate steatosis. In view of her renal failure, she was started on Intron A 3 million Units 3 times a week monotherapy. After 8 weeks of therapy, she decompensated with jaundice and ascites. Her admission labs include Hb 10.8 gm/dl, platelets of 650000, PT/INR 17.1/1.3. Creatinine 9.3 mg/dl, Albumin of 2.2 g/dl, AST 100 U/l, ALT 55 U/l, Alkaline phosphatase 320 U/l. Repeat autoimmune markers were negative, HCV RNA was negative. Ultrasound revealed enlarged liver, patent portal vein. Transjugular liver biopsy revealed a pressure gradient of 14mmHg consistent with moderate portal hypertension. Biopsy showed grade 3 inflammatory activity, bridging fibrosis (stage 2) and severe, massive steatosis and steatohepatitis. Her decompensation was attributed to interferon therapy in the absence of infectious, drug and autoimmune etiology. Interferon therapy was stopped, and was worked up for possible liver/kidney transplant. During her workup, she continued to deteriorate with worsening jaundice, ascites and eventually expired. Interferon therapy in patients with chronic hepatitis C can cause decompensation of liver disease due to a number of causes including exacerbation of autoimmune disease. In our patient the only reason for decompensation was a severe form of steatohepatitis, a clear worsening of moderate steatosis seen on her
liver biopsy 2 years ago. Sub fulminant Steatohepatitis has been described in a few case reports but this is the first case of interferon-induced steatohepatitis reported in the literature. Hence in conclusion, patients with moderate steatosis should be informed of possible worsening of steatohepatitis on Interferon therapy.

974 Statins Produced Symptoms of Acute Cholecystitis in a Patient with Familial Heterozygous Hypercholesterolemia Ketul Patel, MD, Roja Ramisety, MD, Benaznin Dianczok, MD, FACP. Internal Medicine, Providence Health Medical Center, Southfield, MI.

Heterozygous familial hypercholesterolemia (FH) is characterized by defects in LDL receptor function. This results in increased plasma levels of LDL cholesterol, tendinous xanthomata, and premature atherosclerosis. Over 600 different defects of LDL receptor function have been described. Here we present a 34 year old female with FH that developed symptoms of acute cholecystitis after starting statin therapy.

Case report: A 34-year old female with FH was referred to the Lipid Clinic for intolerance to statins. The patient was diagnosed with FH at age 17. Her first exposure to statin therapy was in 1994 with LDL cholesterol greater than 250mg/dL. Several days after starting Simvastatin she developed severe colicky RUQ abdominal pain, nausea and vomiting. Her stools became foul smelling, clay colored and floated. She presented to a local ER where she appeared quite ill but was afebrile and had a tender RUQ. Acute cholecystitis with CBD stone was suspected. Remarkably, the patient did not demonstrate gallstones on ultrasound. HIDA scan and ERCP were performed which did not demonstrate any other abnormalities. Simvastatin was discontinued, her symptoms resolved and she was discharged. Upon reinitiation of Simvastatin, her symptoms recurred. As new statins became available and were tried, she reacted similarly. She was never jaundiced during the attacks. She was ultimately started on a combination of Ursodeoxycholic acid 300mg BID and Rosuvastatin 5mg daily. Her LDL decreased and she no longer suffered abdominal symptoms. A follow up for 3 years, she has remained virtually symptom free and LDL has decreased to 139mg/dL. We propose the following mechanism for her symptoms and treatment. Two pathways supply cholesterol to hepatocytes; endogenous pathway and an exogenous pathway via LDL receptors. With severe LDL receptor dysfunction such as patients with FH, hepatocytes may only obtain cholesterol by endogenous manufacture. Inhibition of HMG CoA reductase by statins depletes endogenous cholesterol. Thus bile acid synthesis is inhibited. This paucity of bile acids results in acholic stools, steatorrhea and right upper quadrant pain. Our conclusion is that providing exogenous bile acids prevent her statin induced symptoms. With a comprehensive understanding of the genetic composition of FH, cholesterol and bile acid biosynthetic pathways, and pertinent clinical observations, the patient was successfully treated.

975 A Case of S. aureus Enterocolitis Shyam J. Thakkar, MD,* Radheshyam Agrawal, MD. Department of Gastroenterology, Allegheny General Hospital, Pittsburgh, PA.

Patient (PT) with hemorrhagic enterocolitis was initially suspected to have IBD; however, diagnostic evaluation suggests a S. aureus enterocolitis. 49-year-old male presented with abdominal cramps, bloody diarrhea, and purulent discharge. Rectal absceses was diagnosed and treated. PT was discharged, but returned with worsening symptoms (SXs). CT scan showed thickening of duodenem and jejunum. Enteroscopy showed ulcerated duodenum and jejunum with necrotic areas. Pathology showed moderate to severe acute and chronic inflammation and acute inflammatory exudate. PT was transferred to tertiary center where he was in mild distress, tachycardic, and had continued complaints of initial SXs. Abdomen was soft, distended with hypoactive bowel sounds and diffuse tenderness. CRP = 13.9; ESR = 45; WBC = 24.1; bands = 40. Stool culture: many PMNs, S. aureus. IV fluids and empiric antibiotics were started. Hypercoagulable and ischemic workup was negative. SXs waxed and waned, bandemia persisted. Day 10, enteroscopy showed normal endoscopy to jejunum and flexible sigmoidoscopy showed ulceration, friability, congestion, erythema, and exudate from rectum to splenic flexure (Fig). Day 12, clinical status worsened. Exploratory laporotomy revealed toxic megacolon. Pathology from total abdominal colecoty and ileum sections showed chronic active colitis with cryptitis, crypt abscesses, focal mucosal inflammation, transmural acute inflammation, and necrosis. Post-op, luminal SXs resolved. PT was discharged with no maintenance therapy and has remained in clinical and endoscopic remission at 6 month follow up. Though endoscopic and pathologic findings may suggest Crohn’s disease (CD), certain aspects are inconsistent. Necrosis on pathology and remission induced by surgery are not findings of acute CD. Other possibilities include S. aureus enterocolitis. Although S. aureus is commonly isolated in stool samples of PTs taking antibiotics without apparent symptomatic sequelae, S. aureus enterocolitis may still occur, albeit rarely. The pathologic manifestations of S. aureus enterocolitis is typically a mildly inflamed mucosa; however, focal or complete structural necrosis may occur. This case brings to awareness the existence of this rare entity. [figure1]

976 Chronic Hepatitis C Treatment Guidelines Need Revision: A Case of Hepatitis C Non-Responder Mabboob A. Khan, MBBS,* William R. Somers, MD. Internal Medicine, Williamsport Hospital and Medical Center, Williamsport, PA and Gastroenterology, Susquehanna Health System, Williamsport, PA.

A 44 year-old obese African American male weighing more than 400 lbs, known to have hypertension and used to inject cocaine and drink alcohol was diagnosed with chronic hepatitis C. Initial workup showed that his viral load was 1000000 and had hepatitis C genotype 1b and biopsy showed grade II-III inflammation and stage II-III fibrosis with mild steatosis. In 2000 the patient was started on Ribavirin 600 mg twice daily and Interon A 3000000 units Q 3 weekly but the patient after taking the first few doses never took it again and never showed up in the clinic for a follow-up until
may 2003 when he requested to be treated again and was determined to get rid of hepatitis C at this time. Was started again on 5/29/03 but on higher dose of Ribavirin 1600mg daily and Pegasys 180 mcg weekly. This time he was compliant with the medications but after 12 weeks of treatment his viral load was 326000 that was a log drop from 6.31 to 5.51 and was not a good response. The chances of his obtaining SVR were low, especially considering the fact that according to the published studies the treatment response rates are lower in patients older than 40 years, weighing over 85 kg and genotype 1 with high viral load. And finally African American patients had lower response rates compared to Caucasians. But the patient insisted to take it for a longer duration. The treatment was continued with the same medications and the same dosage. After getting the treatment for 42 weeks the viral load was less than 50 copies/ml. Total duration of treatment was 72 weeks approximately 18 months and the viral load on 11/30/2004 was less than 50 copies/ml. The treatment was continued till 11/15/2004 and on 04/25/2005 the viral load remained less than 50 copies/ml. He obtained SVR which is undetectable HCV RNA at the end of the 24 week of treatment-free follow-up period. His treatment course was without any complications other than having pancytopenia that resolved after finishing the treatment and his weight came down from 400 to 280 pounds while on treatment but was back to over 300 pounds again in few months after stopping treatment. Lack of early virology response at 12 weeks (defined as HCV RNA undetectable or >2log10 lower than baseline) is a ground for discontinuation of treatment. This case still gives us room to do further studies on chronic hepatitis C treatment and recommendations for treatment.

High-Grade Neuroendocrine Tumor in a 21 Year Old Man with X-Linked Hyper IgM Syndrome

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Case report: A 21-year-old male was admitted for further evaluation of painless jaundice of two months duration. His past medical history was significant for Hyper IgM syndrome. Two months prior to presentation, he was in his usual state of health when he developed watery non-bloody diarrhea, dark urine, jaundice and pruritis. His diarrhea improved but his jaundice and pruritis persisted. His physical examination was unremarkable except for导演 examination. His abdominal examination was soft and nontender. There were no signs of chronic liver disease. The examination of the skin revealed no rash or lesions. The patient was on atorvastatin 10mg/dL with direct bilirubin of 6.4 mg/dL, CA-125 of 97, CA 19–9 of 187 and alpha fetoprotein value of 1.7. Endoscopic Ultrasound was then performed which revealed coarse, lobular echo-texture in the body and tail of the liver. MRI of the liver done confirmed the same. The pancreatic duct was dilated in the head of the pancreas to approximately 6 mm. There were several round masses in the peripancreatic region compressing the common bile duct and uncinate process of the pancreas. He was then admitted for further evaluation to our institution. At the time of admission significant studies were as follows: alkaline phosphatase 586 U/L, Aspartate amino transferase 70U/L, Alanine amino transferase 75U/L, and total bilirubin 10mg/dL with direct bilirubin of 6.4 mg/dL, CA-125 of 97, CA 19–9 of 187 and alpha fetoprotein value of 1.7. Endoscopic Ultrasound was then performed which revealed coarse, lobular echo-texture in the body and tail of pancreas. There was extensive periporal and peripancreatic lymphadenopathy. A collection of nodes was seen to be extrinsically compressing the CBD, causing the obstruction. EUS guided fine needle aspiration was performed. Cytological examination revealed malignant cells. Flow cytometry of the aspirated mass revealed no evidence of lymphoma. The patient then underwent an ultrasound-guided biopsy of the liver masses. Pathological examination revealed small blue monotonous appearing tumor cells. Immunohistochemical staining was consistent with high-grade neuroendocrine tumor. He was then enrolled in a clinical trial with irinotecan (CPT-11) and cisplatin.

Discussion: High Grade Neuroendocrine tumors involving the pancreas and liver have been rarely reported. Whether this disease is associated with XHIGM or its treatment needs to be studied.

A Large Liver Mass Presenting as Abdominal Pain in a Chronic Oral Contraceptive User

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A 29 year old African American female with no known past medical history presented to the hospital with epigastric and right upper quadrant dull pain for 10–12 hours in duration. The pain was associated with nausea and vomiting of bilious material. There was no hematemesis. There was a report of fever and chills. No weight loss, change in bowel habits or prior episodes. There was no history of alcohol or tobacco use. The patient was taking Lovonogestrol 0.15mg and Ethinylestradiol 0.03mg daily for 9 years. On examination the patient appeared in mild discomfort. Her temperature was 104.3F, Blood Pressure was 146/90 and Pulse rate was 126/min on admission. There were no signs of chronic liver disease. The examination of the abdomen revealed an obese, soft and was non-tender; however, a mass-like structure was palpated in the right upper quadrant. The patient was kept NPO. Routine labs were normal except for elevated transaminases (AST 91 and ALT 169) Urine BHCG was negative. CT scan of the abdomen and pelvis was performed and revealed several large hypodense lesions distributed between the right and left lobes of the liver, largest measuring 15.1 × 9.2 cm. Additionally a solid enhancing 15.5 × 3 cm lesion was noted in the right toe of the liver. Oral contraceptive medications were promptly discontinued. A MRI of the Liver was completed; revealed a heterogeneous mass involving the left lobe of the liver, measuring 14.8 × 6.9 cm; with features of internal hemorrhage; an additional 6 × 5.4 cm mass in the lateral left hepatic lobe with compression of the stomach. Signal intensities suggestive of focal nodular hyperplasia. In subsequent days following admission the ALT/AST had elevated to 1593 and 166 respectively; declining to 594 and 56 on the 6th hospital day. The patient was referred for Hepatobiliary surgical intervention of the hemangioma. Hepatic hemangiomas are benign tumors of the liver that are composed of masses of blood vessels that are atypical or irregular in arrangement and size. They are the most common benign tumors of the liver, found in as many as 7% of healthy people; four to six times more common in women than in men. Etiology remains unknown. Chronic oral contraceptive use is strongly associated with the development of hepatic adenomas; may increase rate of complications in patients with Focal Nodal Hyperplasia (FNH). The association of these medications with hemangiomas is less clear.

Unusual Case of Obstructive Jaundice in Elderly Patient

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In elderly patients the commonest causes of obstructive jaundice are cholelithiasis and pancreatic and biliary causes. Here we present an unusual cause of obstructive jaundice.

Case: 65 year old male patient presented with 3 weeks of jaundice and progressive right upper quadrant pain. Patient denied any fever or weight of loss. Social history was significant for heavy alcohol use and tobacco smoking. Physical examination reflected only deep icterus and mild epigastric tenderness. Lab findings revealed obstructive jaundice with total bilirubin 17.7 mg/dl, direct bilirubin 16.8 mg/dl and WBC count of 16000 mm3.
Imaging studies done at an outside hospital which showed biliary dilatation with common bile duct of 15 mm. No pancreatic or hilar mass was identified. ERCP which revealed lot of edema proximal to the ampulla of Vater with ulceration of the duodenum. This ulcerated area was biopsied. Examination of the ampulla revealed a large ampulla with a compressed and pushed down papillary orifice. Free deep cannulation of the bile duct could not be achieved, though on opacification smooth narrowing of the common bile duct was visualized. Cytology could not be successfully obtained. Considering above findings repeat imaging including magnetic resonant cholangiopancreatogram (MRCP) and spiral computed tomography (CT) were done. MRCP reflected the findings on ERCP but showed no mass lesion in the pancreas or peripancreatic area. Spiral CT showed findings of a soft tissue fullness in the periampullary area. Serum CA 19-9 was minimally elevated with a normal CEA. Biopsies from the duodenal ulcer surprisingly reflected squamous cell carcinoma (SCC). Further extensive investigations including magnetic resonant imaging and CT imaging of the lungs, head and neck failed to reveal the primary site. Exploratory laparotomy was done which showed a peripancreatic mass along with jejunal and ileal metastasis. A Roux-en-Y cholecdochojejunostomy and gastrojejunostomy was done. Histology from surgical specimens reflected SCC. Patient is presently followed by oncology service.

**Discussion:** A wide variety of neoplastic lesions may involve the ampulla of Vater, but SCC is very rare at this location. Tobacco smoking may be considered as risk factor for the SCC of the ampulla of Vater. The management of these patients involves the extensive workup to rule out any other synchronous lesions and the involvement of the surgical team.

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**Invasive Intestinal Strongyloides Infection Mimicking Crohn’s Ileitis: A Case Report**

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To report an atypical presentation of Strongyloides stercoralis infection in an immunocompetent patient. We closely analyzed the evaluation, treatment, and clinical course of a forty-one year old Hispanic male who presented to the emergency department of our institution with right lower quadrant pain and fever. After patient follow-up, a literature review was performed to determine the pathophysiology and clinical presentations of Strongyloides stercoralis infection. Upon initial presentation, this patient complained of a one-week history of constant, progressive, right lower quadrant abdominal pain associated with subjective fever. He did not have any previous history of medical or surgical disease and was not taking any medications. Review of systems was noteworthy only for watery diarrhea. Physical examination revealed an objective temperature of 101 degrees Fahrenheit and significant abdominal tenderness localized to the right lower quadrant. Laboratory evaluation including basic blood cell counts and chemistries was essentially normal. A CT scan of the abdomen was performed and revealed inflammatory changes of the terminal ileum associated with local mesenteric lymphadenopathy. Endoscopic evaluation demonstrated gross inflammation of the terminal ileum. Upon review of pathology slides from biopsies taken from the terminal ileum, we discovered Strongyloides stercoralis larvae and adult worms invading the mucosa. After treatment with ivermectin, the patient's symptoms of abdominal pain, fever, and diarrhea quickly resolved. He remains asymptomatic ten months after treatment. Terminal ileitis is an unusual presentation of intestinal strongyloides infection, especially in an immunocompetent patient. Gastrointestinal involvement with this parasite typically includes duodenitis resulting in upper abdominal pain, nausea, and vomiting. This infection should be considered in the differential diagnosis in patients presenting with terminal ileitis, particularly in cases where empiric steroid therapy for suspected Crohn's disease could result in disseminated strongyloides infection.

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**Ascites Can Still Be Challenging**

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Ascites is a common finding in clinical practice. It is typically due to liver disease but its presence may indicate other significant medical problems. The etiological approach of ascites is relatively easy but a mixed picture can sometimes complicate the workup. T.R. is a previously healthy 33 year old white male who was referred to a gastroenterology clinic for elevated liver enzymes and ascites discovered during a recent hospitalization for pneumonia. The patient denied any prior alcohol or medication use. Physical examination revealed ascites and jaundice. Preliminary studies included AST = 22; ALT = 32; total bilirubin = 2.9; alkaline phosphatase = 259; INR = 1.3; globulin = 3.7 and albumin = 4. Ultrasound and computerized tomography scan of the abdomen showed the presence of ascitis, a non-dilated biliary tree, and a normal-appearing liver. Doppler/Duplex ultrasound of the liver was unremarkable. Paracentesis revealed a normal appearing ascitic fluid with 2970 white blood cells (63% neutrophils), albumin of 2 and protein of 4.5. The serum-ascites albumin gradient was 2. Gram stain and cultures were negative with normal cytology. Transjugular liver biopsy showed signs of chronic venous outflow impairment and no signs of venous caval thrombosis. Despite empiric antibiotic therapy, the patient’s condition deteriorated requiring admission to the hospital. An echocardiogram revealed paradoxical movement of the interventricular septum. Cardiac catheterization showed equalization of pressures in all cardiac chambers indicating constrictive pericarditis. A pericardectomy was done and revealed thickened pericardium. Pathological examination of pericardial tissue samples confirmed constrictive pericarditis. Post-operatively, the patient improved with normalization of liver function tests and resolution of his ascites. Two distinct but interrelated pathological processes contributed
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to the patient’s ascites. A post-infectious inflammatory serositis and constrictive pericarditis-induced congestive hepatopathy resulted in the neutrocytic and “cardiac” characteristics of the ascitic fluid respectively. Although the evaluation of ascites is standard for the most part, it can still be challenging.

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EUS Guided Foreign Body Extraction
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A 48 year-old female with a history of schizophrenia presented with a one month history of mid-epigastric pain. The pain was initially dull and post-prandial. By the time she sought medical attention it was constant and “knife-like.” The pain did not improve despite therapy for H. pylori infection detected by stool studies 6 weeks prior to presentation and PPI use. CT scan performed on admission showed a foreign body – most likely a needle – within the wall of the distal duodenum. It appeared to perforate the duodenal wall and lie largely within the peritoneum. Additionally, we were unable to assess if it had incompletely perforated the wall of the abdominal aorta (fig. 1). Upper endoscopy (GIF-160, Olympus America) performed under monitored anesthesia care identified a sewing needle penetrating the wall of the 2nd portion of the duodenum. The needle was pulsating in synchrony to her pulse and granulation tissue had formed at its base. Given the proximity of the needle to the aorta, endoscopic ultrasound was performed using a 12 mHz mini-probe (Olympus America). Endoscopic ultrasound (EUS) showed that the needle, while merely a few millimeters from the abdominal aorta, did not penetrate the serosa of the duodenum and was confined to the muscularis propria (fig. 2). The needle was successfully removed thru an overtube without complication using a rat tooth forceps. The patient subsequently denied using sewing instruments and related that most of her meals are prepared at fast food establishments. EUS was an invaluable tool in this difficult case. By accurately determining the depth of penetration and clarifying the needle’s proximity to major vessels, EUS facilitated a non-surgical, endoscopic solution to this sartorial dilemma. [figure1][figure2]

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Diagnosis of Severe Celiac Disease in the Puerperium
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Celiac disease, originally thought to occur only rarely in childhood, is now recognised as a common condition that can be diagnosed at any age. Pregnancy has been implicated in the presentation or reactivation of celiac disease and some cases of presentation during the puerperium have been reported. We describe two cases of celiac disease, which were manifested during the first month of the puerperium as malabsorption. Two 30-years old Caucasian females, during the first month of the puerperium of the second pregnancy, developed diarrhea of liquid stools that gradually worsened over 3–5 months, associated with fatigue and weight loss (7–8 kg). The patients had history of anemia since childhood and had one previous pregnancy and puerperium without symptoms. At admission physical examination revealed palor, muscular atrophy and peripheral edema; the abdominal exam was normal. Laboratory studies revealed iron deficiency anemia, hypoproteinemia with hypoalbuminemia, hypocalemia and increase of aminotransferases and prothrombin time. The patients were treated initially with total parenteral nutrition. Microbiological tests performed were negative. Upper gastrointestinal endoscopy showed duodenal mucosa with pattern suggestive of celiac disease. Duodenal biopsies revealed flat mucosa with intraepithelial lymphocytes. Antibodies anti-gliadin and anti-transglutaminase were increased. Both patients improved slowly with gluten-free diet and left the hospital asymptomatic after 2 and 3 weeks. Maternal exposure to fetal antigens and changes in blood concentrations of the female sex hormones during pregnancy and the puerperium may activate latent celiac disease through an unknown mechanism. Celiac disease should be considered as a possible diagnosis when chronic diarrhea presents during the puerperium. An early diagnosis it is important because with gluten-free diet it may prevent worsening to severe malabsorption.
We describe a rare case of a patient presenting with a lower GI bleed resulting from a fistulous connection between a splenic artery pseudoaneurysm and the sigmoid colon after a remote episode of acute pancreatitis. A 54-year-old white man working in Haiti with a history of alcohol-related pancreatitis presented with a 1 month of intermittent blood per rectum. He was admitted to a hospital where a colonoscopy revealed a bleeding ‘polyp’ at 40 cm that was cautioned. No blood transfusions were given and no EGD was performed. Patient had also been complaining of 8 kg weight loss, decreased appetite and low grade fever. There was no abdominal pain. On presentation he had a low blood pressure (90/62 mm Hg). He was pale and his abdomen was soft and non tender. Rectal exam revealed blood in the vault. His WBC was 8300/mm3, hemoglobin was 5.4 g/dL, hematocrit 17.5%, and Platelets 146, 000/mm3. Serum chemistry was normal as was his coagulation profile. He was transfused 2 units of red cells. After resuscitation an EGD was performed that was reported as being normal. On colonoscopy maroonish fluid was seen in the colon with no active bleeding. The terminal ileum was normal. Angiogram of the superior and inferior mesenteric arteries revealed with no luminal extravasation. A Meckel’s Scan was also normal. Next morning, on enteroscopy prominent gastric fundal folds suggestive of isolated gastric varices were visualized. Suspecting a splenic vein thrombosis a CT scan of the abdomen was ordered revealing a 3.5 × 3.5 cm splenic artery ‘false’ aneurysm with thickened sigmoid colon wall and extravasated fluid (blood) around it suggestive of an aneurysm communicating with the large bowel. During surgery, a splenic artery pseudoaneurysm, splenic vein thrombosis, a large retroperitoneal hematoma and a fistulous connection between the sigmoid colon and splenic artery were seen. He underwent a splenectomy, left hemicolectomy, ligation of the splenic vessels and partial pancreatectomy and made an uneventful recovery. Hemorrhage from splenic pseudoaneurysms has been reported in up to 37% of patients. Mortality for treated patients is 10–33%. The type of surgery depends on location of the aneurysm. Transcatheter arterial occlusion or selective embolization may be used by interventional radiologists for non-surgical management.

### Case:

A 51-year-old man with multiple myeloma (MM) presented with melena and a Hct of 14. Upper endoscopy showed circumferential erythematous, friable mucosa with diffuse oozing in the distal bulb and second portion of duodenum. Hemostasis was achieved by injection of epinephrine. He also had perianal discomfort and bleeding, exam revealed a large verrucous plaque on the left side of the anus extending to perineum. Patient was treated with high doses of PPI. 10 days later the patient returned to hospital complaining of intermittent melena and recent bright red blood per rectum. Repeat endoscopy showed an antral ulcer, inflamed, friable mucosa in duodenum with narrowing, and no active bleeding. Colonoscopy showed erythema, edema and friable mucosa with oozing in the sigmoid colon. All sites including the anal lesion were biopsied. Histopathology demonstrated squamous hyperplasia with dermal amyloid deposits in the anal lesion. The gastric, duodenal and colon biopsies also showed amyloid deposit. Within 2 weeks he developed rapidly progressive dysphagia, inability to maintain oral intake and weight loss. Endoscopy showed no inflammation, ulcer or stricture formation in esophagus. Esophageal biopsy showed amyloid deposit in the mucosa. Speech was normal and he was able to initiate a swallow. The patient underwent a jejunostomy tube placement for feeding.

### Discussion:

This case demonstrates rare symptomatic involvement of almost the entire GI tract with amyloidosis causing upper and lower GI bleeding, dysphagia and a perianal lesion masquerading as squamous carcinoma. Esophageal involvement with rapid onset of severe dysphagia requiring J-tube placement is very unusual and represents a motor disorder of the esophagus. Condylomatous cutaneous amyloidosis has been reported, but most of the time well after the diagnosis of amyloidosis has been made. Our case demonstrates the importance of considering GI amyloidosis in the differential diagnosis of a variety of GI symptoms.

### Conclusion:

This case demonstrates the importance of considering GI amyloidosis in a differential diagnosis of unusual GI symptoms. The patient was treated with high doses of PPI and a jejunostomy tube placement for feeding, but his symptoms persisted. Endoscopy-assisted CE was done using an overtube and placing the capsule from the diverticulum with an ERCP balloon catheter and assisted by an anesthesiologist to ensure airway protection (Figure 2). Three weeks later, endoscopy-assisted CE was done using an overtube and placing the capsule in the stomach with a Roth net. CE demonstrated multiple angiodyplasias of the small bowel. The patient was placed on SQ octreotide with a satisfactory response to therapy. Eventhough most patients undergoing capsule endoscopy have a prior EGD, special attention should be placed in the upper esophagus during endoscopy to rule out the presence of a Zenker’s diverticulum.
Ataxia and Slurred Speech Following Severe Pouchitis
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A 74 year old woman with PSC and cirrhosis (Child class B) presented to the hospital with slurred speech, unsteady gait, and falls. She has a history of chronic ulcerative colitis for which she underwent ileal pouch-anal anastomosis in the 1980s. 2 weeks prior to presentation she was briefly hospitalized for worsening diarrhea with fecal incontinence despite chronic ciprofloxacin. She responded clinically to metronidazole and had been dismissed on oral metronidazole 500 mg t.i.d. for histologically confirmed pouchitis. This medication was discontinued on admission. On examination, she was alert and oriented but was severely dysarthric. Finger to nose was slow bilaterally and her gait was ataxic. Strength was preserved. There were no sensory deficits or asterixis.Ascitic fluid analysis showed no infection. Brain imaging was performed. MRI of the head without and with IV gadolinium demonstrated homogeneous abnormal increased T2 signal within the cerebellar dentate nuclei. (Figure 1) Within 24-hours of discontinuation of metronidazole, her neurologic deficits improved significantly. Physical and speech therapy were initiated. Her speech and gait improved dramatically and she he was dismissed to a subacute facility for further rehabilitation. In the setting recent metronidazole treatment for pouchitis, the patient’s clinical presentation and MRI findings are consistent with metronidazole neurotoxicity. In this uncommon occurrence, brain MRI characteristically demonstrates increased signal intensity (T2) within the dentate nuclei. Clinical symptoms resolve after discontinuation of metronidazole; the MRI abnormalities also reverse within weeks of metronidazole withdrawal. Because metronidazole is extensively metabolized by the liver, patients with cirrhosis may be more susceptible to toxic effects of the drug. Neurotoxicity is an uncommon effect of metronidazole use that may be more likely to occur in patients with hepatic impairment. Recognition of the clinical presentation is essential as the neurologic symptoms are nearly always reversible with medication withdrawal.
Gastrointestinal duplication is an uncommon congenital abnormality which mostly presents in infancy or childhood. Tubular bowel duplication has sometimes been reported to present with rectal bleeding. Ileal duplication is common while colonic duplication, either cystic or tubular is a rather unusual clinical entity that remains asymptomatic and undiagnosed in most cases. Colonic duplication has primarily been reported in pediatric populations with only far fewer cases reported in adults. We report a case of asymptomatic tubular duplication of sigmoid colon in a 53 years old Caucasian male. Screening colonoscopy was done which revealed a sessile non-obstructing mass in the sigmoid colon 25 cm from the anal verge. The mass measured 5 cm in length and 12 mm in diameter. There was no bleeding from the mass and it was biopsied with a hot snare. Biopsy showed anomalous colonic mucosa lined by tubular structure consistent with tubular bowel duplication. The pathologists at Armed Forces Institute of Pathology had never identified a prior case demonstrating this pathology. To the best of our knowledge there has been no prior report of this pathologic finding in either medical or pathologic literature.

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*Listeria Monocytogenes (LM) Bacteremia after Infliximab for Crohn’s Disease (CD)*

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A 27 yo male with CD was admitted with fever. He had been discharged 9 days earlier after hospitalization for a CD exacerbation during which he received IV hydrocortisone and his first infusion of infliximab (10 mg/kg). Colonoscopy revealed extensive pseudopolyps, shallow ulcerations, sparing of the cecum and rectum, and no pseudomembranes. Stool studies for *C. difficile* revealed antigen+, toxin B-, toxin A+, and he was treated with Flagyl 500mg TID X 10 days. A PICC line was placed for total parenteral nutrition (TPN). Initial presentation was 5 months ago with bloody diarrhea, abdominal pain, and an 80 lb wt loss. Prior treatment consisted of oral mesalamine and continuous oral steroids at varying doses. He worked as a maintenance engineer at a meat packing plant. Admission medications were prednisone 60mg qD, Asacol 1200mg TID, Flagyl 500mg TID. A PICC line was placed for total parenteral nutrition. His infusion of infliximab was scheduled to be monthly. His first infusion of infliximab was scheduled to be in 2 weeks. Despite this, he developed bloody diarrhea within days-weeks of therapy discontinuation. The patient underwent colonoscopy to evaluated for underlying mucosal or diverticular disease. No abnormalities were identified. Although stool was negative for *C. diff* toxin prior to colonoscopy and the patient was on vancomycin at the time of colonoscopy, aspirate from the appendix was positive for *C. diff* toxin. All colonic biopsies were normal. It was postulated that the appendix might be harboring spores and be contributing to infection relapse. Upon discontinuation of vancomycin, the patient developed bloody diarrhea once again. She was referred to pediatric surgery and underwent appendectomy. Appendiceal tissue had prominent lymphoid follicles, but no active inflammation. The patient is now more than 12 months s/p appendectomy and has not had a recurrence of *C. difficile* colitis. Stools remain negative for *C. diff* toxin. In adults, one mechanism of relapse is the survival of spores in diverticula where they escape the normal cleansing actions of diarrhea and may not be exposed to high luminal concentrations of antibiotics. Although this has not been reported previously, we propose that the appendix may serve as a possible reservoir for *C. diff* spores in patients with relapsing infection refractory to standard medical therapy. Appendectomy proved curative in our patient.

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The Appendix: A Possible Reservoir for Clostridium difficile

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Over 3 million cases of *C. difficile* colitis occur in the United States annually. Relapse occurs in 10–25% of patients. We report the case of a female child referred at the age of 4 yrs for treatment of relapsing *C. diff* colitis. Prior to diagnosis, she was healthy and had not been on antibiotics, been in a hospital setting or around individuals receiving chronic medical care. Over the 15 months that followed initial diagnosis, the patient received a total of 6 courses of metronidazole and 3 courses of vancomycin with prolonged dosing of each. In addition, she was given probiotic therapy with Lactobacillus GG and Saccharomyces boulardii. Despite this, she developed bloody diarrhea due to *C. difficile* colonization colonized) or exogenously. The risk for, and severity of, infection is higher in immunocompromised pts. Anti-tumor necrosis factor (anti-TNF) agents interrupt normal cellular immunity required for decontamination (anti-TNF) agents, converting a colonized state to systemic infection. Rare reports of *C. difficile* bacteremia following anti-TNF use suggest that these agents may facilitate systemic infection. Failure of *C. difficile* clearing from the gut may result in dissemination to other body sites. We report a case of *C. difficile* bacteremia following infliximab exposure. A 39-year-old female was referred to pediatric surgery and underwent appendectomy. Appen-diceal tissue had prominent lymphoid follicles, but no active inflammation. The patient is now more than 12 months s/p appendectomy and has not had a recurrence of *C. difficile* colitis. Stools remain negative for *C. diff* toxin. In adults, one mechanism of relapse is the survival of spores in diverticula where they escape the normal cleansing actions of diarrhea and may not be exposed to high luminal concentrations of antibiotics. Although this has not been reported previously, we propose that the appendix may serve as a possible reservoir for *C. diff* spores in patients with relapsing infection refractory to standard medical therapy. Appendectomy proved curative in our patient.

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Pegylated Interferon and Ribavirin Therapy Precipitating Acute Renal Failure and Nephrotic Range Proteinuria

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The combination of Pegylated Interferon (Peg-Interferon) and Ribavirin is considered now the standard treatment for chronic hepatitis C infection. Renal side effects of this combination are not infrequent but usually limited to mild proteinuria or a transient increase in serum creatinine. We report a case of acute renal failure, nephrotic-range proteinuria and severe pan-cytopenia in a patient receiving Peg-Interferon and Ribavirin for chronic hepatitis C infection. A 53 year-old African-American female with history of essential hypertension and chronic hepatitis C (genotype1) who presented with profound weakness three months after starting the combination of Peg-Interferon alfa-2b and Ribavirin. On presentation she was found to have hemoglobin of 4.1 g/dl, white blood cell count of 0.8 k/uL, nephrotic-range proteinuria with 4.9 g/24 hour, and a serum creatinine of 12.3 mg/dl (normal range 0.9–1.3 mg/dl). Her baseline creatinine was 1.1 mg/dl. Other etiologies of acute renal failure were excluded; the patient was euolemic with no history of exposure to nephrotoxic drugs. Anti-nuclear antibodies and Antineutrophil cytoplasmic antibodies were negative, monoclonal protein evaluation was normal, serum cryoglobulin screen was negative, C3 was normal and C4 slightly decreased. A renal ultrasound showed no hydronephrosis. Interferon therapy was discontinued on presentation and the patient received hemodialysis for a period of two weeks. The patient’s renal function demonstrated improvement and she was left with a creatinine...
of 2.6 mg/dl, ten weeks after discontinuing the Peg-Interferon. The patient also had immune-mediated pancytopenia. Her hemoglobin and white count recovered six weeks after the treatment was stopped. The patient did experience a sustained anti-viral response to therapy and has remained negative for Hepatitis C virus RNA in the serum. There are few reported cases of acute renal failure secondary to Peg-Interferon therapy. Although the patient had hypertension, her baseline creatinine was normal and the decline in renal function was abrupt. The concurrent development of severe pancytopenia supports a profound response to Peg-Interferon that precipitated all of the adverse reactions. Acute renal failure is an infrequent complication of Peg-Interferon therapy that should be recognized in the proper clinical setting. Cessation of treatment may result in recovery of renal function.

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A Case of a Vesical Diverticula Causing Constipation
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Constipation is generally defined as infrequent stools and or difficult defecation. Most cases of constipation reflect a disorder of bowel function rather than structure. Systemic and structural gastrointestinal causes require exclusion. Lesions that obstruct fecal flow to the point of producing constipation must be advanced and distally located. These can include both benign and malignant processes. Of the benign lesions, a vesical diverticula is an extremely rare cause of constipation.

Case Report: 82 year old man with a history of Parkinsons disease, benign prostatic hyperplasia and urinary incontinence presented to the outpatient radiology department for cat scan (CT) for complaints of constipation and vague lower abdominal discomfort. He reported decrease in his frequency of stool as well as a change in the caliber of the stool over the last several months. Symptoms had previously been attributed to his Parkinsos as well as pain medication for his arthritis. Colonoscopy performed two years prior was reportedly normal. CT revealed significant colonic dilation of the sigmoid and descending colon with rectal narrowing as a result of a bladder diverticulum. Flexible sigmoidoscopy was subsequently performed under fluoroscopy which excluded an intraluminal obstructing lesion and documented that the rectal narrowing was caused by the bladder and diverticulum. A Foley catheter was inserted with resultant decompression of the bladder and significant improvement in extrinsic compression.

Discussion: Bladder diverticula with gastrointestinal manifestations are rare. These diverticula often occur at the entrance of the upper urinary system into the bladder junction. Acquired diverticula are usually related to bladder obstruction, more commonly as a result of benign prostatic hyperplasia (BPH). Patients with bladder diverticula are usually asymptomatic and require no further intervention. A diverticula only becomes significant if it becomes very large. In these cases, the diverticulum may cause incomplete bladder excretion (leading to stagnation of urine) predisposing to urinary tract infections, harbor an undetected neoplasm, or cause colonic obstruction. The definitive treatment of a symptomatic bladder diverticulum is therefore surgical excision.

Summary: Constipation is a relatively common complaint which may be the result on an uncommon process.

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A Case of Vanishing Bile Duct Syndrome in a Patient with T-Cell Leukemia/Lymphoma of the Liver
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Vanishing bile duct syndrome (VBDS) is a rare entity which may be caused by a multitude of etiologies like idiopathic, drug-induced, Hodgkin’s disease, chronic rejection and after liver transplant. VBDS is characterized by destruction of intra-hepatic bile ducts and patients usually present with symptoms of jaundice and pruritus. Patients with lymphoma can develop jaundice on the basis of infiltrative involvement of the liver and spleen. To our knowledge, we are reporting the first case of a gamma delta T-cell Leukemia/lymphoma (T-LGL) resulting in VBDS. In this case, 78 year old female with a history of myelodysplastic syndrome diagnosed 8 months prior to presentation, developed a 2 week and clay colored stools. She was noted to have hepatosplenomegaly on physical examination. Laboratory workup revealed elevated alkaline phosphatase and bilirubin levels as well as an ANA + at 1:80. CBC showed WBC 5 with 23% neutrophils and 71% lymphocytes and severe anemia. Further work up with MRCP showed non-visualization of the intra-hepatic bile ducts. A liver biopsy revealed an atypical sinusoidal lymphoid infiltrate, portal cholangitis, pericholangitis and paucity of bile ducts consistent with VBDS and portal and lobular hepatitis. Immunotyping on the liver biopsy and flow cytometry of the peripheral blood revealed the atypical lymphoid cells to be consistent with T-LGL with a predominant CD8 (T suppressor) phenotype (CD3+, CD4 focal, CD8+, CD2+, CD7-, CD 57+). PCR demonstrated a monoclonal TCR gamma gene rearrangement. On review of peripheral blood smear, increased large granular lymphocytes were seen. According to latest (WHO) classifications, T-LGL is characterized by a persistent increase in peripheral blood large granular lymphocytes, represents 2–3% of cases of small lymphocytic leukemia, and is synonymous with T-cell CLL. The disorder typically involves the peripheral blood bone marrow, liver and spleen but rarely lymph nodes. The disease usually follows an indolent course. The common variant of T-LGL has an immunoprofile of CD3+ CD4+, CD8+, TCR alpha beta+, however a rare variant and TCR gamma delta+ is recognized. Our case appears to represent this rare variant of T-LGL. To our knowledge, VBDS has never been reported in any case of T cell leukemia/Lymphoma, including TLLG and cases with hepatic involvement by T cell leukemia/lymphoma, thus the first reported case of VBDS associated with-cell Leukemia/lymphoma (T-LGL).

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Common Bile Duct Stricture Secondary to Repetitive Abdominal Trauma: A Case Report and Review of the Literature
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Trauma induced biliary strictures are rare entities. Typically these types of strictures are associated with a major traumatic event, most commonly a MVA. Here we introduce a case of a 19-year-old man who developed a symptomatic benign CBD stricture resulting from repetitive abdominal trauma.

Case Presentation: A 19-year-old AA male presented with abdominal pain and pruritis. The initial work up revealed mild elevation in the liver panel studies. An US of the abdomen showed no cholelithiasis, cholecdocholeithiasis, or other abnormalities. The patients abdominal pain persisted and he developed jaundice. A further rise in alkaline phosphatase and bilirubin was seen on follow up laboratory studies, consistent with an obstructive process in the biliary tree. This prompted a repeat US, which displayed both common bile duct and common hepatic duct dilatation. A subent CT of the abdomen showed no additional abnormalities. The patient had a MRCP revealing tapering of the distal common bile duct. Consequently the patient underwent an ERCP showing a 3–3.5 cm segment of narrowing in the distal CBD, which was subsequently balloon dilated. Cytology brushings were negative for malignant cells. A stent was placed across the area of stricture, after which the patients liver studies normalized. A liver biopsy was performed, to exclude other conditions such as primary sclerosing cholangitis. This revealed centrolobular cholestasis consistent with large bile duct obstruction. At follow up ERCP the stent was removed with no further evidence of stricture. A social history revealed that the patient was involved in martial
Hemobilia Due to Hepatic Artery Pseudoaneurysm. An Unusual Complication after Cholecystectomy and T-Tube Placement

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Hemobilia is one of the causes of obscure gastrointestinal hemorrhage. Arterio-biliary fistula secondary to hepatic artery pseudoaneurysm is an uncommon cause of hemobilia. Hepatic artery pseudoaneurysm has been reported as a rare complication of laparoscopic cholecystectomy. We here report a case of hemobilia due to arterio-biliary fistula in a patient one month after cholecystectomy and percutaneous T-tube placement. A 54 year old woman underwent laparoscopic cholecystectomy for symptomatic cholelithiasis. During the procedure, there was a concern of injury to the common hepatic duct due to difficult gall bladder dissection. Laparoscopic cholecystectomy was converted to an open cholecystectomy which did show common hepatic duct laceration which was repaired and a T-tube was placed. Patient did well for a month after the surgery, when she developed right upper quadrant abdominal pain, jaundice and noted to have migrated out T-tube. Subsequently, T-tube was removed due to malfunction. A computed tomography scan of the abdomen showed dilation of the intra and extra hepatic biliary ducts. Patient underwent endoscopic retrograde cholangiography (ERC) and found to have gross hemobilia. ERC images showed dilated common bile duct with multiple cast-like filling defects, consistent with blood clots. A biliary stent was placed to maintain biliary drainage. Patient continued to require blood transfusions due to ongoing hemobilia. A selective hepatic arteriogram showed hepatic artery pseudo-aneurysm causing arterio-biliary fistula leading to hemobilia. A covered stent was placed in the right hepatic artery occluding the fistula, which resulted in complete resolution of bleeding.

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Manometric, Endoscopic and Histopathologic Correlates of Diffuse Esophageal Spasm Secondary to Eosinophilic Esophagitis: Reversal with Corticosteroids

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Case: An 80 year old Caucasian male presented for evaluation of a several year history of recurrent, intermittent dysphagia to solids and liquids. His symptoms were associated with severe, intermittent, substernal chest pain. Previous endoscopic, radiographic and manometric studies had failed to provide a diagnosis and repeated esophageal dilations had provided only transient relief. On presentation, a barium swallow revealed mild narrowing of the distal esophagus. High resolution manometry demonstrated a normotensive lower esophageal sphincter with complete deglutitive relaxation. Repetitive, high amplitude, simultaneous esophageal body contractions were identified (> 300 mmHg). EGD with biopsies revealed an eosinophilic infiltration of the mucosa and muscularis mucosa of the esophagus diagnostic for eosinophilic esophagitis. Concomitant biopsies of the gastric antrum and small intestine were normal. There was a normal absolute peripheral eosinophilic count (0.3 K/UL). Endoscopic ultrasound revealed a markedly hypertrophied muscularis mucosa. The patient underwent treatment with systemic corticosteroids and had symptom resolution. Repeat endoscopic ultrasonography of the esophagus revealed normalization of the muscularis mucosa with biopsies showing clearance of the eosinophilic infiltrate.

Discussion: Eosinophilic esophagitis is a disease characterized by eosinophilic infiltration of the esophageal mucosa. It is increasingly recognized in adults as an important etiology of dysphagia, chest discomfort and food impactions. Previously, only two case reports in the literature described muscularis involvement with both patients undergoing esophagectomy. This case report provides a unique presentation of eosinophilic esophagitis demonstrating muscularis mucosa involvement with an associated spastic esophageal motility disorder. Moreover, we illustrate successful treatment of the disease with systemic corticosteroids. This was documented by improvement of muscular hypertrophy on endoscopic ultrasound and motility abnormalities on esophageal manometry as well resolution of tissue eosinophilia.
A 43-year-old African American male with no known past medical history presented with one episode of hematemesis approximately 1 gallon in quantity. Day prior to admission patient developed “crampy” bilateral non-radiating lower abdominal pain. Patient also noted diaphoresis. He denied any history of change in bowel habits, melena or hematochezia, nausea or vomiting prior to this episode. He denied use of NSAIDS or previous occurrences. Social History was significant for smoking ½ pack per day for 23 years and 1 pint/day consumption of vodka for 13 years. On examination the patient looked well and was in no apparent distress without tachycardia or orthostasis. The examination of the abdomen was soft and non-tender; no guarding or rebound. No hepatomegaly was appreciated. No signs of chronic liver disease. Rectal examination revealed dark brown stool; no melena or bright red blood. The patient was kept NPO. Nasogastric tube was unrevealing for active bleeding. Laboratory examination showed a hemoglobin of 8.9 (MCV 95;RDW 13). Liver transaminases, coagulation profile, Amylase and Lipase were normal. Upper Endoscopy revealed a large fungating friable, ulcerated mass in the lesser curvature of the stomach that was not bleeding; biopsies were obtained. CT scan of the abdomen and pelvis showed a relatively thicker wall of the greater curvature. Patient subsequently had another episode of hematemesis requiring surgical intervention. Biopsy obtained during upper endoscopy and surgical resection revealed Gastrointestinal Stromal Tumor (GIST) 4 cm extending from mucosa to superficial muscularis propria, with high mitotic rate (275/50 HPFs), benign lymph nodes, resection margins free (GIST) 4 cm extending from mucosa to superficial muscularis propria, with high mitotic rate (275/50 HPFs), benign lymph nodes, resection margins free. Pathology revealed a high-grade gastrointestinal stromal tumor (GIST) with 4 cm extending from mucosa to superficial muscularis propria, with high mitotic rate (275/50 HPFs). Examination of the abdominal wall and project intra-luminally. They most commonly occur in the stomach (50–70%) and a diagnosis is established by staining positive for CD-117 antigen on Immunohistochemistry in the majority of cases, which was not present in our case.

Flexible sigmoidoscopy revealed grossly purulent material overlying erythematous, edematous rectal/sigmoid mucosa. The patient developed hypotension, tachycardia, and a rigid abdomen during the procedure. Colonic perforation was confirmed and the patient proceeded to the operating room where it was determined that she had sustained a stercoral perforation in the likely background of radiation colitis. Extensive abdominal surgery and ICU support were required post-operatively.

Stercoral ulceration/colitis is an uncommon inflammatory process involving the colonic wall related to fecal impaction. These cases represent very severe stercoral ulcerations/inflammation with dramatic, yet representative, presentations. Elderly, immobile, or chronically constipated individuals are particularly at risk. Early identification and intervention in the form of cathartics, enemas, and disimpaction can help avoid negative sequelae such as pressure necrosis and colonic perforation.

An 80 year old male with a history of heart disease on anticoagulation was admitted with nausea, bilious vomiting and abdominal pain. He also reported an episode of new fevers, chills, left lower quadrant abdominal pain, and complaints of "marble-like" stools. Physical exam revealed fever of 38.5C, moderate diaphoresis, tachycardia, and a rigid abdomen during the procedure. Colonic perforation was confirmed and the patient proceeded to the operating room where it was determined that she had sustained a stercoral perforation in the likely background of radiation colitis. Extensive abdominal surgery and ICU support were required post-operatively.

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a history of melencolic stools. His INR was found to be over 20 upon admission as a result of coumadin therapy for atrial fibrillation. The patient underwent a diagnostic EGD after correction of his INR. The endoscopy revealed antral erosions but no evidence of upper GI bleeding. Abdominal x-rays showed multiple air fluid levels suggestive of small bowel obstruction. A subsequent CT scan was obtained and demonstrated a high grade obstruction at the level of the proximal to mid ileum. The patient failed to improve with nasogastric suction and supportive care. An exploratory laparotomy was then performed. At approximately 60 cm from the ileum, the small bowel was described as bruised and thickened due to ecchymosis. There was intussusception of the ecchymotic segment into adjacent small bowel causing an obstruction. The intussuscepted segment was easily reduced intra-operatively. Careful examination of the remaining bowel and colon was normal except for diverticulosis of the colon. The patient made an uneventful recovery. This is an interesting and rare case of mucosal hemorrhage secondary to coagulopathy causing intussusception. A patient may present with rare and unusual complications as a result of medical treatment. Complications such as these may be treated effectively if recognized early.

### Outcomes Research

#### 1004

**Uniformity and Standardization of GI Endoscopy Text Reports: A Call for the Use of a Common Language**

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**Purpose:** The medical record is one of the most important medical and legal tools for patient continuity of care, clinical outcomes research, and quality assurance in most ambulatory surgical centers, hospitals and medical centers. Uniformity and structured documentation of the GI procedures facilitates medical information retrieval for clinical research and medical therapy, and may help to improve multi-center studies. This study assessed the standardization, and uniformity of the GI Endoscopy Text reports, and is a call for the use of common language.

**Methods:** From July 2005 to December 2005, the endoscopy reports (performed at one university medical center) of 200 random cases were retrieved and reviewed. The data was collected by looking at six specific parameters: (1) Patient age, (2) Gender, (3) Mention of the Size of lesion in millimeters, (4) Mention of the Anatomical location of the lesion or the endoscopic abnormality, (5) Endoscopic pictures taken, or not, and finally (6) the final postoperative diagnosis being mentioned separately and clearly.

**Results:** The study identified substantial variation among the content and format of the endoscopy reports that have been generated by the five different GI endoscopists at the same medical center. We reviewed 200 endoscopies (90 males, 110 females). The mean patient age for the Upper Endoscopies was 60 years (range 35–89 yr), and 61 years for the Lower Endoscopies (range 34–89 yr). Endoscopic abnormalities were noted in 78% of the Upper GI Endoscopies reviewed, and in 67% of the Lower GI Endoscopies reviewed, with considerable variation in how those abnormalities were reported.

**Conclusions:** There is great opportunity and considerable potential for improving the content and standardization of the GI endoscopy reports. The use of standardized terminology (including the Minimal Standard Terminology Format) and reduction in the variation among different endoscopic reports would be helpful. The size of Endoscopic abnormalities should be documented in millimeters, there should be a clear postoperative diagnosis, a minimum of four photos have to be taken even if the exam is normal (showing the cecum, splenic flexure, hepatic flexure, and the rectum for example), and hopefully in the near future, each patient will get a CD of his entire endoscopic exam before leaving the endoscopy suite, leading eventually to establishment of a computerized network in Digestive Endoscopy.

#### 1005

**Impact of Non-Gastroenterologists Performing Gastrointestinal Endoscopy on the Practice of Gastroenterologists and Variations in Practice of Gastrointestinal Endoscopy by Non-Gastroenterologist Endoscopists and Gastroenterologists in Georgia, United States: A Market Research Survey**

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**Purpose:** Most gastroenterologists perform gastrointestinal endoscopies, however all gastrointestinal endoscopies are not performed by gastroenterologists. There exists a perception in the medical community is that the endoscopies are increasingly taken over from the gastroenterologists (GE) by the non-gastroenterologist endoscopists (NGE) causing substantial impact on the practice of gastroenterologists. The goal of this study was to determine whether GE’s and NGE’s feel threatened by this competition to their practice of endoscopy.

**Methods:** A telephone survey of GE’s (N = 100) and NGE’s (N = 100, 59 family physicians and 41 general surgeons) was conducted in the State of Georgia, United States in 2004. The names and telephone numbers of the physicians were randomly obtained from the Yellow Pages section of the BellSouth telephone directory. A 12 questionnaire telephone survey was administered and responses were recorded and analyzed.

**Results:** All the GE’s practiced in urban areas compared to 65% of the NGE’s who practiced in rural areas (p < 0.001). GE’s performed an average of 27 endoscopies per week compared to six endoscopies per week by NGE’s. GE’s claimed that they spent 56% of their time in endoscopy compared to 11% of their time by NGE’s (p < 0.001). The average wait time for a non-urgent new patient to see a GE was five weeks compared to one week for NGE. 50% of the GE’s were in group practice compared to 14% of the NGE’s. The average work week of a GE was 48 hours compared to 62 hours of a NGE. 62% of the GE’s performed endoscopies in out-patients surgical centers compared to 90% of the NGE’s in hospitals (p < 0.001). 55% of the GE’s agreed that compensation for the endoscopy is adequate compared to 70% of the NGE’s (p < 0.05). 72% of the GE’s believe that there is shortage of gastroenterologists compared to 80% of the NGE’s (p = 0.20). 10% of the GE’s were willing to refer their patients for endoscopy compared to 26% of the NGE’s (p < 0.01). 90% of the GE’s thought NGE’s are not a threat to their practice whereas 92% of the NGE’s thought GE’s are not a threat to their practice.

**Conclusions:** Neither GE’s, nor NGE’s view each other as a threat to their practice of gastrointestinal endoscopy. The numbers of endoscopies performed by the GE’s are more when compared to the NGE’s. NGE’s provide endoscopy services in rural areas that are not served by GE’s.

#### 1006

**Patient Concerns towards Endoscopy; a Larger Problem Than Suspected in an Inner City Population**

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**Purpose:** Anxiety and high levels of concern for discomfort can affect patient attitudes and compliance with endoscopic procedures. Only a few prior studies have investigated preprocedure concerns towards endoscopy; none have documented more than two-thirds of patients having concerns, and none have looked at this in a diverse patient population background. In this study, we sought to investigate patient concerns towards both upper and lower endoscopic procedures.

**Methods:** This was a prospective study in which a questionnaire was given to patients prior to undergoing elective outpatient GI endoscopic procedures at an inner city, tertiary care hospital in Philadelphia, PA. Patients were asked to indicate their greatest concerns regarding their upcoming test. They were also asked if they had delayed their exam, and if so, what their reasoning for this was.
Results: Five hundred consecutive patients referred for outpatient GI endoscopy completed the survey (42% men and 58% women). Fifty eight percent of respondents were African-American and with a mean age of 54 years. Eighty three percent of our sample reported preprocedure concerns and 32% of those reported more than one concern. Primary reasons were specified in the following order: 1) Finding out results of test (34%), 2) Having the procedure itself (19%), 3) preparation prior to the test (14%), 4) undergoing anesthesia (12%), 5) experiencing pain (10%), and 6) having an IV placed (4%). Sixteen percent of all patients delayed their test > 6 months from the time they were initially advised to have their test. Colonoscopy was significantly more likely to have a delay than upper endoscopy (p ≤ 0.05). Women were significantly more likely to delay their tests than men (p ≤ 0.025) while there was no statistical difference among race. The most common reasons for this delay were: 1) feeling that the test was not important (32%), 2) fear of the procedure (16%), and 3) too busy to have the test done (16%). We found that 47% had undergone prior endoscopic procedures and there was a trend towards less of a delay if a previous endoscopic test was performed. Conclusions: We determined a higher percentage of patients reporting preprocedure concerns than previously reported in the literature. Female gender, having a colonoscopy, and lack of prior endoscopic exam were associated with delays in endoscopic procedures. Interventions to improve communication and education for patients are essential to reduce patient apprehensions towards endoscopy.

1007 What Shapes Provider Behavior When Prescribing NSAIDs?

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Purpose: To identify factors that influence NSAID prescribing behavior of physicians; and to assess the impact of guideline recommendations in shaping prescribing behavior.

Methods: A qualitative study of physician interviews from a major medical school; including VA and non-VA, county and private health care facilities, primary care and sub-specialty physicians. Interviews were conducted by a single investigator using a standard interview guide. Transcripts were analyzed using the constant comparative method. In a series of iterative steps, comments and quotations were assembled into distinct categories using a coding system and then integrated by the investigators through group meetings. The consensual process allowed for standardization of the coding system and refinement of the categories into a final taxonomy of major themes.

Results: Twenty-five physicians were interviewed including 16 internists, two each from geriatrics, infectious diseases, and physical medicine and rehabilitation, and one from rheumatology, nephrology and vascular surgery. Major themes included the influence of pharmaceutical representatives and direct to consumer marketing, clinical inertia, formative training, anecdotal experiences, formulary restrictions and patient requests or preferences. Guidelines had limited impact due to lack of awareness of recommendations, tacit approval without specific knowledge, conviction that their personal prescribing practices were safe, belief in limited applicability to patients, variability in the perceived validity of recommendations, and/or difficulty in implementation due to drug cost or polypharmacy. A dominant influence was a reliance on clinical heuristics (“rules of thumb”) acquired during formative training; later influenced and reinforced by encounters with patients and pharmaceutical marketing.

Conclusions: NSAID prescribing behavior is not uniformly shaped by guideline recommendations. The influence of the pharmaceutical industry in defining patient preferences (direct to consumer marketing) and clinical heuristics (academic detailing of physicians-in-training and clinical practitioners) is prevalent. The role of formulary restrictions, medication cost and potential complications of polypharmacy is also influential in shaping provider prescribing behavior.

1008 Utilization and Therapeutic Intent of PPI Prescription among Elderly NSAID Users

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Purpose: To examine prescription of proton pump inhibitors (PPIs) among elderly NSAID users to determine therapeutic intent and to assess provider recognition of the necessity for gastroprotection.

Methods: Administrative data identified patients ≥ 65 years with an NSAID and PPI prescription from 01/01/00–12/31/02 at a major VA medical center. Chart abstraction identified therapeutic intent of PPI prescription and assessed provider awareness of gastroprotection. The outcome of interest was an appropriate therapeutic intent, defined as GERD or endoscopic esophagitis, hypersecretory state, dyspepsia, ulcer with bleeding, perforation, or obstruction, H. Pylori eradication or NSAID gastroprotection. Logistic regression predicted appropriate therapeutic intent while adjusting for demographic characteristics, number of co-morbidities, type of NSAID prescribed, prescription of PPI following gastroscopy and prescribing provider.

Results: Among 1491 patients (73 years [SD 5.6], 73% Caucasian, 99.8% male), 64% were prescribed a PPI for an appropriate indication. A geriatric or primary care physician prescribed 68% of prescriptions; most (85%) for outpatients. Patients who used the VA only for pharmacy services were 60% less likely to be prescribed a PPI for an appropriate indication (OR 0.41; 95% CI: 0.31 – 0.54), as were inpatients (OR 0.47; 95% CI: 0.34 – 0.64) or prescriptions initiated by a cardiologist or otolaryngologist (OR 0.40; 95% CI: 0.25 – 0.64). Among non-selective NSAID users (80%), only 10% of providers identified the need for PPI. Gastroprotection was more likely if the provider was a rheumatologist (OR 46.7; 95% CI: 15.9 – 136.9), if the patient was African American (OR 2.5; 95% CI: 1.6 – 3.9) or had 3 to 5 co-morbidities (OR 1.8; 95% CI: 1.1 – 2.9). Among inpatients, the need for gastroprotection was less recognized (OR 0.40; 95% CI: 0.20–0.84), and 45% of PPI prescriptions were initiated for unknown reasons.

Conclusions: The intent of PPI prescription is unclear among 36% of elderly NSAID users. Few providers recognize the need for gastroprotection and the medical specialty of the provider plays a key role in both appropriate use of PPIs and recognition of the need for gastroprotection. Inpatient prescription of a PPI is often associated with failure to recognize the importance of gastroprotection or an unknown therapeutic intent.

1009 Predictors of Successful Completion of Gastroenterology Research: Lessons from Analysis of American College of Gastroenterology Funding Grants

Tuba Esfandyari, MD, M.Sc., Gavin C. Harewood, MD, M.Sc.,* Gastroenterology & Hepatology, Mayo Clinic College of Medicine, Rochester, MN.

Purpose: The American College of Gastroenterology (ACG) and other professional gastroenterology organizations provide annual funding for gastroenterology research. The optimal use of resources mandates understanding of predictive factors associated with successful completion of funded research projects and subsequent academic career advancement. The goals of our study were to evaluate a) features of ACG-funded clinical research grant applications that are associated with subsequent completion
and publication of the study, and b) features of the grant recipient that predict subsequent career advancement in academic medicine.

**Methods:** All grants awarded by the ACG for clinical research projects between 1983 and 2002 were identified. Subsequent publication of study findings in manuscript form in the peer-reviewed medical literature was assessed. An analysis of the CRISP data was searched to assess the success in receiving independent funding from the NIH. The current institution of the Primary Investigator, academic or non-academic, was identified using directories of the major gastrointestinal professional organizations.

**Results:** The ACG bestowed 307 clinical research awards with a total value of $3595954 (2002 value, $4269894) on 277 investigators from 1983 to 2002. Of the 307 awardees, 38% were trainees, 51% had completed training and 11% unknown. Over half of the award recipients came from institutions ranked in the top 50 organizations receiving NIH funding. The area of research most commonly funded was endoscopy (23.5%), followed by hepatology (19.0%) and motility (18.0%). Overall, 59.4% of funded studies proceeded to publication with a mean time to publication of 3 years. Only current position in an academic institution (67% vs. 44% of non-academic, p = 0.0002) and non-trainee status (70% vs. 53%, p = 0.007) were associated with publication. Of the 277 funded investigators, 66.3% subsequently remained in academic medicine. Investigator gender, rank of institution and area of research were not predictive of remaining in academic medicine, using multivariate logistic regression analysis.

**Conclusions:** Over half of ACG clinical research awards ultimately parlay into published manuscripts. Non-trainees and members of academic institutions appeared more likely to complete their studies to publication. The majority of recipients of research grants remain in academic medicine.

### Table 1.

<table>
<thead>
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<tr>
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### Table 2.

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### 1010

**The Rockall Risk Scoring System in Non Variceal Upper Gastrointestinal Hemorrhage: Data from the Ring Study**

*Marco Soncini,* Omero Triossi, Pietro Leo, Giovanna Magni, The RING Study Group. Gastroenterology, Hospital S. Carlo Borromeo, Milano, Italy; Gastroenterology, Hospital S. Maria delle Croci, Ravenna, Italy; Gastroenterology, Hospital Annunziata, Cesena, Italy and etiCRO, QBGROUP Spa, Padova, Italy.

**Purpose:** Non-variceal upper gastrointestinal hemorrhage (NVUGH) is a frequent reason for ordinary hospital admission (OH). In Italy the use of prognostic scores to stratify the risk has not been adequately validated, so the impact on clinical management of a rating system like the Rockall Score (RS) remains to be established. Since 2001 the RING study is been collecting hospital discharge files (HDF) from Italian hospital gastroenterology units (GU), giving a broad picture of the patients admitted for this pathology.

**Methods:** We analyzed the HDF collected between 2001–2005 from 12 GU, which issued more than 26000 HDF for OH and have been using the RS for defining NVUGH since 2003.

**Results:** There were 2832 HDF (10.7%) with a main diagnosis of NVUGH: 1335 ‘before’ the RS was introduced, 1497 ‘after’ the introduction of the RS. Patients’ mean age was 67.7 ± 16.7 years, with a M/F ratio of 1.7 and no significant changes over the years. There were no differences in the distribution of diagnoses in NVUGH pts before/after the introduction of the RS, though the mean hospital stay became shorter: from 7.1 ± 5.0 to 6.3 ± 4.9 days, and mortality declined from 2.8% to 2.3%, in parallel with the findings for the caselast as a whole. Between 2003 and 2005 the RS was calculated for 1102 OH. Diagnoses were more accurate: significantly fewer undefined causes and an increase in peptic ulcer (Tab 1). The mean RS was 4.6 ± 2.2: 17.8% low (0–2), 48.7% intermediate (3–5) and 33.5% high (≥6). Mean hospital stay, rebleeding and mortality were correlated with the severity of the score (Tab 2).

**Conclusions:** The RS enables the clinician to formulate a more precise diagnosis and substantially shortens the time in hospital, especially for patients at low risk of rebleeding and death, so more resources can be dedicated to critically ill patients.

### 1011

**Does the Timing of Laxatives Make a Difference in Colonoscopy Prep Outcomes?**

*Douglas J Sprung, MD,* GI, The Gastroenterology Group, Maitland, FL.

**Purpose:** To compare the outcomes of beginning the same Fleet phosphate (FPS) colonoscopy preparation in the morning versus the evening.

**Methods:** 100 patients were prospectively randomized to either beginning their FPS prep at 8 am (group A) or 5pm (group B). Each group took 2 doses of 1.5 ounces of FPS and a liquid diet for 24 hours before the colonoscopy. Group A took FPS at 8 am and 3pm, group B at 5pm and 9pm. The FPS was mixed in fluids of their choice. There were 50 patients in each group. There was a single physician observer who performed all the colonoscopies.

**Results:** In group A patients felt their prep was poor 4%, fair 10%, and good 86% of the time, while the observer felt the prep was poor in 4%, fair in 20%, good in 54% and excellent in 22%. 48% complained of nausea with the prep, and 60% complained of a bad taste. In group B 100% felt their prep was good, whereas the observer felt it was poor in 8%, good in 16% and excellent in 76%. 36% complained of nausea and 92% complained of a bad taste. 78% defecated an average of twice after midnight.

**Conclusions:** 1. Beginning a FPS prep later in the day yielded a significantly better colonic preparation, especially of the right colon. Patients were able to work the day before the procedure thereby avoiding lost revenue or vacation time. 2. No serious clinical complications occurred in this prospective study due to FPS. 3. The main disadvantage of the later prep time is the likelihood of having to defecate during the night.

### 1012

**Does Gender Disparity Remain in GI Practice?: A 10 Year Prospective Cohort Study**

*Aparajita Singh, MD, Suriya V Sastri, MD, Carol Barke, MD,* Gastroenterology and Internal Medicine, Cleveland Clinic, Cleveland, OH and Willowbrook, IL.

**Purpose:** Women compose 50% of medical students but only 16% of the GI workforce. Data show that women in GI have lower income, fewer children, and are less likely to be board certified or professionally advanced than men at 3 and 5 yrs after graduation from fellowship. This study determined if these disparities lessen after 10 yrs of GI practice.

**Methods:** This is a prospective cohort study of 390 gastroenterologists who previously completed a survey at the time of graduation from GI fellowship,
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1013

Prospective Randomized Trial of Cefoperazone-Sulbactam Versus Cefazidime Plus Amikacin and Metronidazole in the Treatment of Intra-Abdominal Infections


Purpose: Monotherapy appears to be a desirable option for treatment of intra-abdominal infections due to the simplicity of its administration, fewer side effects and wide spectrum. This prospective, randomised, open-label, parallel group, phase IV multi-centric study evaluated the efficacy and safety of cefoperazone-sulbactam compared with cefazidime plus amikacin and metronidazole in the treatment of intra-abdominal infections in Indian patients.

Methods: Subjects received study medication [cefoperazone-sulbactam (2–8 g/day) or cefazidime (2–6 g/day) plus amikacin (15 mg/kg/day) plus metronidazole (500 mg tds)] intravenously for 5–14 days. Three hundred and six subjects were clinically evaluable (cefoperazone-sulbactam, n = 154; cefazidime/amikacin/metronidazole, n = 152).

Results: Significantly more patients in the cefoperazone-sulbactam group had continued resolution of their clinical signs and symptoms at the 30-day follow-up visit (92% versus 82%; p = 0.017). The difference between treatments was 10% (95% confidence interval 2.1–18.1), which was higher than the pre-defined non-inferiority limit of > -12.5. The findings were similar even for microbiological outcomes (success or presumed success: cefoperazone-sulbactam, 93%; cefazidime/amikacin/metronidazole, 80%) at the end of treatment. The incidence of treatment related adverse events was 6% with cefoperazone-sulbactam, vs. 16% with cefazidime/amikacin/metronidazole. There were more discontinuations in the cefazidime/amikacin/metronidazole group (10% vs 3%).

Conclusions: Empirical cefoperazone-sulbactam monotherapy is a useful alternative to the current standard combination treatment for serious intra-abdominal infections.

1014

Complications of Video Capsule Endoscopy

Alfred Trang, MD, Marc Broovich, MD, Thomas Read, MD, Sarfraz Ahmad, MD, Philip F. Cauhaj, MD,* Surgery, The Western Pennsylvania Hospital, Pittsburgh, PA.

Purpose: Video capsule endoscopy has become a useful tool for the diagnosis of small bowel pathology otherwise undetected by conventional methods. With the increasing use of capsule endoscopy, surgeons must be aware of the possible complications of its use. We report the outcomes of video capsule endoscopy at the Western Pennsylvania Hospital.

Methods: During a 7-month period, 29 patients underwent video capsule endoscopy. There were twenty-four women and five men; mean age was 58 years ranging from 21 to 78 years. Almost all of the patients had remarkable endoscopic and colonoscopic evaluations. Indications for procedure were anemia (N = 17), melena (N = 6), abdominal pain (N = 4), r/o lymphoma (N = 1) and r/o GVHD (N = 1).

Results: Twenty-two patients completed the study without difficulty. Five did not complete the study but were able to pass the capsule afterwards. Two patients required surgical intervention to retrieve retained capsules. The capsules were stuck at ileal strictures secondary to Crohn’s disease. There were no perforations and no mortalities.

Conclusions: Video capsule endoscopy provides a new alternative for diagnosing small bowel pathology. Although rare, this procedure is not without complications. Retained capsule appears to be the most common complication. It is unknown at this time how long an asymptomatic retained capsule may be left in the bowel. Surgeons need to be aware of these complications in order to deal with them.

1015

Pantoprazole 40 Mg (PANTO) Is Superior to Esomeprazole 40 Mg (ESO) in Resolving Sleep Disturbances in GERD Patients


Purpose: Nighttime (NT) GERD symptoms are linked to disturbed NT sleep caused by impaired next-day functioning, daytime sleepiness, and reduced productivity in the workplace and potentially reduce quality of life.

Methods: To discover reasons for previously identified differences in health-related quality of life (HRQoL) in GERD patients on different treatment regimens. GerdDyzerTM is a validated tool for the HRQoL assessment in international clinical GERD studies. Using the GerdDyzerTM database from all clinical studies in patients with EE grade A-D the effects of 4 weeks treatment with PANTO or ESO 40 mg qd on sleep disturbances were evaluated (PANTO: N = 578; ESO: N = 452). In addition to weekly assessment of HRQoL by GerdDyzerTM, sleep disturbances were assessed daily by ReQuestTM. Mean scores for the ReQuestTM dimension sleep disturbances were calculated at baseline and after 28 days. ‘Excellent’ HRQoL was defined as a GerdDyzerTM sum score < the minimal clinically important difference of 3.78. ‘Good’ NT sleep was defined as a score of the ReQuestTM dimension sleep disturbances < 0.1 (corresponding to 1 cm on the VAS). Irrespective of sleep quality at baseline, rates of patients experiencing ‘good’ sleep after 28 days of treatment were compared between treatment groups by Fisher’s exact test. Patients rates showing an improvement to ‘good’ sleep from baseline to end of treatment were compared between treatment groups by Chi-Square test.
Results: Baseline scores of the ReQuestTM dimension sleep disturbances were similar in both treatment groups (PANTO: 0.96; ESO: 1.05). Irrespective of treatment, 10.29% of patients reported ‘good’ sleep and had ‘excellent’ HRQoL at baseline. After 28 days of treatment, the percentage increased to 61.03. Both regimens markedly increased the rate of patients with ‘good’ sleep. The proportion of patients with ‘good’ sleep was significantly higher in the PANTO group compared to the ESO group (80.39% vs 65.28%, p < 0.0001). Indeed, a comparison of patients rates with an improvement to ‘good’ sleep showed a statistically significant superiority of PANTO versus ESO: 43.32% vs 35.42% (p = 0.012).

Conclusions: This analysis demonstrated in a large population the superiority of PANTO to ESO in improving the sleep quality of GERD patients and offers an explanation for differences in patients’ HRQoL.

1016
GERDyzerTM-Treatment Satisfaction Module: Correlation with Symptom Assessment by ReQuestTM-GI

Purpose: To analyze if GERD patient satisfaction with medication measured by GERDyzerTM treatment satisfaction module (GERDyzerTM-TSM) correlates with GERD symptoms assessed by ReQuestTM.

Methods: GERDyzerTM-TSM consists of 7 questions about patient satisfaction with medication assessed by VAS. ReQuestTM is a validated self-assessment diary to measure frequency and intensity of various symptoms. Fulfillment of expectations 0.52 < 0.0001. Enabling to lead normal life 0.50 < 0.0001. Onset of positive impact 0.46 < 0.0001. Duration of positive impact 0.51 < 0.0001. Enabling to lead normal life 0.50 < 0.0001. Fulfillment of expectations 0.52 < 0.0001. Continuation of medication intake 0.41 < 0.0001. Total 0.54 < 0.0001.

GERDyzerTM-TSM-Dimensions Correlation coefficient with ReQuestTM-GI p-value
Overall satisfaction 0.50 < 0.0001
Symptom relief 0.49 < 0.0001
Onset of positive impact 0.46 < 0.0001
Duration of positive impact 0.51 < 0.0001
Enabling to lead normal life 0.50 < 0.0001
Fulfillment of expectations 0.52 < 0.0001
Continuation of medication intake 0.41 < 0.0001
Total 0.54 < 0.0001

Conclusions: This analysis demonstrated in a large population the superiority of PANTO to ESO in improving the sleep quality of GERD patients and offers an explanation for differences in patients’ HRQoL.

1017
Gastrointestinal Bleeding in the Setting of Acute Myocardial Infarction
Amer Kassar, MD, Abdullah Al Arabi, MD, Vaishali Hotanalli, MD, Mohammed Barew, MD,* Internal Medicine, St. John Hospital, Detroit, MI.

Purpose: 1- Construct a demographic profile of patients develop gastrointestinal bleed after acute myocardial infarction. 2- Determine in hospital morbidity and mortality. 3- Determine the role of endoscopic intervention. 4- Identify predictors of poor outcomes and survival.

Methods: A retrospective chart review involved two groups. The study group includes patients admitted for acute myocardial infarction and developed gastrointestinal bleed after receiving anticoagulation and/or antiplatelet agents. The control group includes patients admitted for acute myocardial infarction without gastrointestinal bleed, over the same period of time. Information was collected based on the following: demographic data, preadmission medications, treatment of myocardial infarction, diagnosis and treatment of gastrointestinal bleed, laboratory values, mortality, and in-hospital complications.

Results: GI bleed was more common among elderly, female, and caucasian patients. Patients with history of peptic ulcer disease and previous GI bleed had a higher incidence of GI bleed, with P values of 0.005 and 0.030 respectively. Patients who were on asa or other NSAIDS had a higher incidence of GI bleed, with P values of 0.002 and 0.010 respectively. Patients presented with symptoms of upper GI bleed in more than 90% of patients. Endoscopic procedures were performed in only 28% of patients with GI bleed. However, the source of bleed was identified in more than 65% of these patients, without significant complications from performing these procedures. Patients with GI bleed after acute MI had significantly higher in-hospital and ICU length of stays, with P values of <0.005 and 0.031 respectively. We also found that the mortality rate, acute renal failure, and arrhythmias were higher in patients with GI bleed after acute MI.

Conclusions: Gastrointestinal bleeding after acute MI will increase the mortality rate, arrhythmias, and acute renal failure. The use of asa or NSAIDS is associated with a higher incidence of gastrointestinal bleeding after acute MI, and is more commonly seen among elderly patients, especially caucasians and females. We generally treat gastrointestinal bleeding after acute MI conservatively with continuous infusion of PPIs without endoscopic procedures. In this study we showed that endoscopy, with or without intervention, can identify the source of bleed in 65% of patients without significant complications from performing the procedures.

1018
Risk Factors for Gastrointestinal Bleeding in Patient’s on Long Term Warfarin Therapy
Sumit Sharma, MD, Jevon Tang, MD, Pallavi Shah, MD,* Lawrence Perlmuter, PhD, Axel Feller, MD Department of Gastroenterology, North Chicago VA Medical Center and Rosalind Franklin University of Medicine and Sciences/Chicago Medical School, North Chicago, IL.

Purpose: To examine the risk factors for Gastrointestinal (GI) bleed in patients on warfarin and proton pump inhibitors (PPI) therapy.

Methods: The study is a retrospective review of medical records of 626 Veteran male patients, identified from the pharmacy database for having received warfarin for at least 2 weeks between the years 2000 and 2005. Variables like age, NSAID, aspirin, selective serotonin receptor uptake inhibitor (SSRI), PPI and antiplatelet use, history of GI bleed, history of GERD, chronic renal failure (CRF; serum creatinine > 1.5 mg/dl), history of peptic ulcer disease (PUD), Prothrombin Time (PT) and International Normalized Ratio (INR) values at the time of GI bleed were collected. Clinical characteristics of subjects who suffered a GI bleed were compared with subjects who did not. Spearman Rho correlation was used to study the relationship between INR and the above variables in all subjects and separately in the subset of subjects with and without GI bleed. Chi-square test was used to compare categorical
variables and a co-morbid score was calculated by counting the number of the above risk factors in the two groups.

**Results:** Out of 626 subjects, 63 (9.9%) were identified with a GI bleed. The mean age was similar for bleeders 74.8 (SD 10.3) and non-bleeders 72.5 (SD 11.7); p = 0.144. Subjects with GI bleed were more likely to have chronic renal failure (36.5% vs. 12%; p < 0.001), aspirin (36.9% vs. 20.8%; p < 0.001), PPI use (53.9% vs. 35.5%; p = 0.004), history of GI bleed (46% vs. 0.01%; p < 0.001) and history of PUD (12.6% vs. 0.05%; p < 0.03). GI bleed (r = 0.27; p < 0.001), history of GI bleed (r = 0.09, p < 0.025), SSRI use (r = 0.079, p < 0.048) and PT (r = 93; p < 0.001) were found to have significant positive correlation with INR while INR values were lower in subjects on PPI (r = −0.094; p < 0.019). After controlling for age and history of GI bleed, PPI use was found to have a significant negative correlation with INR (r = −0.198; p < 0.008) in all subjects. The co-morbid score, however, was higher in the GI bleed group (2.3, SD = 1.5) than the non-GI bleed group (1.2, SD = 1.2). Subjects who were using PPI had more co-morbidities and significant association with GI bleed (p < .004).

**Conclusions:** Subjects with GI bleed while using PPI have more co-morbid conditions as risk factors for GI bleed, the above observations could be a bystander effect.

### Table 1019

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<th>Type of Catheter</th>
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<td>Triple</td>
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To characterize the medical therapies used by Crohn’s disease patients in a university-based outpatient Gastroenterology clinic.

**Methods:** Medical records of patients with a diagnosis of Crohn’s Disease seen at a university-based outpatient gastroenterology clinic between October 2003 and October 2004 were reviewed. Data was collected on patients’ ethnicity, age, gender, duration of illness, requirement for surgery and treatment history.

**Results:** During the study period, 158 office visits were identified, involving 61 unique patients. Four of the 61 patients were excluded from the study due to incomplete or erroneous medical records, resulting in a total of 57 patients in our study population. The mean age was 41.4 years (range 19 – 86) with a mean duration of illness of 12.5 years (range 0 – 42). 72% of patients...
were male and 28% were female. 29% had a history of Crohn’s-related intestinal surgery. 81% percent of the patients with Crohn’s disease were non-Hispanic Caucasians. Despite the large Hispanic population served by our institution, only 3/57 (5%) of our clinic patients with Crohn’s disease were Hispanic. Table 1 reports the specific medical treatments used by patients in our study population. Further analysis of the patients in our study group receiving infliximab shows that only 57% were concurrently receiving immunomodulator therapy. Similarly, our data reveal that, among post-surgical Crohn’s disease patients, only 48% were being treated with immunomodulators.

Conclusions: Although the medical regimens delivered to outpatients with Crohn’s disease at our institution are similar to those in published reports, this study suggests that our patients may not be receiving the optimal therapy. In particular, immunomodulator agents are underutilized in Crohn’s disease patients at increased risk for treatment failure (patients receiving infliximab) and disease recurrence (post-surgical patients). These findings have important implications for improving the care and outcomes of IBD patients at our institution.

Correlation Coefficients

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<th>sIBDQ</th>
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*p<0.001; **p = 0.02; ***p = 0.10

1023

Digestive Diseases in the American Indian Population of the U.S. Central Plains: Disparities in Prevalence, Screening, and Treatment

Bob Kizer, MD,* Gleb Haynatzki, PhD, Mary Lazarte, MD, Reshma Patel, John O’Brien, MD, Asma Dajani. Gastroenterology, Creighton University School of Medicine, Omaha, NE; Internal Medicine, Creighton University School of Medicine, Omaha, NE and College of Medicine, Creighton University School of Medicine, Omaha, NE.

Purpose: Little is known about the prevalence of digestive diseases among the American Indian population of the United States central plains. The Fred Leroy Clinic of Omaha, NE, provides medical care for over 4000 American Indians from 70 tribes throughout the Dakotas, Nebraska, and Kansas.

Methods: A retrospective study of random Fred Leroy charts. Each chart was reviewed for documentation of Body Mass Index in kg/m², colorectal cancer (CRC), cholelithiasis, viral hepatitis, and 6 other digestive diseases. Data was collected on health care screening. The prevalence of each of these conditions was compared to the prevalence in the entire United States. The one-sample z-test for proportions was used in statistical analyses.

Results: 449 adult patient charts were reviewed. 138 male; 311 female. 330 age 19–50 years old; 119 age 50–79. The BMI was calculated for 447 patients. The prevalence of overweight/obesity (BMI >25, 381 patients) in this population is 85.3% (U.S.-65%, p < 0.00001), the prevalence of obesity (BMI >30, 268 patients) is 60.0% (U.S.-30%, p < 0.00001). No significant difference in the prevalence of CRC existed between the study population and the U.S. population. Of 123 persons eligible for CRC screening, only 14 (11.4%) were offered screening, significantly less than the 42.5% (p < 0.00001) of eligible U.S. patients underwent CRC screening in 2000. 61 patients (13.6%) have a history of cholelithiasis. No significant difference exists between the prevalence in this population and the U.S. prevalence of 10–15% (p < 0.00001). 27 patients (6%) have a history of Hepatitis C infection (U.S.-1.7%, p < 0.00001).

Conclusions: This is the first study looking at the prevalence of digestive diseases other than cholelithiasis in the American Indian population of the U.S. central plains. This population has a 20% higher prevalence of overweight/obesity compared to the U.S. and three times the prevalence of Hepatitis C. No statistically significant difference exists between these populations for prevalence of cholelithiasis, contrary to previous studies. This population lacks access to CRC screening, which is standard-of-care in the U.S. The prevalence of CRC in this population may be underestimated. The reasons behind these disparities are unclear.
PRECiSE 2 Data Demonstrate a High Association between Work Productivity, Daily Activities and Clinical Endpoints in Crohn’s Disease

Martin C.J. Brown, M.Sc., Ole Østergaard Thomsen, MD, Oana Purcaru, PhD,* Stefan Schreiber, MD Global Health Outcomes Research, UCB, Slough, United Kingdom; Gastroenterology, Herlev Univ. Hosp., Copenhagen, Denmark; LACO, Diegem, Belgium and Medicine, Christian-Albrechts University, Kiel, Germany.

Purpose: Certolizumab pegol is a PEGylated Fab’ fragment of a humanized anti-TNFα monoclonal antibody being developed for Crohn’s disease (CD). The PRECiSE 2 26-week (wk) maintenance trial1 showed that certolizumab pegol 400mg sc every 4 wks (after open-label induction) was effective and well tolerated in patients (pts) with active CD. This analysis investigated the relationship between work and daily activity impairment in PRECiSE 2, evaluated by the validated WPAI questionnaire, and the primary clinical endpoint — CD Activity Index (CDAI) — and a measure of health-related quality of life (HRQoL) — the Inflammatory Bowel Disease Questionnaire (IBDQ).

Methods: Relationships between WPAI dimensions and CDAI and IBDQ Wk26 subscales and global scores for the ITT population were assessed using Kendall’s tau coefficient, a measure of the strength of dependence, showing to what extent 2 variables move together.

Results: Lower WPAI dimension scores (representing a lower impact of CD on work productivity and daily activities) were associated with lower abdominal pain and general wellbeing subscale scores and global CDAI score (representing lower disease severity), as reflected by high positive Kendall’s tau values. Similarly, lower WPAI dimension scores were associated with higher IBDQ dimension and global scores (representing better HRQoL), as reflected by high negative Kendall’s tau values.

Conclusions: Lower levels of disease severity and higher levels of HRQoL were associated with improvements in work productivity and in the ability to carry out daily activities for pts in PRECiSE 2.

REFERENCE


Kendall’s tau coefficientsa Wk26 (N = 423b)

<table>
<thead>
<tr>
<th>WPAI dimensions</th>
<th>% work time missed</th>
<th>% impairment while working</th>
<th>% overall work impairment</th>
<th>% activity impairment</th>
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<tr>
<td><strong>IBDQ</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bowel symptoms</td>
<td>0.33</td>
<td>0.49</td>
<td>0.5</td>
<td>0.49</td>
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<td>0.35</td>
<td>0.51</td>
<td>0.49</td>
<td>0.54</td>
</tr>
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<td>0.55</td>
<td>0.55</td>
<td>0.51</td>
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<tr>
<td>Social function</td>
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<td>0.58</td>
<td>0.61</td>
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<tr>
<td>Global</td>
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<td>0.58</td>
<td>0.58</td>
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<tr>
<td><strong>CDAI</strong></td>
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<td></td>
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<tr>
<td>Abdominal pain</td>
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<td>0.43</td>
<td>0.42</td>
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<tr>
<td>General wellbeing</td>
<td>0.37</td>
<td>0.46</td>
<td>0.45</td>
<td>0.44</td>
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<tr>
<td>Global</td>
<td>0.32</td>
<td>0.43</td>
<td>0.43</td>
<td>0.44</td>
</tr>
</tbody>
</table>

a p-value ≤ 0.0001. b n may differ due to missing data

PRECiSE 2 Data

Fospropofol Disodium for Moderate Sedation during Colonoscopy Produces Clear-Headed Recovery

James Jones, MD,* Chao Wang, PhD Clinical Research, MGI PHARMA, Baltimore, MD

Purpose: Fospropofol disodium (AQUAVAN® Injection, AQ) is a prodrug of propofol under development for use in diagnostic and therapeutic procedures requiring moderate sedation. This analysis assessed the level of antegrade amnesia both at screening and at recovery during a randomized, double-blind, multicenter, dose-response study that was designed to determine the optimal dose of AQ for colonoscopy.

Methods: Patients aged ≥18 years with an ASA status I–IV undergoing colonoscopy were enrolled and then randomly assigned to receive an initial bolus dose of either AQ (2.0, 5.0, 6.5, or 8.0 mg/kg) or midazolam (MD) 0.02 mg/kg following pretreatment with fentanyl citrate (50 μg/kg). Psychometric testing was performed at baseline and during recovery with the Hopkins Verbal Learning Test-Revised (HVLT-R™), an instrument designed to measure verbal learning and memory. In this test, patients listened to a list of 12 words, remembering as many as possible after each of 3 readings. After a 20-minute delay, patients recalled as much as they could (delayed recall) and then performed an auditory recognition task of words they had been asked to learn.
Results: 127 patients were randomized and completed the study. The sedative dose of AQ (6.5 mg/kg) was associated with memory retention during recovery that was higher than that produced in patients in the 2.0, 5.0, and 8.0 mg/kg AQ groups and the MD group (Recovery, mITT population [Figure]).

Conclusions: Patients recovering from sedation with AQ during elective colonoscopy have minimal antegrade amnesia compared with MD and similar to that seen at baseline, suggesting the drug is associated with a clear-headed recovery. Memory retention was highest in patients who received an initial bolus dose of 6.5 mg/kg of AQ.

Conclusions: At baseline, PRECISE 2 patients showed markedly impaired health status. Following certolizumab pegol therapy, the health status of patients rapidly improved and was similar to that in the general population. Patients receiving certolizumab pegol sustained a significantly higher health status than those receiving placebo.

REFERENCE

### Table: IBDQ Change from Baseline

<table>
<thead>
<tr>
<th>IBDQ Domain</th>
<th>Certolizumab Pegol Induction Phase* (Wk 6)</th>
<th>Placebo (N = 210)</th>
<th>Certolizumab Pegol (N = 215)</th>
<th>p-value*</th>
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<tbody>
<tr>
<td>Total score</td>
<td>52.4</td>
<td>46.8</td>
<td>49.0</td>
<td>&lt;0.001</td>
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<tr>
<td>Bowel Symptoms</td>
<td>16.2</td>
<td>13.9</td>
<td>15.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Systemic Symptoms</td>
<td>9.1</td>
<td>8.0</td>
<td>8.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Emotional Function</td>
<td>18.3</td>
<td>16.6</td>
<td>16.8</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Social Function</td>
<td>8.8</td>
<td>8.2</td>
<td>8.4</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>

*Intention-to-treat population; †Repeated-measures stepwise ANCOVA (SF-36) or logistic regression (EQ-5D)

### Figure 2.

**1027**

Impact of Crohn’s Disease and Treatment with Certolizumab Pegol 400 mg Every 4 Weeks on Patient-Reported Health Status: Data from PRECISE 2

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**Purpose:** We assessed the impact of Crohn’s disease (CD) and treatment with certolizumab pegol on the health status reported by patients in PRECiSE 2. This study1 showed efficacy and tolerability for subcutaneous (SC) certolizumab pegol in patients with a CD Activity Index (CDAI) score of 220–450 points.

**Methods:** After certolizumab pegol 400mg SC induction at Weeks (Wks) 0, 2, 4, patients with a clinical response (CDAI score decrease ≥ 100 points) at Wk 6 were randomized to certolizumab pegol 400mg or placebo every 4 wks from Wk 8 to 24. Health status was assessed using Short-Form Health Survey 36-item (SF-36) and EuroQol-5 Dimensions (EQ-5D) questionnaires at baseline, Wk 6, 16 and 26.

**Results:** Baseline physical and mental health were lower for patients with CD than for those with irritable bowel syndrome or gastro-esophageal reflux disease, and the general population. Domains most affected were SF-36 Role Physical and EQ-5D Pain/Discomfort; least affected were SF-36 Physical Function and EQ-5D Self-Care. After induction therapy, scores approximated those found in the general population: SF-36 domain scores improved by 17–45 points; SF-36 component summary scores by 10–11 points and EQ-5D VAS by 24 points (Table). Certolizumab pegol sustained improvements from Wk 6 to 26 at levels significantly greater than with placebo in all SF-36 domains except Physical Function, in the EQ-5D VAS score and in 3 out of 5 domains of EQ-5D (Table).
domains (Table). Moreover, during the maintenance phase, the proportion of patients with an IBDQ response (increase in total score from baseline ≥ 16 points) was significantly higher with certolizumab pegol than with PBO (p < 0.001).

Conclusions: Following certolizumab pegol induction treatment, HRQoL was rapidly improved to levels that are indicative of remission in patients with active CD. This improvement was significantly maintained in all domains of the IBDQ throughout the study compared with PBO.

REFERENCE


1029

A Diet High in Fruits and Low in Meats Reduces the Risk of Colorectal Adenomas

Gregory L. Austin, MD, M.P.H., Linda S. Adair, PhD, Joseph A. Galanko, PhD, Christopher F. Martin, M.S., Robert S. Sandler, MD, M.P.H.,*,
Division of Gastroenterology and Hepatology, University of North Carolina, Chapel Hill, NC.

Purpose: Recent evidence suggests dietary patterns, rather than specific food items, may be a better predictor of colorectal adenomas or cancers than specific dietary components, such as fiber. The purpose of this study was to assess whether dietary patterns are associated with an increased risk of colorectal adenomas and whether adjusting for total energy consumption prior to creating clusters affects this relationship.

Methods: Data from a case-control study of 725 individuals undergoing a colonoscopy were utilized. Cases (N = 203) were those with at least one adenoma on colonoscopy and controls (N = 502) were those who did not have any adenomas. Dietary data were collected by telephone interview utilizing the National Cancer Institute’s Food Frequency Questionnaire (FFQ) and nutrient estimates were calculated for 18 different food groups. To standardize comparisons, all food groups were transformed into z-scores. Participants were first clustered without energy adjustment, then clustered again based on their consumption of these same food groups per 1000 kcal consumed.

Results: There was no significant relationship between dietary clusters and colorectal adenomas without energy adjustment. In fact, clusters formed as a byproduct of total energy consumption. After adjusting for total energy consumption, three distinct clusters emerged: 1) Fruit Cluster (high whole grain and fruit consumption and low vegetable and meat consumption), 2) Vegetable Cluster (high vegetable and average fruit and meat consumption), and 3) Meat Cluster (low fruit and vegetable and high meat consumption). After adjusting for age, gender, body mass index, smoking, alcohol consumption, and use of non-steroidal anti-inflammatory drugs, the Vegetable Cluster (OR 2.17: 95% CI 1.20–3.90) and Meat Cluster (OR 1.70: 95% CI: 1.04–2.80) were at significantly increased odds of having had an adenoma compared to the Fruit Cluster. Using the energy-adjusted models, the adjusted percentages of having an adenoma were 19% for the Fruit Cluster, 33% for the Vegetable Cluster, and 28% for the Meat Cluster.

Conclusions: A dietary pattern of high fruit and low meat consumption appears to be protective against having a colorectal adenoma compared to a dietary pattern of increased vegetable or meat consumption.

1030

Helicobacter pylori Infection and Iron Deficiency Anemia in an Adult Population: A Single University Experience

Jeffrey Rauch, MD, Derek Patel, MD, John Garvie, MD, Gordon Hunt, MD,* Medicine, University of California, San Diego, San Diego, CA.

Purpose: To determine the prevalence of iron deficiency anemia (IDA) in H. pylori-infected adults treated at an academic institution.

Methods: This is a retrospective observational case series of H. pylori-infected patients as diagnosed by gastric biopsy/pylorotek and/or serology, between January 2004 and June 2005. The medical records of 279 H. pylori-infected patients were reviewed for the following information within six months of H. pylori testing: age, gender, race; lowest hemoglobin/hematocrit/MCV/ferritin/iron/transferrin levels; the indication for testing, and testing modality. Exclusion criteria included active GI hemorrhage, pregnancy, thalassemia, aplastic anemia, history of bleeding diathesis, hemophilia, vonWillebrands disease, malignancy, end stage renal disease, recent surgery, menorrhagia, pancytopenia, or intracranial hemorrhage.

Results: 163 H. pylori-infected patients met exclusion criteria and had laboratory data. 40 of 163 patients (25%) had anemia. Of these 40 patients, 13 (33%) had appropriate laboratory studies to evaluate for iron deficiency. Ten of these 13 patients (77%) had IDA. Ability to determine the overall prevalence of IDA within a population of H. pylori-infected subjects was limited by inadequate laboratory data.

Conclusions: In patients with H. pylori infection and anemia who undergo laboratory evaluation of iron stores, a majority (77%) have iron deficiency. However, only a minority of patients with H. pylori and anemia at our academic institution are appropriately evaluated for iron deficiency. These data suggest that IDA within the H. pylori-infected patient population is underappreciated and potentially underdiagnosed. Additional studies to determine if eradication of H. pylori infection contributes to the resolution of IDA are needed.

1031

The Efficacy of Domperidone in the Treatment of Gastroparesis

Aarvind Sugumar, MD, Arti Barnes, MD, Pankaj Parriacha, MD,* Internal Medicine, University of Texas, Galveston, TX and Internal Medicine, University of Iowa, Iowa City, IA.

Purpose: Inspite of being widely used in over 20 countries for the treatment of Diabetic gastroparesis for several decades, oral domperidone has only just received FDA approval in the US. This paper aims to analyze and compare studies dealing with the efficacy of domperidone in Diabetic gastroparesis, with a focus on their methodological and scientific merit.

Methods: Our assessment was focused on clinical trials done specifically for domperidone in diabetic gastroparesis using earlier review articles as a platform. Literature in English from 1979 to 2005 was searched using MEDLINE and PUBMED. A standard form with 56 categories was used to collect data, which included sample sizes, study design, outcome measures and their statistical significance. Studies were assigned a quality score based on methodological criteria using guidelines set by Schoenfeld[i], Jadad[ii] and the US preventative Services Task Force[iii].


Results: Information from 28 trials contained in 11 full articles, 17 abstracts and 14 reviews from 1981 to 2003 were analyzed. The average study quality score was 8.36 out of a possible 15 and total sample size 1003. Overall 55% of the studies demonstrated significant efficacy of domperidone on the improvement of symptoms, 60% of the studies showed an efficacy in gastric emptying and 67% of the studies proved the drug effective in reducing hospital admissions.

Conclusions: Most of the trials had limited power because of a very small sample size and other methodological limitations. The quality of studies made the evidence Level 2 and the recommendation for the use of Domperidone as Grade B. The assessment tools and outcome measures varied considerably, making a meta-analysis unfeasible.
1032

Outcome Data in 104 Patients Presenting to a Community Clinic for Capsule Endoscopy
Russell Havranek, MD,* Charles Randall, MD, Carlo Taboada, MD, David Stump, MD, Gary Gossen, MD, Franz Zurita, MD, Jorge Munoz, MD, Bassem Mazloum, MD, Anson Liu, Janie Jamie. Research, Gastroenterology Clinic of San Antonio, San Antonio, TX; Medicine, University of Texas Health Science Center at San Antonio, San Antonio, TX and GERSA, Gastroenterology Research of San Antonio, San Antonio, TX.

Purpose: Capsule endoscopy (CE) is gaining popularity and increased utilization in the gastrointestinal community due to its ability to visualize small intestine mucosa with ever-improving resolution. The purpose of this study was to see how results of CE changed or added to a patient’s diagnosis. Additionally, we looked at several therapeutic decisions based upon the findings produced by CE.

Methods: 104 patients were reviewed both retrospectively and prospectively. 68 had iron-deficiency anemia (IDA) and/or obscure bleeding (OB); 17 had a diagnosis of Crohn’s Disease (CD); 13 for pain with diarrhea; and 6 had an abnormal imaging study or endoscopic exam.

Results: Of the 68 patients with IDA or OB, 29 had findings that could account for the presenting diagnosis. 18 had significant vascular ectasias; 4 had small bowel ulcers; 3 had tumors; 3 had NSAID strictures and 1 had radiation enteritis. In the 17 CD patients, 8 had small intestinal lesions that had previously gone undetected. Only 2 patients in the pain and diarrhea group had findings. Both of these patients had ulcerative enteropathy consistent with NSAIDs. In the 6 with imaging or endoscopic abnormalities, 3 had confirmed findings at CE, 2 had ileal Crohn’s and 1 had NSAID enteropathy.

Conclusions: 1. 42 patients (40.4%) undergoing CE had a finding that established or confirmed a diagnosis. 2. CE allowed a treatment regimen to begin where prior evaluations had failed. 3. CE has the highest yields in patients with IDA, OB or CD. 4. This study suggests that CE should be incorporated early in the evaluation of these subtype groups.

1033

Safety and Outcomes of Percutaneous Endoscopic Gastrostomy in Patients with Amyotrophic Lateral Sclerosis
Charles Randall, MD,* Anson Liu, Carlo Taboada, MD, Russell Havranek, MD, Carlayne Jackson, MD, Jairo Melo, MD, Sharun Asgasi, Carleigh Jacobs, Janet Ford. Research, Gastroenterology Clinic of San Antonio, San Antonio, TX; Medicine, University of Texas Health Science Center at San Antonio, San Antonio, TX; Neurology, University of Texas Health Science Center at San Antonio, San Antonio, TX; GI, Methodist Hospital, San Antonio, TX and GERSA, Gastroenterology Research of San Antonio, San Antonio, TX.

Purpose: Nutritional intervention is becoming increasingly important in prolonging the quality of life in patients with ALS. Referrals for gastrostomy (PEG) placement are thus increasing in this population of special patients. In this study we looked at the outcomes of PEG placement with regards to safety and morbidity.

Methods: A total of 47 patients were referred from the University ALS clinic for PEG placement. For those patients requiring BiPAP at home, this device was applied prior to sedation in the endoscopy suite of Methodist Hospital. Patients having a FVC of near 50 or less had respiratory therapy assisting for PEG placement. For those patients requiring BIP AP at home, this device was applied prior to sedation in the endoscopy suite of Methodist Hospital. Patients having a FVC of near 50 or less had respiratory therapy assisting

Results: 46 patients went home following a brief stay in the recovery room without complications. Of the 46 patients only 5 had transient desaturation (below SaO2 90%) that responded within 1 minute of oxygen delivery adjustments. 1 patient had respiratory distress and was admitted for 24-hour observation. He did well and was discharged without important consequences.

Conclusions: 1. 100% of ALS patients undergoing PEG placement had a successful procedure. 2. 97.9% of the cases were done as an outpatient. 3. PEG placement is safe and associated with a low rate of morbidity in ALS patients undergoing endoscopy at an experienced center.

1034

Ulcerative Colitis: Annual Costs of Care and Resource Utilization in Patients ≥65 Years of Age from a Payer Perspective
O. Dabbous, MD,* H. Thompson, M.S., S. Yan, M.S., M. Bala, PhD, R. Arjani, PhD, J. Gdovin, PhD, B. Tang, MD, M.I. Rahman, MD Centocor, Inc., Horsham, PA and Applied Health Outcomes, Palm Harbor, FL.

Purpose: To assess the annual costs of care and resource utilization for pts ≥ 65 yrs with ulcerative colitis (UC) from a medical claims database.

Methods: A retrospective analysis, using the PharMetrics database, of pts ≥ 65 yrs of age with a diagnosis of UC (ICD-9 code 556.x) from Jan. 1, 2000 through June 30, 2005 was conducted. Pts had to be continuously enrolled for 6 months pre-and 12 months post-UC diagnosis, and have 2 distinct claims for UC. Mean per pt healthcare resource utilization and costs were calculated for pts in the yr following their initial UC diagnosis. Outcomes are presented for UC pts by disease severity grps. Grp 1 required hospitalization for UC; Grp 2 required chronic aggressive pharmacotherapy (i.e. corticosteroids or immunosuppressants) for ≥4 months; and Grp 3 included all remaining pts.

Results: 650 pts were analyzed. Average age of pts was 75 yrs and 58% were females. Mean annual total cost for all pts was $15811. Grp 1 pts incurred the highest mean cost ($30394), while Grps 2 and 3 incurred $10804 and $9476, respectively. Inpt hospitalization costs had the largest component ($7926, 50%) of the mean annual total cost for all pts. The next highest cost components were outpts ($1941, 12%), prescription meds ($1641, 10%), physician office visits ($1052, 6.7%), and lab procedures ($357, 2.3%). Also, Grp 1 had the highest resource utilization (Table).

Conclusions: UC in pts ≥ 65 yrs is associated with a high cost of care. Pts requiring hospitalization incurred the highest cost. New therapies that can reduce hospitalizations have the potential to decrease overall cost of care for pts with UC.

<table>
<thead>
<tr>
<th></th>
<th>Grp 1</th>
<th>Grp 2</th>
<th>Grp 3</th>
<th>All Pts</th>
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<tbody>
<tr>
<td>N (%)</td>
<td>190 (29)</td>
<td>108 (17)</td>
<td>352 (54)</td>
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<td>Age</td>
<td>77</td>
<td>74</td>
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<td>Females (%)</td>
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<td>$10,804</td>
<td>$9,476</td>
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<td>$19,053</td>
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<td>Total healthcare visits</td>
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<tr>
<td>Inpt admissions (days)</td>
<td>2 (12)</td>
<td>0.3 (1.9)</td>
<td>0.3 (1.3)</td>
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<td>4.6</td>
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<tr>
<td>ER visits</td>
<td>0.8</td>
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<td>Physician visits</td>
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<tr>
<td>Lab visits</td>
<td>7.4</td>
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<tr>
<td># of prescriptions</td>
<td>28</td>
<td>38</td>
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<td>23</td>
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</tbody>
</table>

1035

Impact of Age on Annual Costs of Care and Resource Utilization in Patients with Ulcerative Colitis from a Payer Perspective
O. Dabbous, MD,* S. Yan, M.S., M. Bala, PhD, H. Thompson, M.S., R. Arjani, PhD, J. Gdovin, PhD, B. Tang, MD, M.I. Rahman, MD Centocor, Inc., Horsham, PA and Applied Health Outcomes, Palm Harbor, FL.
Purpose: To assess the impact of age on annual costs of care and resource utilization for pts with UC using a medical claims database. **Methods:** A retrospective analysis, using the PharMetrics database, of pts with a diagnosis of UC (ICD-9 code 556.x) from January 1, 2000 through June 30, 2005 was conducted. Pts had to be continuously enrolled for 6 months pre-and 12 months post-UC diagnosis, and have 2 distinct claims for UC. Mean per pt healthcare resource utilization and costs were calculated for pts in the yr following their initial UC diagnosis. Outcomes are presented for UC pts by age groups: pediatric ≤ 18 yrs of age; adults 18 to 64 yrs; and adults ≥ 65 yrs of age.

**Results:** The study cohort consisted of 15105 pts with UC. Almost 50% of the pts were males. Mean annual total cost for all UC pts in the study were $13233. Pediatric UC pts incurred the highest mean cost ($23113), followed by adults ≥ 65 yrs $15811, and adults 18 to 64 yrs $12693. Inpt hospitalization costs constituted the largest component ($5276, 42%) of the mean annual total costs for all pts. The next highest cost components were prescription medications ($2423, 18%), outpts ($1310, 10%), physician office visits ($899, 6.8%), and lab procedures ($470, 3.6%). Resource utilization was highest in the adults ≥ 65 yrs followed by pediatric, and adults 18 to 64 yrs (Table).

**Conclusions:** UC in pediatric pts is associated with a high cost of care that is almost twice the cost for the adults UC pts. New therapies that can reduce hospitalizations have the potential to decrease overall cost of care for pts with UC.

### Mean Healthcare Costs and Resource Utilization

<table>
<thead>
<tr>
<th>N (%)</th>
<th>Pediatric (&lt;18 yrs)</th>
<th>Adults (18–64yrs)</th>
<th>Adults ≥ 65 yrs</th>
<th>All pts</th>
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<tr>
<td>589 (3.9)</td>
<td>13866 (92)</td>
<td>650 (4.3)</td>
<td>15,105</td>
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</tr>
<tr>
<td>Age</td>
<td>13</td>
<td>44</td>
<td>75</td>
<td>44</td>
</tr>
<tr>
<td>Females</td>
<td>48</td>
<td>54</td>
<td>58</td>
<td>54</td>
</tr>
<tr>
<td>Deyo-Charlson Comorbidity Index Score</td>
<td>1.4</td>
<td>1.3</td>
<td>2.9</td>
<td>1.3</td>
</tr>
<tr>
<td>Total healthcare costs</td>
<td>$23,113</td>
<td>$12,693</td>
<td>$15,811</td>
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<td>Inpt</td>
<td>$15,051</td>
<td>$5,276</td>
<td>$7,926</td>
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<td>Outpt</td>
<td>$1,413</td>
<td>$1,276</td>
<td>$1,941</td>
<td>$1,310</td>
</tr>
<tr>
<td>ER</td>
<td>$283</td>
<td>$264</td>
<td>$332</td>
<td>$268</td>
</tr>
<tr>
<td>Physician</td>
<td>$1,088</td>
<td>$884</td>
<td>$1,052</td>
<td>$899</td>
</tr>
<tr>
<td>Lab</td>
<td>$677</td>
<td>$467</td>
<td>$357</td>
<td>$470</td>
</tr>
<tr>
<td>Prescription</td>
<td>$2,207</td>
<td>$2,469</td>
<td>$1,641</td>
<td>$2,423</td>
</tr>
<tr>
<td>Total healthcare visits</td>
<td>15</td>
<td>13</td>
<td>19</td>
<td>14</td>
</tr>
<tr>
<td>Inpt admissions (days)</td>
<td>0.6 (4.3)</td>
<td>0.3 (1.8)</td>
<td>0.8 (4.5)</td>
<td>0.4(2.0)</td>
</tr>
<tr>
<td>Outpt visits</td>
<td>2.5</td>
<td>2.0</td>
<td>3.3</td>
<td>2.0</td>
</tr>
<tr>
<td>ER visits</td>
<td>0.4</td>
<td>0.5</td>
<td>0.5</td>
<td>0.4</td>
</tr>
<tr>
<td>Physician visits</td>
<td>11</td>
<td>11</td>
<td>15</td>
<td>11</td>
</tr>
<tr>
<td>Lab visits</td>
<td>5.0</td>
<td>4.1</td>
<td>6.0</td>
<td>4.2</td>
</tr>
<tr>
<td># of prescriptions</td>
<td>19</td>
<td>23</td>
<td>28</td>
<td>23</td>
</tr>
</tbody>
</table>

---

**1036**

UC: Annual Costs of Care and Resource Utilization in Adult Pts 18 to 64 Years from a Payer Perspective

O. Dabbous, MD,* S. Yan, M.S., M. Bala, PhD, R. Arjunji, PhD, H. Thompson, M.S., B. Tang, MD, J. Gilovin, PhD, M.I. Rahman, MD Centocor, Inc., Horsham, PA and AHO, Palm Harbor, FL.

**Purpose:** To assess the annual cost of care & resource utilization for adult UC pts 18 to 64 yrs of age from a medical claims database. **Methods:** A retrospective analysis, using the PharMetrics database, of adult pts 18 to 64 yrs with a dx of UC (ICD-9 code 556.x) from Jan. 1, 2000 through June 30, 2005 was conducted. Pts had to be continuously enrolled for 6 months pre-and 12 months post-UC dx, and have 2 distinct claims for UC. Mean per pt healthcare resource utilization and costs were calculated for pts in the yr following their initial UC dx. Outcomes are presented for UC pts by disease severity grps. Grp 1 required hospitalization for UC; Grp 2 required chronic aggressive pharmacotherapy (i.e. corticosteroids or immunosuppressants) for ≥4 months; and Grp 3 included remaining pts.

**Results:** The cohort had 13856 UC pts. Average pt age was 44 yrs & 56% were females. Mean annual total costs for all pts with UC were $12693 vs $3661 for non-UC pts. Grp 1 pts incurred the highest mean cost ($36155), while Grps 2 & 3 incurred $11401 & $6493, respectively. Inpt hospitalization costs had the largest component ($5276, 42%) of the mean annual total costs for all pts. The next highest cost components were prescription meds ($2469, 20%), outpts ($1276, 10%), physician office visits ($884, 7.0%), and lab procedures ($467, 3.7%). Resource utilization was also highest in Grp 1 (Table).

**Conclusions:** UC in adults 18 to 64 yrs is associated with a high cost of care that is almost 3-fold the cost for those without UC. Pts requiring hospitalization incurred the highest cost. New therapies that can reduce hospitalizations have the potential to decrease overall cost of care for UC pts.

### Healthcare Costs and Resource Utilization by Disease Severity

<table>
<thead>
<tr>
<th>Grp</th>
<th>N (%)</th>
<th>Mean Annual Total Cost (in $)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2387 (17)</td>
<td>36,155 (+11,401)</td>
</tr>
<tr>
<td>2</td>
<td>3088 (22)</td>
<td>11,401 (+6,493)</td>
</tr>
<tr>
<td>3</td>
<td>8381 (61)</td>
<td>6,493 (+12,693)</td>
</tr>
</tbody>
</table>

### Other relevant information:

**1037**

The Prevalence and Costs To Treat GI Comorbidities in Persons with Constipation

Richard A. Brook, M.S.,* Nathan L. Kleinman, PhD, Arthur K. Melkonian, MD, Robert W. Baran, Phar.MD, Thompson, M.S., B. Tang, MD, J. Gilovin, PhD, M.I. Rahman, MD Centocor, Inc., Horsham, PA and AHO, Palm Harbor, FL.

**Purpose:** To compare the prevalence and costs associated with specific GI comorbidities among persons with or without constipation. **Methods:** A retrospective analysis was conducted using the Human Capital Management Services Research database, which represents multiple US-based employers and contains employee data from 2001–2005. Prevalence and costs among persons with constipation (C) ICD-9 codes (564.0, 564.00, 564.01, and 564.09) were compared with a 24:1 propensity score-matched cohort of controls without constipation (NC). Comorbidities were examined over 1 year. The index date in the C cohort was defined as 3 months prior
to the date of first diagnosis during 2001 or later; the average C index date was used in the NC cohort. GI comorbidities were assessed using Agency for Healthcare Research and Quality specific GI categories. Costs were the sum of the insurance payments for each category. The prevalence of GI comorbidities was calculated for both cohorts. Satterthwaite t-tests were used to assess significance of cost differences, and z-scores of log odds ratios were used to assess prevalence differences between cohorts.

**Results:** Data were available for 1215 persons with C and 29160 propensity score-matched NC controls. Table 1 presents prevalence and costs per person for both cohorts. All prevalence comparisons were highly significant ($P < 0.0001$). Most cost differences were significant ($P \leq 0.03$).

<table>
<thead>
<tr>
<th>GI Comorbidity</th>
<th>Prevalence (%)</th>
<th>Costs per Person ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GI Hemorrhage</td>
<td>15.4</td>
<td>79.5</td>
</tr>
<tr>
<td>Hemorrhoids</td>
<td>15.2</td>
<td>76.6</td>
</tr>
<tr>
<td>Esophageal Disorders</td>
<td>14.4</td>
<td>66.7</td>
</tr>
<tr>
<td>Diverticulosis/Diverticulitis</td>
<td>7.5</td>
<td>75.3</td>
</tr>
<tr>
<td>Anal and Rectal Conditions</td>
<td>5.8</td>
<td>73.2</td>
</tr>
<tr>
<td>Stomach/Duodenum Disorders</td>
<td>5.2</td>
<td>15.0</td>
</tr>
<tr>
<td>Intestinal Obstruction w/out Hernia</td>
<td>2.7</td>
<td>76.1</td>
</tr>
<tr>
<td>Enteritis/Ulcerative Colitis</td>
<td>1.6</td>
<td>55.1</td>
</tr>
</tbody>
</table>

* all prevalence comparisons $P < 0.0001$

**Conclusions:** Patients with constipation have significantly more GI comorbidities than patients without constipation. These comorbidities incur additional costs, suggesting a need for comprehensive patient management.

**1038**

**Cost of Illness for Constipation: Medical, Pharmacy, and Work Absence Costs in Employees with or without Constipation**

**Methods:** A retrospective analysis was conducted using the Human Capital Management Services Research database, which represents multiple US-based employers and contains employee data from 2001–2005. Data fields included medical, pharmacy, payroll, work absence (where available), and demographics. ICD-9 Codes (Constipation), 564.00 (Unspecified), 564.01 (Slow Transit), and 564.09 (Other) distinguished employees with C from employees with no claims for these codes (NC). Two-part regression modeling was used to determine the annual cost differences between C and NC employees while controlling for age, job tenure, gender, salary, region, and Charlson Comorbidity Index score. Direct medical (inpatient and outpatient hospital or clinic, emergency department (ED), laboratory, and other. ICD-9 Codes 564.0 (Constipation), 564.00 (Unspecified), 564.01 (Slow Transit), and 564.09 (Other) were used to distinguish employees with constipation (C) from the nonconstipation (NC) cohort (employees with no claims for these ICD-9 codes). The index date in the C cohort was defined as 3 months prior to the date of first diagnosis during 2001 or later; the average C index date was used in the NC cohort. Two-part regression models were used to compare each category of costs between cohorts. Age, gender, marital status, race, salary and other job-related variables, region of the US, and Charlson Comorbidity Index score were included in the models as independent variables to control for possible confounding factors.

**Results:** Data were available for 1138 persons with C and 113701 NC controls. Overall, the constipation cohort was 1.86 years younger, 12.7% more likely to be female, 6.6% less likely to be white, 3.3% more likely to be black, 1.5% more likely to work full-time, and compensated $49866 less in annual salary per person ($P < 0.0001$). The C cohort incurred $3105 per person additional annual costs for all services. Costs by category for the C cohort versus NC cohort were: outpatient hospital or clinic ($2135 vs. $733), inpatient hospital ($1645 vs. $581), doctor’s office ($1064 vs. $561), ED ($141 vs. $45), laboratory ($27 vs. $9), and other locations ($51 vs. $29). The incremental increase in cost (%) for C (vs. the NC cohort) by POS category were: outpatient hospital or clinic (45.2%), inpatient hospital (34.3%), doctor’s office (16.2%), ED (3.1%), laboratory (0.6%), and other locations (0.7%). All POS category comparisons were significant ($P < 0.0002$).

**Conclusions:** Patients with constipation have significantly higher costs of care throughout the healthcare system and at all POS locations.
Assessment of Work Absences Associated with Constipation
Nathan L. Kleinman, PhD,* Richard A. Brook, M.S., Arthur K. Melkonian, MD, Robert W. Baran, Phar.MD Analysis & Research Services, HCMS, Cheyenne, WY. Retrospective Analysis, The JSTARs Group, Newfoundland, NJ and Medical Outcomes Research, Takeda Pharmaceuticals North America, Lincolnville, IL.

Purpose: To assess the annual work absence associated with constipation (C) in an employed population.

Methods: A retrospective analysis was conducted using the Human Capital Management Services Research Reference database, which represents multiple US-based employers and contains employee data from 2001–2005. Data fields analyzed included medical, payroll, work absence, and demographics. This analysis compared the annual absences for employees with and without C diagnoses. ICD-9 Codes 564.0 (Constipation), 564.00 (Unspecified), 564.01 (Slow Transit), and 564.09 (Other) were used to distinguish employees with C from the nonconstipation (NC) cohort (employees with no claims for these ICD-9 codes). The index date in the C cohort was defined as 3 months prior to the date of first diagnosis during 2001 or later; the average C index date was used in the NC cohort. Two-part regression modeling was used to determine the differences between the cohorts while controlling for age, job tenure, gender, salary, region, and Charlson Comorbidity Index score.

Results: Data were available for 273931 employees (Table 1). C was associated with 5.06 annual mean incremental absence days (compared with the NC cohort), of which long-term disability accounted for 62.1% (3.14 additional days, P = 0.0325), short-term disability for 28.8% (1.46 additional days, P = 0.0012), and Sick Leave 13.9% (0.71 additional days, P < 0.0001).

Conclusions: Persons with C incur more than 65% more annual paid work absence days than persons without C. These results likely underestimate the impact of C, as the analysis was limited to persons who sought medical treatment, were diagnosed, and received a C diagnosis on their medical claims. Further study of the impact of untreated C on work absences is needed.

1041 Assessing Direct and Indirect Costs in Ulcerative Colitis: The Perspective of a Self-Insured Telecommunications Company
E. Hillson, MD,* O. Dubbous, MD, H. Thompson, M.S., S. Dybicz, Phar.MD, W.G. Ervin, Phar.MD, B. Stuart, PhD, J. Schaneman, PhD, J.N. Astuto, PhD, A. Kersh, PhD, D. Broussard, MD Centocor, Horsham, PA; Omnicare, KOP, PA; U of Maryland, Baltimore, MD; OCI, Cheyenne, WY and Verizon, Marietta, GA.

Purpose: To advance understanding of the cost drivers associated with UC and benchmark the impact on a large self-insured provider.

Methods: Claimant records for a retrospective cohort of pts with UC (ICD-9 code 556.x) from a database of a self-insured employer, consisting of approx. 500000 employees, retirees, or dependents from 2002 to 2004 were analyzed to determine costs attributed to direct utilization and short-term disability (STD). 18 months of continuous enrollment was required [6-month pre and 12 months post-index date]. A randomly selected, age and gender matched control group, of non-UC claimants was the comparator. Individual claimants (UC and Controls) with costs ≥ 3 Sds from the overall mean were excluded on a basis of outlier status (N = 13, n = 50). Multiple linear regression technique was used to determine the predictors of cost, adjusting for CMS-HCC scores. A disease severity stratification algorithm classified UC pts into 3 mutually exclusive cohorts, mild [untreated or treated with aminosalicylates or topical therapy]; moderate [addititional therapies (e.g., oral corticosteroids, immunomodulators)]; or severe [requiring hospitalization for UC] cohort.

Results: Healthcare costs were evaluated for 1044 UC pts. Mean annual unadjusted total costs for all UC pts were $12120 vs $5128 for the non-UC group (N = 4178). The regression model indicated UC was a predictor of higher costs vs the control group (coefficient = 5136.37, p < 0.005). When stratified by disease severity, the severe UC cohort had 79.6% higher mean total costs vs the moderate group ($21999 vs $12248) and the moderate UC cohort had a 24.3% higher mean total costs vs the mild group ($12248 vs $9847). After adjustment for CMS-HCC scores in the regression analysis, the severe group was a significant predictor of increased cost, vs the mild and moderate pts (coeficient = 5847.84, p = 0.03). Additionally indirect costs for 211 (19.96%) UC pts filed claims for disability dispensation, with a mean payment of $2366.

Conclusions: Utilization expenditures for the UC cohort were over 2 times more costly vs pts without UC. Healthcare costs were highest for pts with severe UC. These results highlight the impact of UC healthcare expenditures on a self-insured employer. Increased awareness and attention to UC is warranted.

1042 Steroid Sparing Results in Further Improvement in Quality of Life in UC Patients in Remission
W.J. Sandborn, MD,* W. Reinsch, MD, G. Radford-Smith, MD, M. Bala, PhD, P. Rutgeerts, MD, D. Present, MD, B.E. Sands, MD, D. Rachmilewitz, MD, S. Tan, M.S., D. Eisenberg, PhD, A. Olson, MD, W.J.S. de Villiers, MD Mayo Clinic, Rochester, MN; U Hospital Vienna, Vienna, Austria; Royal Brisbane Hospital, Herston, Australia; Centocor R&D, Inc., Malvern, PA; Hospital Leuven, Leuven, Belgium; Mt Sinai Medical Center, NY, NY; MGH, Boston, MA; Shaare Zadek Medical Center, Jerusalem, Israel and U of Kentucky, Lexington, KY.

Purpose: IFX has been shown to improve health related quality of life (HRQL) and achieve clinical remission while discontinuing steroids through 30 wks in pts with moderate-to-severe active UC. For pts in remission at wk 30, we compared the improvement in HRQL between those who discontinued steroid use, and those who had not.

Methods: 728 pts were randomized (1:1:1) to PBO, IFX 5, or 10 mg/kg with tx at baseline, wks 2, 6, and q 8 wks (ACT 1 & ACT 2). HRQL was assessed using the IBDQ and SF-36. Pts on steroids at baseline and in remission at wk 30 were categorized into 2 grps: those who discontinued steroids at wk 30, and those who had not. Remission was defined as a Mayo score ≤ 2 points, with no individual subscore > 1. Analysis of variance on van der Waerden scores was used to compare change from baseline in HRQL scores.

Results: Among 408 pts on steroids at baseline, 91 were in remission at wk 30. Of these 91 pts, 70 discontinued steroids at wk 30. Baseline scores of the IBDQ & physical and mental component summaries (PCS & MCS) of the SF-36 were similar between pts who discontinued steroids at wk 30 and those who had not. Pts who discontinued steroids at wk 30 had more improvement in the IBDQ and PCS vs those still on steroids. The difference was significant for PCS (Table).
Conclusions: Among pts in remission at wk 30, those who discontinued steroid use had more improvement in HRQL than those who had not. In the management of UC, steroid sparing, in addition to remission, should be an important goal in improving pts' HRQL.

<table>
<thead>
<tr>
<th></th>
<th>Pts who had discontinued steroids at wk 30</th>
<th>Pts who had discontinued steroids at wk 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>21</td>
<td>70</td>
</tr>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IBDQ</td>
<td>134.2 (121.0)</td>
<td>129.1 (131.0)</td>
</tr>
<tr>
<td>PCS</td>
<td>40.7 (41.0)</td>
<td>40.1 (40.4)</td>
</tr>
<tr>
<td>MCS</td>
<td>38.9 (37.7)</td>
<td>39.3 (40.1)</td>
</tr>
<tr>
<td>wk 30 improvement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IBDQ</td>
<td>55.2 (58.0)</td>
<td>64.7 (65.5)</td>
</tr>
<tr>
<td>PCS</td>
<td>5.9 (7.4)</td>
<td>9.8 (10.4)**</td>
</tr>
<tr>
<td>MCS</td>
<td>11.4 (9.6)</td>
<td>11.0 (9.2)</td>
</tr>
</tbody>
</table>

∗∗p < 0.05

19 pts in remission at wk 30 out of the 408 pts on steroids at baseline ** p < 0.05

### 1043

**Infliximab Improves Quality of Life in UC Regardless of Baseline Disease Activity**

B. Feagan, MD,* W. Reineisch, MD, S. Yan, M.S., W.J. Sandborn, MD, P. Rutgeerts, MD, D. Eisenberg, M.S., M. Bala, PhD, J. Johanns, PhD, A. Olson, MD, S. Hanauer, MD, B.E. Sands, MD RRI, London, ON, Canada; U Hosp Vienna, Vienna, Austria; Centocor R&D, Malvern, PA; Mayo Clinic, Rochester, MN; Hosp Leuven, Leuven, Belgium; U Chicago, Chicago, IL and MGH, Boston, MA.

**Purpose:** To evaluate the long-term effect of IFX on health related quality of life (HRQL) in moderate-to-severe active UC in ACT 1 and the consistency of HRQL improvement by baseline disease severity(ACT 1 & ACT 2).

**Methods:** Moderate-to-severe active UC pts(baseline Mayo score between 6 & 12, inclusive) were enrolled in ACT 1(N = 364) and ACT 2(N = 364). Pts were randomized to PBO, IFX 5 or 10 mg/kg at baseline, wks 2, 6, and q8 wks through wk 22 in ACT 2 and through wk 46 in ACT 1. HRQL was assessed using the IBDQ and the SF-36 Physical and Mental Component Summaries (PCS, MCS). Results at wk 54 are reported for ACT 1 and analyses using combined data from the trials were used to determine improvement in HRQL by baseline disease severity (moderate UC: Mayo score <10; severe UC: Mayo score ≥10). ANOVA on van der Waerden scores was used to compare grps.

**Results:** In ACT 1, at wk 54, the IFX grps had greater improvements from baseline than PBO (p < 0.05 except for MCS in the 5 mg/kg grp), with the following comparisons [mean (median)] between the combined IFX grp vs PBO: Total IBDQ [32 (23) vs 13 (0.0)], PCS [6.0 (2.5) vs 2.7 (0.0)], and MCS [5.1 (0.0) vs 1.3 (0.0)]. All 4 IBDQ dimensions and all 8 scales of the SF-36 showed greater improvements in the combined IFX grp vs PBO (p < 0.05). Moderate UC pts had higher baseline IBDQ, PCS and MCS scores vs severe pts (Table). In both grps, there was greater improvement in all 3 HRQL scores in the combined IFX grp vs PBO, at both wk 8 & 30. The magnitude of improvement in HRQL was similar regardless of baseline disease severity.

**Conclusions:** Moderate-to-severe active UC pts had significant improvement in HRQL through 1yr. IFX results in consistent improvement in HRQL in UC pts, irrespective of baseline disease severity.

### 1044

**Impact of Fistula on Healthcare Resource Utilization and Costs among Pts with CD**

O. Daboub, MD,* R. Arjunji, PhD, J. Gdovin, PhD, H. Thompson, M.S., B. Tang, MD, M.J. Rahman, MD Centocor, Horsham, PA and AHO, Palm Harbor, FL.

**Purpose:** To evaluate the impact of fistula on healthcare costs & resource utilization in CD pts.

**Methods:** A retrospective analysis, using the PharMetrics database, of pts with a dx of CD (ICD-9 code 555.x) from Jan. 1, 2000 through June 30, 2005 was conducted. Pts had to be continuously enrolled for 6 months pre- and 12 months post-CD dx, and have 2 distinct claims for CD. Mean per pt healthcare resource utilization & costs were calculated for pts in the yr

### Table: Mean baseline score and mean improvement from baseline at wks 8 & 30

<table>
<thead>
<tr>
<th></th>
<th>Moderate UC (Mayo score &lt;10)</th>
<th>Severe UC (Mayo score ≥10)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PBO</td>
<td>Combined IFX</td>
</tr>
<tr>
<td>CD pts without fistula</td>
<td>Mean</td>
<td>Mean</td>
</tr>
<tr>
<td># of pts (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>56</td>
<td>43</td>
</tr>
<tr>
<td>Age (yrs)</td>
<td>41</td>
<td>42</td>
</tr>
<tr>
<td>Charlson comorbidity score</td>
<td>1.2</td>
<td>1.6</td>
</tr>
<tr>
<td>Total healthcare costs</td>
<td>$15,412</td>
<td>$35,043</td>
</tr>
<tr>
<td>Inpatient costs</td>
<td>$6,950</td>
<td>$20,327</td>
</tr>
<tr>
<td>Outpt costs</td>
<td>$1,677</td>
<td>$3,358</td>
</tr>
<tr>
<td>ER costs</td>
<td>$319</td>
<td>$328</td>
</tr>
<tr>
<td>Physician costs</td>
<td>$969</td>
<td>$1,519</td>
</tr>
<tr>
<td>Lab costs</td>
<td>$456</td>
<td>$488</td>
</tr>
<tr>
<td>Drug costs</td>
<td>$2,840</td>
<td>$3,732</td>
</tr>
<tr>
<td>Cost related to fistula surgery</td>
<td>$0</td>
<td>$595</td>
</tr>
<tr>
<td>Total healthcare visits</td>
<td>14</td>
<td>19</td>
</tr>
<tr>
<td>Inpt admissions (days)</td>
<td>0.5 (2.4)</td>
<td>0.7 (7.0)</td>
</tr>
<tr>
<td>Outpt visits</td>
<td>2.4</td>
<td>3.7</td>
</tr>
<tr>
<td>ER visits</td>
<td>0.5</td>
<td>0.6</td>
</tr>
<tr>
<td>Physician visits</td>
<td>11.0</td>
<td>14.1</td>
</tr>
<tr>
<td>Lab visits</td>
<td>4.5</td>
<td>5.3</td>
</tr>
<tr>
<td># of prescriptions</td>
<td>25.6</td>
<td>26.2</td>
</tr>
</tbody>
</table>

*p < 0.05 PBO vs combined IFX
following their initial CD dx. Outcomes are presented for CD pts with and without fistula.

**Results:** There were 13054 pts who met the selection criteria. 12263 (94%) pts had CD with no diagnosis of fistula. Pts with fistula were mostly male (57%). Total mean per pt healthcare costs were higher for pts with fistula ($55043 vs $15512). Inpatient hospital days (7.0 vs 2.4 days) and their costs ($20327 vs $5950) combined with physician office visits (14 vs 11) and their costs ($1519 vs $969) were the primary factors contributing to higher total healthcare costs in the fistula cohort.

**Conclusions:** Proper & early ty of CD may prevent fistula. Pts with CD & fistula have significant healthcare cost and resource consumption at a much higher rate than pts without fistula. Additional studies should assess the impact of various treatments on progression to fistula among pts with CD in a real-world setting.

**1045**

**Hepatic Effects of Lovastatin Exposure in Patients with Differing Types of Liver Disease**

T.R. Levin, MD, A. Avins, MD, M. Manos, PhD, L. Ackerson, PhD, W. Zhao, M.S., R. Murphy, D.J. Watson, PhD, P. Hwang, PhD, A. Replogle, J.G. Levine, MD,* Div of Research, Kaiser Permanente (KP), Oakland, CA and MRL, Merck & Co Inc, Blue Bell, PA.

**Purpose:** We previously reported that exposure to lovastatin (lova) was associated w/a significant reduction in a variety of adverse liver-disease (LD) outcomes in patients (pts) w/existing LD. Here we examined if these effects were consistent across a spectrum of baseline LD disorders.

**Methods:** This retrospective cohort study used data from 1995 through mid-2005. Adult members of KP were identified who had at least 2 elevated ALT or AST tests w/in a 6- to-18 month period, evidence of chronic viral hepatitis, or carried a LD diagnosis. Lova use was gathered from pharmacy databases. The outcome was the 1st occurrence of a new ALT level that was at least 3 x ULN (or 3 x baseline value if elevated), or a new diagnosis of cirrhosis or liver failure. Pts were hierarchically classified into 1 of 5 groups based on criteria for entry to the analytic cohort: chronic viral hepatitis, alcoholic LD, fatty LD, all other LD diagnoses, & those w/elevated liver tests (LTs). Incidence rates of outcomes were calculated w/in baseline LD groups; incidence rate ratios were calculated as the incidence rate during lova-exposed periods divided by the rate during lova-unexposed periods. Multivariate analyses were conducted w/extended Cox models adjusting for age & gender.

**Results:** A total of 73232 pts met the entry criteria and were at risk for an outcome event. Overall, lova exposure was associated w/a lower risk of each outcome that was consistent across all baseline LD subsets(Table). All reductions were significant except fatty liver, likely due to the small number of cases (3 exposed, 76 unexposed); these results persisted after multivariate adjustment.

**Conclusions:** Lova exposure was associated w/a significantly lower risk of adverse LD outcomes; this effect was apparent in all baseline LD subgroups, though not all effects retained significance in stratified analyses.

<table>
<thead>
<tr>
<th></th>
<th>Overall</th>
<th>Baseline Diagnosis</th>
<th>Viral Hepatitis</th>
<th>Alcoholic LD</th>
<th>Fatty LD</th>
<th>Other LD</th>
<th>Elevated LTs</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>73,232</td>
<td>21,389</td>
<td>1,865</td>
<td>1,055</td>
<td>9,736</td>
<td>39,167</td>
<td></td>
</tr>
<tr>
<td>Incidence Rate Ratio</td>
<td>0.48</td>
<td>0.70</td>
<td>0.43</td>
<td>0.53</td>
<td>0.52</td>
<td>0.63</td>
<td></td>
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<tr>
<td>95% CI</td>
<td>0.42–0.55</td>
<td>0.49–0.97</td>
<td>0.24–0.71</td>
<td>0.11–1.62</td>
<td>0.34–0.80</td>
<td>0.52–0.76</td>
<td></td>
</tr>
<tr>
<td>Hazard Ratio (Adjusted)</td>
<td>0.54</td>
<td>0.71</td>
<td>0.38</td>
<td>0.62</td>
<td>0.54</td>
<td>0.76</td>
<td></td>
</tr>
<tr>
<td>95% CI</td>
<td>0.47–0.62</td>
<td>0.51–0.99</td>
<td>0.23–0.65</td>
<td>0.19–1.97</td>
<td>0.37–0.80</td>
<td>0.63–0.92</td>
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</tr>
</tbody>
</table>

**1046**

**Annual Costs of Care and Resource Utilization in Pediatric Patients with UC from a Payer Perspective**

O. Dabbous, MD,* S. Yan, M.S., H. Thompson, M.S., M. Bala, PhD, R. Arjunji, PhD, J. Gilovin, PhD, B. Tang, MD, M.I. Rahman, MD, Centocor, Inc., Horsham, PA and AHO, Palm Harbor, FL

**Purpose:** To assess the annual costs of care and resource utilization for pts <18 yrs of age with UC using a medical claims database.

**Methods:** A retrospective analysis, using the PharMetrics database, of pts <18 yrs with a dx of UC (ICD-9 code 556.x) from Jan. 1, 2000 through June 30, 2005 was conducted. Pts had to be continuously enrolled for 6 months pre and 12 months post-UC diagnosis, and have 2 distinct claims for UC. Mean per pt healthcare resource utilization and costs were calculated for pts in the yr following initial UC dx. Outcomes are presented for UC pts by disease severity grps. Grp 1 required hospitalization for UC; Grp 2 required chronic aggressive pharmacotherapy (i.e. corticosteroids or immunosuppressants) for ≥4 months; and Grp 3 included all remaining pts.

**Results:** The cohort had 589 pts with UC. Average age of pts was 13 yrs and 52% were males. Mean annual total costs for all pediatric UC pts were $23113. Grp 1 pts incurred the highest mean cost ($59409), while Grps 2 and 3 incurred $9918 and $4310, respectively. Inpt hospitalization costs had the largest component ($15051, 65%) of the mean annual total costs for all pts. The next highest cost components were prescription meds ($2207, 9.5%), outpt visits ($1413, 6.1%), physician office visits ($1088, 4.7%), and lab procedures ($677, 3.0%). Grp 1 had the highest resource utilization (Table).

**Conclusions:** Pediatric UC is associated with a higher cost of care vs non UC pts. Pts requiring hospitalization incurred the highest cost. New therapies that can reduce hospitalizations have the potential to decrease overall cost of care for pediatric pts with UC.

Mean healthcare costs and resource utilization

<table>
<thead>
<tr>
<th></th>
<th>Grp 1 (184)</th>
<th>Grp 2 (167)</th>
<th>Grp 3 (238)</th>
<th>All pediatric pts (589)</th>
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<tbody>
<tr>
<td>Age</td>
<td>13</td>
<td>13</td>
<td>13</td>
<td>13</td>
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<tr>
<td>Females (%)</td>
<td>52</td>
<td>42</td>
<td>48</td>
<td>48</td>
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<tr>
<td>Deyo-Charlson Comorbidity Index Score</td>
<td>2.5</td>
<td>1.1</td>
<td>0.9</td>
<td>1.4</td>
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<tr>
<td>Total healthcare costs</td>
<td>$59,409</td>
<td>$9,918</td>
<td>$4,310</td>
<td>$23,113</td>
</tr>
<tr>
<td>Inpt</td>
<td>$46,731</td>
<td>$1,234</td>
<td>$256</td>
<td>$15,051</td>
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<tr>
<td>ER</td>
<td>$1,940</td>
<td>$1,615</td>
<td>$1,868</td>
<td>$1,413</td>
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<tr>
<td>Physician</td>
<td>$1,681</td>
<td>$1,016</td>
<td>$681</td>
<td>$1,088</td>
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<tr>
<td>Lab</td>
<td>$936</td>
<td>$778</td>
<td>$406</td>
<td>$677</td>
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<tr>
<td>Prescription</td>
<td>$3,016</td>
<td>$3,072</td>
<td>$976</td>
<td>$2,207</td>
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<tr>
<td>Total healthcare visits</td>
<td>$21</td>
<td>15</td>
<td>10</td>
<td>15</td>
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<tr>
<td>Inpt admissions (days)</td>
<td>1.7 (13)</td>
<td>0.1 (0.5)</td>
<td>0.03 (0.1)</td>
<td>0.6 (4.3)</td>
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<tr>
<td>Outpt visits</td>
<td>3.7</td>
<td>3.2</td>
<td>1.2</td>
<td>2.5</td>
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<tr>
<td>ER visits</td>
<td>0.8</td>
<td>0.4</td>
<td>0.4</td>
<td>0.5</td>
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<tr>
<td>Physician visits</td>
<td>14.4</td>
<td>11</td>
<td>8.6</td>
<td>11</td>
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<tr>
<td>Lab visits</td>
<td>7</td>
<td>5.4</td>
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<td>5.0</td>
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<tr>
<td># of prescriptions</td>
<td>23</td>
<td>25</td>
<td>11</td>
<td>19</td>
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</tbody>
</table>

**1047**

**Impact of 0.5mg QD, 1mg QD and 1.0mg BID Alosetron Hydrochloride on Patient Satisfaction with IBS Treatment in Women with Chronic, Severe Diarrhea-Predominant IBS (D-IBS)**

Vanessa Z. Ameen, MD,* Susan H. Gordon, M.S., Marquita A. West, B.S., Amy T. Heath, M.S., Eric G. Carter, MD, PhD Clinical Pharmacology and Discovery Medicine, GlaxoSmithKline, Research Triangle Park, NC; Clinical Development, GlaxoSmithKline, Research Triangle Park, NC and Statistics, GlaxoSmithKline, Research Triangle Park, NC.
Purpose: The 5HT₃ antagonist alosetron is indicated at a dose of 1mg-BID for women with severe, chronic, D-IBS who have failed conventional therapy. Lower doses of alosetron were assessed in a severe pt population in a randomized, double-blind, placebo-controlled study (S3B30040) to determine overall satisfaction with alosetron relative to placebo and baseline treatments.

Methods: 705 women with chronic, severe D-IBS were equally randomized to 12wks of placebo, 0.5mgQD, 1mgQD, or 1mgBID alosetron, followed by a 4wk follow-up period. Pts recorded satisfaction scores for their IBS medication using a 7-point scale (ranging from very unsatisfied to very satisfied) at Randomization and at Week 12/Final visit. The treatment groups were compared at Week 12/Final Visit and with the IBS treatment used at baseline.

Results: At baseline, 51% pts were using antidiarrheals, and 24% other drugs for functional GI disorders. 13% pts had used alosetron previously. At baseline, only 14% pts were somewhat satisfied, satisfied, or very satisfied with their IBS treatment. All alosetron doses significantly improved the level of satisfaction with treatment compared to placebo (p ≤ 0.003), and compared to baseline (p < 0.001) for all alosetron doses, (Figure).

Conclusions: The 0.5mgQD, 1mgQD and 1mgBID alosetron dosing regimens are effective in improving satisfaction with IBS treatment in women with chronic, severe D-IBS compared to conventional therapy. [figure 1] validated algorithm. Unadjusted incidence density ratios were calculated in the 365 days following exposure. Cox Proportional Hazard Models assessed risk of UGIE, while adjusting for demographics, UGIE risk factors, co-morbidity, prescription channeling (i.e., propensity score), geographic location and multiple time-dependent pharmacological covariates including aspirin, steroids, anticoagulants, antiplatelets, statins and selective serotonin reuptake inhibitors.

Results: Among 481985 patients (97.8% male; 85.3% white; mean age 73.9 [SD 5.6]), NSAID+PPI or coxib was prescribed to 19.8% and 3205 UGIE occurred in 293594 person years. The unadjusted incidence density ratio was 1.44 UGIE/1000 person-years (95% CI: 1.23–1.80) for NSAID+PPI, and 1.17 UGIE/1000 person-years (95% CI: 1.09–1.30) for coxib, when compared with NSAID alone. When adjusted for prescription channeling and confounders, the risk was 1.79 (95% CI: 1.62–1.99) among NSAID alone, versus 1.08 (95% CI: 0.69–4.68) among NSAID+PPI. Coxib prescription was associated with a risk of 1.75 (95% CI: 1.48–2.08); further reduced with a PPI (1.14; 95% CI: 0.59–5.25).

Conclusions: Provider adherence to NSAID prescription guidelines is associated with fewer UGIE. An adherent strategy lowers, but does not eliminate, the risk of an NSAID-related UGIE.

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Treatment Outcomes to Peg-Interferon and Ribavirin in a Government Sponsored Clinic for an Underserved Population with Chronic Hepatitis C
Johanna Iurrino, MD, Carlos J. Romero, MD, Carlos J. Sanchez, MD, Vanessa Velazquez, BS, Adelaida Ortiz, MD, Pablo J. Costas, MD, Esther A. Torres, MD, M.A.C.G.* Department of Medicine, University of Puerto Rico, San Juan, Puerto Rico.

Purpose: Recent studies have revealed a lower HCV treatment response and a higher treatment discontinuation rate in Hispanics compared to Caucasians. HCV treatment is not covered by the Puerto Rico government health care system. A pilot government-sponsored clinic was established at the University of Puerto Rico for the treatment of this underserved population. The aim of this study is to describe the outcomes and treatment response of Peg-interferon and Ribavirin in treatment-naive chronic HCV patients in this clinic.

Methods: A retrospective analysis to investigate the outcomes of HCV patients treated with Peg-interferon and Ribavirin in a pilot clinic during 2003–2005. Frequencies and percentages to summarize patient’s groups and Fisher’s exact test to analyze the distribution of all groups were used.

Results: 156 (106 M:50 F, mean age 41.9) patients started treatment. Genotype 1 was found in 72.4%. Treatment was discontinued in 47 (30%): 24 (51%) were early non-responders, 16 (34%) had adverse effects, 5 (10.7%) developed co-morbidities during treatment, 2 (4.3%) had unrelated deaths. Another 46 patients (29.5%) were lost to follow-up after having started treatment. Thirty-three patients (40.4%) completed treatment. When patients with an early discontinuation are excluded, 37/63 (58.7%) had End-of-treatment response (ETR), while the ETR on those intended to treat was 23.7%. Recurrence of viremia was observed in 5/37 (13.5%) of those with ETR. Sustained viral response (SVR) was seen in 16/63 (25.4%) patients who completed treatment, while the SVR on those intended to treat was 16/156 (10.3%). Sixteen of 37 (43.2%) patients were lost to follow up to assess SVR. No significant correlation was found between ETR and age, gender, viral genotype, initial HCV RNA, early virological response, or degree of fibrosis (p > 0.05).

Conclusions: The high rate of treatment discontinuation in our population surpasses the previously reported rates in U.S. Latinos and Caucasians. Treatment response to Peg-interferon and Ribavirin seems to be lower in our population. The pilot clinic for treatment of HCV did not fulfill its goals. Quality of life assessment, clinic coordinator, treatment of side effects and educational material should be provided to improve patient compliance and decrease rate of discontinuation. Further studies should assess reasons for higher treatment discontinuation in Hispanics.
Improving Patient Compliance with Appointments and Preparation for Outpatient Endoscopic Procedures

Robin Forman, D.O., Vidushi Golla, MD, Emily Glazer, MD, Brett Bernstein, MD, David Clain, MD,* Division of Digestive Diseases, Beth Israel Medical Center; New York, NY.

Purpose: It has been our experience that patients followed by fellows in gastroenterology (GI) clinic tend to miss scheduled appointments. Several factors may contribute to this lack of compliance including language barriers, housing situation, and means of transportation. We investigated whether implementation of a telephone notification system impacted show rates and prep quality for outpatient endoscopic procedures.

Methods: The patients of six GI fellows at an urban academic medical center were included in this study. A case control crossover study took place over an eight-week period. For the first four weeks, patients of three fellows were called prior to scheduled procedures, constituting the case group, while those of the other three fellows were not called, serving as controls. During the second four-week period the groups were reversed. Date, time, location, and instructions on bowel preparation were reviewed at each phone call. Phone calls were made 24 to 72 hours prior to scheduled procedures and translators were available for non-English speaking patients. Paired t-tests and Chi-square test were used to analyze continuous and dichotomous variables, respectively.

Results: There were a total of 113 patients in this study, 52 cases and 61 controls. Patient demographics were similar between the two groups (Table 1). In the case group, 58% of patients were reached via telephone, 29% were unreachable (no answer), and a message was left on an answering machine. In the case group, 58% of patients were reached via telephone, 29% were unreachable (no answer), and a message was left on an answering machine. In the case group, patients reached by phone (60%) had a significantly better prep quality (p = 0.001) compared to the patients not reached by phone (41%).

Conclusions: This study showed that both show rates and prep quality are significantly improved by the implementation of a telephone notification system. A strategy such as this one would predictably be effective for improving patient compliance; however, larger case control studies are needed to validate this theory.

Demographics and Outcomes

<table>
<thead>
<tr>
<th>Variable</th>
<th>Cases</th>
<th>Controls</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
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<td>Age, Mean (SD)</td>
<td>55 (9)</td>
<td>54 (9)</td>
<td>0.98</td>
</tr>
<tr>
<td>Male, N (%)</td>
<td>19 (37)</td>
<td>28 (46)</td>
<td>0.07</td>
</tr>
<tr>
<td>Show rate, %</td>
<td>87</td>
<td>75</td>
<td>0.02</td>
</tr>
<tr>
<td>Prep Quality, %</td>
<td>64</td>
<td>58</td>
<td></td>
</tr>
<tr>
<td>Good</td>
<td>33</td>
<td>30</td>
<td>0.005</td>
</tr>
<tr>
<td>Fair</td>
<td>3</td>
<td>12</td>
<td></td>
</tr>
</tbody>
</table>

Health Resource Use and Medical Costs among ERCP Patients

Elizabeth Montgomery, Elise Pelletier, M.S., Ann Roy, M.P.H., Doug Pleskow, MD,* Reimbursement & Outcomes Planning, Boston Scientific Corporation, Marlborough, MA and Gastroenterology, Beth Israel Deaconess Medical Center, Boston, MA.

Purpose: To evaluate health resource use (HRU) and medical costs among ERCP patients.

Methods: All patients undergoing an ERCP in 2002 were identified by CPT-4 procedure codes from a nationally representative private payer claims database, using the date of the first ERCP as the index event. Patients had to be continuously enrolled in a health plan, 18 years of age or older, with no prior ERCP. ERCP-related procedures were defined as diagnostic and surgical procedures that are specific to the common bile duct and pancreas. Treatment patterns, HRU, and medical costs were examined for 1 year prior to and following the index date. Paid claims were used as a proxy for medical costs.

Results: The study included 2345 patients (mean age 53 years; 37% male). PRE-INDEX: Eighty-six percent of patients received at least 1 ERCP-related diagnostic procedure; 17% had at least 1 ERCP-related surgical procedure; 60% of these patients had a lap cholecystectomy within 30 days. Thirty-two percent had an inpatient hospitalization (mean 1.6 admissions; 7.8 aggregate hospital days) and 43% had an emergency room (ER) visit. Overall and ERCP-related costs over 1 year averaged $12756 (median $5918) and $2609 (median $219), respectively. Inpatient facility and professional costs made up 92% of the ERCP-related total costs. INDEX: Total costs averaged $9198 (median $5644); 50% of the ERCPs were performed in an inpatient setting. POST-INDEX: Twenty-two percent of patients received a repeat ERCP (mean 1.6 procedures); 80% of these procedures occurred within the first 6 months. Forty-five percent of patients underwent an ERCP-related diagnostic procedure; 34% had an ERCP-related surgical procedure, with 62% having a lap cholecystectomy within the first 30 days. Thirty-four percent of patients had an inpatient hospitalization (mean 2.1 admissions; 14.2 aggregate hospital days), while 30% had an ER visit. Overall costs averaged $2182 (median $7156); ERCP-related costs averaged $6085 (median $892). Over 95% of these ERCP-related costs were inpatient facility and professional costs.

Conclusions: During the 1 year before and after an ERCP, patients experienced diagnostic testing, repeat ERCP, and interventional procedures that resulted in an average total pancreaticobiliary cost of $43777, with 50% attributable to post-index costs. Additional research into the impact of inpatient hospitalizations and the corresponding length of stay on post-index medical costs may be warranted.

Infliximab Reduces UC-Related Hospitalizations Requiring High-Dose Corticosteroids

W.J. Sandborn, MD,* W. Reinisch, MD, S. Yan, M.S., J.F. Colombel, MD, G.R. Lichtenstein, MD, B.E. Sands, MD, D. Eisenberg, PhD, S. Xu, PhD, A. Olson, MD, P. Rutgeerts, MD Mayo Clinic, Rochester, MN; U Hosp Vienna, Vienna, Austria; Centocor, Malvern, PA; Hopital Claude Huriez, Lille, France; U Penn, Philadelphia, PA; MGI, Boston, MA and Hosp Leuven, Leuven, Belgium.

Purpose: To examine impact of IFX on UC-related hospitalizations (HOSP) in ACT 1 and HOSP requiring high-dose corticosteroids (CS) in ACT 1 & ACT 2.

Methods: 728 pts in ACT 1 & 2 received PBO or IFX 5 or 10 mg/kg at baseline and at wks 2, 6, and q8 wks through wk 22 in ACT 2 and wk 46 in ACT 1. HOSP requiring IV/oral CS ≥ 40mg were compared for 30 wks in the ACT 1 and 2 combined data and for 54 wks in ACT 1, as surrogate of acute severe flare of UC. For ACT 1 wk 144, the # of HOSP was compared between treatment grps, and between non-responders, responders not in remission, and pts in remission at wk 54. ANOVA on van der Waerden scores was used to compare # of HOSP and chi-square test was used to compare percentages.

Results: In ACT 1, wk 54 responses in the combined IFX vs PBO grps were 44.9% vs 19.8% (p < 0.001); remission rates were 34.6% vs 16.5% (p < 0.001). Mean HOSP duration was 14 days; 50% of HOSP occurred within 41 days of baseline; 67.9% of HOSP involved UC-related surgeries/procedures. Reduction of HOSP was sustained through 1yr in ACT 1, with approx 50% lower mean # of HOSP in the combined IFX grp vs PBO (12 vs 22 per 100 pts, p = 0.061). Time to first HOSP was longer in the combined IFX grp vs PBO (p = 0.032). At wk 54, pts in remission and pts in response but not in remission had lower mean # of HOSP (0 and 0 per 100 pts) vs non-responders (23 per 100 pts; p < 0.001). Table 1 shows fewer HOSP with high-dose CS in combined IFX grp vs PBO. Through 54 wks of ACT 1 and
30 wks of ACT 2, 32 pts had HOSP and required high-dose CS; 11 of which had colectomy.

Conclusions: IFX through 1yr sustained the reduction in UC-related HOSP observed through 30 wks of treatment, and showed fewer UC-related HOSP requiring CS≥ 40mg through 30 wks and 1yr. Responders and pts in remission at wk 54 had no UC-related hospitalizations through 1yr, while non-responders had a substantial number of UC-related HOSP.

UC-related hospitalizations requiring high-dose CS

<table>
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<tr>
<th></th>
<th>30 wks (ACT 1 &amp; ACT 2 combined)</th>
<th>54 wks (ACT 1 only)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IFX (n = 484)</td>
<td>PBO (n = 244)</td>
</tr>
<tr>
<td></td>
<td>IFX (n = 243)</td>
<td>PBO (n = 121)</td>
</tr>
<tr>
<td>mean number/100 pts</td>
<td>2.7 (13)</td>
<td>7.8 (19)</td>
</tr>
<tr>
<td>p value</td>
<td>0.025</td>
<td>0.055</td>
</tr>
<tr>
<td>% (n) of pts</td>
<td>2.7% (13)</td>
<td>5.7% (14)</td>
</tr>
<tr>
<td></td>
<td>3.7% (9)</td>
<td>8.3% (10)</td>
</tr>
</tbody>
</table>

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Magnesium Citrate Plus Golytely Versus Golytely Alone in Bowel Preparation for Colonoscopy

Hin W. Lee, MD, Ronald Griffin, MD,* Stanley Condon, MD, Yoshi Mineyama, PhD. Gastroenterology, Loma Linda University Medical Center, Loma Linda, CA and Gastroenterology, Loma Linda VA Medical Center, Loma Linda, CA.

Purpose: Inadequate bowel preparation for colonoscopy can lead to failure to detect missing polyps or small cancers, prolonging the time of procedure, and increasing cost due to the need of a repeat exam. The predictors of poor bowel preparation include male gender, failure to follow instructions, and diabetes. Sharma et al has shown that magnesium citrate pretreatment two hours prior to 4L Golytely compared to Golytely alone reduced the amount of Golytely consumed and the amount of liquid stools aspirated. Sharma et al. subsequently found that magnesium citrate plus 2L Golytely produced a better quality of bowel preparation than 4L Golytely alone. Al-Shuriek, however, found conflicting results, with Golytely preparation superior to the combination of magnesium citrate and 2L Golytely. The aim of this study is to compare Magnesium Citrate given one day prior to 4L Golytely versus 4L Golytely alone in bowel preparation quality for colonoscopy.

Methods: 52 patients scheduled for outpatient colonoscopy were randomized into Groups 1 (n = 28) and 2 (n = 24). Patients in Group 1 received magnesium citrate 300ml at 6:00pm two days prior to colonoscopy, and began a clear liquid diet. They received 4L Golytely at 1:00pm the day prior to colonoscopy. Patients in Group 2 followed the same regimen without magnesium citrate pretreatment. The quality of bowel preparation was evaluated by two experienced endoscopists using a Global Preparation Assessment scale (1-4, 1 = excellent, 4 = poor) and Stool Score (0-11) that were validated in prior studies. The results in the two groups were compared. Statistical significance is defined by P value < 0.05.

Results: The baseline characteristics between the two groups were similar as to age, gender, presence of diabetes, and narcotic use. The mean Global Assessment Scale for Group 1 was 2.07, and for Group 2 was 1.79 (p > 0.05). The mean Stool Score for Group 1 was 3.27, and for Group 2 was 2.77 (p > 0.05). When combining the two groups together, mean Stool Score for left colon was 2.38, and for right colon was 3.69 (p < 0.05).

Conclusions: Magnesium Citrate given one day prior to Golytely did not improve bowel preparation quality compared to Golytely alone. An incidental finding was that the quality of bowel preparation was significantly better in left colon than right colon in both groups.

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Impact of Age on Healthcare Costs and Resource Utilization in Patients with Crohn’s Disease from a payer perspective

O. Dabbous, MD,* H. Thompson, M.S., R. Arjunji, PhD, B. Tang, MD, J. Galovin, PhD, M.I. Rahman, MD Centocor, Inc., Horsham, PA and AHO, Palm Harbor, FL.

Purpose: To evaluate the impact of age on healthcare costs and resource utilization in pts with CD.

Methods: A retrospective analysis, using the PharMetrics database, of pts with a dx of CD (ICD-9 code 555.x) from Jan. 1, 2000 through June 30, 2005 was conducted. Pts had to be continuously enrolled for 6 months pre-and and 12 months post-CD dx, and have 2 distinct claims for CD. Mean/pt healthcare resource utilization and costs were calculated for pts in the yr following their initial CD dx. Outcomes are presented for all pts with CD, and by the following age groups: pediatric (<18 yrs, adults 18 to 64 yrs, and pts ≥ 65 yrs).

Results: The cohort consisted of 13454 CD pts. Over half of the pts were females and the mean age was 42 yrs. Mean annual total healthcare costs for all pediatric CD pts were $16700. The mean healthcare costs were highest among pediatric and pts ≥ 65 with CD ($19347 and $19900). Inpt hospitalization costs had the largest component of the mean annual total cost for all pts followed by drug, and outpt costs. Resource utilization was highest for pts ≥ 65 yrs.

Conclusions: There is limited data assessing the healthcare costs and resource utilization in pts with CD by age group. Healthcare costs among this pt population are high. Pediatric pts and pts ≥ 65 yrs had higher mean healthcare costs than adults 18 to 64 yrs, primarily driven by inpt hospitalizations. New therapies that can reduce hospitalizations have the potential to decrease overall cost of care for CD pts.

Mean Healthcare Costs and Resource Utilization

<table>
<thead>
<tr>
<th></th>
<th>All Pts</th>
<th>Pediatric &lt; 18yrs</th>
<th>Adults 18–64yrs</th>
<th>Adults ≥65yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>N (%)</td>
<td>13,454</td>
<td>864 (6.0)</td>
<td>12190 (91)</td>
<td>400 (3.0)</td>
</tr>
<tr>
<td>Outcome</td>
<td>Mean</td>
<td>Mean</td>
<td>Mean</td>
<td>Mean</td>
</tr>
<tr>
<td>Female (%)</td>
<td>55</td>
<td>45</td>
<td>56</td>
<td>57</td>
</tr>
<tr>
<td>Age (yrs)</td>
<td>42</td>
<td>13</td>
<td>43</td>
<td>75</td>
</tr>
<tr>
<td>Deyo-Charlson Comorbidity Index Score</td>
<td>1.2</td>
<td>1.0</td>
<td>1.2</td>
<td>3.0</td>
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<tr>
<td>Total healthcare costs</td>
<td>$16,700</td>
<td>$19,347</td>
<td>$16,407</td>
<td>$19,900</td>
</tr>
<tr>
<td>Inpt costs</td>
<td>$7,875</td>
<td>$9,615</td>
<td>$7,629</td>
<td>$11,601</td>
</tr>
<tr>
<td>Outpt costs</td>
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<td>$2,171</td>
<td>$1,751</td>
<td>$1,970</td>
</tr>
<tr>
<td>ER costs</td>
<td>$323</td>
<td>$306</td>
<td>$321</td>
<td>$405</td>
</tr>
<tr>
<td>Physician costs</td>
<td>$1,005</td>
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</tr>
<tr>
<td>Lab costs</td>
<td>$454</td>
<td>$697</td>
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<td>$322</td>
</tr>
<tr>
<td>Drug costs</td>
<td>$2,859</td>
<td>$3,114</td>
<td>$2,878</td>
<td>$1,717</td>
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<tr>
<td>Total healthcare visits</td>
<td>15</td>
<td>15</td>
<td>15</td>
<td>20</td>
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<tr>
<td>Inpt stays (days)</td>
<td>0.5 (2.8)</td>
<td>0.5 (3.3)</td>
<td>0.5 (2.7)</td>
<td>1.0 (6.4)</td>
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<tr>
<td>Outpt visits</td>
<td>2.5</td>
<td>3.2</td>
<td>2.4</td>
<td>3.6</td>
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<tr>
<td>ER visits</td>
<td>0.5</td>
<td>0.5</td>
<td>0.5</td>
<td>0.6</td>
</tr>
<tr>
<td>Physician visits</td>
<td>11.3</td>
<td>11.0</td>
<td>11.2</td>
<td>15.0</td>
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<tr>
<td>Lab visits</td>
<td>4.6</td>
<td>5.0</td>
<td>4.5</td>
<td>6.2</td>
</tr>
<tr>
<td># of prescriptions</td>
<td>24.8</td>
<td>20.1</td>
<td>25.0</td>
<td>27.7</td>
</tr>
</tbody>
</table>

1055

Quality of Life (QOL) in Inflammatory Bowel Disease (IBD) and Irritable Bowel Syndrome (IBS): A Pilot Comparison of Clinic (CL) and Online Respondents (OLR)

Tiffany N. Havlicek, M.S., Jason Bratten, B.S., Margo Klein, R.N., Laurie Keefer, PhD, Michael P. Jones, MD,* Division of Gastroenterology, Northwestern University, Chicago, IL.
Purpose: The internet is increasingly used to recruit and evaluate pts with a variety of disorders. Internet-based studies allow access to potentially large samples but no data exist comparing OLR and CL pts with similar GI disorders. We conducted a preliminary assessment of QoL in pts with active IBD and IBS recruited from a gastroenterology clinic and online.

Methods: Pts were recruited from a university GI clinic and several online sites (IBSgroup; Healingwell; Northwestern Center for Functional Gastrointestinal and Motility Disorders). The diagnosis of IBD and IBS was confirmed for CL pts, but OLR were self-identified. For this pilot study, type and extent of IBD were not ascertained. Respondents completed the SF-36 and the IBS-QOL. While the IBS-QOL is regarded as condition-specific for IBS, it correlates highly with the IBDQ (r = −0.83) and has been used in IBD populations (Cin Gastro Hepat 2006;4:474).

Results: At the time of abstract submission, the IBD group included 48 CL pts and 71 OLR. The IBS group included 135 CL pts and 47 OLR. IBD CL and OLR groups did not differ by age (mean ± SDEV: 38 ± 13 vs. 40 ± 12; p = 0.55). IBD OLR were more likely to be female (59/12M vs. 29/19M; p = 0.01). IBS CL and OLR groups also did not differ by age (37 ± 13 vs. 38 ± 12; p = 0.45). IBS OLR were more likely to be male (37/14M vs. 126/23M; p = 0.06). For both IBS and IBD, OLR had clinically and statistically significantly poorer QoL as measured on all scales of the SF-36 and IBS-QOL. Total IBS-QOL and SF-36 Mental and Physical Component Summaries (MCS and PCS) scores are shown in the figure. For SF-36, lower values equate with poorer QOL while higher values indicate poorer QOL for the IBS-QOL. Differences were maintained when the analysis was controlled for gender.

Conclusions: For both IBS and IBD, OLR had significantly poorer QOL. These preliminary data demonstrate that OLR may represent a clinically distinct population requiring further characterization particularly with respect to healthcare utilization and gender differences. Data obtained from online surveys may not generalize to broader clinical populations. [figure1]

Canadian IBS Observational Study Shows Tegaserod Patients Have Greater Improvements in QoL as Compared to the Control Group

P Pare, MD,*  J. Gray, MD, S. Lam, MD, R. Balshaw, PhD, S. Khorasheh, M.A., M. Barbeau, B.A., S. Kelly, PhD, M. Omar, PhD. Centre Hospitalier Affilie Universitaire de Quebec, Quebec, QC, Canada; Hawse Clinic, Calgary, AB, Canada; Syreon Corporation, Vancouver, Canada; Novartis Pharmaceuticals Inc, Dorval, Canada and Novartis Pharmaceuticals Corp, East Hanover.

Purpose: Abdominal pain/discomfort, bloating and constipation are gastrointestinal (GI) symptoms related to irritable bowel syndrome (IBS), associated with impaired health-related quality of life (QoL) and work productivity. LOGIC (Longitudinal Outcomes Study of GI Symptoms in Canada) is a prospective, observational study that followed patients (pts) for 1 year and evaluated the treatment patterns and health outcomes of pts with IBS symptoms in Canada.

Methods: LOGIC enrolled 1556 pts from 147 community and specialist physician sites in Canada. Clinical data and pt-reported outcomes were collected at baseline (BL) and Months 1, 3, 6, 9 and 12. QoL was assessed with the IBS-QOL. Tegaserod pts (T) at BL and non-tegaserod pts (Non-T) were compared. Unadjusted mean QoL at BL and Month 12 (M12) were compared between groups using the Wilcoxon rank-sum test. The within-subject slope of the QoL scores was compared using a mixed model ANOVA. The model compared the average slope of the T and Non-T pts after adjusting for IBS severity (measured by the Total Symptom Severity score), usual bowel pattern (normal, constipated, diarrhea, alternating), duration of symptoms, gender, history of T use, and BL IBS-QOL.

Results: Of 1556 pts enrolled, 1375 were either T-users (n = 362) or Non-T-users (n = 1013). At BL, T pts had a mean IBS-QOL score of 61.46 compared to Non-T pts (68.36, p < 0.001). By M12, the unadjusted mean scores were 67.65 for T and 72.63 for Non-T pts (p = 0.476). After adjusting for BL covariates, T pts showed significantly greater improvement in IBS-QOL scores over the 12 months compared with non-T pts (mean improvement of 0.69 vs. 0.31 points/month or 8.28 vs. 3.72 over 12 months, respectively, p < 0.001).

Conclusions: The LOGIC study followed treatment in a real-world setting with physicians treating pts with IBS symptoms. Pts using T at BL showed more improvement in their IBS-QOL scores than the Non-T pts at 12 months. This significant difference was also observed when data up to month 6 were analyzed, suggesting that the effect appears fairly early and is stable over time. This is the first long-term prospective observational study to show that T has a positive impact on health-related QoL in a usual care setting. This research was funded by Novartis.

A Case-Control Study of Risk Factors for Ischemic Colitis

L. Chang,* K.H. Kahler, M.J. Czaja,* J. Kralstein. CURE, UCLA, Los Angeles, CA; Novartis Pharmaceuticals Corp, East Hanover, NJ and HealthCore Inc, Wilmington, DE.

Purpose: Several studies have uncovered a positive association between gastrointestinal (GI) motility disorders, including irritable bowel syndrome (IBS) and constipation, and ischemic colitis (IC). This large-scale population study explored other potential risk factors for IC.

Methods: A matched case-control study was conducted using the HealthCore Managed Care Database. From 1/1/2000 to 2/28/2005, patients with IC (diagnosis of vascular insufficiency of the intestine on the same day as, or within 3 months of, colonoscopy or colon resection) were included in the case group. Each patient was matched with 4 non-IC controls based on age, gender, sex, length of pre-index follow-up, and health plan/geographic

<table>
<thead>
<tr>
<th>Variable</th>
<th>Odds Ratio</th>
<th>95% Wald Confidence Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>IBS</td>
<td>2.005</td>
<td>1.622</td>
</tr>
<tr>
<td>Constipation</td>
<td>1.621</td>
<td>1.339</td>
</tr>
<tr>
<td>Aortic surgery</td>
<td>3.576</td>
<td>1.791</td>
</tr>
<tr>
<td>Hypotension</td>
<td>1.853</td>
<td>1.411</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>1.337</td>
<td>1.116</td>
</tr>
<tr>
<td>Abdominal surgery</td>
<td>1.255</td>
<td>1.015</td>
</tr>
<tr>
<td>12-Month oral contraceptive use</td>
<td>1.053</td>
<td>1.004</td>
</tr>
<tr>
<td>Shock</td>
<td>4.318</td>
<td>2.299</td>
</tr>
<tr>
<td>Colon carcinoma</td>
<td>1.684</td>
<td>1.186</td>
</tr>
<tr>
<td>Atherosclerosis</td>
<td>1.242</td>
<td>1.005</td>
</tr>
<tr>
<td>Operations on the cardiovascular system</td>
<td>1.209</td>
<td>1.011</td>
</tr>
<tr>
<td>Ileostomy</td>
<td>3.801</td>
<td>2.005</td>
</tr>
<tr>
<td>Laparoscopy</td>
<td>2.901</td>
<td>1.252</td>
</tr>
<tr>
<td>Bloating</td>
<td>2.022</td>
<td>1.511</td>
</tr>
<tr>
<td>Dyspepsia</td>
<td>1.325</td>
<td>1.027</td>
</tr>
<tr>
<td>Dysentery</td>
<td>2.904</td>
<td>1.391</td>
</tr>
<tr>
<td>Deyo-Charlson score</td>
<td>1.045</td>
<td>1.014</td>
</tr>
<tr>
<td>12-Month laxative use</td>
<td>4.725</td>
<td>3.711</td>
</tr>
<tr>
<td>12-Month H2 blocker use</td>
<td>1.065</td>
<td>1.017</td>
</tr>
</tbody>
</table>
location. The following pre-index IC risk factors were evaluated: cardiovascular, metabolic, or GI-related comorbidities; IBS/constipation-related comorbidities; cardiovascular, GI, or gynecologic surgeries; GI procedures; and GI medications. Multivariate conditional logistic regression was used to identify significant pre-index IC risk factors.

**Results:** A total of 1754 patients with IC and 6970 non-IC controls were identified (primarily women[64%]; mean ages, 63 and 62 years, respectively). Per the multivariate regression model, 19 factors were associated with increased risk for IC (as indicated by odds ratios greater than 1). For example, those with IBS were two times more likely than those without IBS to develop IC after controlling for all other factors.

**Conclusions:** Findings from this large-scale database study confirm that IBS and constipation are associated with IC, and they identify other risk factors that increase the risk for IC.

### 1058

**Frequent Nocturnal Complaints of Heartburn and Acid Regurgitation Are Associated with Higher GERD Severity Scores**  
Lawrence F. Johnson, MD, Bonnie B. Dean, PhD, Daniel Aguilar, M.P.H., Ronnie Fass, MD, James E. McGuigan, MD, William C. Orr, PhD, Diana Morgenstern, MD, Dubois W. Robert, MD,∗  
Outcomes Research, Cerner LifeSciences, Beverly Hills, CA; University of Alabama at Birmingham, Birmingham, AL; University of Arizona, Tucson, AZ; University of Florida College of Medicine, Gainesville, FL; Lynn Health Science Institute, Oklahoma City, OK and Wyeth Pharmaceuticals, Collegeville, PA.

**Purpose:** To assess the relationship between frequent nighttime symptoms of gastroesophageal reflux disease (GERD) and patient perception of GERD severity.

**Methods:** A general population of US adults participated in a web survey, which included the GERD Symptom & Medication Questionnaire (GERD-SMQ), a validated GERD screener. Frequency and severity of nighttime and daytime heartburn and acid regurgitation during the previous 3 months were each assessed. Nighttime GERD (NTG) cases were defined as: (a) ≥2 nights/week with classic GERD symptoms, or (b) <2 nights/week with classic GERD symptoms but no daytime symptoms; daytime GERD (DTG) cases were GERD cases not satisfying NTG criteria. The prevalence of frequent nighttime and daytime classic symptoms (acid regurgitation and heartburn) and AG-Sx during the previous 3 months were assessed. Nighttime GERD (NTG) was defined as: (a) ≥2 nights/week with classic GERD symptoms, or (b) <2 nights/week with classic GERD symptoms but no daytime symptoms; daytime GERD (DTG) cases were GERD cases not satisfying NTG criteria. The prevalence of frequent AG-Sx (≥2 days or nights/wk) was assessed.

**Results:** 2805 of 18213 invited to participate responded. Of eligible respondents (n = 2603, mean age = 46 years, 55% women), 668 were GERD cases with current symptoms; 303 met NTG criteria and 365 met DTG criteria. Compared with DTG cases, more NTG cases reported at least one nighttime AG-Sx (84% vs 68%, p < 0.05). More NTG cases reported each nighttime AG-Sx (p < 0.05 for all except snoring) compared with DTG cases (see table). A greater proportion of NTG cases also reported at least one daytime AG-Sx (75% vs 60%, p < 0.05). NTG cases reported more daytime AG-Sx (p < 0.05 for all except sinusitis) compared with DTG cases (data not shown).

**Conclusions:** Patients with frequent nocturnal classic GERD symptoms have more frequent nighttime and daytime AG-Sx which may contribute to the overall burden of illness in GERD.

### Prevalence of Frequent Nighttime AG-Sx by NTG vs DTG

<table>
<thead>
<tr>
<th>Symptom</th>
<th>NTG (%)</th>
<th>DTG (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Globus</td>
<td>37.6</td>
<td>14.5</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>47.2</td>
<td>37.0</td>
</tr>
<tr>
<td>Dry coughing</td>
<td>40.3</td>
<td>29.0</td>
</tr>
<tr>
<td>Throat clearing</td>
<td>54.1</td>
<td>34.5</td>
</tr>
<tr>
<td>Sore throat</td>
<td>34.0</td>
<td>14.0</td>
</tr>
<tr>
<td>Snoring</td>
<td>48.5</td>
<td>41.7</td>
</tr>
<tr>
<td>Wheezing</td>
<td>27.7</td>
<td>17.0</td>
</tr>
<tr>
<td>Choking</td>
<td>19.8</td>
<td>6.3</td>
</tr>
<tr>
<td>Chest pain</td>
<td>39.3</td>
<td>12.1</td>
</tr>
</tbody>
</table>

*p < 0.05 for differences in prevalence among NTG vs DTG*

### 1060

**Increasing BMI Is Associated with Classic and Atypical GERD Symptoms**  
Bonnie B. Dean, PhD, Lawrence F. Johnson, MD, Brian Calimlim, Daniel Aguilar, M.P.H., James E. McGuigan, MD, William C. Orr, MD, Ronnie Fass, MD, Diana Morgenstern, MD, Ning Yan, PhD, Robert W. Dubois, MD,∗  
Medicine, University of Alabama, Birmingham, AL; Cerner LifeSciences, Beverly Hills, CA; University of Arizona, Tucson, AZ; University of Florida, Gainesville, FL; Lynn Health Science Institute, Oklahoma City, OK and Wyeth Pharmaceuticals, Collegeville, PA.

**Purpose:** To assess symptoms considered to be atypical for GERD (AG-Sx) among individuals with nighttime GERD (NTG) and daytime GERD (DTG).

**Methods:** A web survey among US adults was conducted, which included the GERD Symptom & Medication Questionnaire (GERD-SMQ), a validated GERD screener. Frequency and severity of nighttime and daytime classic symptoms (acid regurgitation and heartburn) and AG-Sx during the previous 3 months were assessed. Nighttime GERD (NTG) was defined as: (a) ≥2 nights/week with classic GERD symptoms, or (b) <2 nights/week with classic GERD symptoms but no daytime symptoms; daytime GERD (DTG) cases were GERD cases not satisfying NTG criteria. The prevalence of frequent AG-Sx (≥2 days or nights/wk) was assessed.

**Results:** 2805 of 18213 invited to participate responded. Of eligible respondents (n = 2603, mean age = 46 years, 55% women), 668 were GERD cases with current symptoms; 303 met NTG criteria and 365 met DTG criteria. Compared with DTG cases, more NTG cases reported at least one nighttime AG-Sx (84% vs 68%, p < 0.05). More NTG cases reported each nighttime AG-Sx (p < 0.05 for all except snoring) compared with DTG cases (see table). A greater proportion of NTG cases also reported at least one daytime AG-Sx (75% vs 60%, p < 0.05). NTG cases reported more daytime AG-Sx (p < 0.05 for all except sinusitis) compared with DTG cases (data not shown).

**Conclusions:** Patients with frequent nocturnal classic GERD symptoms have more frequent nighttime and daytime AG-Sx which may contribute to the overall burden of illness in GERD.

### Prevalence of Frequent Nighttime AG-Sx During the Previous 3 Months

<table>
<thead>
<tr>
<th>Symptom</th>
<th>NTG (%)</th>
<th>DTG (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Globus</td>
<td>37.6</td>
<td>14.5</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>47.2</td>
<td>37.0</td>
</tr>
<tr>
<td>Dry coughing</td>
<td>40.3</td>
<td>29.0</td>
</tr>
<tr>
<td>Throat clearing</td>
<td>54.1</td>
<td>34.5</td>
</tr>
<tr>
<td>Sore throat</td>
<td>34.0</td>
<td>14.0</td>
</tr>
<tr>
<td>Snoring</td>
<td>48.5</td>
<td>41.7</td>
</tr>
<tr>
<td>Wheezing</td>
<td>27.7</td>
<td>17.0</td>
</tr>
<tr>
<td>Choking</td>
<td>19.8</td>
<td>6.3</td>
</tr>
<tr>
<td>Chest pain</td>
<td>39.3</td>
<td>12.1</td>
</tr>
</tbody>
</table>

*p < 0.05 for differences in prevalence among NTG vs DTG*
Purpose: To evaluate the relationship between body mass index (BMI) and symptoms of GERD, both classic and the less recognized potential symptoms such as cough.

Methods: A sample of US adults participated in a web survey assessing weight, height, and the GERD Symptom & Medication Questionnaire (GERD-SMQ), a validated screening tool. Frequency of classic and atypical GERD symptoms (AG-Sx) were determined during the previous 3 months. Respondents were classified into the following weight categories: low/normal (BMI < 25), overweight (BMI 25.0–29.9), and obese (BMI ≥ 30).

The chi square procedure compared differences in proportions of respondents with frequent symptoms (2 or more days/night per week) by BMI category.

Results: A total of 2805 of 18213 invited to participate responded to the survey. 2360 satisfied the study criteria and were included in this analysis. Among GERD cases, there was a significant higher proportion of AG-Sx among those with low/normal weight, 32% (n = 775) overweight, and 35% (n = 831) obese. Results supported an association between increasing BMI and occurrence of both classic and AG-Sx. A significantly greater proportion of overweight and obese persons reported classic and AG-Sx compared to persons in the low to normal range of BMI. Increased BMI was significantly associated with heartburn, acid regurgitation, and particularly with AG-Sx such as coughing, snoring, and throat clearing.

Conclusions: In a large general adult population, not only were classic symptoms of GERD associated with increasing BMI, but some AG-Sx were as well. GERD may represent a common and underappreciated consequence of obesity that can present with classic symptoms, and may also have atypical manifestations.

GERD symptoms by BMI

<table>
<thead>
<tr>
<th>Percent with frequent symptoms</th>
<th>BMI&lt;25.0</th>
<th>BMI 25.0–29.9</th>
<th>BMI≥30.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classic Symptoms</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heartburn</td>
<td>10</td>
<td>13</td>
<td>16*</td>
</tr>
<tr>
<td>Acid regurgitation</td>
<td>7</td>
<td>9</td>
<td>10*</td>
</tr>
<tr>
<td>Atypical Symptoms</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Globus</td>
<td>11</td>
<td>11</td>
<td>15*</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>25</td>
<td>27</td>
<td>38*</td>
</tr>
<tr>
<td>Dry cough</td>
<td>20</td>
<td>19</td>
<td>27*</td>
</tr>
<tr>
<td>Throat clearing</td>
<td>29</td>
<td>30</td>
<td>38*</td>
</tr>
<tr>
<td>Sore throat</td>
<td>10</td>
<td>11</td>
<td>13</td>
</tr>
<tr>
<td>Snoring</td>
<td>19</td>
<td>32</td>
<td>44*</td>
</tr>
<tr>
<td>Wheezing</td>
<td>9</td>
<td>11</td>
<td>16*</td>
</tr>
<tr>
<td>Choking</td>
<td>5</td>
<td>6</td>
<td>8*</td>
</tr>
<tr>
<td>Chest pain</td>
<td>8</td>
<td>10</td>
<td>14*</td>
</tr>
<tr>
<td>Hoarse voice</td>
<td>8</td>
<td>8</td>
<td>9</td>
</tr>
</tbody>
</table>

*p < 0.05 across severity groups.

1062

Patients with Severe GERD Report More Frequent Nighttime and Daytime Atypical GERD Symptoms

William C. Orr, MD, Daniel Aguilar, M.P.H., Bonnie B. Dean, PhD, Lawrence F. Johnson, MD, Ronnie Fass, MD, James E. McGuigan, MD, Diana Morgenstern, MD, Robert W Dubois, MD.* Sleep & GI Physiology Lab, Lynn Health Science Institute, Oklahoma City, OK; Cerner LifeSciences, Beverly Hills, CA; University of Alabama at Birmingham, Birmingham, AL; University of Arizona, Tucson, AZ; University of Florida College of Medicine, Gainesville, FL and Wyeth Pharmaceuticals, Collegeville, PA.

Purpose: To assess the prevalence of nighttime and daytime symptoms considered to be atypical for GERD (AG-Sx) by GERD severity level.

Methods: A web survey among US adults was conducted, which included the GERD Symptom & Medication Questionnaire (GERD-SMQ), a validated GERD screener. Frequency and severity of nighttime and daytime classic GERD symptoms (Sx) (heartburn and acid regurgitation) and AG-Sx (table) during the previous 3 months were assessed. GERD cases with AG-SM-Q score ≥ 10-point Likert scale during the daytime or nighttime. Severity classification was: mild (1–4), moderate (5–7) and severe (8–10). Prevalence of frequent (>2 days/night per wk) AG-Sx was assessed by severity level.

Results: 2805 of 18213 invited to participate responded. 2603 satisfied the study criteria (mean age = 46 years; 55% women). Among GERD cases with severe AG-Sx, significantly lower mental and physical HRQOL scores for each Sx assessed. Among GERD patients, there may be an incremental negative impact of AG-Sx on mental and physical functioning.

Mean SF-36 Scores Among GERD Cases With Frequent Nighttime AG-Sx

Mean MCS | Mean PCS
Nighttime AG-Sx | AG-Sx | No AG-Sx | AG-Sx | No AG-Sx
---|---|---|---|---
Globus | 37.5 | 43.7 | 36.9 | 44.5
Sinusitis | 39.6 | 44.1 | 39.8 | 44.7
Dry cough | 38.8 | 44.0 | 38.2 | 44.9
Throat clearing | 39.0 | 44.6 | 38.6 | 45.7
Sore throat | 37.8 | 43.5 | 37.2 | 44.3
Snoring | 41.0 | 43.2 | 40.4 | 44.4
Wheezing | 37.3 | 43.6 | 36.6 | 44.3
Choking | 36.5 | 43.0 | 35.0 | 43.7
Chest pain | 38.2 | 43.5 | 37.5 | 44.3

*p < 0.007 for all mean differences (both MCS and PCS) between GERD cases with and without AG-Sx

1061

Reduced Mental and Physical Functioning among Patients with Frequent Atypical GERD Symptoms

James E. McGuigan, MD, Daniel Aguilar, M.P.H., Bonnie B. Dean, PhD, William C. Orr, MD, Ronnie Fass, MD, Lawrence F. Johnson, MD, Diana Morgenstern, MD, Robert W Dubois, MD.* Department of Medicine, University of Florida College of Medicine, Gainesville, FL; Cerner LifeSciences, Beverly Hills, CA; Lynn Health Science Institute, Oklahoma City, OK; University of Arizona, Tucson, AZ; University of Alabama at Birmingham, Birmingham, AL and Wyeth Pharmaceuticals, Collegeville, PA.

Purpose: To assess health-related quality of life (HRQOL) among GERD cases with frequent symptoms considered to be atypical for GERD (AG-Sx).

Methods: A sample of US adults participated in a web survey including the GERD Symptom & Medication Questionnaire (GERD-SMQ), a validated GERD screener. Frequency of nighttime and daytime AG-Sx during the previous 3 months were assessed. Frequent symptoms were defined as ≥2 days/night per week with each AG-Sx. The Short-Form-36 (SF-36) assessed HRQOL. SF-36 Mental Component Summary (MCS) and Physical Component Summary (PCS) scores were calculated and mean differences were compared for GERD cases with vs. without frequent AG-Sx. Lower mean scores signified worse HRQOL.

Results: 2805 of 18213 invited to participate responded. 2603 satisfied the study criteria (mean age = 46 years, 55% women); 701 were GERD cases. Overall, 74% and 66% of GERD cases reported at least one nighttime and daytime AG-Sx, respectively. Mean MCS and PCS scores among GERD cases were significantly lower among those with vs without each nighttime AG-Sx (p < 0.007 for all AG-Sx). Similar reductions in mean MCS and PCS were seen among GERD cases with daytime AG-Sx when compared to those without each daytime symptom. Mean MCS and PCS scores were between 4 and 10 points lower among GERD cases with AG-Sx compared with those without AG-Sx.

Conclusions: Nighttime or daytime AG-Sx were associated with significantly lower mental and physical HRQOL scores for each Sx assessed. Among GERD patients, there may be an incremental negative impact of AG-Sx on mental and physical functioning.
with current classical GERD symptoms, 155 were mild, 341 moderate, and 168 severe. All nighttime AG-Sx exhibited increasing prevalence with increasing GERD severity (see table). The prevalence of nighttime AG-Sx was higher among severe GERD cases (p < 0.05 for all AG-Sx except snoring). Similarly, all daytime AG-Sx except choking exhibited increasing prevalence with increasing GERD severity (p < 0.05 for all two-way comparisons across severity levels)(data not shown).

**Conclusions:** All daytime and nighttime AG-Sx were most prevalent in those with severe GERD. Among GERD patients, AG-Sx are common and may be indicative of more severe disease.

Prevalence of Frequent Nighttime AG-Sx by GERD Severity

<table>
<thead>
<tr>
<th>Nighttime AG-Sx</th>
<th>Mild (n = 155)</th>
<th>Moderate (n = 341)</th>
<th>Severe (n = 168)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Globus</td>
<td>13.6</td>
<td>22.0</td>
<td>42.3</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>32.9</td>
<td>41.1</td>
<td>51.8</td>
</tr>
<tr>
<td>Dry cough</td>
<td>22.6</td>
<td>33.4</td>
<td>47.0</td>
</tr>
<tr>
<td>Throat clearing</td>
<td>29.0</td>
<td>44.3</td>
<td>56.0</td>
</tr>
<tr>
<td>Sore throat</td>
<td>10.3</td>
<td>22.3</td>
<td>36.9</td>
</tr>
<tr>
<td>Snoring</td>
<td>37.4</td>
<td>46.0</td>
<td>50.0</td>
</tr>
<tr>
<td>Wheezing</td>
<td>14.8</td>
<td>19.9</td>
<td>32.7</td>
</tr>
<tr>
<td>Choking</td>
<td>6.5</td>
<td>11.1</td>
<td>20.8</td>
</tr>
<tr>
<td>Chest pain</td>
<td></td>
<td></td>
<td>25.2</td>
</tr>
</tbody>
</table>

*p < 0.05, mild vs. moderate; †p < 0.05, mild vs. severe; ∧p < 0.05, moderate vs. severe

**Conclusions:** The MDQ-2W is a reliable instrument which accurately captures dysphagia symptoms over a two week period similar to that gained during a physician interview.

### 1064

The Clinical Outcomes of Electively Intubated Patients Undergoing Urgent/Emergent EGD for Acute UGI Bleeding

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**Purpose:** Acute UGI bleeding and endoscopy have potential risks of aspiration and negative outcomes. Airway protection is expected to decreased such risk but is only reserved for the minority of patients and is left to the discretion of the endoscopist. The outcomes of prophylactically intubated patients undergoing urgent/emergent diagnostic and/or therapeutic EGD for UGI bleeding.

Clinical characteristics and outcomes in UGI bleeders in the ICU

<table>
<thead>
<tr>
<th>Total pts</th>
<th>Non-ventilated (n = 136)</th>
<th>Ventilated for other reasons (n = 14)</th>
<th>Elective intubation (n = 15)</th>
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<tr>
<td>Mean age (in ICU) (n = 165)</td>
<td>64.6</td>
<td>64.5</td>
<td>71.3</td>
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<tr>
<td>Duration of procedure (mean) (min)</td>
<td>21.6</td>
<td>19.6</td>
<td>28.4</td>
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<tr>
<td>Length of stay (ICU) (d)</td>
<td>4.2</td>
<td>3</td>
<td>13.2</td>
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<tr>
<td>Length of stay (total) (d)</td>
<td>10.5</td>
<td>9.5</td>
<td>18.7</td>
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<tr>
<td>Findings at EGD</td>
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<tr>
<td>&gt; Varices</td>
<td>34</td>
<td>28</td>
<td>0</td>
</tr>
<tr>
<td>&gt; Clean based ulcer</td>
<td>37</td>
<td>34</td>
<td>2</td>
</tr>
<tr>
<td>&gt; Ulcer with adherent clot</td>
<td>4</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>&gt; Ulcer with visible vessel</td>
<td>12</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>&gt; Eosphagitis</td>
<td>43</td>
<td>35</td>
<td>4</td>
</tr>
<tr>
<td>&gt; D&gt; grade C or D</td>
<td>18</td>
<td>13</td>
<td>2</td>
</tr>
<tr>
<td>&gt; Dieulafay</td>
<td>8</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>&gt; Tumor</td>
<td>3</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>&gt; MWT</td>
<td>8</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>&gt; AVM</td>
<td>2</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Complications</td>
<td></td>
<td></td>
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<tr>
<td>&gt; Aspiration PNA</td>
<td>9</td>
<td>3 (2.2%)</td>
<td>n/a</td>
</tr>
</tbody>
</table>

*p < 0.05
1065

Venlafaxine (VEN) Experience in Patients (pts) with Visceral and Somatic Hypersensitivity Syndrome (VSHS)

Marcelo A. Barreiro, MD, M.Sc.* Gary D. James, PhD, Daniel D. Osorio, Disorders of Function Clinic, Binghamton University, Binghamton, NY and Decker School of Nursing and Institute for Primary and Preventative Health Care, Binghamton University, Binghamton, NY.

Purpose: Clinicians must deal with pts with Functional Gastrointestinal Disorders and other coexisting Functional Disorders, heretofore called VSHS, for which there are limited therapeutic options. Antidepressants are useful in the management of many of these pts. A serotonin-norepinephrine re-uptake inhibitor Venlafaxine (VEN) has been reported of use in some pain syndromes.

Aims: 1) To determine response and adherence to treatment with VEN in pts with VSHS 2) To evaluate in an open-label, observational pilot study, whether VEN decreased reported pain and psychosomatic symptoms (PS) in patients with VSHS.

Methods: The subjects of this study were 138 pts seen at the DFC and diagnosed with VSHS. Published symptom-based diagnostic criteria were used to determine FD. PS were evaluated using the SCL-90-R, health related quality of life (QOL) was assessed using the QOL Inventory (QOLI) and pain severity was evaluated using a 10 cm Visual Analog Scale. Pain was further characterized as visceral or somatic. All patients signed consent. All pts received a 20 min education session about the use of VEN to treat their symptoms.

Results: Of 138 pts offered VEN 24 refused treatment, 12 accepted treatment but never took the drug, 18 discontinued VEN prematurely because of symptoms of Hypervigilance(HV) and 15 failed to return for scheduled appointments. Eleven pts were discontinued from treatment because of miscellaneous, non-VEN related reasons. Two pts took VEN as instructed and didn't improve. Thirty-three pts improved and agreed to return to the DFC for retesting. Pain scores declined (−4.5 ± 2.8, p < .001), QOLI improved (+1.8 points, p < .001), the Global Symptom Index from the SCL-90-R declined (−10.7 points, p < .001) and systolic (−11 mmHg, p < .001) and diastolic (−6 mmHg, p < .001) pressure declined following VEN treatment. Another 23 pts clinically improved but lacked follow-up measurements. Dosages of VEN ranged from 37.5 to 300 mg/day. The average length of treatment was 191 days.

Conclusions: Because of perceived social stigma, non-compliance or HV, 50% of the VSHS patients did not benefit from a potentially beneficial medication. Forty one percent had good tolerance to VEN and 24% had significant measurable improvement in clinical and reported psychological symptoms. These results underscore the difficulties of practicing physicians who treat this complex group of pts.

1066

Anal Cancer in Ontario, 1971–2002: The Relationship to Socioeconomic Status, Gender and the HIV Epidemic

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Purpose: Epidermoid anal cancer (EAC) may be on the rise, disproportionately affecting certain populations such as women with other HPV-related conditions and persons with HIV. In this population-based study, we examine the incidence and survival from EAC for the entire population of Ontario, Canada.

Methods: Using the Ontario Cancer Registry (OCR), we identified all new cases of EAC diagnosed between 1971–2002. The cohort was divided into 3 eras based on the date of diagnosis, pre HIV (1971–80), HIV (1981–1995) and HAART (1996–2002). Age- and sex-adjusted incidence rates were calculated. Change in incidence over the study period was tested using regression techniques. Survival was assessed using Cox proportional hazards models, incorporating age at diagnosis, sex, era and income into the models.

Results: We identified 1706 cases of EAC during the study period, 247 (15%) in the pre-HIV era, 806 (50%) in the HIV era, and 599 (35%) in the HAART era. Women accounted for 66% of the cases (p < 0.0001 vs. men). Mean age at diagnosis was 62 years; women were significantly older than men at diagnosis (p < 0.0001). More cases lived in low-income areas (p < 0.0001). The incidence of EAC rose significantly during the study period (p < 0.0001). In 1971, the incidence overall, amongst women and amongst men was 0.30, 0.46, and 0.13 per 100000, respectively. In 2002, incidence had increased to 1.08 (overall), 1.54 (women) and 0.60 per 100000 (men). Survival was better in women and younger patients, although there was a significant interaction between age and sex. For each 5 year increase in age at diagnosis, women’s survival was 22% worse whereas men’s survival was 13% worse. Survival was poorer in the HAART era relative to the HIV era (HR: 1.24, 95% C.I.: 1.05–1.46).

Conclusions: In Ontario, the incidence of EAC rose significantly between 1971–2002, disproportionately affecting women and persons living in low-income areas. The sex distribution of EAC may reflect a higher burden of other HPV-related diseases, higher rates of anal intercourse than previously recognized, or greater susceptibility to EAC amongst women. The poorer survival in those diagnosed in the HAART era may be due to the development of EAC in long-term HIV survivors. Further study of HIV- and sex-related factors of EAC is required to explain our findings.

1067

An Effectiveness and Cost-Effectiveness Analysis of Surveillance Colonoscopy in Patients with a Personal History of Adenomas

Sameer D. Saini, MD, Philip S. Schoenfeld, MD, Sandeep Vyan, MD,* Internal Medicine, University of Michigan, Ann Arbor, MI.

Purpose: The purpose of this study was to model the effectiveness and cost-effectiveness of multi-society guideline recommendations for post-polypectomy surveillance colonoscopy.

Methods: A Markov model was developed to compare the effectiveness and cost-effectiveness of several surveillance strategies. The published literature was used to estimate polyp and cancer transition rates, risks, benefits, and costs. The target population was men and women over the age of 50 with a new diagnosis of colonic adenomas. The model was calibrated to one- and three-year data from the National Polyp Study and lifetime data from the SEER registry.

Results: In the base-case analysis, colonoscopy every 3 years for all patients (the 3/3 strategy) was the most effective approach, with an 83% reduction in colorectal cancer (CRC) mortality compared to no surveillance. The incremental cost-effectiveness ratio (ICER) of this strategy was $162000 per
Purpose: Natalizumab is a recombinant humanized antibody derived from murine monoclonal antibody raised against human α4 integrin. Recent studies have reported that natalizumab might be effective for the treatment of active Crohn’s disease. We conducted a meta-analysis to analyze the efficacy and safety of Natalizumab for induction of remission in Crohn’s disease.

Methods: A thorough literature search was conducted on Medline and Cochrane Clinical Trials Registry of all published randomized clinical trials (RCTs) 1966 to 2006. Abstracts of gastroenterology scientific meetings were hand searched. 2 independent reviewers assessed the studies. Standard forms were used to extract data regarding study design, outcome measures, and adverse effects. Mantel–Haenszel method (fixed-effects model) was used for pooling trial results.

Results: 3 RCTs satisfied the inclusion criteria (1183 pts). No significant heterogeneity was present among the studies (I² = 0%). 2 studies evaluated moderate to severe Crohn’s disease, while one study evaluated mild to moderately active disease. The efficacy was evaluated by using the Crohn’s Disease Activity Index (CDAI). Doses studied were 3mg/kg, 6mg/kg and 300mg. Patients were given a single infusion of Natalizumab in 1 study, 2 infusions in another and 3 infusions in the third trial. All the studies measured the primary end points at different times (2, 8 and 10 wks). Natalizumab showed higher rate of induction of remission in comparison to placebo at the study defined primary end points (RR = 1.27, CI = 1.03 to 1.57). Natalizumab also continued to show higher rate of induction of remission after 12 weeks of therapy (RR = 1.32, CI = 1.07 to 1.62). Health related quality of life and C-Reactive Proteins levels improved with Natalizumab compared to placebo. Overall, Natalizumab was well tolerated. Headache was one of the most common side effects. 7% of patients treated with Natalizumab developed antibodies against the drug. Acute infusion reactions occurred in 9% of the patients. There was no significant increase in the risk of infection among the patients treated with Natalizumab. 1 patient developed progressive multifocal leukoencephalopathy after therapy with Natalizumab.

Conclusions: Natalizumab induces clinical remission in Crohn’s disease. Further studies are needed to confirm the findings and also to better define the safety profile of Natalizumab.

Inflammatory Bowel Disease

1070

Effects of Nanocrystalline Silver (NPI 32101) on a Rat Model of Ulcerative Colitis

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Purpose: Nanocrystalline silver (NPI 32101) produced by physical vapor deposition has been demonstrated to have antimicrobial and anti-inflammatory properties. The objectives of this study were to assess the effect of NPI 32101 on a rat model of ulcerative colitis and to investigate the possible mechanisms of action of the effects observed.

Methods: Ulcerative colitis was induced in rats using dinitrobenzene sulfonic acid (DNBS) intracolonically. NPI 32101 nanodispersion in polyvinyl alcohol, sulfasalazine or vehicle was administered either orally (1ml) or intracolonically (250 μl) once daily for 5 days. Animals were sacrificed after 5 days of treatment and the extent of colonic inflammation was evaluated macroscopically by grading the stool consistency, thickness of colonic wall and size of colonic ulcers. Colonic tissue was prepared for histological and immunohistochemical examination. Colonic homogenates were analyzed to detect activity of matrix metalloproteinase-9 (MMP-9) by gelatin zymography.

Results: Results demonstrate that DNBS produced severe colonic inflammation in rats with pathology resembling ulcerative colitis. Rats treated with vehicle showed no significant reduction of colonic inflammation, compared to no treatment group. Oral administration of NPI 32101 40mg/kg, but not 4mg/kg, significantly reduced colonic inflammation compared to placebo group. On the other hand, intracolonically treated group of NPI 32101, 40 and 4mg/kg, but not 0.4mg/kg, significantly reduced the inflammation. Sulfasalazine (100mg/kg), either orally or intracolonically, reduced...
colonic inflammation. Histopathological analysis of colonic tissues mirrored the macroscopic observations. Immunohistochemical staining of colonic tissues demonstrated that NPI 32101 significantly suppressed the expression of MMP-9, TNF-α, IL-1β, and IL-12, whereas sulfasalazine significantly suppressed MMP-9, IL-1β, and TNF-α, but not IL-1β, compared to placebo. Gelatin zymography of the colonic homogenates demonstrated that NPI 32101 and sulfasalazine reduced MMP-9 activity.

**Conclusions:** This study shows a concentration-response for NPI 32101 administered orally or intracolonically in the treatment of ulcerative colitis in a rat model and as effective as sulfasalazine. Intracolonic NPI 32101 is about 10 times more potent than oral NPI 32101. This study suggests that NPI 32101 given orally or intracolonically may have therapeutic potential for treatment of ulcerative colitis. NPI 32101 suppresses MMP-9, TNF-α, IL-1β and IL-12; mechanisms by which NPI 32101 may exert its anti-inflammatory effects.

1071

**Laparoscopic Restorative Proctocolectomy: Is the Anastomosis Compromised?**

Christopher M. Foglia, MD, David S. Bub, MD, Stephen R. Gorfine, MD, Joel J. Bauer, MD,* Surgery, The Mount Sinai Hospital, New York, NY.

**Purpose:** One of the major technical issues in the performance of restorative proctocolectomy (RPC) is the complete mobilization of the small bowel mesentery, while maintaining adequate blood supply to the pouch. Inadequate mobilization can lead to tension and ischemia and subsequently anastomotic complications or the need for diverting ileostomy. The aim of this study was to evaluate whether a laparoscopic (lap) technique can be used to create an ileal pouch-anal anastomosis (IPAA) without compromising the anastomosis.

**Methods:** Forty-six patients undergoing lap RPC were examined over a 7-year period. These patients were matched by age, gender and operative indication to a group of 44 patients undergoing open RPC. In all patients, the intent was to perform a mucosectomy with hand-sewn IPAA without complimentary ileostomy. A diverting ileostomy was performed at the discretion of the operating surgeon when there was thought to be compromise to the anastomosis. Patient specific demographics, intra-operative and post-operative variables and complications were examined retrospectively using a prospectively gathered database as well as hospital and office chart review.

**Results:** The lap group contained 13 men and 33 women, while the open group contained 14 men and 30 women. There were no significant differences in patient age (mean: lap 32.8, open 34.1), or indication for surgery (lap: ulcerative colitis 43; polyposis syndromes 3;open, ulcerative colitis 40, polyposis syndromes 4). In the lap group 44 patients (96%) had mucosectomy and 42 patients (91%) had hand-sewn anastomoses, vs. 37 patients (84%) who had mucosectomy and hand-sewn anastomosis, in the open group. Two patients in the lap group had mucosectomies but there was not adequate length on the pouch to perform a hand-sewn anastomosis, and a stapled anastomosis was employed. All other patients had stapled anastomoses using a double-stapled technique. There were 5 diverting loop ileostomies (11%) created at the time of operation in the lap group, vs. 6 (14%) in the open group. Post-operatively there were 7 early anastomotic complications and 9 late strictures in the lap group, vs. 4 early anastomotic complications and 5 late strictures in the open group. These differences were not statistically significant.

**Conclusions:** The technical issues of pouch mobilization to achieve adequate length for mucosectomy and hand-sewn IPAA are not compromised by using laparoscopy to perform RPC when compared to open surgery. Laparoscopic RPC is a safe and feasible alternative to open surgery.

1072

**Geographic and Temporal Variations in the Mortality from Crohn’s Disease and Ulcerative Colitis**

Amnon Sonnenberg, MD,* Gastroenterology, P3-GI, Portland VA Medical Center, Portland, OR.

**Purpose:** The present study was aimed to test whether Crohn’s disease (CD) and ulcerative colitis (UC) showed similarities in their geographic and temporal variations among different countries.

**Methods:** Mortality data from 19 different countries between 1950 and 2004 were analyzed, including Australia, Austria, Belgium, Canada, Chile, Denmark, England, Finland, France, Germany, Italy, Japan, Mexico, Netherlands, Scotland, Sweden, Switzerland, Taiwan, and USA. The age-specific death rates of each individual country, as well as the average age-specific rates of all countries, were plotted against the period of death.

**Results:** On average, UC mortality was 1.7-times higher than CD mortality. Among the oldest age groups 75–84 and over-85 yrs, mortality from UC rose during the initial 15 yrs between 1950 and 1965 followed by a smooth decline. Among the age groups 55–64 and 65–74 yrs, the initial rise was shorter and the subsequent decline more pronounced. The steepest decline occurred in the youngest age groups 15–24, 25–34, 35–44 yrs. This fan-like appearance of the UC period-age contours was consistent with an underlying birth-cohort phenomenon. The time trends of CD mortality in the age groups 15–24, 25–34, and 35–44 yrs were characterized by an initial rise between 1950 and 1960 and a subsequent fall. In the middle age groups, the fall did not start before 1975. In the oldest age groups, no fall occurred but the rise continued unabated until recent times. If the age-specific trends of CD were superimposed on those of UC, in each age group separately, the decline in CD appeared to have started only after reaching the levels of UC. This pattern was clearly discernible in the average rates of all countries lumped together and in the data from individual countries with large numbers of IBD deaths, such as Canada, England, Germany, Netherlands, and USA. Three countries presented noteworthy exceptions. In Japan, low CD mortality continued to rise unabated by comparatively much higher UC mortality. In Belgium and France, the age-specific death rates rose in both, CD and UC, with the latter remaining more frequent than the former most of the time. Overall, there was a significant linear correlation between the age- and period-adjusted death rates of CD and UC among different countries with r = 0.703, n = 19, p = 0.0008.

**Conclusions:** The relationships between the temporal changes of CD and UC and the correlation between the geographic variations of the two diseases suggest the existence of a shared environmental risk factor.
additional 21 adalimumab-exposed pregnancies that did not meet the cohort study criteria have been enrolled in the registry. Of these 21, 12 involved exposure in the first trimester and were prospectively identified. Further, five of these 12 had used adalimumab for the treatment of Crohn’s disease. As of May 1, 64 pregnancies were completed, and one patient was lost to follow-up. In the cohort study, all six adalimumab-exposed pregnancies resulted in full-term live born infants with no malformations. In the registry group, seven prospective outcomes are known: one twin pregnancy resulted in spontaneous abortion of one fetus while the other infant was delivered prematurely and diagnosed with congenital hip dysplasia. The remaining six pregnancies resulted in healthy full-term infants with no major birth defects reported.

Conclusions: Based on preliminary data, no concerns have been raised regarding increased risks for adverse pregnancy outcomes associated with early pregnancy exposure to adalimumab. Firm conclusions await accumulation of sufficient sample size in the cohort study.

1074
Identification of a Novel KIT Mutation Associated with Inflammatory Bowel Disease
Ashkan Farhadi, MD, M.S., Ija Chan, PhD, Ali Banan, PhD, Jeremy Z. Fields, PhD, Ali Keshavarzian, MD. Section of Gastroenterology and Nutrition, Rush University Medical Center, Chicago, IL.

Purpose: Mast cells (MC) are important end effectors of the brain gut axis (BGA) and we previously reported that MC in IBD patients had exaggerated responses to BGA stimulation. KIT is a receptor tyrosine kinase that plays a principal role in mast cell growth and differentiation. Whether KIT mutation plays a role in KIT regulatory mechanisms and increased MC activity in IBD remains to be explored.

Methods: Molecular genetic analysis was performed on 5 Crohn’s disease (CD), 2 ulcerative colitis (UC) and 3 control subjects (NL). Colonial mucosal biopsies that were obtained during colonoscopy were snap frozen in liquid nitrogen and stored at −80°C. For RT-PCR, total RNA was extracted from these samples using RNeasy extraction kits (Qiagen), and converted to cDNA using Invitrogen SST-I c-DNA synthesis kits. The primary PCR amplification was performed using PCR Supermix (Invitrogen) and the primer pair specific for KIT position 964 to 2582 (forward: AATATCTTCCCCCATGATAAA; reverse: AATCCCATAGGACCAGCA). A 1.38 kb DNA product (position 964 to 2345) was generated with a nest primer set (forward: AATATCTTCCC-CATGATAAA; reverse: cctttgccactggtaagaa). The DNA was subjected to sequencing analysis and the result was aligned with the Genbank Database with the NCBI Genomic Blast program.

Results: Sequencing of the KIT juxtamembrane (J) region revealed that one patient with UC expressed a heterozygous valine to glycine V560G/V (GTT to GGT) mutation and two patients with CD carried homozygous methionine to leucine M540L (ATG to CTG) mutations. Amino acid sequences in the regions of this mutation were completely conserved in all of the healthy controls.

Conclusions: This report is the first to describe a novel mutation in the KIT functional regulatory region in IBD. This mutation may play a pivotal role in KIT, shedding of the ectodomain, and internalization and auto-activation of mucosal MC. The functional significance of this mutation for MC regulation in the pathogenesis of IBD should be investigated.

1075
Reduced Immunostaining of c-kit Receptors in Mucosal Mast Cells of IBD Patients Is Not Due to Mast Cell Overactivation
Ashkan Farhadi, MD, M.S., Ali Keshavarzian, MD,∗ Shriram Jakate, MD, Malika Shaikh, M.S., Jeremy Z. Fields, PhD, Ali Banan, PhD. Section of Gastroenterology and Nutrition, Rush University Medical Center, Chicago, IL.

Purpose: The deleterious effects of stress in IBD have been attributed to activation of the Brain Gut Axis (BGA) and its end effectors, mast cells (MC). We previously showed that stress resulted in exaggerated activation and degranulation of mucosal MC in IBD patients. We also showed that c-kit immunostaining is significantly reduced in IBD patients. In this study we investigated whether, this phenomenon is due to overstimulation of MC in IBD.

Methods: We recruited 15 subjects with inactive IBD and 7 healthy controls. Subjects underwent 5 consecutive days of a Cold Pressor Test (CPT) to activate the BGA and to model “stress.” Biopsies of the sigmoid colon were taken during unprepared sigmoidoscopy before the first CPT and after the last CPT and formalin fixed samples were stained for both MC granules (MCg) and for the c-kit receptor which stains MC membranes (MCm). MC degranulation was assessed using electron microscopy.

Results: We previously showed that there is no significant difference in the number of MC, using the MCg technique, between IBD and control subjects, either before or after stress. However, there was a significantly reduced number of MC using the MCm technique – at both baseline and post stress sampling times – in IBD compared to controls (p = 0.01 and 0.04, respectively). MC number from the membrane staining technique was independent of stress-induced MC degranulation using EM.

Conclusions: The MCm (c-kit) staining technique yields an extremely low MC count in subjects with IBD before and after stress. This finding is not associated with MC overactivation and may be due to shedding of the ectodomain of the c-kit due to overactivity of TNF-α converting enzyme or due to an inherent or acquired defect in the juxtamembrane portion of the c-kit receptor in IBD. Further studies are needed to determine the role of the abnormal mucosal mast cell membrane c-kit receptor in the pathogenesis of IBD.

1076
Tetomilast (OPC-6535) Protects Against Reactive Oxygen Species-Induced Cell Injury Independent of Phoshodiesterase Type 4 Inhibition
Yongye Liu, PhD,∗ Miranda Fong, M.S., Junichi Kambayashi, MD, PhD. Cardiology, Otsuka Maryland Medicinal Laboratories, LLC, Rockville, MD.

Purpose: Reactive oxygen species (ROS) play an important role in both initiating and mediating inflammatory diseases. Tetomilast is known to inhibit ROS production by neutrophils, and is currently being evaluated in chronic obstructive pulmonary disease. The anti-inflammatory mechanism of tetomilast has not been fully elucidated, although the drug is known to inhibit phosphodiesterase type 4 (PDE4). In this study, we investigated whether tetomilast possesses other mechanisms of actions by comparing it with PDE4 inhibitors in a ROS induced cell injury model.

Methods: H9c2 cells derived from embryonic rat heart were exposed to 50, 100 and 200 μM H₂O₂ for 20 hours to induce cell injury. Tetomilast (1, 3, 10 μM), cilomilast (1, 3, 10 μM), or roflumilast (0.1, 1, 3 μM) (concentrations chosen on relative potency to inhibit PDE4) was added into the culture media in various time points before the addition of H₂O₂. Cell necrosis was quantified with propidium iodine staining of the nucleus and lactate dehydrogenase release. Cell apoptosis was also determined.

Results: Tetomilast concentration-dependently reduced cell injury. At 10 μM tetomilast reduced cell injury by about 80%. Significant protection was also observed at 3 μM but not at 1 μM. Cilomilast and roflumilast had no protection, suggesting the protection from tetomilast is independent of PDE4 inhibition. Tetomilast also significantly attenuated H₂O₂-induced depolarization of mitochondrial inner membrane potential and Annexin-V staining, indicating an anti-apoptotic effect. Two results suggest that the protection from tetomilast involves modulation of gene expression and new protein synthesis: (1) cycloheximide, a protein synthesis inhibitor, significantly attenuated the protection; (2) dependent on the concentrations of H₂O₂, the protection requires 2–4 hours pretreatment of cells with tetomilast before
the exposure to H2O2; and more protection was observed with longer pre-
treatment.

Conclusions: Tetomilast protects H2O2-induced cell injury independent of
its known PDE4 inhibition. Furthermore, the protection by tetomilast may
involve the upregulation of cytoprotective genes. Since ROS play a pivotal
role in inflammatory diseases, the reduction of their generation as demon-
strated previously, and cytoprotection against their injury, as shown here, may
further explain some of the beneficial effect of tetomilast in the treatment of
IBD.

1077

The Effect of Tetomilast (OPC-6535) on Cultured Human Vascular
Endothelial Cells
Bing Sun, MD, PhD,* Helen Chen, B.S., Lian Tao, M.S., Junichi
Kambayashi, MD, PhD. Mol. Res. & Tech., Otsuka MD Medicinal Labs.
LLC, Rockville, MD.

Purpose: Tetomilast is currently in clinical development for the treatment
of inflammatory bowel disease and chronic obstructive pulmonary disease.
Leukocyte adhesion to endothelium and transmigration into the damaged
tissue are essential features of the inflammatory process; endothelial perme-
ability and adhesion molecule expression are increased with inflammation.
Although the mechanism of action for tetomilast has not been fully eluci-
dated, tetomilast is known to inhibit phosphodiesterase 4 (PDE4). To inves-
tigate the mechanisms involved in tetomilast’s anti-inflammatory action, we
used primary vascular endothelial cells (EC) to study its effect on cell mono-
layer permeability and adhesion molecule expression, as compared with that
of PDE4-selective inhibitors.

Methods: Human umbilical vein EC (HUVEC) were cultured on a mem-
brane insert. The permeability increase was induced by incubation with
thrombin (0.2 unit/mL) or histamine (10 μM) at 37 °C for 1 hr and quantified
by the detection of diffused FITC-dextran through the HUVEC monolayer.
For the study of adhesion molecule expression, a cell-based ELISA was used
to measure VCAM-1, ICAM-1, and E-selectin expression in HUVEC and
human lung microvessel EC (HLMVEC) following TNF-α stimulation.

Results: Tetomilast (20 μM) inhibited thrombin- or histamine-induced per-
meability increase by 29.2% and 58.8%, respectively, whereas the PDE4
inhibitors cilomilast (30 μM) and rolflumilast (0.3 μM) did not. In both
cell types, a concentration-dependent inhibition of E-selectin expression by
tetomilast (5 to 30 μM) was observed with both 30-min and overnight (16-
hr) pretreatments, whereas inhibition of ICAM-1 and VCAM-1 was clearly
seen only with overnight pretreatment. In contrast, cilomilast, rolipram (both
up to 30 μM), and roflumilast (up to 0.3 μM) had no such effect on expres-
sion of any of the adhesion molecules. cDNA microarray data showed that
preincubation with tetomilast for 6 hr downregulated interferon regulatory
factor (IRF)-1 expression. Using a luciferase-based IRF-1 pathway-specific
reporter assay in HLMVEC, the inhibitory effect of tetomilast on IRF-1
pathway was observed over the same concentration range.

Conclusions: Tetomilast may mediate its anti-inflammatory effect par-
tially through the inhibition of vascular permeability increase and adhesion
molecule expression, independent of PDE4 inhibition. Our data indicate
that tetomilast inhibits VCAM-1 and ICAM-1 expression on EC, likely by
inhibiting IRF-1 pathway.

1078

A Rare Case of Thromboembolic Disease in a Patient
with Crohn’s Disease
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Firdous A. Siddiqui, MD,* Gastroenterology, Wayne State University –
Detroit Medical Center, Detroit, MI and Internal Medicine, Wayne State
University – Detroit Medical Center, Detroit, MI.

Purpose: Inflammatory bowel disease (IBD) is associated with an increased
risk of vascular complications. The most important of which are venous and
rarely arterial thromboembolic events. These extraintestinal manifestations
represent a significant cause of morbidity and mortality in IBD patients.
The most common thrombotic casualties are limb thrombophlebitis and
pulmonary emboli. Arterial thrombi have been reported but are rare. The
occurrence of thrombosis in IBD patients is partially attributed to the existing
hypercoaguable state in IBD. Here we report an interesting case of arterial
thrombosis in a patient with Crohn’s disease.

Case: Our patient is a 37 year old Caucasian female with a 13 year history of
Crohn’s disease, who presented to the ER with acute onset of sharp left foot
pain. Her foot was dusky, numb and had no doppler signal. She was diagnosed
with acute limb ischemia and was immediately taken to the operating room.
An intraoperative angiogram showed a thrombus in the distal femoral-to-
popliteal arterial region, for which she underwent a thromboembolectomy.
Patient regained arterial flow, use of the limb and had a remaining uneventful
hospital course. Extensive cardiac workup failed to reveal a source of the
clot. Anticoagulation therapy was initiated. A workup for hypercoaguable
state, which included testing for Factor V Leiden, homocysteine, protein
C and S, was negative. Our patient presently is doing well without other
vascular complications.

Conclusions: The incidence for thrombotic complications in IBD has been
reported as low as 1% – 6% in one study to as high as 39% in another post-
mortem study. The cause of hypercoaguableity is unclear and seems to be
related to activity of disease and coagulation abnormalities. It is also pos-
tulated that there is activation of markers of the coagulation cascade and
disturbed fibrinolysis. Arterial clots have been reported but are rare. Al-
though there are no screening guidelines for these disorders in IBD patients,
we feel that clinicians should be aware of such serious complications that
warrant prompt diagnosis and treatment.

1079

The Risk of Developing Crohn’s Disease after an Appendectomy:
A Meta-Analysis of Observational Studies
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Purpose: Studies exploring the relationship between appendectomy and the
subsequent development of Crohn’s disease (CD) have reported conflicting
findings. This relationship is complicated by the interval between surgery
and the diagnosis of CD. In response to the varied results we conducted a
systematic review of the literature and meta-analysis to assess the risk of
developing CD after an appendectomy and whether this risk is altered by the
timing between appendectomy and CD diagnosis.

Methods: A literature review was conducted using MEDLINE and manual
search methods to identify all case-control and cohort studies that evaluated
the relationship between an appendectomy and the subsequent onset of CD.
Authors were contacted when data was insufficient. Summary relative risks
(RR) with 95% confidence intervals (CI) were calculated using a random
effects model. A subset of studies that analyzed their data according to the
interval between date of appendectomy and the diagnosis of CD were assessed
separately. Publication bias was evaluated using Egger’s test.

Results: Among the 14 studies identified the summary estimate for CD
after an appendectomy was not significant (RR = 1.39; 95% CI: 0.98–1.97).
Among the 4 studies that assessed the time between an appendectomy and
the diagnosis of CD, the risk of CD was strongly elevated within the first year
after the operation (RR = 9.12; 95% CI: 6.79–12.25). When CD diagnoses
established during the first year after appendectomy were disregarded, the
RR of developing CD dropped (RR = 1.48; 95% CI: 1.17–1.89). The risk of
CD was greatest within 1 to 5 years of the appendectomy (RR = 2.17; 95%
CI: 1.57 – 2.99) and was not significant (RR = 1.10; 95% CI: 0.77–1.55)
after 5 years. The Egger’s test did not reveal evidence of publication bias
(p = 0.2).

Conclusions: Appendectomy does not appear to be a risk factor for the
development of CD; the marked drop in RR’s early after an appendectomy
Calprotectin is an accurate screening test and a reliable marker of disease activity and response to therapy. It plays an important role in the management of patients with IBD including diagnosis, of IBD activity at least comparable with CRP. Calprotectin may have an even greater role in the management of patients with IBD whose symptoms may mimic appendicitis.

1080
The Accuracy of Fecal Calprotectin for the Diagnosis and Assessment of Disease Activity in Inflammatory Bowel Disease
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Purpose: Current markers of activity in inflammatory bowel disease (IBD) are either non-specific or invasive. Fecal calprotectin (CP) has been proposed as a marker of intestinal inflammation and was shown to predict relapse in patients with both ulcerative colitis (UC) and Crohn’s disease (CD). The accuracy of CP for the diagnosis and assessment of disease activity in IBD is unknown.

Methods: Patients with suspected or established IBD seen in a referral medical center were prospectively evaluated. Patients who had CP testing were considered eligible. Clinical, laboratory, endoscopic and radiological data were collected. IBD extent and severity were determined by combining endoscopy and radiology (CT enteroclysis) data and quantified using both standardized scores as well as a simplified system. The sensitivity, specificity and accuracy of CP for IBD were determined using variable cutoff values. The correlation of CP with IBD extent, severity and other inflammatory markers was analyzed using the Spearman function.

Results: Of the 37 patients included, 27 had IBD [mean age 41 and 44% male; 7 patients had UC, 17 CD, 3 microscopic colitis (MC)]. The average IBD duration was 8.5 years (0–39). The mean CP level was 567 ug/g (17–2500) in the IBD group (including 2 patients in remission) and 187 (16–1264) in the non-IBD group (including 2 patients with C. difficile colitis). Excluding infectious colitis patients, a CP cutoff value of 55 ug/g, yielded a sensitivity, specificity and accuracy for IBD of 89%, 88% and 88% respectively. Fecal CP values correlated with endoscopic severity (r = 0.58, p < 0.01), clinical activity (r = 0.54, p < 0.01), C-reactive protein (r = 0.55, p < 0.001) and to a lesser degree with disease extent (r = 0.46, p = 0.03). CP was similar to CRP for predicting endoscopic severity (r = 0.58 vs. 0.52). In addition, all 3 patients with MC had elevated CP (mean = 153 ug/g) and normal CRP (<1.0).

Conclusions: Calprotectin is an accurate screening test and a reliable marker of IBD activity at least comparable with CRP. Calprotectin may have an important role in the management of patients with IBD including diagnosis, evaluation of disease activity and response to therapy.

1081
Clostridium difficile Infection in Patients with Ileal Pouch-Anal Anastomosis (IPAA)
B. Shen, MD, Z.-D. Jiang, PhD, Y. Fazio, MD, K. Sherman, R.N., B.S.N., L. Rodriguez, F. Remzi, MD, A. Bennett, MD, H.L. DuPont, MD,* Department of Gastroenterology, Cleveland Clinic, Cleveland, OH; Infectious Disease, University of Texas School of Public Health, Houston, TX and Internal Medicine, St. Luke’s Episcopal Hospital, Houston, TX.

Purpose: The importance of C. difficile infection in patients with IPAA is not known.

Methods: Consecutive 115 ulcerative colitis (UC) patients with IPAA were enrolled from our Pouchitis Clinic from May 2005 to March 2006. Pouch aspirate specimens were collected during pouch endoscopy and analyzed for C. difficile toxin A & B by ELISA. 18 clinical variables were assessed. Diagnosis of pouch disorders was based on clinical, endoscopic, radiographic, and histologic assessments. Logistic regression models were constructed to study possible etiology and adverse consequences of C. difficile infection.

Results: 21 patients (18.3%) tested positive for C. difficile. 6 C. difficile positive patients (3 refractory pouchitis, 2 Crohn’s disease, & 1 irritable pouch syndrome) had repeated endoscopic & lab evaluation after 2–4 weeks of combined antibiotic therapy (tinidazole + rifaximin or ciprofloxacin). 5 patients with refractory pouchitis or Crohn’s disease went into clinical and endoscopic remission corresponding to disappearance of C. difficile.

Conclusions: C. difficile infection is prevalent in patients with IPAA, with risk factors being males gender and a pre-operative left colitis. C. difficile infection in this population has no apparent association with previous antimicrobial treatment, but treatment may alter the outcome in these cases.

1082
Assessing Intestinal Inflammation Using a New Rapid In Vitro Assay That Detects Lactoferrin
Darcy A. Whitlock, M.S., Stephanie F. Sigmon, B.S., James H. Boone, M.S.* , Research & Development, TechLab, Inc., Blacksburg, VA.

Purpose: The clinical differentiation of inflammatory bowel disease (IBD) from irritable bowel syndrome (IBS) is a difficult process due to the overlapping variety of symptoms. A rapid diagnosis is essential for determining specific medical therapy and for optimizing patient care. Lactoferrin, a marker of activated neutrophils, is a validated indicator of intestinal inflammation, which offers a noninvasive aid for ruling out IBS and for monitoring disease activity in IBD. The aim of our study was to evaluate a rapid membrane test for detecting elevated fecal lactoferrin (IBD EZ VUE™) in the differentiation of active IBD from IBS and as an indicator of disease activity.

Methods: Fecal specimens were collected from 116 patients (94 IBD/22 IBS) and from 27 healthy controls. The male: female ratio was 1:1.9 with 73 pediatric and 70 adult specimens. Uncoded samples were tested for elevated lactoferrin using the rapid membrane assay and results were confirmed by enzyme-linked immunosorbent assay (IBD-CHEK™). Disease diagnosis was based on clinical histories and disease activity was assessed using the Harvey Bradshaw Activity Index (HBAI).

Results: Compared with disease diagnosis and activity, the rapid membrane assay differentiated active IBD from IBS and healthy controls with 100% sensitivity, specificity, and correlation for adult patients. Active IBD was separated from inactive IBD in adults with 100% sensitivity, specificity, and correlation. In the pediatric group (0–20 years old), active IBD was differentiated from IBS and healthy controls with 100% sensitivity, 91.7% specificity, and 98.1% correlation. The assay was 100% sensitive and 89.5% specific, with 96.7% correlation for discriminating active IBD from inactive IBD in pediatric patients. Lactoferrin levels in active IBD patients were significantly elevated compared to inactive IBD, IBS, and healthy controls (p < 0.002).

Conclusions: The IBD EZ VUE™ rapid membrane assay was sensitive and specific for determining IBD activity in pediatric and adult patients. The test
was comparable to the HBAI and lactoferrin ELISA, and rapidly detected elevated lactoferrin to help differentiate IBD from IBS. Periodic testing for lactoferrin in IBD patients can aid the determination of disease state and management of patient care.

1083
Nutritional Changes in Crohn’s Disease Patients Treated with Infliximab
Dawn M. Wiese, B.S., Bret A. Lashner, MD*, Douglas L. Seidner, MD
College of Medicine, Cleveland Clinic Foundation, Cleveland, OH and Gastroenterology, Cleveland Clinic Foundation, Cleveland, OH.

Purpose: To assess the enterocyte function & body composition that occur in Crohn’s disease pts beginning infliximab therapy, we evaluated pts immediately before infliximab (INF) administration & after 6 wks & 6 mos of therapy.

Methods: CD pts beginning INF for ileocolonic, non-fistulizing disease were entered. Assessment included: 1) Disease activity (Harvey Bradshaw Index (HBI) & IBD Questionnaire (IBDQ)), 2) A combined index of inflammation & enterocyte function (Prognostic Inflammatory & Nutrition Index (PINI)), 3) Enterocyte function (plasma folate, homocysteine (hcy), citrulline & other micronutrients), & 4) Body composition (lean mass from DEXA & indirect calorimetry for resting energy expenditure (REE)).

Results: To date, 8 pts have been enrolled & 5 have completed the 6-mo evaluation. All pts had active disease at the initiation of INF, but only 3/5 completed pts had active inflammation characterized by CRP > 1.0 mg/dl. In these 3 pts, there was a large improvement in both IBDQ & HBI. This group had an improvement in enterocyte function as per changes in BMI, folate and hcy. In all of these pts the PINI was > 1.0 at entry and < 1.0 by 6 mos. In the 2 completed pts who did not have elevated CRP at baseline, there was no significant change in disease activity as per the IBDQ & HBI. The REE decreased in both of these pts, but there was little change in PINI, folate or hcy. The 2 pts with the greatest increase in citrulline had the greatest increase in BMI.

Conclusions: These findings suggest that CD pts with active inflammation, characterized by an elevated CRP, will have improvements in inflammation & nutrition (PINI) with INF. An improvement in enterocyte function and/or increased food intake could account for the improved plasma folate & hcy levels & increased BMI. The largest increases in BMI are most likely explained by enterocyte function as measured by citrulline. Although REE results were inconsistent with other nutritional parameters, most pts had a decrease in REE suggesting that INF has positive effects on metabolism. These finding also support the use of PINI in CD pts as an overall marker of inflammation & nutrition and possible predictor of response to INF.

Change after 6 mos of INF

<table>
<thead>
<tr>
<th>IBDQ</th>
<th>PINI</th>
<th>Folate (ng/ml)</th>
<th>Citrulline (umol/L)</th>
<th>BMI (kg/m²)</th>
<th>REE (kcal/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High CRP (N = 3)</td>
<td>87</td>
<td>-2.3</td>
<td>+4.4</td>
<td>-4</td>
<td>+2.2</td>
</tr>
<tr>
<td></td>
<td>94</td>
<td>-9.0</td>
<td>+3.4</td>
<td>-30</td>
<td>+1.4</td>
</tr>
<tr>
<td></td>
<td>52</td>
<td>-7.4</td>
<td>+3.7</td>
<td>+7</td>
<td>+6.7</td>
</tr>
<tr>
<td>Low CRP (N = 2)</td>
<td>6</td>
<td>-0.1</td>
<td>+0.6</td>
<td>+12</td>
<td>+2.5</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>-0.1</td>
<td>+2.1</td>
<td>0</td>
<td>+0.3</td>
</tr>
</tbody>
</table>

1084
Incidence and Risk Factors for Herpes Zoster among Patients with Inflammatory Bowel Disease
Gaurav Gupta, B.S.,* Ebbign Lautenbach, MD, M.P.H., M.S.C.E., James D. Lewis, MD, M.S.C.E., Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania School of Medicine, Philadelphia, PA; Centers for Education and Research on Therapeutics, University of Pennsylvania School of Medicine, Philadelphia, PA and Department of Internal Medicine, University of Pennsylvania School of Medicine, Philadelphia, PA.

Purpose: An increased risk of herpes zoster in patients with inflammatory bowel disease (IBD) is hypothesized based on altered immune function, especially among patients receiving immunosuppressive medications. However, the incidence and risk factors for zoster infection among IBD patients has not yet been established.

Methods: We performed a retrospective cohort study and a retrospective nested case-control study using 1988 to 1997 data from the General Practice Research Database. In the cohort study, 7510 Crohn’s disease (CD) and 11375 ulcerative colitis (UC) patients were matched on age, sex, and primary care practice to 75450 randomly selected controls without CD or UC. In the nested case-control study, 185 CD patients with zoster and 266 UC patients with zoster were matched on sex and year of birth to 1787 IBD patients without zoster.

Results: In the cohort study, the incidence of zoster was higher in patients with CD and UC compared with their matched controls (UC incidence rate ratio [IRR], 1.21; 95% CI, 1.05–1.40; CD IRR, 1.61; 95% CI, 1.35–1.92). In the nested case control study, receipt of a prescription for corticosteroids (adjusted odds ratio [OR] = 1.5, 95% CI 1.1–2.2) or azathioprine/6-mercaptopurine (adjusted OR = 3.1, 95% CI 1.7–5.6) were both associated with zoster.

Conclusions: Patients with IBD, especially those on immunosuppressive medications, are at higher risk for herpes zoster compared to the general population. Future studies should clarify the relative risk associated with anti-TNFα therapies and determine the utility of the new zoster vaccine for patients with IBD.

1085
A Descriptive Study of Fertility Rates in Men with Inflammatory Bowel Disease
Terence W. Friedlander, MD, Musa Khaliq, MD, Uma Mahadevan, MD,* Medicine, Univ. of California San Francisco, San Francisco, CA and Gastroenterology, Univ. of California San Francisco, San Francisco, CA.

Purpose: To evaluate infertility rates (inability to conceive after 1 year of unprotected intercourse) and specific factors (medications, surgery, disease activity, tobacco use) that influence fertility among a cohort of men with Inflammatory Bowel Disease (IBD).

Methods: An anonymous questionnaire was mailed to 351 consecutive men in the UCSF IBD database. Patient demographics, medical, surgical, and sexual histories, tobacco exposure, as well as fertility history and pregnancy outcome were assessed.

Patient Demographics

<table>
<thead>
<tr>
<th>N</th>
<th>46</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age (yr)</td>
<td>39.5 (range 25–67)</td>
</tr>
<tr>
<td>IBD History</td>
<td></td>
</tr>
<tr>
<td>Crohn’s Disease</td>
<td>23 (50%)</td>
</tr>
<tr>
<td>Ulcerative Colitis</td>
<td>21 (45.7%)</td>
</tr>
<tr>
<td>Indeterminant Colitis</td>
<td>2 (4.3%)</td>
</tr>
<tr>
<td>Perianal involvement</td>
<td>14 (30.4%)</td>
</tr>
<tr>
<td>Surgery at any time for IBD</td>
<td>19 (41.3%)</td>
</tr>
<tr>
<td>Median time since diagnosis (yr)</td>
<td>10.5 (range 2–39)</td>
</tr>
<tr>
<td>Exposure History</td>
<td></td>
</tr>
<tr>
<td>Tobacco use at any time</td>
<td>13 (28.2%)</td>
</tr>
<tr>
<td>Sexual History</td>
<td></td>
</tr>
<tr>
<td>Difficulty achieving or maintaining erection, or early ejaculation</td>
<td>12 (26.1%)</td>
</tr>
<tr>
<td>Sought fertility counseling</td>
<td>5 (10.9%)</td>
</tr>
<tr>
<td>Partner infertile</td>
<td>2 (4.3%)</td>
</tr>
</tbody>
</table>
Crohn’s disease is an inflammatory condition of the GI tract that

Peggy D. Headstrom, MD, Stephen J. Rulyak, MD, Scott D. Lee, MD,
with Crohn’s Disease

Prevalence of and Risk Factors for Vitamin B12 Deficiency in Patients

Conclusions: Active IBD during conception may significantly impair male fertility. Further studies with a larger cohort and matched healthy controls are needed.

Results: Forty-six men answered the questionnaire. Patient demographics and fertility outcomes are in the Table below. There were a total of 58 pregnancies. Forty-nine (84.5%) were delivered at or near term, with 4 (6.9%) miscarriages and 5 (8.6%) elective terminations. Overall 4 patients reported (6.9%) infertility, however among patients with active IBD at the time of conception (n = 19), 15.8% experienced infertility.

Conclusions: Active IBD during conception may significantly impair male fertility. Further studies with a larger cohort and matched healthy controls are needed.

Prevalence of and Risk Factors for Vitamin B12 Deficiency in Patients with Crohn’s Disease

Peggy D. Headstrom, MD, Stephen J. Rulyak, MD, Scott D. Lee, MD,* Division of Gastroenterology, University of Washington, Seattle, WA.

Purpose: Crohn’s disease is an inflammatory condition of the GI tract that can commonly involve the terminal ileum which is the site of B12 absorption. The aim of this study was to define the prevalence of vitamin B12 deficiency in a population with Crohn’s disease and to identify risk factors associated with B12 deficiency.

Methods: Medical records of 201 patients with Crohn’s disease evaluated at a tertiary care center were retrospectively reviewed to determine the prevalence of B12 deficiency and to evaluate for risk factors associated with B12 deficiency. The prevalence of B12 deficiency in a control population of 40 patients with ulcerative colitis was also assessed.

Results: The prevalence of an abnormal B12 level in patients with Crohn’s disease was 18.4% (95% CI 13.1–23.8%) compared with 5% (95% CI 0–11.8%) (p = .035) in ulcerative colitis controls. Risk factors for B12 deficiency in patients with Crohn’s disease included prior ileal (OR, 7.22; 95% CI 1.97–26.51) or ileocolonic (OR, 5.81; 95% CI 2.09–16.12) resection and the need for ongoing medical therapy (OR, 2.59; 95% CI 1.03–6.47). Neither disease location nor duration was independently associated with the risk of B12 deficiency.

Conclusions: Abnormal B12 levels are common in patients with Crohn’s disease. Given the complications that can be seen with low B12 levels, and the high prevalence in this population, we would advocate that patients with Crohn’s disease be screened for B12 deficiency as part of the ongoing care for the management of the Crohn’s disease. Special attention should be given to those that have had a prior ileal or ileocolonic surgery.

Home Infusion of Infliximab Can Be Adequately Reimbursed and Provides a Safe and Convenient Alternative for Patient Treatment

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Purpose: Infliximab is currently approved for treatment of patients with Crohn’s disease (CD), ulcerative colitis (UC), rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis. When originally approved for commercial use in October, 1998, the medication was prescribed generally for hospitalized patients. Over time, it was recognized infliximab could be infused safely in a monitored outpatient (opt) clinic setting. Such infusions proved lucrative for clinics and avoided hospitalization for the patient although the patient still required transportation to the clinic. Since 1999, we have utilized home infusions (HI).

Methods: Data were collected on all consecutive outpatients with IBD from September 1, 2005 to May 1, 2006 that received infliximab infusions in the outpatient setting either at an infusion center or at home. Age, sex, number of infusions, acute infusion reactions, and reimbursed charges for infusions were recorded. Comparison was made with between clinic-based infusions and home infusions.

Results: The opt infusion center population included patients with CD (n = 65), UC (n = 9), and ankylosing spondylitis (n = 1), and the home setting included 13 patients with CD. Mean age was 36.7 ± 11.9 yrs for 37 F that received opt clinic infusions and 36.7 ± for 34 M. In home patients, mean age was 39.1 ± 10.8 for 8 F and 36.7 ± 11.9 for 5 M. The total number of clinical infusions was 254 (3.4 ± 1.3/patient) and the total number of home infusions was 54 (4.2 ± 2.0/patient; p = NS), 2 acute infusion reactions occurred in the infusion center (puritus and hives, vasovagal rxn) and lead to infusion discontinuation in both cases (no SAE). No acute infusion reactions occurred at home. Mean reimbursed costs for medication, supplies, nursing and related charges was $4538 (4089 for the infusion center and was $4350 for home patients infused (p = NS). Medicaid supplies medication and therefore reimbursed charges for those patients did not include medication.

Conclusions: Home (or work) infusion is practical, safe, and can be adequately reimbursed. Reimbursement is similar to the opt clinic, but patient convenience is significantly improved. Because of the lack of capital depreciation costs other than for the infusion pump, home infliximab infusion is less expensive overall than opt clinic infusion despite similar reimbursement. The barrier to home infliximab infusion is not safety, but insurance coverage.

Closure of Entero-Vesical Fistula in Crohn’s Disease with Infliximab: Three Years Follow up of Two Cases

Flavio Steinwurz, MD, F.A.C.G.* Gastroenterology, Hospital Israelita Albert Einstein, Sao Paulo, Brazil.

Purpose: Fistula is one of the most common and unpleasant complications of Crohn’s disease. Infliximab showed efficacy in healing perianal and abdominal wall fistula. We treated 2 patients with entero-vesical fistula, both females, with infliximab and after they achieved the healing of the lesions they were followed for 3 years in order to evaluate the maintenance of the fistula closure.

Methods: Two patients with Crohn’s disease complicated with entero-vesical fistula, verified by urinary tract infection, abdominal CT and ultrasound, were treated with infliximab 5mg per Kg every 8 weeks. At the beginning they were on antibiotic (ciprofloxacin 500 mg bid). They had clinical evaluations every month on the first 6 months and every 3 months afterwards. Both had blood and urine tests done every month for the first 6 months, and every 3 months afterwards. Ultrasound every 3 months and CT every 6 months were also performed.
Results: The 2 patients achieved healing of the entero-vesical fistula right after the second infusion of infliximab and remained with no symptoms for the 3 years of follow up. After 3 months they could take the antibiotic off, and had no recurrence of the urinary tract infection. Clinical evaluation and blood tests showed remission of the disease and urine tests were normal. Ultrasound showed no more evidence of thickness on the bladder wall, and no signs of possible fistula. They completed 3 years of follow up and remained with no symptoms and all the tests performed were absolutely normal.

Conclusions: The treatment of entero-vesical fistula in Crohn’s disease with infliximab showed good results, with sustained healing for 3 years of follow up. Despite few reports in the literature and very restricted experience, the use of infliximab in the treatment of entero-vesical fistula in Crohn’s disease seems to be a valid option.

1089

Predictive Value of Radiographic Findings in Patients with Ileal Thickening on Computerized Tomography Scanning for Establishing the Diagnosis of Crohn’s Disease

Joseph Merrill, MD, Christopher Gasink, MD, Faten Aberra, MD, Chinyu Su, MD, Gary R. Lichtenstein, MD,* Gastroenterology, University of Pennsylvania, Philadelphia, PA.

Purpose: Mural thickening of the terminal ileum (TI) is a common radiographic finding in Crohn’s disease (CD). Over 95% of patients with CD demonstrate TI thickening on abdominal CT scan. However, few studies have critically analyzed the accuracy of radiographic findings used currently to establish the presence of CD. Our objective was to determine the predictive value of mural thickening of the TI for Crohn’s disease in patients not yet diagnosed and to assess for radiographic findings that increase the predictive value.

Methods: A computer database of 15685 abdominal CT scans performed at the University of Pennsylvania (1995–1997) identified 151 patients with ileal thickening. Prospective clinical data for 5 to 8 years post-CT scan was mandated for inclusion. This data was available for 103 of 151 patients to assess for a clinical CD diagnosis. All scans, by selection, showed ileal thickening. Scans were reviewed by three radiologists, blinded to patients’ diagnoses, for 24 specific radiographic findings. Analysis was performed to ascertain sensitivity, specificity, positive predictive values (PPV) and negative predictive values (NPV) of various radiographic findings for diagnosis of CD. Two-sided Fisher’s exact test was used to determine possible correlation.

Results: Thirty (29%) of patients were diagnosed with CD during follow up. The presence of lymphadenopathy, mesenteric hypervascularity, and fibrofatty proliferation of the mesentery were significantly associated with a subsequent diagnosis of CD. The sensitivity, specificity, PPV, and NPV of these radiographic findings for diagnosing CD are shown in the Table 1. Of note, location and length of the segment was not significant. The combination of ileal thickening, fibrofatty proliferation, lymphadenopathy, and mesenteric hypervascularity was 100% specific to a diagnosis of Crohn’s disease, although not sensitive.

Conclusions: Although CT evidence of terminal ileal thickening is found in the majority of patients with CD, it is a poor predictor of CD. Findings on CT scan that improve the PPV or NPV of ileal thickening include mesenteric hypervascularity, lymphadenopathy and fibrofatty proliferation.

Table 1

<table>
<thead>
<tr>
<th>CT finding</th>
<th>Crohn’s sensitivity</th>
<th>Specificity</th>
<th>PPV/NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fibrofatty proliferation</td>
<td>p = 0.001</td>
<td>30%</td>
<td>77%</td>
</tr>
<tr>
<td>Mesenteric hypervascularity</td>
<td>p = 0.014</td>
<td>20%</td>
<td>95%</td>
</tr>
<tr>
<td>Lymphadenopathy</td>
<td>p = 0.003</td>
<td>76%</td>
<td>55%</td>
</tr>
</tbody>
</table>

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Declining Prevalence of New Cases of Ulcerative Colitis

Douglas J. Sprung, MD, Gregory M. Sprung,* GI, The Gastroenterology Group, Maitland, FL.

Purpose: To evaluate the prevalence trend for ulcerative colitis (UC) over the past 6.5 years in a community practice.

Methods: A retrospective study of all patients with a diagnosis of UC seen between 1/2000–6/2006 at our 2 man private clinical GI practice in Orlando, FL was undertaken. Patients were divided into those who received a new diagnosis of UC and those who already had the diagnosis but had changed doctors or geographic location. The prevalence of new cases was assessed by year. Only patients with at least proctosigmoiditis were included.

Results: 107 new patients with UC were seen in our practice during this time frame. 55 were new diagnoses, 51% female, 49% male. There was an increase in cases from 2000 to 2002, with 9,12, and 12 patients diagnosed respectively. However, there was a decreasing prevalence from 2003 to 2006, with 8,7,5 and 2 (for half of 2006) patients diagnosed for those respective years.

Conclusions: 1. Although these are relatively small numbers of patients, there appears to be a declining prevalence trend for UC over the past 6.5 years in our community in central Florida. 2. Almost 50% of new patients seen with UC in our practice had already been diagnosed elsewhere and were either changing doctors or geographic location. These patterns may make data collection very difficult to assess, if the same patients are included in other geographical data bases from where they moved.

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Inflammatory Bowel Disease: A Comparison of Clinical Characteristics and Treatment Outcomes between Caucasians and Ethnic Minorities in Lower Manhattan

David A. Labowitz, D.O., M.P.H., Robin Forman, D.O., Tidashi Golla, MD, Emily Glazer, MD, Henry C. Bodenheimer, Jr., MD, Albert D. Min, MD,* Division of Digestive Diseases, Beth Israel Medical Center, New York, NY.

Purpose: Inflammatory bowel disease (IBD) in minority patients is not as well recognized as in Caucasian patients. The purpose of this study was to compare disease characteristics and clinical outcomes of IBD between Caucasians and various minority populations.

Methods: A chart review was conducted comparing a group of 28 minority patients (Black 22%, Hispanic 60%, Asian 18%) to a group of 27 Caucasian patients with Crohn’s disease (CD) and ulcerative colitis (UC) seen in GI clinics at Beth Israel Medical Center, NY. The two groups were compared on disease type, gender, and duration of illness. Patient demographics, age of symptom onset, lag time to diagnosis, disease characteristics and severity, treatment modalities, family history, insurance type, and comorbid condition were also compared. Categorical variables were analyzed with Chi-square and Fisher’s exact T-test, and a non parametric test, the median test, was used for the continuous variables.

Results: Analysis of the two groups revealed no significant differences in disease type, gender, and disease duration (p = 0.4985, p = .0763, p = 0.679, respectively). Age at the time of diagnosis was significantly older in minority patients when compared to Caucasian patients (p = 0.005). The two groups differed with respect to steroid use (p = 0.003). Family history of IBD was more frequent in Caucasian patients (p = 0.04). In addition, Caucasian patients were significantly more likely to have private insurance (p < 0.0001). The table below presents the results of comparisons on other disease outcomes.

Table 1

<table>
<thead>
<tr>
<th>CT finding</th>
<th>Crohn’s</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV/NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fibrofatty proliferation</td>
<td>p = 0.001</td>
<td>30%</td>
<td>77%</td>
<td>75%/77%</td>
</tr>
<tr>
<td>Mesenteric hypervascularity</td>
<td>p = 0.014</td>
<td>20%</td>
<td>95%</td>
<td>66%/75%</td>
</tr>
<tr>
<td>Lymphadenopathy</td>
<td>p = 0.003</td>
<td>76%</td>
<td>55%</td>
<td>41%/85%</td>
</tr>
</tbody>
</table>
Table

<table>
<thead>
<tr>
<th></th>
<th>Group</th>
<th>Caucasian</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median</td>
<td>Median</td>
</tr>
<tr>
<td></td>
<td>(range)</td>
<td>(range)</td>
</tr>
<tr>
<td><strong>Age of diagnosis (years)</strong></td>
<td>33 (16–71)</td>
<td>22 (13–46)</td>
</tr>
<tr>
<td><strong>Lag time to diagnosis (months)</strong></td>
<td>7 (1–288)</td>
<td>4 (1–60)</td>
</tr>
<tr>
<td><strong>Hospitalizations</strong></td>
<td>1 (0–7)</td>
<td>1 (0–4)</td>
</tr>
<tr>
<td><strong>Relapses</strong></td>
<td>2 (0–10)</td>
<td>1 (0–5)</td>
</tr>
<tr>
<td><strong>Surgeries</strong></td>
<td>0 (0–2)</td>
<td>0 (0–1)</td>
</tr>
<tr>
<td><strong>p-value</strong></td>
<td>0.005</td>
<td>0.4186</td>
</tr>
<tr>
<td><strong>0.5921</strong></td>
<td>0.2158</td>
<td>0.0438</td>
</tr>
</tbody>
</table>

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**Tetomilast (OPC-6535): A Novel Inhibitor of Human CD4 T Cell Proliferation and Interferon-γ Release**

Yasmin Shakur, PhD, James Hensley, B.Sc., Yongge Liu, PhD, Junichi Kambayashi, MD,* PDE Research, Otsuka Maryland Medicinal Laboratories, Rockville, MD and Cardiology, Otsuka Maryland Medicinal Laboratories, Rockville, MD.

**Purpose:** Tetomilast, an anti-inflammatory compound, is being developed for the treatment of inflammatory bowel disease (IBD). Although its mechanism of action has not been fully elucidated, it is known to inhibit phosphodiesterase 4 (PDE4) activity. To investigate the mechanisms involved in tetomilast’s anti-inflammatory action, we compared its effects on CD4 T cells, which have been associated with the pathogenesis of IBD, with that of several known PDE4 inhibitors.

**Methods:** The effect of tetomilast on recombinant human PDE4 subtypes was determined by PDE assay. IC50 was calculated from dose-response curves for tetomilast and for the PDE4 inhibitors cilomilast, rolipram, and roflumilast. Human CD4 T cells were purified from the blood of healthy donors using a commercial CD4 T cell isolation kit. CD4 T cells were stimulated using anti-CD3 and anti-CD28 antibodies and incubated in the absence or presence of test compounds for 72 hr at 37°C. For determination of T cell proliferation, [3H]-thymidine (0.2 μCi/well) was added for the last 18 hr of the incubation period. Interferon-γ (INF-γ) released into the culture medium was determined by ELISA.

**Results:** Tetomilast was found to be a potent inhibitor of PDE4 subtypes. Its selectivity for inhibiting the high-affinity rolipram-binding (HARB) conformer of PDE4 was reduced compared with that of rolipram. Tetomilast’s PDE4 inhibitory potency was similar to that of rolipram and cilomilast and was at least 100× less than that of roflumilast. At 10 μM, tetomilast caused a significantly greater inhibition of CD3/CD28-stimulated T cell proliferation than did the equivalent PDE4-inhibitory concentrations of 10 μM cilomilast, 10 μM rolipram, and 0.1 μM roflumilast. Tetomilast also demonstrated greater inhibition of INF-γ release from CD3/CD28-stimulated T cells as compared with the other PDE4 inhibitors.

**Conclusions:** Compared with rolipram, tetomilast showed a reduced selectivity for inhibition of the HARB conformer of PDE4, predicting a reduction in side effects, which have been associated with binding of PDE4 inhibitors to the HARB site in the CNS and gastrointestinal tract. Tetomilast’s inhibition of CD3/CD28-stimulated CD4 T cell proliferation and INF-γ release was significantly greater than that of the other PDE4 inhibitors tested, suggesting that other mechanisms beyond PDE4 inhibition may account for the pharmacologic activity of tetomilast.

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**The Risk of Coronary Heart Disease with Inflammatory Bowel Disease**

Raja Shekhar R, Sappati Biyani, MD, Jay Kumar Menon, MD, Adnan Zaidi, MD, Nabil M. Fahnmy, MD, F.A.C.G., Karl P Nelson, PhD, James F King, MD, M.A.C.G.,* Elizabeth Baum, MD, IM, Canton Medical Education Foundation, Canton, OH; GI, Gastroenterology & Hepatology Specialists, Canton, OH; Cardiology, Cardiovascular Consultants Inc., Canton and Ohio Research, Aultman Health Foundation, Canton, OH.

**Purpose:** Inflammatory processes with the presence of excess serum acute phase proteins, cytokines and cell adhesion molecules are increasingly being implicated in atherosclerotic processes. The association between IBD and CAD is not well established. Considering the role played by the diffuse systemic inflammatory reaction in IBD, we planned to assess the traditional risk factors of CAD in patients with IBD.

**Methods:** A case-controlled, retrospective chart review study of 42 consecutive patients (17 females and 25 males) from 1999 to 2005 diagnosed with IBD (15 UC and 27 Crohn’s) and with CAD was conducted. Controls (n = 137) are patients with CAD. They were age- sex-matched (35 females and 102 males) with the IBD+CAD patients. The Framingham risk score (FRS) estimates the 10-year risk of CAD. It is based on age, sex, HTN, DM, total cholesterol, HDL cholesterol and smoking. The FRS of IBD+CAD patients was compared with that of controls. Values are expressed as mean ± SEM (n).

**Results:** The FRS for the IBD+CAD patients is 7.43 ± 0.76 (42) and that of the CAD only patients is 8.70 ± 0.36 (137). Comparison by t-test indicated no significant difference between the groups (p = 0.100). However, since gender and age contribute to the risk score, we controlled for these effects by performing ANCOVA. When the risk score is adjusted for the group and gender with age as a covariate, there is a statistically significant difference in the adjusted total score between the two groups [IBD+CAD: 8.06 ± 0.51 (42); CAD: 9.95 ± 0.32 (137); p = 0.002] and between males and females [Male: 6.36 ± 0.36 (127); Female: 11.66 ± 0.48 (52); p < 0.001]. In two groups of patients with CAD, the patients with IBD had a lower risk score.

**Conclusions:** In comparison to patients with CAD, patients with IBD and CAD had a lower FRS risk score but still had the disease. Prospective cohort studies will be needed to further evaluate the incidence of CAD in the IBD patient population. [figure1]
Fisher chapter. Subjects were provided a pre-addressed, pre-stamped return envelope and instructed to return completed surveys with no identifying information.

Results: Survey response was 20% (637); 63% female, 34% male. Complete responses to education questions were obtained from 219 subjects with IBD. Patients felt IBD most affected education by increasing stress levels (49%). 71% indicated poor perceived coping support from educators. 52% felt teachers were indifferent towards IBD. 71% stated their disease status did not change their career or educational plans from previous plans. 50% stated their diagnosis had no influence on education or career direction. A greater percentage (30%) of IBD patients had graduate education than shown by either national or Illinois population data. IBD patients had higher representation in occupations that required skilled labor and are largely sedentary. This trend held true even when pre-disease occupations were considered. Patients’ activity level and environmental exposure assessment indicated a sedentary lifestyle as 59% stated they primarily sat at a desk while at work. Of the 12% whose work involved physical exertion, 48% had a light exertion. 96% spend most of their workday indoors. 94% of patients had air-conditioning and 80% had carpeting. However, 72% of patients had windows near their area of work. Of the patients who did exercise, 67% did it indoors.

Conclusions: Patients with IBD tend to attain higher levels of education than the non-IBD population. Students did not feel they had much invested support or interest in their disease from their educators. However, their illness did not affect long term educational or career decisions. These more skilled occupations represented more sedentary occupations with artificial environmental exposures. These factors may have a role in the pathogenesis of IBD.

1095
Mortality in Patients with Ulcerative Colitis – Experience of a Tertiary Care Center
Sandra El-Hachem, MD, Bret Lashner, MD, Jhyon Dounit, MD, Ioannis Okonomou, MD, Bo Shen, MD,* Gastroenterology and Hepatology, Cleveland Clinics Foundation, Cleveland, OH.

Purpose: The last decade has witnessed major advances in the medical and surgical treatment of ulcerative colitis (UC). Deciding on the appropriate modality of treatment in some patients has become more ambiguous. The identification of mortality and its causes in this patient population may provide useful information for deciding on appropriate therapy. Aim of study is to assess mortality and to identify its causes in a large cohort of UC patients in a tertiary-care center.

Methods: A retrospective chart review of 2445 patients with UC based on ICD code, of which 45 had indeterminate colitis from 1999 to 2004, was undertaken. Diagnosis of UC and indeterminate colitis was based on a combined assessment of clinical, endoscopic, and histopathologic features. Death information and relevant demographic and clinical data was obtained from the electronic medical records and Social Security Death Index. Descriptive statistics were applied.

Results: The mortality rates for patients with UC and indeterminate colitis were 1.6% (38/2403) and 6.7% (3/45), respectively (p = 0.012). Of the 41 deaths, the mean age was 59.7 ± 14.7 yrs (95% CI, 55.2, 64.3). The mean duration of UC from time of diagnosis till death was 16.4 ± 12.0 yrs (95% CI, 10.9, 21.8). 39% of patients at time of death were on corticosteroid therapy. Information on the causes of mortality was available in 22 patients out of the 41; 9 patients died from non-UC related causes (7 had non-colorectal cancers and 2 had cardiopulmonary disease). Of the 8 deaths from UC non-surgical related causes, 4 died from Colorectal cancer, 3 from complications of PSC and 1 from severe malnutrition and sepsis. 5 patients died from direct surgical complications. The patients that died from UC non-surgical related causes appeared to have a longer duration of disease than those patients who died from UC surgical related causes (p = 0.05).

Conclusions: The mortality rate in indeterminate colitis patients appeared higher than that in UC patients. In those who died from UC, there was a trend pointing towards increased mortality from UC non-surgically related causes with a longer duration of disease.

<table>
<thead>
<tr>
<th>Identified causes of mortality N = 22</th>
<th>Surgery related death</th>
<th>Non-surgery related death</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td># of Deaths</td>
<td>5/22 (22.7%)</td>
<td>8/22 (36.4%)</td>
<td>0.36</td>
</tr>
<tr>
<td>Mean Age, yrs</td>
<td>55.8 ± 7.7</td>
<td>56.9 ± 11.1</td>
<td>0.85</td>
</tr>
<tr>
<td>Mean Duration of disease, yrs</td>
<td>11.3 ± 3.2</td>
<td>25.2 ± 9.8</td>
<td>0.05</td>
</tr>
<tr>
<td>Immunosuppressant use at time of death</td>
<td>3/5 (60.0%)</td>
<td>2/7 (28.6%)</td>
<td>0.27</td>
</tr>
</tbody>
</table>

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Adjunctive Antibiotic Therapy with Rifaximin May Help Reduce Crohn’s Disease Activity
Ira Shafran, MD, PA.,* Private Practice, Shafran Gastroenterology Center, Winter Park, FL.

Purpose: Bacteria may play an important role in the inflammatory cascade of Crohn’s disease (CD), and antibiotics may be useful in CD management. Rifaximin is a nonabsorbed, oral antibiotic with broad-spectrum activity and a safety profile comparable to placebo. Given these favorable characteristics, the potential benefits of rifaximin in CD management were examined.

Methods: A chart review of CD patients (pts) treated with rifaximin from 2001 to 2005 was conducted at a single center. Concomitant medications were permitted. Crohn’s Disease Activity Index (CDAI) scores were determined retrospectively with remission defined as CDAI score < 150 and secondary efficacy endpoints determined as 70-point or 100-point reductions from baseline.

Results: Data from 68 pts (mean CD duration, 17 y) were analyzed. Most pts (94%) were treated with rifaximin 200 mg t.i.d., with treatment lasting a median of 16.6 wk. Thirty-one pts (46%) were also treated with steroids at least once during rifaximin therapy. The median baseline CDAI score was 221, and 34 pts (50%) were identified with fistulizing disease. Overall, induction of CD remission was reported in 44 pts (65%), with a similar response rate (65%) achieved in 17 pts with CD in the small intestine only. A slightly lower response rate (55%) was observed in 11 pts with CD in the large intestine only. A slightly higher rate of remission (70%) was achieved in 37 pts who did not receive steroids compared with the rate (58%) for 31 pts treated with steroids. In addition, a 70-point reduction from baseline CDAI score was observed in 34 pts (50%), and a 100-point reduction was observed in 29 pts (43%). Consistently greater monthly improvements from baseline in CDAI scores occurred through at least 4 months post-rifaximin initiation. Interestingly, remission was detected in 67% of 18 patients who received rifaximin monotherapy.

Conclusions: Rifaximin therapy was associated with clinical improvement in pts with CD. Although the direct contribution of rifaximin could not be fully evaluated in this observational study, data suggest that rifaximin, with or without steroids, may be beneficial in the treatment of CD, warranting further studies.

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Conduct of Clinical Trials in UC: Impact of Independent Scoring of Endoscopic Severity on Results of a Randomised Controlled Trial
Maria T. Abreu, MD, Simon PL, Travis, DPhil,* Rachel M. Cooney, MD, Milan Lukas, MD, Eugeniusz Butruk, MD, Iskren Kotzev, MD, Bryan F. Warren, FR.C.Path., Piotr W. Krazeski, MD, Dan J. Schnell, PhD, Bruce R. Yacyszyn, MD, Christian A. Bernhardt, PhD Gastroenterology, Mt Sinai School of Medicine, New York, NY; Gastroenterology, John Radcliffe
**Perianal Skin Tags in Inflammatory Bowel Disease**

Jennifer L. Bonheur, MD, Burton I. Korelitz, MD*, Jared Braunstein, MD, Georgia Panagopoulos, PhD Division of Gastroenterology, Lenox Hill Hospital, New York, NY and New York University School of Medicine, New York, NY.

**Purpose:** The association between intestinal Crohn’s disease (CD) and specific perianal abnormalities called anal skin tags (AST) has been recognized but not well-defined. Skin tags have been classified into two types: 1) edematous, hard, often cyanotic, tender or painful and typically arising from a healed anal fissure or ulcer, or 2) raised, broad or narrow, single or multiple, soft or firm and painless, often referred to as “elephant ears.” The aims of this study were to 1) better characterize those skin tags identified by the term “elephant ears.” 2) compare their incidence in patients with CD and UC, 3) make observations regarding the relationship of the skin tags to the location of the primary bowel disease, 4) to record the relationship of the AST to perirectal abscesses, fistulas, and rectal strictures and 5) to discuss the value of AST in the diagnosis of CD.

**Methods:** A retrospective chart review was performed between 2001 and 2002 for 170 consecutive patients seen in the private office of the senior investigator who specializes in inflammatory bowel disease. Data with respect to location of disease for these patients was obtained from an extensive computer database kept by the senior investigator. Photos were taken at colonoscopy for help in identification of specific features and comparisons.

**Results:** AST were found more frequently in patients with CD (46.7%) as compared to patients with UC (25.0%) confirming previous observations that they are more diagnostic of CD (p = 0.005). Subset analysis revealed a trend with a lower incidence of AST in patients with ileocolitis (16.3%) as compared to 36.7% in patients with ileitis and 46.9% in patients with colitis (p = 0.067). A subset of 44 patients with other perianal manifestations of CD(i.e., fissures, abscesses, rectal strictures, and fistulas) was analyzed to determine the relationship between their presence and the presence of AST. There appeared to be no statistically significant association between the presence of these other perianal findings and AST in patients with UC (n = 10, p > 0.70) or CD (n = 34, p > 0.20). No gender differences were found.

**Conclusions:** We are providing descriptive characteristics of those AST found in patients with IBD, their most prominent features found in CD and how and when they help in differentiation from UC. Moreover, our preliminary conclusions support the diagnostic significance of AST heralding the diagnosis of CD when they are discovered on physical exam.

**Remission (registration) – Central Reader vs Investigator**

<table>
<thead>
<tr>
<th></th>
<th>Peptide</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central Reader</td>
<td>27.3%</td>
<td>25.4%</td>
</tr>
<tr>
<td>Investigator</td>
<td>30%</td>
<td>44.4%</td>
</tr>
</tbody>
</table>

**Conclusions:** Observer assessment of endoscopic activity for UC needs to be validated and techniques standardized. It is possible to conduct clinical trials with an independent observer. Remission rates defined by regulatory authorities for registration trials are highly dependent on the observer. The quality and robustness of UC trials will benefit from the inclusion of an independent observer and internationally agreed definitions of activity and remission.

Research was funded by P&G Pharmaceuticals, Mason, OH.
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Sagittal Sinus Thrombosis as a Complication of Crohn's Disease
Irfan M. Hisamuddin, MD, Shahed L. Brown, MD, Robin R. Rutherford, MD,* Medicine, Emory University School of Medicine, Atlanta, GA.

Purpose: Thromboembolism is a frequently described complication of Inflammatory Bowel Disease although few case reports exist in the literature of neurologic complications of Inflammatory Bowel Disease. We describe a rare case of sagittal sinus thrombosis as a complication of Crohn's Disease.

Case Report: A 26-year-old female who presented to the hospital with fever, diarrhea and abdominal pain was diagnosed with Crohn's disease. On a six months follow up she presented with worsening of her abdominal pain and diarrhea. At this office visit, she also had complaints of a sinus headache behind her left eye. About 2 weeks following this office visit, patient went to the emergency room with a throbbing headache radiating to her neck that she described as worst headache of her life. Her pain was aggravated by light and she had only mild improvement with OTC painkillers. She was also experiencing nausea, dizziness, weakness and blurry vision. Her exam was notable for maxillary and frontal sinus tenderness. Non-contrast CT of head showed no evidence of intracranial mass or bleed. An LP revealed no RBCs with normal glucose and protein, but there was an elevated lymphocyte count. She was discharged from the ER with pain medication. The patient returned to the GI clinic three days later electively for Crohn's management, still having severe headaches with nausea and vomiting. The pain was still mostly frontal in location with associated pain behind her left eye. She was admitted to the hospital and a neurology consult was obtained. She underwent an MRA/MRV with findings suggestive of non-occlusive thrombus within the superior sagittal sinus with extension into the proximal transverse sinus. A work-up initiated to evaluate for an underlying hypercoagulable state was inconclusive. The patient denied cigarette use, and there was no record of oral contraceptives or other hormonal therapy use. The patient was subsequently started on IV heparin and coumadin. She was instructed to stay on coumadin until her MRA/MRV to determine resolution of thrombosis.

Conclusions: Thromboembolism is a serious and not infrequent complication of Inflammatory Bowel Disease although case reports of CNS thrombosis in Crohn's Disease are very rare in the literature. Clinicians need to have a high index of suspicion, especially for unusual presentations and should strongly recommend preventive measures against the risk factors described above in IBD patients in specific and all patients in general.

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Disability in the Inflammatory Bowel Diseases: Impact of Awareness of the Americans with Disabilities Act
Nicholas J. Procaccini, MD, JD, Stephen J. Bickston, MD,* Division of Gastroenterology/Hepatology, University of Virginia, Charlottesville, VA.

Purpose: Given the relative dearth of information on Inflammatory Bowel Disease (IBD) patients and workforce participation in the United States we sought to determine what percentage of a sample of IBD patients were on or had applied for disability or were not working. We then looked at what effect other factors such as education level and knowledge of the Americans with Disabilities Act (ADA) had on employment outcomes in our IBD patients.

Methods: Retrospective survey based study on patients seen in the IBD clinic at the University of Virginia. A database of over 1000 patients diagnosed with IBD is maintained at the University of Virginia Digestive Health Center of Excellence as part of ongoing research studies. Study surveys were sent in an alphabetical fashion to potential subjects in the database. Participation of Excellence as part of ongoing research studies. Study surveys were sent in an alphabetical fashion to potential subjects in the database. Participation was strictly voluntary.

Results: One hundred seventy three subjects agreed to participate by returning their surveys (52.4% response rate). Overall, 32.3% (46/142) of subjects who were not retired, were either disabled, denied disability and not working, or looking for work. The disability rate was 20.4% (29/142). An additional 7.0% (10/142) had applied for disability, been denied, and were not employed. Those subjects with some post-college education including those with graduate/professional degrees were employed at a rate of 91.2% (31/34). College graduates and those with some college education were employed at a rate of 72.0% (36/50). Finally subjects with high school education or less were employed at a rate of 41.9% (18/43) (Chi-square = 21.82, p < .001). Overall, 62.4% of subjects indicated familiarity with the ADA. Of subjects who were currently employed 66.0% (64/97) were aware of the ADA compared to 44.4% (20/45) awareness for those that were not employed (Chi-square = 5.90, p < .025).

Conclusions: IBD affects patients' ability to work and persons with IBD appear to have high levels of disability or unemployment. Educational level of patients appears to play a substantial role in employment outcomes. Notably, a significantly smaller percentage of subjects who were not working had awareness of the benefits conferred by the ADA than their counterparts who maintained employment. Targeting of patients who are at high risk for disability and education of rights entitled under the ADA may lead to greater employment among patients with IBD.

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MMX Mesalamine for the Treatment of Active Mild-to-Moderate Ulcerative Colitis: An Evidence-Based Medicine Analysis
William J. Sandborn, MD,* Gary R. Lichtenstein, MD, Michael A. Kamm, MD, Karen Barrett, Raymond E. Joseph, MD IBD Clinic, Mayo Clinic, Rochester, MN; Gastroenterology, University of Pennsylvania, Philadelphia, PA; Gastroenterology, St. Mark's Hospital, London, United Kingdom; Shire Pharmaceuticals Inc., Basingstoke, United Kingdom and Shire Pharmaceuticals Inc., Wayne, PA.

Purpose: Current mesalamine (5-ASA) treatments for ulcerative colitis (UC) are often associated with complex dosing regimens that may lead to poor compliance and reduced efficacy. SPD476–302, a randomized, placebo-controlled, phase III study recently demonstrated the efficacy of MMX™ mesalamine (SPD476), a high-strength (1.2g/tablet) 5-ASA formulation designed for once-daily dosing, in inducing remission in patients with mild-to-moderately active UC. Given the importance of evidence-based medicine for patient care, number needed to treat (NNT) analyses are frequently used for making treatment decisions in clinical practice. The purpose of this analysis is to assess the NNT associated with MMX mesalamine-related induction of remission in UC.

Methods: In study SPD476–302, patients with mild-to-moderate UC received MMX mesalamine 2.4g/day given once daily (QD), MMX mesalamine 4.8g/day given QD, Asacol® given three times daily (TID) or placebo. The primary endpoint was clinical and endoscopic remission (modified UC-disease activity index score of ≤1, with a rectal bleeding and stool frequency score of 0, no mucosal friability, and ≥1 point reduction in sigmoidoscopy score from baseline) after 8 weeks’ treatment. An NNT analysis was completed for remission at 8 weeks.

Results: See table.

Conclusions: NNT analysis shows that, versus placebo, for one patient with mild-to-moderately active UC to achieve clinical and endoscopic remission

Evidence-based analysis of remission

<table>
<thead>
<tr>
<th></th>
<th>MMX mesalamine</th>
<th>MMX mesalamine</th>
<th>Asacol®</th>
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<tbody>
<tr>
<td></td>
<td>2.4g/day</td>
<td>4.8g/day</td>
<td>2.4g/day</td>
</tr>
<tr>
<td>Patients in remission, n (%)</td>
<td>34/84 (40.5)*</td>
<td>35/85 (41.2)*</td>
<td>28/86 (32.6)NS</td>
</tr>
<tr>
<td>Difference in remission rate vs placebo, %</td>
<td>18.4</td>
<td>19.1</td>
<td>10.5</td>
</tr>
</tbody>
</table>

NNT for one patient to achieve remission (95% confidence interval)

<p>| |</p>
<table>
<thead>
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<tbody>
<tr>
<td>NNT</td>
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<tr>
<td></td>
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<tr>
<td>5.4 (3.1, 21.3)</td>
</tr>
<tr>
<td>5.2 (3.1, 18.4)</td>
</tr>
<tr>
<td>9.6 (4.2, ∞)</td>
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</tbody>
</table>

*p < 0.01, NS = not significant vs placebo
current approved 5-ASA treatments require multiple-daily dosing, which is inconvenient, potentially leading to reduced compliance and suboptimal efficacy. MMX mesalamine (SPD476), a high-strength formulation of 5-ASA designed for once-daily (QD) dosing, uniquely combines a gastroresistant film (to delay drug release until pH >7, usually in the terminal ileum) and MMX Multi Matrix System™ technology (to provide consistent drug delivery in the colon). The effect of gender on clinical outcome with MMX mesalamine therapy has not previously been studied.

Methods: Two randomized, double-blind, placebo-controlled, phase III studies (SPD476–301 and –302) were pooled to examine efficacy in men and women. Patients received MMX mesalamine 2.4g/day (given QD [SPD476–302] or twice-daily [BID, SPD476–301]), MMX mesalamine 4.8g/day (given QD in both studies) or placebo. The primary endpoint was the same in both studies: clinical and endoscopic remission using stringent criteria (modified UC-disease activity index ≤1 point reduction in sigmoidoscopy score from baseline).

Results: A significantly greater proportion of both men and women receiving MMX mesalamine 2.4g/day or 4.8g/day achieved remission vs. placebo (Table). For all treatment groups, including placebo, a higher percentage of women achieved remission than men. Although gender significantly affected remission rates (p = 0.008 for all treatment groups combined), logistic regression analysis of treatment by gender interaction did not suggest a difference in MMX mesalamine effect by gender (p = 0.920).

Conclusions: MMX mesalamine, a novel, high-strength formulation of 5-ASA, effectively induces remission of mild-to-moderate UC in both men and women. QD dosing with MMX mesalamine may increase compliance and therapeutic success in men and women with UC. This research was funded by Shire Pharmaceuticals Inc., Wayne, PA, USA.

8-week remission rates by gender

<table>
<thead>
<tr>
<th>Gender</th>
<th>MMX mesalamine 2.4g/day</th>
<th>MMX mesalamine 4.8g/day</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male, n (%)</td>
<td>25/85 (29.4%)</td>
<td>25/87 (28.7%)</td>
<td>12/84 (14.3%)</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>39/87 (44.8%)</td>
<td>36/87 (41.4%)</td>
<td>18/87 (20.7%)</td>
</tr>
</tbody>
</table>

*p < 0.05, **p < 0.01 and ***p < 0.001 vs. placebo.

Use of Allopurinol with 6-Mercaptopurine in Inflammatory Bowel Disease To Achieve Optimal Metabolite Levels: A Review of Four Cases

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Purpose: Approximately 1/3 of patients with IBD do not respond to or are intolerant of 6MP therapy. A subgroup of patients fail to attain optimal 6-thioguanine nucleotide (6TGN) levels despite medication dose escalation and instead shunt towards the potentially hepatotoxic metabolite 6-methylmercaptopurine (6MMPN). The aim of this study was to review and report cases in which 6MP was combined with allopurinol 100 mg daily, in an effort to achieve optimal metabolite levels (6TGN >235 and 6MMPN < 7500 pmol/8×108 RBC).

Methods: A retrospective chart review was undertaken of all IBD cases through May 2006 in which 6MP was used in combination with allopurinol.

Results: 4 patients were treated with allopurinol + 6MP therapy. All 4 patients had been unable to achieve optimal 6TGN metabolites on conventional 6MP therapy due to shunting towards 6MMPN. 3 patients with elevated 6MMPN had abnormal liver enzymes; 1 patient with 6MMPN of 27369 had normal liver enzymes. All four patients achieved optimal 6TGN and undetectable 6MMPN with allopurinol + 6MP therapy. 2 patients experienced transient side effects. All patients with abnormal liver enzymes normalized with combination therapy. Optimal metabolites were achieved in a mean of 38 days, with a weight-based dose of 6MP 0.35–0.61 mg/kg. Three of the patients experienced clinical benefit with combination therapy. [Figure1]

Conclusions: The addition of allopurinol 100 mg daily to 6MP can result in optimal 6TGN in patients who preferentially shunt away from this therapeutic

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MMX Mesalamine Is Well Tolerated in Patients with Active Mild-to-Moderate Ulcerative Colitis: Pooled Analysis of Adverse Events from Three Randomized Studies

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Purpose: Although mesalamine (5-aminosalicylate; 5-ASA) is the standard first-line therapy for mild-to-moderate ulcerative colitis (UC), it often requires multiple-daily dosing, contributing to poor patient compliance and potentially resulting in sub-optimal outcomes. MMX™ mesalamine (SPD476) is a high-strength (1.2g/tablet) formulation that can be administered once daily (QD). This novel formulation uniquely combines a gastroresistant polymer film (to delay release of the active drug until the terminal ileum; pH >7.0) and MMX Multi Matrix System™ technology (to ensure consistent 5-ASA delivery through the entire colon). Recent studies have demonstrated that 8 weeks of treatment with MMX mesalamine (2.4g/day [given QD or twice daily] or 4.8g/day [given QD]) is effective for inducing clinical and endoscopic remission in patients with mild-to-moderate UC.

Methods: Data from three 8-week studies (SPD476–202, −301 and −302) were analyzed to examine the safety and tolerability of MMX mesalamine (2.4g or 4.8g/day).

Results: In total, 560 patients received MMX mesalamine 2.4g/day (n = 191), 4.8g/day (n = 190) or placebo (n = 179). Of these patients, 10 (<2%) reported 13 serious AEs: 7 with placebo, 4 with MMX mesalamine 2.4g/day, and 2 with MMX mesalamine 4.8g/day. Two cases of pancreatitis, a well-described rare side effect of mesalamine, (1 in each MMX mesalamine group) were considered possible or probably related to study medication; both cases resolved without sequelae after treatment discontinuation. Overall, 7.3%, 3.1% and 1.1% of patients withdrew due to AEs in the placebo, MMX mesalamine 2.4g/day and 4.8g/day groups, respectively. Most discontinuations were caused by worsening UC or lower-GI symptoms.

Conclusions: This pooled analysis confirms that MMX mesalamine (2.4g and 4.8g per day) is well tolerated, with fewer discontinuations due to AEs than placebo. With convenient once-daily administration, and a similar safety profile to other mesalamine medications, MMX mesalamine has the potential to increase compliance, thereby improving treatment success in mild-to-moderate UC patients. This research was funded by Shire Pharmaceuticals Inc., Wayne, PA, USA.
6TGN/6MMPN achieved with Effective weight-based dose of Clinical Outcome 6MP/allopurinol ceased as not Time from initiation of allopurinol

Duration of disease prior to initiation of allopurinol Shunting demonstrated by 6TGN/6MMPN (pmol/8 x 108 RBC)

Case 1 Case 2 Case 3 Case 4

<table>
<thead>
<tr>
<th>Age</th>
<th>Gender</th>
<th>Weight (kg)</th>
<th>Race</th>
<th>Diagnosis</th>
<th>Duration of disease prior to initiation of allopurinol</th>
<th>TPMT genetics</th>
<th>Shunting demonstrated by 6TGN/6MMPN (pmol/8 x 108 RBC)</th>
<th>Justification for allopurinol combination therapy</th>
<th>Concomitant IBD therapy</th>
<th>6MP dose prior to initiating allopurinol (mg)</th>
<th>6MP dose in combination with allopurinol (mg)</th>
<th>6TGN/6MMPN achieved with combination therapy (pmol/8 x 108 RBC)</th>
<th>Effective weight-based dose of 6MP (mg/kg)</th>
<th>Time from initiation of allopurinol to optimal metabolites (days)</th>
<th>Adverse events</th>
<th>Clinical Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>36</td>
<td>Male</td>
<td>120</td>
<td>Caucasian</td>
<td>Crohn's colitis</td>
<td>3 yrs</td>
<td>Not tested</td>
<td>134/9,558</td>
<td>Shunting, abnormal ALT, failed multiple other therapies including clinical trials</td>
<td>-</td>
<td>150</td>
<td>50*</td>
<td>275/Undetectable</td>
<td>0.42</td>
<td>25</td>
<td>None</td>
<td>6MP/allopurinol ceased as not benefiting patient. Patient later diagnosed with NASH.</td>
</tr>
<tr>
<td>30</td>
<td>Male</td>
<td>82</td>
<td>Caucasian</td>
<td>Ulcerative Colitis</td>
<td>6 yrs</td>
<td>Normal alleles</td>
<td>109/9,432</td>
<td>Shunting abnormal ALT, steroid dependent</td>
<td>Mesalamine</td>
<td>125</td>
<td>50*</td>
<td>294/Undetectable</td>
<td>0.61</td>
<td>69</td>
<td>None</td>
<td>Continues 6MP + allopurinol in clinical remission off steroids.</td>
</tr>
<tr>
<td>48</td>
<td>Male</td>
<td>90</td>
<td>Caucasian</td>
<td>Ulcerative Colitis</td>
<td>10+ yrs</td>
<td>Not tested</td>
<td>82/27,369</td>
<td>Shunting, abnormal ALT, steroid dependent</td>
<td>Mesalamine</td>
<td>150</td>
<td>50*</td>
<td>319/Undetectable</td>
<td>0.56</td>
<td>69</td>
<td>None</td>
<td>Continues 6MP + allopurinol in clinical remission off steroids.</td>
</tr>
<tr>
<td>21</td>
<td>Male</td>
<td>71</td>
<td>Indian</td>
<td>Ulcerative Colitis</td>
<td>14 mos</td>
<td>Not tested</td>
<td>181/13,757</td>
<td>Shunting, abnormal ALT, steroid dependent</td>
<td>Mesalamine</td>
<td>100</td>
<td>25</td>
<td>357/Undetectable</td>
<td>0.35</td>
<td>28</td>
<td>None</td>
<td>Continues 6MP + allopurinol in clinical remission off steroids.</td>
</tr>
</tbody>
</table>

Although the patient was taking 75 mg at the time of the blood draw, the timing shortly after increasing 6MP from 50 to 75 mg, suggests that the lower dose was being reflected.

### MMX Mesalamine for Maintaining Remission of Ulcerative Colitis (UC): Interim Safety Results

**Purpose:** The inconvenience of current 5-aminosalicylate (5-ASA) dosing regimens for UC contributes to poor compliance, and increases the risk of disease flare. MMX™ mesalamine is a high-strength (1.2g/tablet) 5-ASA formulation designed for once-daily (QD) dosing that has demonstrated efficacy and good tolerability in inducing clinical and endoscopic remission of mild-to-moderate UC in two phase III studies (SPD476-301 and −302). A further study, SPD476-303, is assessing the safety of maintenance therapy with MMX mesalamine.

**Methods:** SPD476–303 is a randomized, multicenter, open-label, extension study comprising acute and maintenance phases. Patients not achieving remission in studies 301 or 302 were enrolled into the acute phase and received MMX mesalamine 4.8g/day (2.4g given twice daily [BID]) for 8 weeks. Patients in remission after studies 301 or 302, or the acute phase of 303 could opt to enter the maintenance phase of 303 where they were randomized to receive 1 years’ MMX mesalamine 2.4g/day, given QD or 1.2g BID. A pre-specified interim analysis was conducted after 4 months’ therapy.

**Results:** A total of 313 and 458 patients were dosed in the acute and maintenance phases, respectively. In the maintenance phase, 146 patients reported ≥1 treatment-emergent AE (TEAE). Most TEAEs were mild-to-moderate and gastrointestinal (GI), including: aggravated colitis (0.4%), nausea (0.7%), dyspepsia (0.9%), rectal hemorrhage (0.9%), diarrhea (1.1%), upper-abdominal pain (1.3%), abdominal pain not otherwise specified (1.5%), UC (1.7%) and aggravated UC (2.4%). GI disorders led to 7/10 and 4/9 patient withdrawals in the QD and BID arms respectively. Treatment-related AEs (55 in total) occurred in 40 patients, 14 of whom reported GI events: 8/19 patients and 6/21 in the QD and BID arms respectively. Only one SAE (out of 21) was considered possibly treatment-related (elevated liver enzymes possibly due to mononucleosis). In the acute phase one serious adverse event (SAE, pancreatitis) was considered possibly or probably treatment-related.

**Conclusions:** Maintenance treatment with MMX mesalamine (2.4g/day) is well tolerated with a similar safety profile to other 5-ASAs. The tolerability and convenience of MMX mesalamine may increase patient compliance and enhance treatment outcomes.

Research funded by Shire Pharmaceuticals Inc., Wayne, PA, USA

### Patients’ Experiences of Living with Ulcerative Colitis: Findings from a Large Survey of the Crohn’s and Colitis Foundation of America (CCFA)

Edward V. Loftus, Jr., MD,* Gastroenterology, Mayo Clinic, Rochester, MN.
Purpose: A number of clinical and community-based studies have demonstrated that ulcerative colitis (UC) is associated with a diminished quality of life (QoL) and an impaired life satisfaction. Community-based studies should be considered particularly relevant as they reflect the real-world perceptions of patients and their expectations relating to UC and its management.

Methods: A large, internet-based, cross-sectional survey of a random sample of members of the Crohn’s and Colitis Foundation of America (CCFA) was conducted to gain knowledge and understanding of patients’ experiences with UC and first-line treatments.

Results: Invitations to participate were sent to 49410 members. In total, 1595 usable replies were received from members with UC. Overall, 74% of respondents reported at least one flare of UC during the previous year. A substantial proportion of patients reported that their disease had caused key changes to their lifestyle, with 46% spending less time away from home and 37% becoming involved in fewer social activities. The major symptom concerns highlighted by the respondents included loss of bowel control (60% of patients) and decreased energy levels and QoL (49% of patients). The respondents were receiving a variety of aminosalicylates for the management of their UC. Treatment satisfaction differed between the various medications, with higher remission rates resulting in higher satisfaction rates. Importantly, 65% of patients disclosed that they had been poorly compliant with their current therapy. The most common reasons cited for non-compliance included the dosing frequency, the number of pills and the inconvenience associated with the medication. When requested to describe their ideal therapy, patients replied that high efficacy (97%), lack of side effects (74%), non-parenteral dosing (46%), non-rectal dosing (36%), low cost (23%), fewer pills (23%) and less frequent dosing (23%) were ‘very important’.

Conclusions: This North American survey provides further evidence of the negative impact of UC on the lives of patients. It also provides important information regarding the attitudes of patients towards first-line treatments for UC. Ultimately, effective, well-tolerated and convenient treatments are most likely to increase compliance and improve outcomes and QoL for patients with UC.

This survey was supported by CCFA and an unrestricted grant from Celltech Pharmaceuticals. Funding for writing support was provided by Shire Pharmaceuticals Inc., PA, USA.

1108 Prevalence of Helicobacter pylori Infection in Korean Patients with Inflammatory Bowel Disease
Sang Hun Hwang, MD, Dong Il Park, MD;* Kyu Chan Huh, MD, Hyo Sun Choi, MD, Jung Ho Park, MD, Hong Joo Kim, MD, Yong Kyun Cho, MD, Chong Il Sohn, MD, Woo Kye Jeon, MD, Byung Ik Kim, MD. Departments of Internal Medicine and Gastroenterology, Kangbuk Samsung Hospital, Sungkyunkwan University School of Medicine, Seoul, Korea and Department of Internal Medicine, Konyang University College of Medicine, Daejeon, Korea.

Purpose: The incidence of H. pylori infection was reported to be lower in individuals with inflammatory bowel disease (IBD) than in the normal populations of some western countries. In Korean populations, the prevalence of H. pylori infection is high and IBD is relatively uncommon. The aim of this study was to assess the prevalence of H. pylori infection in Korean patients with IBD. Another aim of the study was to assess the possible effect of drug therapy and phenotypic characteristics on the infection of H. pylori.

Methods: We studied 97 (mean age 40.1 years, range 13–78) unselected patients with IBD, including 63 with ulcerative colitis (UC) and 34 with Crohn’s disease (CD). 270 healthy age- and sex matched subjects (mean age 41.3 years, range 16–80) served as controls. Infection rates of H. pylori with IBD patients (97) and the control groups (270). The relationship between drug therapy and the phenotypic characteristics and the prevalence of H. pylori infection were also analyzed.

Results: Concerning positivity for H. pylori infection, significant differences between patients with IBD (54.1%) and controls (28.9%; P < 0.001), but not between patients with UC (34.9%) and CD (17.6%; P = 0.14) were noticed. When analyzed by age, the 15 to 29-year age group (P = 0.002) and the 30 to 44-year age group (P = 0.010) had a significantly different positive rate from that in the control group. The history of any drug therapy had no influence on H. pylori status in patients with CD. Among the previous therapies in patients with UC, steroid (P = 0.012) and ciprofloxacin (P = 0.027) were significantly related to lower incidence of H. pylori infection. The prevalence of H. pylori infection among patients with CD was not related to phenotypic characteristics such as age, location and behavior of disease.

Conclusions: Our observations confirm the low prevalence of H. pylori infection in patients with IBD. Difference of H. pylori positivity between the ranges of age may indicate the H. pylori infection influence differently on the bimodal peak age of onset of IBD. Association between H. pylori status and use of steroid and ciprofloxacin in patients with UC was noticed, suggesting that prevalence of H. pylori infection may be inversely correlated with the severity of disease.

1109 Higher Remission and Maintenance of Response Rates with Subcutaneous Monthly Certolizumab Pegol in Patients with Recent-Onset Crohn’s Disease: Data from PRECiSE 2
William J. Sandborn, MD, F.A.C.G., Jean-Frédéric Colombel, MD, Julian Panes, MD, Jürgen Schölmerich, MD, Juliet A. McColl, M.B., B.Ch., Stefan Schreiber, MD,* Gastroenterology, Cedars Sinai Medical Center, Los Angeles, CA; Hepato-Gastroenterologie, Hôpital Claude Huriez, Lille, France; Gastroenterology, Hospital Clinic de Barcelona, Barcelona, Spain; Internal Medicine, Univ. of Regensburg, Regensburg, Germany; Development, UCB, Slough, United Kingdom and Medicine, Christian-Albrechts Univ., Kiel, Germany.

Purpose: PRECiSE 2, a Phase III trial, showed efficacy of certolizumab pegol (a PEGylated Fab’ fragment of humanised anti-TNFα monoclonal antibody) in patients (pts) with Crohn’s disease (CD). Mean CD duration (SD) in the certolizumab pegol arm was 8.6 (7.1) yr (range < 1–33yr). The effect of CD duration on efficacy is presented here.

Methods: Open-label certolizumab pegol 400mg sc was given at Weeks (Wks) 0, 2, 4 to pts with a CD Activity Index score [CDAI] of 220–450. Responding pts (≥100-point decrease from baseline in CDAI) at Wk 6 were randomised to certolizumab pegol 400mg sc or placebo (PBO) every 4 wks (Wks 8–24). Response (defined above) and remission (CDAI ≤150 points) at Wk 26 by baseline disease duration (intent to treat [ITT] population) underwent exploratory analyses.

Results: Certolizumab pegol induced and maintained response and remission irrespective of disease duration, compared with PBO. Maintenance of response at Wk 26 in pts with disease < 3 yr was 75.9% with certolizumab pegol (n = 58) and 39.5% with PBO (n = 81; P < 0.001). In pts with disease < 1 yr, the certolizumab pegol long-term response rate increased to 89.5% (PBO 37.1%; P < 0.01) (Table). This pattern was also seen in Wk 26 remission rates: 58.6% in < 3 yr group (PBO 33.3%; P < 0.01); 68.4% in < 1-yr group (PBO 37.1%; P < 0.05).

<table>
<thead>
<tr>
<th>CD duration (yr)</th>
<th>PBO (n)</th>
<th>Certolizumab pegol (n)</th>
<th>PBO (n)</th>
<th>Certolizumab pegol (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any</td>
<td>36.2 (210)</td>
<td>62.8 (215)</td>
<td>28.6 (210)</td>
<td>47.9 (215)</td>
</tr>
<tr>
<td>&lt; 1</td>
<td>37.1 (35)</td>
<td>89.5 (19)</td>
<td>37.1 (35)</td>
<td>68.4 (19)</td>
</tr>
<tr>
<td>1–2 &lt; 5</td>
<td>50.0 (22)</td>
<td>75.0 (20)</td>
<td>36.4 (22)</td>
<td>55.0 (20)</td>
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<tr>
<td>2–5</td>
<td>36.4 (55)</td>
<td>62.2 (45)</td>
<td>29.1 (55)</td>
<td>46.7 (45)</td>
</tr>
<tr>
<td>≥5</td>
<td>32.7 (98)</td>
<td>57.3 (131)</td>
<td>23.5 (98)</td>
<td>44.3 (131)</td>
</tr>
</tbody>
</table>

*Wk 26 ITT. ‡p < 0.001, †p < 0.01, ‡p < 0.05 vs PBO
Conclusions: Certolizumab pegol was effective in CD irrespective of disease duration at baseline. Wk 26 clinical response and remission rates were higher in pts treated soon after CD developed. These data suggest a benefit of early intervention with certolizumab pegol 400mg sc every 4 wks for long-term maintenance of response and remission in pts with active CD.

Methods: Our demographic database at the Crohn’s and Colitis Center of NJ was reviewed and 56 patient charts were analyzed for disease type, location, treatment regimen, and response. We also included utilization of bone densiometry studies, and family history of IBD.

Results: Of the 56 patients, 48% (n=27) were male, and 52% were female (n=29). Overall, CD represented 16% (n=9) and UC was 84% (n=47) of the total patient population. CD was very rare in male patients (7%). Male IBD patients more commonly had UC, and had pancolitis 64% of the time. Overall 43% of all IBD patients were maintained in remission with 5-ASA agents, while 53% of patients required combination of 5-ASA and immunomodulators. Prednisone was utilized in 60% of patients (n=34) at some point in their disease course. Bone densiometry studies were available in 29% (n=10) patients that were exposed to steroids. Osteopenia (n=4) or osteoporosis (n=4) was seen in 80% of these patients. The average age of patients with bone loss was 42.6 years. Family history of IBD was present in 16% of patients analyzed.

Conclusions: CD is rare in patients of Asian Indian origin. UC is more frequent, and CD is extremely rare in Asian Indian males (7%). Roughly half of all patients with IBD were maintained in remission with 5-ASA agents, a lower response than typically seen in Caucasians, and 53% required a combination of 5-ASA and immunomodulators. Of the patients undergoing bone densiometry studies, 80% of them suffered from either osteopenia or osteoporosis at a young age. Bone densiometry studies need to be aggressively pursued to accomplish a 100% patient compliance with this diagnostic modality in patients of Asian Indian origin.

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A Recursive Partitioning Based Clinical Prediction Rule for Long Term Response to Infliximab in Patients with Crohn’s Disease

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Gastroenterology, Massachusetts General Hospital, Boston, MA.

Purpose: To determine clinical characteristics that predict long-term response to infliximab therapy in patients with Crohn’s disease (CD), and to develop a model that reliably predicts long-term response to infliximab in patients with CD.

Methods: In this single center retrospective cohort study, patients receiving maintenance infliximab therapy were selected, and clinical variables were collected. The clinical response at 2 years was determined and univariate analysis was done to determine predictive factors of this outcome. A classification tree with a recursive partitioning model to predict a 2-year clinical response to infliximab was created. The cohort of patients was randomly partitioned into two groups; 70% of patients (development cohort) were used to develop the classification tree, and the remaining 30% of patients (validation cohort) were used to validate the tree.

Results: One hundred ninety four patients were treated with infliximab for IBD from 1998–2005. Seventy patients were not included in the study because of the following reasons: patient did not have CD (38 patients), patient was lost to follow up within 1 month of starting infliximab (2 patients), patient received episodic infliximab treatment (21 patients), and inadequate clinical data on patient (9 patients). Therefore, 124 patients were included in our study. One hundred and one patients were either treated with infliximab for at least 2 years, or stopped treatment within 2 years. Fifty-seven patients (56%) were classified as having a clinical response to infliximab at 2 years, and 44 patients (44%) stopped infliximab within 2 years. Fifty-seven patients of Asian Indian origin. One hundred and one patients were either treated with infliximab for at least 2 years, or stopped treatment within 2 years.

Conclusions: The derived clinical predictive rule using a classification tree based on recursive partitioning may play a role in the future to guide physicians in selecting patients most likely to benefit from infliximab.

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An Epidemiologic Survey of Patients with Inflammatory Bowel Disease of Asian Indian Origin

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Purpose: Inflammatory bowel disease (IBD) has historically been considered a disease of caucasians. Recent data suggest an increasing recognition of IBD, particularly in minority populations; secondary to location of IBD centers, changes in accessibility of healthcare, and environmental factors. On the basis of personal impression, we theorized that Asian Indian patients more commonly suffer from ulcerative colitis (UC) rather than Crohn’s disease (CD). This has not been systematically reviewed in U.S. literature. We report our experience with 56 patients of Asian Indian origin.

Results: Of the 56 patients, 48% (n=27) were male, and 52% were female (n=29). Overall, CD represented 16% (n=9) and UC was 84% (n=47) of the total patient population. CD was very rare in male patients (7%). Male IBD patients more commonly had UC, and had pancolitis 64% of the time. Overall 43% of all IBD patients were maintained in remission with 5-ASA agents, while 53% of patients required combination of 5-ASA and immunomodulators. Prednisone was utilized in 60% of patients (n=34) at some point in their disease course. Bone densiometry studies were available in 29% (n=10) patients that were exposed to steroids. Osteopenia (n=4) or osteoporosis (n=4) was seen in 80% of these patients. The average age of patients with bone loss was 42.6 years. Family history of IBD was present in 16% of patients analyzed.

Conclusions: CD is rare in patients of Asian Indian origin. UC is more frequent, and CD is extremely rare in Asian Indian males (7%). Roughly half of all patients with IBD were maintained in remission with 5-ASA agents, a lower response than typically seen in Caucasians, and 53% required a combination of 5-ASA and immunomodulators. Of the patients undergoing bone densiometry studies, 80% of them suffered from either osteopenia or osteoporosis at a young age. Bone densiometry studies need to be aggressively pursued to accomplish a 100% patient compliance with this diagnostic modality in patients of Asian Indian origin.

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Association of Vitamin D Receptor Gene Polymorphisms with Inflammatory Bowel Disease

Nosratollah Naderi, MD,∗ Alma Farnood, MD, Manijeh Habibi, M.S., Faramarz Derakhshan, MD, Zahra Motahari, PharmD, Mohammad Reza Agah, MD, Elham Vali Khojeyini, MD, Hedieh Bafai, B.S., Mahta Ghaffarzadeh Rad, B.S., Rahim Aghazadeh, MD, Homayoun Zojaji, MD, Nasser Ebrahimi Daryani, MD, Babak Noorinayer, MD, Mohammad Reza Zali, MD, F.A.C.C.G. Lower GI Department, Research Center for Gastroenterology and Liver Diseases, Shaheed Beheshti University of Medical Sciences, Tehran, Islamic Republic of Iran and Gastroenterology Department, Tehran University of Medical Sciences, Tehran, Islamic Republic of Iran.

Purpose: The vitamin D receptor (VDR) gene maps to a region on chromosome 12 shown to be linked to inflammatory bowel disease (IBD) by wide genome screens. Many studies have recognized the relation of VDR gene polymorphisms with inflammatory and autoimmune disorders. Determining the frequency of these polymorphisms and their possible relation with IBD can improve understandings about genetic background of these diseases. The objective of this study was to assess the association of VDR gene polymorphisms (ApaI, TaqI, BsmI, FokI) with IBD.

Methods: In this case control designed study 100 UC patients, 50 CD patients and 150 sex and age matched healthy controls from Iranian origin were selected. These patients were referred to a tertiary center during a one year period (2004–2005). Assessment of VDR gene polymorphisms was performed by PCR- RFLP method.Genotype- phenotype analysis for these polymorphisms was performed.

Results: Only the frequency of the Fok I polymorphism was significantly higher in UC and CD group. The frequency of the polymorphic allele f was higher in UC and CD patients comparing with controls (p = 0.015, OR = 1.608, 95% CI = 1.093 – 2.365 and p = 0.016, OR = 1.789, 95% CI = 1.110 – 2.882, respectively). The ff genotype was significantly more frequent in UC and CD patients comparing with controls (p = 0.031, OR = 2.407, 95% CI = 1.066 – 5.433 and p = 0.029, OR = 2.774, 95% CI = 1.076 – 7.153, respectively). There were no significant differences between frequencies of other polymorphisms in patients and controls. No association was observed between these polymorphisms and UC or CD phenotypes.
Conclusions: This study suggests a probable association of the Fok I polymorphism in VDR receptor gene and IBD susceptibility in Iranian population.

Is Coronary Artery Disease an Extraintestinal Manifestation of Inflammatory Bowel Disease?
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Purpose: Premature development of CAD is a well recognized consequence of several chronic inflammatory conditions. Rheumatoid arthritis is one chronic inflammatory disease with a strong association to CAD subsequently leading to increased morbidity and mortality. The purpose of our study was to determine whether patients with IBD have an increased risk of CAD given the disease is characterized by recurrent flares of inflammation.

Methods: A retrospective chart review of 392 IBD patients was conducted from two academic centers. The data was obtained from both inpatient and outpatient settings between 1999–2005. 234 charts from one institution and 158 charts from the second institution were evaluated. The following parameters collected included age, gender, race, weight, subtype of IBD, and history of CAD, CABG, PTCA, DM, angina, HTN, hyperlipidemia and tobacco use.

Results: A total of 97 [24.7%] (55 men and 42 women) patients had comorbid IBD and CAD. In total 11/55 (20%) men and 13/42 (30.9%) women were between the ages of 55 and 64, 17/55 (30.9%) men and 12/42 (28.6%) women were between 65 and 74 years of age. 21/55 (38.2%) men and 14/42 (33.3%) women were 75 years and older.

Conclusions: This study suggests an association between the two disease states. However, a larger prospective randomized control trial needs to be conducted to further investigate if there is truly a relationship between IBD and CAD. If further studies support our conclusion, IBD may be deemed an independent risk factor for CAD.

Compliance with 5-ASA Products Is Associated with Decreased Medical Costs
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Purpose: Compliance with medications for chronic illness is known to be poor. Population-based data for adherence rates for first-line therapy for inflammatory bowel disease (IBD) have not been well characterized. Our was to examine the compliance rates for the major 5-ASA products prescribed to patients and correlate clinical characteristics with compliance and healthcare costs.

Methods: The Maryland CareFirst BlueCross BlueShield claims database was queried for all pharmacy and medical claims and corresponding cost information for the period January 1, 2002 to December 31, 2004 for patients who had at least one claim as Asacol®, Pentasa®, Dipentum®, Colazal®, Azulfidine®, sulfasalazine or mesalamine. Prescription refills data were collected and patients were stratified for outcomes based on compliance, defined as a medication possession ratio (MPR) of 80% or higher.

Results: Data for 5712 patients were retrieved; 4947 of which were studied, as they represented new users taking 5-ASA oral monotherapy. The average follow-up period for each patient was 332 days. Just over half of the sample population (57%) was compliant with prescribed medication. The mean MPR was highest for sulfasalazine (82%). Compliance rates were similar for males and females (p = 0.72). More patients under 18 (65%) and 65 and older (59%) were compliant compared with those between 18 and 39 (55%) or between 40 and 64 (57%). On average, non-compliance resulted in higher total health-care costs across all types of health-care services (approximately 32% higher for inpatient services and 44% for outpatient costs). In a multivariate analysis, compliance was highly correlated with average annual total costs. Patients who were persistent with their medications (refilled their prescriptions within 15 days of instructed date and did not switch to another drug) incurred 50% lower medical costs than those who were not (p < 0.05).

Conclusions: Only half of the patients were compliant with medications during the observation period. Age, but not gender, had an effect on compliance rates. Patients who were compliant incurred lower total health care costs than those who were not. The clinical and financial importance of maintenance medications should be emphasized to patients.

Comparison of Certolizumab Pegol, Etanercept, Adalimumab and Infliximab: Effect on Lipopolysaccharide-Induced Cytokine Production by Human Peripheral Blood Monocytes
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Purpose: Proinflammatory cytokines, such as interleukin-1β (IL-1β) are over-expressed by monocytes/macrophages in patients with Crohn’s disease (CD). It has been suggested that anti-tumor necrosis factor α (TNFα) agents mediate an inhibitory effect on lipopolysaccharide (LPS)-induced cytokine production via membrane TNFα signalling. This study compared LPS-stimulated production of IL-1β in the presence of certolizumab pegol (an antibody Fab’ fragment conjugated with polyethylene glycol) and other anti-TNF agents.

Methods: Monocytes were positively selected using CD14+ magnetic microbead-associated cell sorting (MACS) from peripheral blood
mononuclear cells of normal human donors. Purified monocytes were pre-incubated for 1 h with certolizumab pegol, etanercept, adalimumab, infliximab (100 μg/mL to 100 pg/mL) or a relevant control. After extensive washing, the monocytes were incubated — with or without LPS (100 ng/mL) — for 4 hours at 37°C. Supernatants were assessed for IL-1β (by enzyme-linked immunosorbent assay) and a range of chemokines, cytokines and other proteins (by Luminex).

**Results:** LPS-stimulated production of IL-1β by monocytes appeared to be completely inhibited in a dose-dependent manner by certolizumab pegol, infliximab and adalimumab. In contrast, etanercept was much less efficient at mediating this activity, causing only partial inhibition of cytokine production. Certolizumab pegol was approximately 100-fold more potent than infliximab in mediating this activity, causing only partial inhibition of cytokine production. Infliximab and adalimumab. In contrast, etanercept was much less efficient at mediating this activity, causing only partial inhibition of cytokine production. Certolizumab pegol was approximately 100-fold more potent than infliximab and adalimumab at inhibiting the release of IL-1β by monocytes. The effects of infliximab and adalimumab were similar. The LumineX analysis of a panel of cytokines and chemokines showed a range of effects with inhibition of IL-10 and IL-12 being the most profound. Again etanercept was not as potent as the other anti-TNFs agents at inhibiting these cytokines.

**Conclusions:** Effective inhibition of IL-1β production was seen with certolizumab pegol; inhibition was more potent than with adalimumab or infliximab. Even at high concentrations of etanercept, inhibition of IL-1β production was only partial. These are in vitro data, however, the comparative trends in inhibition of cytokine production stimulated by bacterial products appear to reflect the clinical efficacy of these anti-TNF agents in CD. The potent inhibition by certolizumab pegol of cytokine production by monocytes may represent an important mechanism of action in CD.

### 1116

**Crohn’s Disease in the Setting of Immunodeficiency with T-Cell Mediated Immunoproliferative Disorder: A Case Report**

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**Purpose:** The current hypothesis in IBD postulates the loss of immunological tolerance toward luminal antigens with subsequent T-cell mediated over-stimulation of the immune system resulting in chronic inflammation of the GI tract. However, more recent evidence suggests that immunodeficiency with decreased intramural surveillance may play a role in IBD. We present a patient with immunodeficiency due to a lymphoproliferative disorder who was found to have Crohn’s disease.

67 y/o African American male with pancytopenia and low CD4 count due to large granular lymphocyte leukemia (CD3+CD56+CD4–CD8+) since 1991, history of small bowel resection in 2000, and chronic aphthous ulcers in the mouth, presented with intermittent fever, generalized abdominal pain, nausea, vomiting and watery diarrhea with 15 lbs weight loss over 2 months. Abdominal CT showed several small bowel loops matted together with thickened walls and mesenteric lymphadenopathy. A small bowel series demonstrated extensive dilatation of the proximal ileum or distal jejunum with nodularity, thickened folds and ulcerations of the mucosa. Pathology report from prior small bowel resection was consistent with Crohn’s disease showing transmural ulceration and lymphoid aggregates; immunohistochemical analysis was compatible with benign lymphoid infiltration. Stool ova and parasites as well as C. diff toxin, ANA, ASCA, P-ANCA, and HIV were all negative. Colonoscopy with terminal ileum exam and upper endoscopy were unrevealing. Patient underwent exploratory laparotomy that showed a mass in the distal jejunum at site of prior anastomosis; two feet of small intestine were removed. Also a 3 cm by 4 cm conglomerate of mesenteric lymph nodes was dissected out. Pathology was consistent with Crohn’s disease with transmural ulceration and inflammation, extensive pyloric metaplasia in the mucosa and reactive lymphoid hyperplasia in lymph nodes. Immunohistochemical analysis did not support the diagnosis of malignant lymphoma. Patient’s symptoms have almost resolved after surgery with only some residual diarrhea.

The above clinical presentation and pathology findings are supportive of atypical Crohn’s disease in a patient with underlying immunodeficiency. In a patient with underlying T-cell mediated lymphoproliferative disorder, Crohn’s disease needs to be considered in the proper clinical setting.

### 1117

**Investigation of the Pharmacokinetic Properties of Certolizumab Pegol, an Anti-TNF Agent**

**Mark Baker, M.Sc., Sue Stephens, PhD,* Biology, UCB Celltech Ltd, Slough, United Kingdom.**

**Purpose:** Engineered Fab’ fragments represent a promising treatment alternative to whole IgG antibodies. Certolizumab pegol, a PEGylated Fab’ fragment of a humanised anti-tumor necrosis factor (TNF) monoclonal antibody, is one such agent in development for Crohn’s disease and other autoimmune diseases. The elimination half-life (t1/2) and exposure are lower for a Fab’ fragment than for the parent antibody. However, such pharmacokinetic (PK) properties can be improved by PEgylation (site-specific addition of polyethylene glycol [PEG]), which increases t1/2 and decreases volume of distribution and clearance. This study characterised the disposition of certolizumab pegol after iv and sc administration over a range of doses in non-human primates and human subjects.

**Methods:** Certolizumab pegol iv (50, 100, or 400 mg/kg; 60-min infusion) or sc (3 or 31 mg/kg) was given to cynomolgus monkeys (n = 20) in separate studies. Two double-blind, ascending, single-dose studies were conducted in healthy male human volunteers (aged 18–50 years). Certolizumab pegol was administered either iv (0.3, 1.0, 3.0, 10.0 mg/kg; 60-min infusion [n = 16]) or sc (20, 60, 200 mg [n = 24]). PK evaluation and modelling, which also comprised allostery investigations, were performed on primate and human plasma levels of certolizumab pegol.

**Results:** PK properties of certolizumab pegol were consistent across primate and human studies. The PK profile of certolizumab pegol was in line with those of other large biological molecules. The apparent volumes of distribution of certolizumab pegol in primates (46 mL/kg) and humans (45 mL/kg) were equivalent to the species-relevant plasma volumes. The clearance rate was 1.1 mL/h/kg in primates and 0.72 mL/h/kg in humans. Clearance and volume of distribution were amenable to allometric scaling (upon addition of preclinical data from other species). In both species, across the dose ranges studied, certolizumab pegol had a linear PK profile. The elimination t1/2 was 192 hours in primates and 311 hours in humans. Bioavailability of certolizumab pegol was complete, with modelling indicating at least 100% bioavailability in humans and primates.

**Conclusions:** Certolizumab pegol demonstrates predictable linear PK in both humans and primates. Its PK profile shows sustained subcutaneous absorption, high bioavailability, low clearance and prolonged elimination half-life, reflecting the advantages of conjugating a PEG moiety with a Fab’ fragment. Certolizumab pegol is suitable for both intravenous and subcutaneous dosing.

### 1118

**In Patients Suffering from Crohn’s Disease, No Cross Reaction between Antibodies to Infliximab and Certolizumab Pegol Was Detected**

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**Purpose:** Biologics that inhibit the effects of tumour necrosis factor α (TNFα) have shown clinical benefit in a range of inflammatory diseases. Infliximab is an intravenously administered, chimeric full IgG1 monoclonal anti-TNF antibody for Crohn’s disease (CD). Use of infliximab may be limited by the induction of antibodies to infliximab (ATI), subsequent loss of efficacy and occurrence of infusion reactions.1 Certolizumab pegol is
a subcutaneously administered PEGylated Fab’ fragment of a humanised anti-TNF antibody currently in an advanced stage of development for the treatment of CD. Patients who develop antibodies following treatment with infliximab may have an opportunity to switch to treatment with certolizumab pegol if the antibody response to infliximab does not cross-react with certolizumab pegol. The aim of this study was to determine if the antibody response elicited in patients to infliximab cross-reacts with certolizumab pegol.

Methods: Plasma samples were collected from 20 patients who had an antibody response to infliximab. Samples were assayed using ELISA plates coated with certolizumab pegol and then blocked with 0.1% bovine serum albumin. Plasma from patients with ATI was then incubated on the plates. Following a wash step, biotinylated certolizumab pegol was added followed by streptavidin horseradish peroxidase. Colour was developed using 3,3',5,5'-tetramethylbenzidine (TMB) substrate and the absorbance read at 450 nm following a wash step, biotinylated certolizumab pegol was added followed by streptavidin horseradish peroxidase. Colour was developed using 3,3',5,5'-tetramethylbenzidine (TMB) substrate and the absorbance read at 450 nm with reference at 630 nm.

Results: No cross-reactivity with certolizumab pegol was detected in any of the plasma samples (n = 20).

Conclusions: In patients suffering from Crohn’s disease, no cross reaction was detected between ATI and certolizumab pegol. It should therefore be possible for patients with CD who have an antibody response to one anti-TNF to use another anti-TNF agent. Subcutaneous certolizumab pegol represents a possible alternative treatment for patients who develop antibodies after intravenous treatment with infliximab.

REFERENCE

1119

Placental Transfer and Accumulation in Milk of the Anti-TNF Antibody TN3 in Rats: Immunoglobulin G1 Versus PEGylated Fab’

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Purpose: Certolizumab pegol, a PEGylated Fab’ fragment of an anti-TNF monoclonal antibody, has no Fc region. Adalimumab and infliximab are whole immunoglobulin G1 (IgG1) proteins and possess an Fc region. An Fc region allows placental crossing via specific neonatal Fc receptors, FcRs. This is important in Crohn’s disease as it affects women of child-bearing age. This study is the first to compare placental transfer of murinised IgG1 and PEGylated Fab’ versions of hamster anti-murine TNF antibody (TN3) in pregnant rats and assess milk concentrations.

Methods: Pregnant rats (Sprague-Dawley) received 100 mg/kg iv of either TN3 IgG1 (2 groups [grps] of 6) or TN3 PEGylated Fab’ fragment (2 grps of 6). Grp 1 for each agent was dosed on Day (D) 6 and D13 of gestation; Grp 2 on D15. In Grp 1, dam blood was collected every 2–3 days of gestation and fetal blood on D20. In Grp 2, dam blood was collected every 2 days of gestation and every 3–4 days post partum. Pup blood was taken on D7 post partum and milk from dams on D8 post partum. TN3 IgG1 and PEGylated Fab’ concentrations were determined by sandwich enzyme-linked immunosorbent assay.

Results: IgG1 and PEGylated Fab’ had plasma elimination profiles as expected in dam samples; the Fab’ having a slightly shorter half-life. In the PEGylated Fab’ Grp 1, 2/5 fetal samples had concentrations of the Fab’ 0.3% of that in dam plasma. In IgG1 Grp 1, all fetal samples had a mean IgG1 concentration 15.6% of that in dams. In PEGylated Fab’ Grp 2, no Fab’ was detected in pup plasma D7 post partum; 4/5 samples contained agent at 4.9% of the dam plasma concentration. In IgG1 Grp 2, the IgG1 concentration in pup plasma D7 post partum was twice that of dams; milk concentrations were 24% of those in dam plasma.

Conclusions: In the fetuses of 5 rats given anti-TNF PEGylated Fab’ fragment whilst pregnant, PEGylated Fab’ was found at very low concentrations in 2 fetuses but was not detectable in the others. This suggests that anti-TNF PEGylated Fab’ does not undergo active FcRn-mediated placental transport in rats. Biologically relevant IgG1 concentrations were found in fetuses of rats given IgG1, showing that IgG1 had crossed the placenta. Milk concentrations were much lower for PEGylated Fab’ than for IgG1 on D8 post partum. These results may be important for women of child-bearing age needing anti-TNF treatment.

REFERENCE

1120

Patient Perceptions of the Risks and Benefits of Infliximab for the Treatment of Inflammatory Bowel Disease

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Purpose: The purpose of this study was to determine patients’ perceptions of the risks and benefits of infliximab for the treatment of inflammatory bowel disease (IBD).

Methods: Adult patients and parents of patients attending IBD patient education symposiums were asked to complete a survey regarding risks and benefits of infliximab. All surveys were collected before outcomes of infliximab therapy were discussed. Results are reported as simple descriptive statistics and bivariate analyses were performed to test for associations using Kruskal or Kendall tests.

Results: 165 surveys were completed. 53% of respondents were adult patients (median age = 46), and 47% were parents of patients (children median age = 16). The majority of patients (67%) had Crohn’s disease. 33% were either currently taking or had taken infliximab in the past. 59% of respondents expected a remission rate greater than 50% at one year and 18% expected a remission rate greater than 70% at one year. 37% of respondents answered that infliximab is not associated with a risk of lymphoma and 67% responded that the lymphoma risk is no higher than twice that of the general population. 43% of patients responded that there is no increased risk of death due to a side-effect attributable to infliximab, and 83% responded that the risk of death is no higher than twice that of the general population. When given a scenario of a hypothetical new drug for IBD with risks mirroring those estimated for infliximab, 64% of respondents indicated that they would not take the medication, despite its described benefits. 30% of these patients were either currently taking or had previously taken infliximab. Patients actively taking infliximab predicted the highest remission rates (p = 0.05), and parents of patients predicted the lowest (p = 0.01). Parents estimated a higher risk of lymphoma than patients (p = 0.003). Risk and benefit perception was independent of gender and age of patient respondents.

Conclusions: A majority of patients and parents of patients overestimated the benefit of infliximab and greater than one-third answered that there is no increased risk of lymphoma or death. Patients were more optimistic about the medication, despite its described benefits. 30% of these patients were either currently taking or had previously taken infliximab. Patients actively taking infliximab predicted the highest remission rates (p = 0.05), and parents of patients predicted the lowest (p = 0.01). Parents estimated a higher risk of lymphoma than patients (p = 0.003). Risk and benefit perception was independent of gender and age of patient respondents.

1121

Colectomy for Ulcerative Colitis in a Large Private Insurance Claims Database: Types of Colectomy and Associated Follow-Up Surgical Procedures
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3438 Abstracts
Purpose: To describe the types of colectomy and follow-up surgical procedures in a population of privately insured individuals with ulcerative colitis (UC).

Methods: This was a retrospective analysis of claims data of employees and dependents from several large corporations in the US (MarketScan). The database includes 357.5 million outpatient claims and 1.4 million inpatient admissions. We identified a cohort of patients (pts) with a diagnosis of UC who underwent a colectomy between 2001 and 2004 inclusive. ICD-9 and CPT4 codes were used to identify UC pts, types of colectomy and subsequent related surgeries within the first 180 days after initial colectomy. Types of colectomy were classified into five categories: (1) total proctocolectomy (TPC) with ileal pouch–anal anastomosis (IPAA); (2) subtotal colectomy (SC) with ileostomy and Hartmann pouch or ileorectal anastomosis; (3) TPC with ileostomy; (4) segmental colectomy with ileal or colonic anastomosis, or (5) other partial colectomy (OPC). Follow-up surgeries were compared across colectomy types.

Results: A total of 25586 cases of UC were identified. The study sample includes 215 UC pts who had a CPT4 procedure code for colectomy and 180-days of pre- and post-colectomy follow-up. The pt group was 52% male (mean age 42.6 years) and most often insured by a PPO (39%). Common comorbidities included diabetes (8%) and chronic pulmonary disease (8%). The colectomy distribution was: (1) TPC with IPAA (n = 108, 50%); (2) SC with ileostomy (n = 48, 22%); (3) TPC with ileostomy (n = 28, 13%); (4) segmental colectomy with ileal or colonic anastomosis (n = 10, 5%); and (5) OPC (n = 21, 10%). Many patients had a second colectomy-related surgery; ostomy (n = 5, 2%), ostomy closure (n = 91, 42%), and proctectomy (n = 15, 7%). Within the 180 days post-colectomy, 71% of pts with TPC-IPAA had an ostomy closure, and 29% of pts with SC-ileostomy and Hartmann pouch or ileorectal anastomosis had a proctectomy.

Conclusions: In this retrospective study of privately insured UC pts, the most common types of colectomy were TPC-IPAA and SC-ileostomy, both leading to multi-staged surgeries. Among 215 pts with a colectomy, we observed at least 111 additional colectomy-related surgeries. These results highlight the burden of follow-up surgeries in many UC pts undergoing colectomy.

Supported by Schering-Plough.

1122

Colectomy for Ulcerative Colitis in a Large Private Insurance Claims Database: Types of Surgical and Medical Complications Occurring within 180 Days
Edward V. Loftus, MD, David J. Delgado, PhD, Howard S. Friedman, PhD, William J. Sandborn, MD, Mayo Clinic College of Medicine, Rochester, MN; D3D Health Consulting, Inc, Wayne, PA; and Analytic Solutions, LLC, New York, NY.

Purpose: To describe the surgical and medical complications occurring within 180 days of colectomy in a population of privately insured individuals with ulcerative colitis (UC).

Methods: This was a retrospective analysis of claims data of employees and dependents from several large corporations in the US (MarketScan) for the years 2001–2004 inclusive. The database included 357.5 million outpatient claims and 1.4 million inpatient admissions. We identified a cohort of patients (pts) with a diagnosis of UC who underwent colectomy. Colectomy types were classified into five categories: (1) total proctocolectomy (TPC) with ileal pouch–anal anastomosis (IPAA); (2) subtotal colectomy (SC) with ileostomy and Hartmann pouch or ileorectal anastomosis; (3) TPC with ileostomy; (4) segmental colectomy with ileal or colonic anastomosis; or (5) other partial colectomy (OPC). Pts were classified into those experiencing surgical/medical complications or not during the 180 days following their colectomy date. Procedures and diagnoses examined included: treatment of fistulas, abscess, sepsis/pneumonia/bacteremia, and revision of ileostomy or colostomy.

Results: A total of 25586 UC pts were identified. The study sample includes 215 UC pts who had a CPT4 procedure code for colectomy and at least 180 days of pre- and post-colectomy follow-up. The pt group was 52% male (mean age 42.6 years). Pts were most often insured by a PPO (39%). UC colectomy pts (n = 215) experienced a variety of complications, including: fistulas (8.8%), abscesses (20.9%), sepsis/pneumonia/bacteremia (11.6%), and revision of ileostomy or colostomy (2.3%).

Complications by type of colectomy for 215 UC pts

<table>
<thead>
<tr>
<th>Colectomy type (n = 215)</th>
<th>Fistula</th>
<th>Abscess</th>
<th>Sepsis/pneumonia/bacteremia</th>
<th>Revision of ostomy</th>
</tr>
</thead>
<tbody>
<tr>
<td>TPC-IPAA (n = 108)</td>
<td>12.0%</td>
<td>20.4%</td>
<td>11.1%</td>
<td>1.9%</td>
</tr>
<tr>
<td>SC-ileostomy (n = 48)</td>
<td>10.4%</td>
<td>33.3%</td>
<td>14.6%</td>
<td>2.1%</td>
</tr>
<tr>
<td>TPC-ileostomy (n = 28)</td>
<td>0.0%</td>
<td>14.3%</td>
<td>10.7%</td>
<td>7.1%</td>
</tr>
<tr>
<td>Segmental (n = 10)</td>
<td>0.0%</td>
<td>0.0%</td>
<td>10.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>OPC (n = 21)</td>
<td>4.8%</td>
<td>14.3%</td>
<td>9.5%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

Conclusions: This retrospective study of privately insured UC pts treated with a colectomy suggests frequent occurrence of complications post-colectomy. These results highlight the burden of post-operative complications in UC pts undergoing colectomy.

Supported by Schering-Plough.

1123

The Long Term Results on the Use of Cyclosporine in the Treatment of Severe Ulcerative Colitis: A 20 Year Experience
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Purpose: Cyclosporine is a rapidly acting immunosuppressant which has been used in the treatment of severe UC. Several questions still exist regarding its benefit, including long term efficacy and safety. Medical records were reviewed in 144 patients who were treated with CSA. Patients were divided into groups- 1987 thru 1994, and those treated from 1995-present. Long term efficacy and safety were examined in both these subgroups.

Methods: Records of 144 patients were reviewed and patients were divided into two groups. The early subset of patients (1987–1994) were not placed on 6-MP unless clinically warranted, whereas the later subgroup had 6-MP started 2 weeks after discharge from the hospital.

Results: Demographics were similar in both groups, as was location of disease. Patients in both groups were started on parenteral CSA—4mg/kg/day, with the earlier group having a mean CSA level of 512. In the later group, the mean CSA level was 376. In the initial 1987–1993 group, 75 patients were studied. 16/75 underwent colectomy during initial hospitalization. 59/75(79%), advanced to the chronic phase. 42/75(56%), remained well at 6 months, and 34/75(45%) remain well with a mean follow up of 14.7 years. In the later cohort, (1994–2005), 69 patients were studied. All patients were started on 6-MP between 2–3 weeks. In this group, 55/69(80%), succeeded on IV CSA and were entered into the chronic phase. 40/55(73%), were well at 6 months, and 37/69(54%) remain well with a mean follow up of 8.6 years. 76% of patients had an adverse effect. 36/144 had parasthesias, 28/144 had transient hypertension. An increase in serum creatinine was seen in 28/144(19%). Severe adverse effects occurred in 4/144(3%). 1/144 had a grand mal seizure, 1 had acute renal failure leading to Klebsiella sepsis and death, 1 had disseminated CMV which was treated successfully, and 1 developed a non-hodgkins lymphoma while on long term 6-MP.

Conclusions: In this 17 year experience with 144 patients with severe UC, the addition of intravenous CSA, resulted in induction of remission in 80% of patients. In the initial cohort, (1987–1993) during which patients were not started on 6-MP until later in the treatment course, 45% remain well with a mean follow up of 14.7 years. In the later cohort, (1994–2005), during which period 6-MP was added 2 weeks in the chronic phase, 53% remain well with a mean follow up of 8.6 years. The majority of adverse effects were minor, however 1/144 developed renal failure, and 1/144 developed a treatable lymphoma.
Anti-Mycobacterium avium SS Paratuberculosis (MAP) Therapy and Fistula Closure in Patients with Severe Crohn's Disease


Purpose: Crohn’s disease is thought by some to be caused by Mycobacterium avium ss paratuberculosis (MAP). In clinical practice, treatment with antibiotics targeting MAP has occasionally resulted in fistula closure. In one patient, fistula closure occurred whilst on anti-MAP therapy, but only after the fistula was curetted. This unexpected healing prompted anti-MAP to be offered to Crohn’s patients with fistulae, with the option to curette. The purpose of this abstract is to report fistula healing in patients with severe Crohn’s disease when treated with anti-MAP and optional curetting.

Methods: This was a retrospective review of 13 patients on anti-MAP therapy with fistulae arising from severe colonic Crohn’s disease. Of these, only 6 (2M, 4F; 15–39y) were included, as they had a minimum of one year follow-up. Patients received rifabutin (up to 600mg/d), clofazimine (up to 100mg/d) and clarithromycin (up to 1g/d) for between 2 months and 5 years (mean = 18.4 months) after fistulae had opened. Of the patients curetted, 3/5 (60.0%) achieved complete fistula healing, none of which have since recurred, 1/5 (20.0%) achieved partial healing, and 1/5 (20.0%) remained active. Time to resolution of fistula for curetted patients was between 6 to 12 months (mean = 9 months). One non-responsive patient was thought to have a complex fistula and underwent a second curette at the time of this review. Another patient’s fistula closed after 1 year of anti-MAP, without curetting. However, this closure was temporary, as fistula re-opened a year after reported closure.

Conclusions: 1. The administration of anti-MAP therapy combined with curetting if required, may result in partial or prolonged complete healing of fistulae for patients with severe colonic Crohn’s disease. 2. This new method offers another option for Crohn’s patients to heal fistulae.

Longitudinal Scarring in Severe Colonic Crohn’s Disease Treated with Anti-Mycobacterium avium SS Paratuberculosis (MAP) Therapy

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Purpose: Mycobacterium avium ss paratuberculosis (MAP) causes Johne’s disease in animals, and is implicated as the pathogen of Crohn’s disease (CD) in humans. In our clinical experience using anti-MAP to treat CD patients, a novel healing pattern was observed. This review is to report the unusual healing pattern demonstrated by patients with severe colonic CD when treated with anti-MAP therapy.

Methods: A retrospective review of 52 patients with severe colonic CD was conducted. Of these, 41 (21M, 20F; 15–75y) had at least one follow-up colonoscopy during the course of treatment and thus were included in the review. Patients received rifabutin (up to 600mg/d), clofazimine (up to 100mg/d) and clarithromycin (up to 1g/d) for between 6 months and 9 years. A ramp-up dosing schedule was used. Patients underwent colonoscopies at intervals to monitor progress. Photographs of mucosa were taken pre- and during treatment. Histology was monitored throughout treatment.

Results: Visual Appearance: Twenty two of 41 (53.7%) demonstrated unusual scarring whilst on anti-MAP therapy. Scarring was not observed in any patient before commencing therapy. Scars only developed once inflamed mucosa began to heal. Longitudinal scars appeared as branched, elevated white lines. Eleven patients had ≥3yrs of treatment following the appearance of scarring. In 2/11 patients (18.2%), scars began to recede after this time, becoming virtually imperceptible as the mucosa fully healed.

Histology: All 41 patients demonstrated histologically active CD before commencing anti-MAP therapy. At 1–9yrs of therapy (mean = 3.2 years), an improvement in the severity of mucosal inflammation was seen in 16/41 patients (39.0%). Of these, mucosa returned to normal in 7/16 (43.7%). Ten of the 16 patients with improved histology also demonstrated longitudinal scarring.

Conclusions: 1. The presence of scarring, fading to normal mucosa may be indicative of a more profound healing on anti-MAP therapy than is seen with standard immunosuppressants, as longitudinal scarring is not found in even rigidly controlled Crohn’s treated with standard immunosuppressants. 2. Histology generally returns to normal when patients exhibit scarring on anti-MAP therapy. 3. The progressive nature of this healing and consequent scarring suggests that this may be ‘full thickness’ healing. 4. If true, the aim of all Crohn’s therapies should be longitudinal scarring and normal histology.
Purpose: Incidence rates of inflammatory bowel disease (IBD) varies among selected geographic regions around the world. Historically, IBD is rare in Latin America, however some studies suggest that the incidence is rising, especially ulcerative colitis. The aim of our study is to determine the incidence of IBD in a national hospital in a developing country.

Methods: Data on 2362 colonoscopies reports in Hospital Nacional Cayetano Heredia from 1999 to 2006 were analysed. All patients who had complete clinical data, endoscopy findings, pathology and follow-up were included.

Results: There were 30 new patients diagnosed of ulcerative colitis, with a mean age of 33 years and 62% males. Main symptoms were rectal bleeding 24 cases (80%), chronic diarrhea 17 cases (56.67%) and abdominal pain 17 cases (56.67%). The colon compromise was left colitis 11 cases (36.67%), pancolitis 9 cases (30%), extensive colitis 6 cases (20%) and proctitis 4 cases (13.33%). Follow-up showed: remission in 29 cases (96.67%), only one required emergency surgery for toxic megacolon. 12 patients were lost of follow-up during first year. 13 of 18 patients had follow-up longer than one year, 8 of them had recurrence, all were related to abandonment of maintenance treatment due to economic problems. There were only two new patients diagnosed of Crohn disease. Both cases were located in ieleccanal region.

Conclusions: Ulcerative colitis is still rare in Peru, however there is a mild increase in its incidence. The incidence of ulcerative colitis was 3.85 cases per year, with a slight prevalence for men. The main symptoms were rectal bleeding, diarrhea and abdominal pain. The main factor related with recurrence was abandoned of treatmente related to economic problems. Crohn disease is an extremely rare disease in our population.

Efficacy and Safety of Tacrolimus in Refractory Ulcerative Colitis and Crohn’s Disease

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Purpose: The published experience regarding the use of tacrolimus in Crohn’s and Ulcerative Colitis refractory to more commonly used medical therapy has been fairly limited. Our objective was to describe our experience with its use in a cohort of patients which, to the best of our knowledge, represents the largest North American cohort described to date.

Methods: This was a retrospective, single center chart analysis. All patients with ulcerative colitis (UC) or Crohns disease (CD) treated with tacrolimus from 3/1/00 to 10/31/05 were evaluated.

Results: There were 32 UC patients, 15 CD patients. Mean disease duration: UC 81 m(range:1m-3.7 yrs). CD 100m(1m-3.5 yrs). Disease distribution: UC: Pancolitis 12 (37.5%), extensive colitis 6 (18.8%), left-sided 11 (34.4%), proctitis 3 (9.4%). CD: TI 2 (13.3%), SB 2 (13.3%), colon 3 (20.7%), IC 7 (46.7%). 25/32 UC and 7/15 CD received concurrent antimetabolites. Tacrolimus dose (0.1mg/kg bid) was adjusted to maintain serum trough conc of 10-12ng/ml. 1/32 UC and 11/15 CD had failed infliximab. Duration of tacrolimus: UC: mean 29wks (< 1wk-4.7yrs, median 15wks). CD: mean 9.9wks (1wk-5.3yrs, median 4wks). 22/32 UC and 7/15 CD were on steroids; 4/30 UC and 0/7 CD patients were successfully weaned. 12/32 UC proceeded to colectomy (mean time: 28wks (4d-3.5yrs, median 5wks). 6/15 CD proceeded to resection (mean time: 22wks; range: 1wk-5.5yrs, median 4wks). 8/15 CD had a clinical response; 1/15 achieved remission. AE’s included: tremors (4), headache (4), arthralgia (3), nausea (2), insomnia (2), leukoencephalopathy (1) and hypomagnesemia (5). In 6 patients tacrolimus was discontinued because of one of these. There were no opportunistic infections, renal insufficiency, or deaths. Most patients received prophylaxis with trimethoprim-sulfamethoxazole or pentamidine.

Conclusions: Tacrolimus in UC and CD is safe and relatively well tolerated. When used as a rescue therapy a significant number of subjects exhibit a rapid clinical response although remission does not appear durable. Prospective studies assessing tacrolimus for induction and maintenance of remission are necessary.

Oral Rifaximin as Maintenance Therapy for Antibiotic-Dependent Pouchitis

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Purpose: Pouchitis is the most common complication of restorative proctocolectomy. Patients often become antibiotic-dependent, which requires long-term maintenance therapy. This open-labeled study was to evaluate the safety of rifaximin on maintenance therapy for antibiotic-dependent pouchitis.

Results: Twelve hundred five patients were interviewed nation-wide. One hundred ninety three self-reported mild disease, 605 moderate disease and 407 severe disease. When compared to the previous 30-day history of symp- toms, only 35% of patients had moderate disease by symptom scoring, and 26% had severe disease. Fifty-eight percent of patients with objective moderate disease and 44% with objective severe disease were naive to biologic therapy (p < 0.05). For those with former exposure to biologics, 23% re- ported their physician stopped therapy, 17% stopped from loss of efficacy, and 11% for cost. Consistent with patient’s self-reported level of disease, surgery was reported in 21% of mild patients, 39.5% of moderate patients and 67.4% of the severe patients (p < 0.05 for comparisons).

Conclusions: Disease activity and patient perception are not necessarily based on current symptoms; it is important to appreciate the fluctuating na-ture of the disease and its potential bias on patient perception of level of over-all disease activity. Surgical history, however, tends to reflect self-reported disease activity level more accurately. Given the percentage of patients with moderate to severe disease and significant surgical rates, the opportunity for more aggressive therapy appears possible. Newer formulations of easier to administer therapies may make this decision easier for physicians and patients alike.

Supported by UCB Pharma.
and efficacy of rifaximin as maintenance therapy for antibiotic-dependent pouchitis and to assess predictors of response to the therapy.

**Methods:** Eligible adult ulcerative colitis patients with antibiotic-dependent pouchitis from our Pouchitis Clinic received 2-week antibiotic induction therapy for remission followed by oral rifaximin 200 mg/d (dose escalating up to 1800 mg/d as needed). Pouchitis Disease Activity Index (PDAI) symptom (range 0–6) and endoscopy (range 0–6) scores were used to quantify the disease activity. The primary end point was the maintenance of remission with rifaximin.

**Results:** 51 patients (mean age, 47 yrs) with active antibiotic-dependent pouchitis were induced into remission after a 2-week course of single or combination therapy with ciprofloxacin, rifaximin, metronidazole, or tinidazole, followed by rifaximin maintenance therapy (0.5–24 months). At 3 months of maintenance therapy, 33 patients (65%) maintained remission (responders) and 18 patients (35%) had symptom and endoscopy relapse (non-responders) (Table). Follow-up data were available in 18 patients at 12 months of whom 16 patients maintained symptom remission. There were no factors predictive of the 3-month response in the multivariable analysis of 22 variables (including baseline and post-induction PDAI scores and dosages of antibiotics for induction and maintenance therapy). One patient (2%) developed facial rash after rifaximin and discontinued the agent.

**Conclusions:** Rifaximin was well tolerated and appeared to be effective in maintenance therapy in patients with antibiotic-dependent pouchitis, particularly in the patients without an early relapse.

### Table

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*Statistically significant change in score between the two time points within subject group.

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**Cyclosporin in Acute Severe Ulcerative Colitis: A Clinical Series**

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**Purpose:** Acute severe ulcerative colitis (ASUC) is a threatening complication of ulcerative colitis which occurs in approximately 15% patients with UC. Intensive treatment and early recognition have improved outcomes. Cyclosporin (CyA) is widely used for ASUC, however there are limited data on efficacy and outcomes in this setting. Aims: To determine efficacy and outcome of CyA in ASUC.

**Methods:** Data were collected retrospectively on patients presenting with ASUC from 1997 to 2006. All patients included had ASUC as defined by the Truelove and Witts criteria and received intravenous prednisolone. Colectomy was performed in those not responding to medical therapy.

**Results:** There were 6 (six) patients, with median age = 32.8 ± 9.2 years (23–48). The diagnosis of Ulcerative Colitis preceded treatment with CyA in 28.4 ± 24.9 months (0–60). CyA was used in the median dosage of 3 mg/kg (2–4) during 10.2 ± 3.6 days (6–15). Initial Response: 83% of patients responded to treatment (5/6). Time required to response was 2.5 ± 1.2 days (1–4). **Adverse effects:** Necrotizing pneumonia in one patient. Follow-up: Median follow-up time = 49.8 ± 42.2 months (2–107). There was sustained response in 80% of initial responders (4/5), only one patient had clinical relapse. **Ongoing treatment:** Azathioprine- 5 patients, 5-ASA- 3 patients, Infliximab – 1 patient (with previous relapse), corticosteroids- none.

**Conclusions:** CyA was highly effective in a particular subset of ASUC patients. The immunosupression achieved was not followed by a significant increase in serious side effects.

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**Interobserver Variability in the Histologic Diagnosis of Microscopic Colitis**

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**Purpose:** Microscopic colitis accounts for a significant portion of patients with chronic diarrhea and abdominal pain. Microscopic colitis is diagnosed based on histologic criteria after biopsy and grossly normal exam by endoscopy. There has been no investigation into the reproducibility of histologic criteria for microscopic colitis. Our aim was to evaluate interobserver variation in the diagnosis of microscopic colitis.

**Methods:** Ninety colonic biopsies (20 lymphocytic colitis, 20 collagenous colitis, 20 inflammatory bowel disease, and 30 normal) were blindly and independently reviewed by four gastrointestinal pathologists. Each pathologist interpreted these biopsies for specific morphological features which discriminate between microscopic colitis, inflammatory bowel disease, and normal mucosa. The biopsies were classified by each pathologist into six diagnostic categories: lymphocytic colitis, collagenous colitis, active chronic colitis, focal active colitis, normal, or other. The degree of observer agreement was determined using kappa statistics (κ). Kappa values <0.21, 0.21–0.40, 0.41–0.60, 0.61–0.80, and >0.80 were considered to be poor, fair, moderate, good, and very good agreement respectively.

**Results:** The percent agreement with all six diagnostic categories was 69%, κ = 0.76 (95% confidence interval 0.69, 0.84). The percent agreement with final diagnostic categories of microscopic colitis versus non-microscopic colitis was 91%, κκ = 0.90 (95% confidence interval 0.83, 0.96).

**Conclusions:** Interobserver agreement was good in distinguishing between the six diagnostic categories: lymphocytic colitis, collagenous colitis, active chronic colitis, focal active colitis, normal, and other. Interobserver agreement was very good in distinguishing between microscopic colitis and non-microscopic colitis colonic biopsies. The histological criteria for microscopic colitis provide for reproducible interindividual diagnoses in the evaluation of colonic biopsies.

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**Endoscopically Measured Mucosal Healing Correlated with Response to Therapy in Moderately Active UC**

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**Purpose:** Examine the correlation between endoscopically measured mucosal healing and response to therapy with delayed-release oral mesalamine 4.8g/day (investigational 800mg tab) and 2.4g/day (marketed 400mg tab) in patients with moderately active UC.

**Methods:** Data from 2 Phase III, multi-center, randomized, double-blind, 6-week, controlled studies of similar design (ASCEND I&II) were pooled and analyzed. The primary endpoint was treatment success, pre-defined as improvement from baseline in the Physician’s Global Assessment (PGA) accompanied by improvement in at least one other clinical assessment (stool frequency, rectal bleeding, patient functional assessment (PFA), or endoscopy findings) and no worsening in any of the remaining clinical
assessments. Mucosal healing was defined as an endoscopy score of 0 or 1. PFA was based on a 4-point scale, 0 = “generally well” to 3 = “terrible.” Patients with moderately active UC (baseline PGA = 2) and baseline endoscopy score ≥ 2 were included in this analysis. The correlation between mucosal healing and treatment response and PFA was determined.

Results: 423 analyzable patients with moderate UC were randomized in the 2 studies, of which 391 patients met the criteria for these analyses. The 2 treatment groups were balanced at baseline with regard to demographic characteristics, disease history, and disease state characteristics. Overall at 6 weeks, 67% of moderate UC patients who achieved treatment success also had mucosal healing (Kappa = 0.6938). This finding was consistent regardless of dose of 2.4g/day or 4.8g/day (Kappa = 0.7452 and 0.6046, respectively). This finding was also consistently present at 3-weeks (Kappa = 0.7173). An endoscopic score of 0 alone was poorly correlated with treatment success but did improve from 3 to 6 weeks (Kappa = 0.1176 and 0.2252 respectively). Regardless of dose or time, PFA correlated poorly with mucosal healing. Both doses of mesalamine were well tolerated, with adverse events comparable between 4.8g/day and 2.4g/day.

Conclusions: This analysis demonstrates that successful treatment of moderately active UC with mesalamine is associated with improved mucosal integrity as early as 3 and 6 weeks. The lack of association between endoscopic improvement and PFA may be due to the fact that UC patients’ general well-being involves more than mucosal healing.

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Surgical History in Inflammatory Bowel Disease May Affect Bone Mineral Density Screening Practices
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Purpose: Diagnosis of osteoporosis is suboptimal among patients with inflammatory bowel disease (IBD). Important contributors to decreased bone density in IBD include vitamin D and calcium deficiency and/or malabsorption. This nutritional deficiency can be a result of disease activity or from surgical resection of intestinal segments. This study evaluated physician adherence to bone mineral density screening based upon patients’ history of IBD-associated surgery.

Methods: A retrospective medical record review of all IBD patients seen in a university gastroenterology practice between March 2005 and December 2005 was performed. No IBD patients were excluded. Patients’ record was reviewed for the performance of bone mineral density testing and IBD-associated surgery. A database was created using Microsoft Excel. Statistical analysis was performed using chi-square with significance set at $p < 0.05$. The study was approved by the university IRB.

Results: The medical records of 227 IBD patients were reviewed. Sixty patients (26.4%) had a reported history of surgery resulting from IBD-associated complications. Fifty-six of the 60 surgeries involved intestinal resection. Thirty-eight (17%) of IBD patients had BMD testing. Twenty-two of the 167 patients (13.2%) without a history of surgery had BMD testing. Sixteen of the 167 patients (17%) of IBD patients had BMD testing. T wenty-two of the 167 patients (26.4%) had a reported history of surgery resulting from IBD associated surgery. A database was created using Microsoft Excel. Statistical analysis was performed using chi-square with significance set at $p < 0.05$. This finding was consistently present at 3-weeks (Kappa = 0.7173). An endoscopic score of 0 alone was poorly correlated with treatment success but did improve from 3 to 6 weeks (Kappa = 0.1176 and 0.2252 respectively). Regardless of dose or time, PFA correlated poorly with mucosal healing. Both doses of mesalamine were well tolerated, with adverse events comparable between 4.8g/day and 2.4g/day.

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Duodenal Adenoma in a Patient with Crohn’s Disease
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Problem: A 43 y.o. white female with longstanding Crohn’s disease presented for colonoscopy to evaluate her colonic/ileal disease and EGD to evaluate complaints of epigastric pain and longstanding reflux. Colonoscopy revealed relatively quiescent disease with superficial ulcerations at the ileocolic anastomosis. EGD revealed a polypoid lesion in the periampullary region. A biopsy was interpreted as hyperplastic polyp in the setting of ectopic gastric mucosa. Repeat endoscopy with a duodenoscope revealed this was a 5 cm pedunculated polyp on a 2 cm base with villous appearing mucosa. [figure 1] The decision to remove the polyp was based on the size and appearance. Following piecemeal snare polypectomy, histopathology revealed the polyp was a tubular adenoma without advanced dysplasia. Follow up biopsies were negative for residual adenoma. [figure 2] A small bowel enterolysis and capsule endoscopy are pending at this time. A literature review failed to uncover any articles addressing the management of small bowel adenomas in patients with underlying IBD. While the incidence of small bowel adenocarcinoma is reportedly increased 12 fold in patients with Crohn’s disease, the majority of these tumors develop in areas of active disease in the ileum or jejunum. Duodenal adenocarcinoma has been the least commonly reported small bowel neoplasm in Crohn’s disease. In patients with IBD the management of colorectal adenomas has focused on differentiating polyps WITH and WITHOUT dysplastic changes in the surrounding tests. While IBD-associated surgery may be a marker for more complicated disease, it is important that all patients who have IBD undergo BMD testing.
mucosa. The literature has not addressed the management of small bowel adenomas in patients with IBD. Given that all of the reported cases of small bowel adenocarcinoma in patients with Crohn’s have developed in areas of active disease rather than adenomatous polyps, we propose managing these lesions in the same manner as spontaneous lesions in otherwise average risk patients.

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The Effect of Infliximab Treatment on Serum Levels of Proinflammatory Molecules in Patients with Ulcerative Colitis
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Purpose: In ACT 1, the effect of infliximab (IFX) on serum proinflammatory cytokines, chemokines, and adhesion molecules associated with inflammatory bowel disease (IBD), was evaluated in patients (pts) with moderately to severely active UC (endoscopy score ≥ 6) despite the use of concomitant medications [corticosteroids or azathioprine/6-mercaptopurine] were randomized to placebo (PBO), IFX 5 mg/kg, or 10 mg/kg at weeks (wks) 0, 2, 8, and 30 for analysis of TNFα, IL-1β, IL-2R, IL-5, IL-6, sICAM-1, sVCAM-1, and sL-selectin using commercially available and validated ELISAs.

Methods: 346 pts with moderately to severely active UC (endoscopy score ≥ 2, Mayo score ≥ 6 < 12) were randomized to placebo (PBO), IFX 5 mg/kg, or 10 mg/kg at weeks (wks) 0, 2, 6, and q8 wks thereafter through wk 46. Serum was collected from all pts at wks 0, 2, 8, and 30 for analysis of TNFα, IL-1β, IL-2R, IL-5, IL-6, sICAM-1, sVCAM-1, and sL-selectin using commercially available and validated ELISAs.

Results: At baseline, detectable levels of TNFα, IL-1β, IL-2R, IL-5, IL-6, sICAM-1, sVCAM-1, and sL-selectin were measured in 90 to 100% of all tested serum samples. IL-8 was detected in approximately 32% of baseline samples while IL-1β and IL-5 were detected in < 10% of baseline serum samples. Baseline median serum levels of the proinflammatory molecules were generally consistent across the treatment groups (Table 1). Notable decreases in serum levels of IL-6, IL-2R, IL-8, sICAM-1, and sVCAM (measured as median percent change from baseline) at wk 2 were observed following a single IFX infusion relative to PBO (Table 1). TNFα level increases were consistent with earlier observations that biologically inactive, IFX-bound TNF can be detected by immunoassay. At wks 8 and 30, the median percent change from baseline in serum levels of ICAM-1, TNFα, IL-2R and IL-6 continued to distinguish IFX-treated pts from PBO.

Conclusions: IFX treatment of pts with moderately to severely active UC modulates serum levels of selected proinflammatory molecules that have been associated with IBD.

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The Impact of Crohn’s Disease on Workforce Participation and Productivity in the Workplace and Household

Purpose: Crohn's disease (CD) is associated with debilitating clinical symptoms and an important quality of life burden. This analysis focuses on the impact of CD on productivity, which can aid our understanding of the impact of CD on patients and its societal cost.

Methods: CD patients (pts) (≥18 years) completed a Web-based questionnaire containing items regarding demographics, disease and treatment history, the short form of the Inflammatory Bowel Disease Questionnaire (SIBDQ) and the Health Related Productivity Questionnaire (HRPQ). The HRPQ contains 9 items on the influence of CD on key productivity measures: workforce participation (unemployed, under-employed), absenteeism (missed work days) and presenteeism (reduced work output during hours [hrs] worked).

Results: A total of 326 pts completed the survey (70% female, mean age = 46). The majority of pts rated the severity of their current CD as moderate (46.9%; mild = 34.4%; severe = 18.7%). U.S. residents comprised 84.0% of the sample with Canada, Australia and the U.K. accounting for 8.0%, 2.1% and 2.1%, respectively and the remaining 3.8% of respondents coming from 9 other countries. Among the 305 respondents < 65 years, 57% reported they were currently employed full-time, 16% reported part-time employment and the remaining 27% reported that they were not employed. Approximately 38% of pts indicated that CD had at some point kept them from being employed or had forced them to work part-time when they wanted to work full-time. Among the employed, 23.8% of the scheduled work hrs were lost due to CD with 14.6% due to presenteeism and 9.2% to absenteeism. The planned hrs of household work were more affected by CD than the scheduled hrs of employed work, with 38.0% of these hrs lost due to CD. The workforce participation and percentage of hrs of productivity lost at employed and household work of women were substantially above those of their male counterparts (range 170%-185%). Current employment status of CD patients (pts) (≥18 years) completed a Web-based questionnaire containing items regarding demographics, disease and treatment history, the short form of the Inflammatory Bowel Disease Questionnaire (SIBDQ) and the Health Related Productivity Questionnaire (HRPQ). The HRPQ contains 9 items on the influence of CD on key productivity measures: workforce participation (unemployed, under-employed), absenteeism (missed work days) and presenteeism (reduced work output during hours [hrs] worked).

Results: A total of 326 pts completed the survey (70% female, mean age = 46). The majority of pts rated the severity of their current CD as moderate (46.9%; mild = 34.4%; severe = 18.7%). U.S. residents comprised 84.0% of the sample with Canada, Australia and the U.K. accounting for 8.0%, 2.1% and 2.1%, respectively and the remaining 3.8% of respondents coming from 9 other countries. Among the 305 respondents < 65 years, 57% reported they were currently employed full-time, 16% reported part-time employment and the remaining 27% reported that they were not employed. Approximately 38% of pts indicated that CD had at some point kept them from being employed or had forced them to work part-time when they wanted to work full-time. Among the employed, 23.8% of the scheduled work hrs were lost due to CD with 14.6% due to presenteeism and 9.2% to absenteeism. The planned hrs of household work were more affected by CD than the scheduled hrs of employed work, with 38.0% of these hrs lost due to CD. The workforce participation and percentage of hrs of productivity lost at employed and household work of women were substantially above those of their male counterparts (range 170%-185%). Current employment status of CD patients (pts) (≥18 years) completed a Web-based questionnaire containing items regarding demographics, disease and treatment history, the short form of the Inflammatory Bowel Disease Questionnaire (SIBDQ) and the Health Related Productivity Questionnaire (HRPQ). The HRPQ contains 9 items on the influence of CD on key productivity measures: workforce participation (unemployed, under-employed), absenteeism (missed work days) and presenteeism (reduced work output during hours [hrs] worked).

Conclusions: CD was found to significantly influence each of the key productivity measures investigated. Treatments that effectively control the symptoms of CD and have minimal side-effects may have a significant impact on the indirect (productivity) costs associated with CD.
Natalizumab Provides Consistent Induction Efficacy for Patients with Moderate to Severe Crohn’s Disease and Elevated C-Reactive Protein: A Comparison of ENACT-1 and ENCORE

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Purpose: Natalizumab (NAT), a humanized IgG4 monoclonal antibody to alpha4-integrins, disrupts leukocyte migration into gut tissue and ameliorates chronic inflammation. Two phase 3 trials examined the efficacy of NAT as induction therapy. ENACT-1 evaluated the efficacy of 3 monthly infusions of 300 mg NAT for patients (pts) with moderately to severely active Crohn’s disease (CD). A high placebo (pbo) response rate contributed to a lack of statistical significance for the primary endpoint of response (70% point decrease in baseline Crohn’s Disease Activity Index [CDAI] score) at Week 10. Post-hoc analysis of pts with C-reactive protein (CRP) > 2.87 mg/L at baseline of ENACT-1 demonstrated statistical superiority for NAT compared with pbo. The second phase 3 trial, ENCORE, enrolled patients with moderate to severely active CD and evidence of systemic inflammation (CRP > 2.87 mg/L). The aim of this study was to evaluate the consistency of NAT’s induction efficacy in the ENACT-1 and ENCORE induction trials.

Methods: ENACT-1 involved a total of 905 pts (NAT = 724, pbo = 181), of whom, 660 had baseline CRP levels > 2.87 mg/L (NAT = 526, pbo = 134). In ENCORE, 509 pts were randomized 1:1 to receive 300 mg NAT (n = 259) or pbo (n = 250). Infusions were administered at Weeks 0, 4, and 8, and pts were followed until Week 12. The primary endpoint for the ENCORE trial was the proportion of pts with a response by Week 8 that was sustained through Week 12.

Results: The primary endpoint of response at both Weeks 8 and 12 was met with statistical significance in the ENCORE trial (48% NAT vs 32% pbo, p < 0.001). Response rates at Weeks 8 and 12 in the sub-group of pts with elevated baseline CRP levels in ENACT-1 were nearly identical (49% vs 34%, p = 0.002). Similarly, the proportion of patients that achieved remission at both Weeks 8 and 12 was significantly higher in the NAT group compared to the pbo group in the ENCORE trial (26% vs 16%, p = 0.002), consistent with the subgroup analysis remission rates in ENACT-1 (29% vs 19%, p = 0.041).

Conclusions: A comparison of response and remission rates at both Weeks 8 and 12 in NAT pts in the ENCORE trial with those observed in the subgroup analysis from ENACT-1 reveals a striking consistency of results and provides compelling evidence for NAT induction therapy in pts with CD and evidence of systemic inflammation.

Corticosteroid Use Influenced Bone Mineral Density Screening in Inflammatory Bowel Disease

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Purpose: Corticosteroids can have an important role in the medical management of patients with inflammatory bowel disease (IBD). The well established association between chronic steroid use and osteoporosis supports the recommendation of performing bone mineral density testing in all patients with IBD. However, it has been suggested that physicians may inconsistently adhere to bone mineral testing (BMD) guidelines. This study evaluated whether the use of corticosteroids in the management of patients with IBD influenced physicians performing BMD testing.

Methods: A retrospective medical record review of all IBD patients seen in a university gastroenterology practice between March 2005 and December 2005 was performed. No IBD patients were excluded. Physicians’ adherence to BMD testing in all patients was obtained. A database was created using Microsoft Excel and gender comparison was performed. Statistical analysis was performed using chi-square with significance set at p < 0.05. The study was approved by the university IRB.

Results: The medical records of 227 patients (131 women, 96 men) were evaluated. Thirty-eight patients (17%) had BMD testing performed. Twenty-eight women (21% of all women) and 10 men (10% of all men) were recommended BMD testing and had it performed. While there was no statistically significant difference (p = 0.065) in the rate at which BMD testing is recommended and performed in men and women, there was trend for less BMD testing to be performed in men. There was no difference in the rate of abnormal BMD tests between the genders (p = 0.127).

Conclusions: Bone mineral testing should be performed in all patients with IBD. However, this study demonstrated that physicians inconsistently perform BMD testing despite recommendations. There is also a trend to perform more BMD testing in women despite the fact that abnormal BMD tests occur at the same rate in men and women with IBD. Increased physician awareness of the need for BMD testing in all patients with IBD is necessary.

A Patient’s Gender May Influence Bone Mineral Density Testing in Patients with Inflammatory Bowel Disease

Marie L. Borum, MD, F.A.C.G.* Chin Hee Kim, MD Division of Gastroenterology and Liver Diseases, George Washington University, Washington, DC.

Purpose: Inflammatory bowel disease (IBD) is associated with decreased bone density. It has been recommended that bone mineral density (BMD) be performed on all individuals with IBD. Data suggests that there is inconsistent adherence to BMD recommendations. Traditionally, postmenopausal Caucasian women are targeted at efforts to prevent osteoporosis. This may be partially a result of an assumption that men are relatively protected from osteoporosis. Nevertheless, men with IBD are at increased risk for low bone density. This study evaluated whether patient gender influenced physicians’ adherence to BMD testing in IBD patients.

Methods: A retrospective medical record review of all IBD patients seen in a university gastroenterology practice from March 2005 to December 2005 was performed. No IBD patients were excluded. Physicians’ adherence to BMD testing in all patients was obtained. A database was created using Microsoft Excel and gender comparison was performed. Statistical analysis was performed using chi-square with significance set at p < 0.05. The study was approved by the university IRB.

Results: The medical records of 227 IBD patients were reviewed. One hundred fourteen (50%) of the IBD patients reported prior corticosteroid use. Thirty-eight (17%) patients had BMD testing. Twenty-eight of the BMD tests (74% of the tests) were performed in patients who had previously been treated with corticosteroids. Ten of the BMD tests (26% of the tests) were performed in patients who had never been treated with steroids. There was a statistically significant difference (p = 0.002) in the rate at which BMD testing was performed in patients who had been prescribed corticosteroids and those who had not been treated with corticosteroids. The results of the BMD testing revealed that there was not a statistically significant difference (p = 0.715) in the rate at which abnormal tests were found in patients who had been prescribed and those who had not been prescribed corticosteroids.

Conclusions: IBD and corticosteroids are known risk factors for the development of decreased bone density. While this study suggested that it is more likely that patients who have been treated with steroids in the past will undergo BMD testing, the overall rate of physicians’ performing BMD tests is low. Additionally, IBD patients who have been treated with corticosteroids and those who have not been treated with corticosteroids have the same rate of abnormal tests. Improved efforts to increase BMD testing among IBD patients are critical for optimizing care.
Age Disparity in Physician Adherence to Bone Mineral Density Screening in Inflammatory Bowel Disease

Marie L. Borum, MD, F.A.C.G.* Chin Hye Kim, MD Division of Gastroenterology and Liver Diseases, George Washington University, Washington, DC.

Purpose: Metabolic bone disease is a well acknowledged complication of inflammatory bowel disease (IBD). Studies have indicated that there is about a 30% prevalence of osteoporosis. There are several factors that have been identified to increase the risk of bone loss in IBD, including advancing age in all patients and post-menopausal status in women. It is recommended that all IBD patients have bone mineral density (BMD) screening. This study evaluated whether patients’ age influenced physicians’ adherence to recommended BMD testing.

Methods: A retrospective medical record review of all IBD patients seen in a university gastroenterology practice between March 2005 and December 2005 were performed. No IBD patients were excluded. Patients’ age and physicians’ adherence to BMD testing were obtained. Records were also reviewed to determine if patient’s obtained BMD testing when ordered. A database was created using Microsoft Excel. Statistical analysis was performed using chi-square with significance set at $p < 0.05$. The study was approved by the university IRB.

Results: The medical records of 227 patients were evaluated (mean age 40.2 ± 14.2; age range 19–84). There were 172 (76%) patients who were < 50 years of age and 55 (24%) patients who were > 50 years. Thirty-eight (17%) patients had BMD testing recommended. All patients in whom testing was recommended had the test performed. Twenty-three of the screened patients were < 50 years (13% of patients < 50 years) and 15 of the screened patients were > 50 years (31% of patients > 50 years). There was a statistically significant difference ($p = 0.004$) in the rate at which patients > 50 years were screened for bone disease compared to patients < 50 years. There was no difference in the frequency of abnormal bone density studies in patients > 50 years compared to patients < 50 years.

Conclusions: This study revealed that physicians infrequently recommended BMD testing in IBD patients. However, in patients > 50 years, BMD testing was more frequently recommended when compared to younger patients. While physicians may be inclined to obtain BMD tests in older patients because of the known increase risk of bone loss with advancing age and menopause, this study demonstrated that there was no difference in the frequency of abnormal BMD results between the younger and older patients. Interventions which encourage physicians to obtain BMD testing in all IBD patients are necessary to ensure optimal care.

Targetting CCL25/CCR9: A Successful Therapeutic Strategy during Early Chronic Murine Ileitis

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Purpose: CCL25 mediates the homeostatic trafficking of CCR9-expressing lymphocytes to the small intestine, but the function of this chemokine/receptor pair during chronic small intestinal inflammation has yet to be determined. Furthermore, although clinical trials to evaluate the efficacy of targeting the CCL25/CCR9 axis for the treatment of Crohn’s disease are being conducted, preclinical data in animal models of IBD are lacking. The purpose of this study was to provide preclinical data for the potential efficacy of this anti-chemokine strategy in a clinically relevant spontaneous mouse model of Crohn’s disease.

Methods: In the current studies we investigate the expression of CCL25 and CCR9 as a function of disease progression in a spontaneous murine model of chronic ileitis (SAMP1/YitFc), using flow cytometry, real time RT-PCR, ELISA and immunohistochemistry. In addition, we assess the functional role of the axis in the overall disease process through therapeutic studies that target the chemokine or the receptor, during early and late disease.

Results: The percentage of CCR9-expressing lymphocytes increased during early disease, accompanied by the appearance of a population of CCR9high lymphocytes, predominantly within CD8+ T cells. Yet different from patients with primary sclerosing cholangitis, the expression of CCL25 remained restricted to the small intestine, even in mice with bile duct inflammation. Neutralization of the receptor or the chemokine attenuated early disease, but showed no therapeutic efficacy during the later stages, when overall CCR9 expression decreased and the CCR9high population was absent.

Conclusions: Our studies demonstrate that the role of this chemokine axis is not limited to homeostatic recruitment, as previously believed. However these molecules appear to play their most crucial role during the early stages of chronic murine ileitis. Our data suggests that careful selection of patients in whom the disease involves the small intestine and who have elevated levels of CCR9-expressing cells may enhance the response rate of subsequent clinical studies that aim at this chemokine/receptor pair for the treatment of small intestinal Crohn’s disease.

Immunogenicity of Natalizumab in Crohn’s Disease Following Continuous or Interrupted Dosing


Purpose: The short- and long-term immunogenicity of natalizumab in the treatment of Crohn’s disease (CD) has been low (< 10%). A significant temporal gap in dosing of monoclonal antibodies (Ab) can result in heightened immune responses against the Ab and may lead to infusion reactions and diminished efficacy. This study analyzed the immunogenicity of natalizumab in CD patients, with and without dosing interruptions.

Methods: The analysis involved patients who had initially received natalizumab induction therapy in ENACT-1, followed by re-randomization to placebo or natalizumab maintenance therapy or non-participation in ENACT-2, before entry into an open label extension (OLE) study. The primary objective of the OLE was to assess the long-term safety of natalizumab. Efficacy and immunogenicity were secondary endpoints. Formation of Ab to natalizumab was measured using an enzyme linked immunosorbent assay (ELISA). Positivity was defined as anti-natalizumab Ab concentrations > 0.5 μg/mL.

Results: Of 319 patients in this analysis, 299 (94%) had tested Ab- in ENACT-1 and 20 (6%) tested Ab+. Of the 299 previously Ab- patients 18 (6%) became Ab+ in the OLE; 18/20 (90%) previously Ab+ patients remained so. A low overall Ab+ rate in the OLE (11%; 36/319) was observed despite many patients having a prolonged gap in natalizumab dosing. Patients who received natalizumab in ENACT-1 and were Ab- who then received up to 12 months of placebo in ENACT-2 (median 254 days, range 55–302 days) and were then re-dosed with natalizumab in the OLE had an immunogenicity rate (9.9%;14/141), similar to that reported in studies of continuous natalizumab therapy. A gap in therapy >12 months was associated with a higher immunogenicity rate than a shorter gap (11% vs 4.4%). Patients who received continuous natalizumab therapy through ENACT-1, ENACT-2, and the OLE, had very low rates of Ab positivity (1%, 2/150).

Conclusions: In the OLE study, a relatively low percentage of patients became positive for anti-natalizumab Ab following a dose interruption. Patients who were initially Ab- were more likely to be Ab+ after a lapse in dosing than patients who were Ab-. These data suggest that in patients with natalizumab dose interruptions, re-initiation can occur without the development of anti-natalizumab Ab in the significant majority of patients.
5-ASA Prescription Refill Rates for Ulcerative Colitis Are Independent of Formulation and Dosing Regimens
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Purpose: Little data exist on medication refill rates among the different 5-aminosalicylic acid (5-ASAs) for the treatment of ulcerative colitis in an ambulatory setting. Persistence and adherence studies are often limited in size, of short duration, and conducted within the context of controlled maintenance trials. Understanding medication behavior in a real world setting will help in patient management. The purpose of this study was to observe, in clinical practice, the 5-ASA prescription refill profiles in the year following treatment initiation among patients with ulcerative colitis.

Methods: This retrospective cohort study used records of health service utilization from the multiple US health plans within the MedStat MarketScan database. Treatment initiation was defined as use in the year 2003 with no 5-ASA use in the prior 6 months. The study subjects were patients of any age or sex, who had a physician-visit diagnosed with ulcerative colitis (ICD-9-CM 556). Refills of 5-ASA prescriptions were measured in 3 month intervals after treatment initiation.

Results: There were 1680 ulcerative colitis patients who initiated 5-ASA treatment; Asacol® (n = 1045, 62%), Sulfasalazine (n = 294, 17.5%), Colazal® (n = 213, 12.6%), Pentasa® (n = 128, 7.6%). Upon initiation of treatment, the median dosing regimen per formulation was 2.4 g of Asacol® (6 pills of 400 mg), 2.0 g of Sulfasalazine (4 pills of 500 mg), 6.75 g of Colazal® (9 pills of 750 mg), and 4.0 g of Pentasa® (16 pills of 250 mg).

The transition of presumed acute to chronic therapy (month 3) is the most critical period determining the degree of prescription loss for 5-ASA use (figure). After 3 months, the decrease in prescription refills continued at approximately 1.0% per month. [figure1]

Conclusions: Refilling 5-ASA prescriptions appears to be independent of type of formulation or dosing regimen. Further research into patient motivation for long-term adherence is warranted.

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Purpose: An eighteen-year old Caucasian male presented with complaints of right hip pain for ten days. The pain was sudden in onset, constant, worse with leg flexion and internal rotation also associated with groin swelling. The patient denied fevers, weight loss, change in bowel pattern or prior history of similar complaints in the past. He has never been sexually active and denied the use of alcohol, smoking and illicit drug use. The patient has had no known tuberculosis exposure. Physical exam revealed tenderness in right lower quadrant with voluntary guarding and a positive psoas sign. Lab studies found him to be anemic with mild thrombocytosis. A CT scan of the abdomen revealed a right psoas abscess with bowel wall thickening (figure 1). The patient subsequently had a colonoscopy which revealed multiple ulcerations within the ileocecal region. The biopsy demonstrated pathological findings consistent with Crohn’s ileitis (figure 2).

Psoas abscess is an uncommon complication of Crohn’s disease ( < 2%) and a rare initial presentation. Psoas abscess occurs as a result of retroperitoneal perforation of the ileocecal region. Patients can present with sepsis or severe muscle spasm with flexion and internal rotation of the hip. The diagnosis is made with CT scan. Treatment includes drainage of the abscess and appropriate antibiotics. Our patient was found to have Streptococcus anginosus, E. coli and H. parainfluenza cultured from the abscess after surgical drainage. He was placed on antibiotics and started on mesalamine 1gm QID after segmental resection of the diseased area. Since discharge and initiation of therapy, the patient has reported improvement of his symptoms. [figure1] [figure2]
Adalimumab Rapidly Induces Clinical Remission and Response in Patients with Moderate to Severe Crohn’s Disease Who Had Secondary Failure to Infliximab Therapy: Results of the GAIN Study

**Purpose:** To assess the safety and efficacy of adalimumab (ADA), a self-injectable, fully human anti-TNF monoclonal antibody, in the induction of clinical remission (CDAI < 150) and response in patients with active Crohn’s disease (CD) who had secondary failure to infliximab (IFX) therapy.

**Methods:** Patients with moderate to severe CD (CDAI 220–450) and secondary failure to IFX therapy were enrolled in GAIN, a Phase III, double-blind, placebo-controlled study, and were randomized to receive ADA, 160 mg sc at Wk 0 (BL) and 80 mg sc at Wk 2, or placebo (PBO) at both time points. Primary endpoint was remission at Wk 4. Secondary endpoints were clinical response (CR) defined as a decrease from BL CDAI of ≥70 or 100 (CR70/100) at Wk 4. Safety was assessed throughout the study.

**Results:** Patients were randomized to receive ADA (N = 159) or PBO (N = 166). Baseline characteristics were similar between the two arms: mean age, 38 yrs; female, 65%; mean CDAI, 313 (± 62 SD); median CRP, 0.8 mg/dL; immunosuppressant use, 48%. Clinical remission and response rates observed in the ADA arm were significant vs. PBO.

<table>
<thead>
<tr>
<th>Clinical Remission and Response in GAIN</th>
<th>PBO, N = 166</th>
<th>ADA, N = 159</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDAI &lt; 150</td>
<td>4</td>
<td>12 (7%)</td>
</tr>
<tr>
<td>CR100</td>
<td>2</td>
<td>30 (18%)</td>
</tr>
<tr>
<td>CR70</td>
<td>2</td>
<td>41 (25%)</td>
</tr>
<tr>
<td>CR70</td>
<td>4</td>
<td>55 (33%)</td>
</tr>
</tbody>
</table>

* p ≤ 0.001, **p ≤ 0.01, both vs. PBO.

Serious adverse events (SAE) were observed in 4.8% of PBO patients (abcess, 3; sepsis, 1; CD flare, 1; dehydration, 1; abdominal pain, 1) and in 1.3% of ADA patients (CD flare, 1; dehydration, 1). No delayed-hypersensitivity (serum sickness) reactions or deaths occurred. The overall safety profile of ADA was consistent with prior CD trials and the existing RA database.

**Conclusions:** Adalimumab rapidly and significantly induced clinical remission and response in patients with moderate to severe CD who had secondary failure to IFX. Adalimumab was well-tolerated.

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Exposure to Diagnostic Ionizing Radiation in a Population-Based Cohort of Patients with Inflammatory Bowel Disease

**Purpose:** For diagnosis, assessment of activity, evaluation of extraintestinal manifestations, and monitoring of response to therapy, pts with IBD undergo many radiological studies employing diagnostic ionizing radiation (DIR). The chronicity of disease and young age at diagnosis present a challenge to balance appropriate use of these tests against the risk of radiation exposure.

**Methods:** A population-based inception cohort of 220 pts with IBD from Olmsted County, MN, diagnosed between 1/1/90 and 12/31/01, was identified. The cumulative DIR exposure was estimated by identifying every radiological test these pts underwent from their date of symptom onset to the end of the study. Effective doses (ED) for each study were calculated by reviewing the studies of a subset of pts for fluoroscopy times and using known average ED for currently performed exams. Total ED for each test was calculated by multiplying the number of tests by the average ED; the total ED for each pt was the sum of all radiological tests. Linear regression was used to compare the mean total ED over time since symptom onset between pts with Crohn’s disease (CD) and ulcerative colitis (UC).

**Results:** The number of pts with CD and UC was 115 and 105, with a mean age at diagnosis of 39.3 and 38.2 years, respectively. Mean follow-up time was 10.9 years for CD and 10.3 years for UC. Mean cumulative ED was 36.9 mSv (CI 28.6–45.1), upper quartile range 48–279 mSv for CD; 20.7
Natalizumab Induction Therapy Results in Improved Quality of Life in Patients with Crohn’s Disease

Robarts Research Institute, U of Western Ontario, London, ON, Canada.

Purpose: To investigate quality of life (QoL) outcomes during ENCORE, a phase 3, randomized, double-blind, placebo (pbo)-controlled trial evaluating the efficacy and safety of natalizumab (NAT) induction therapy in patients (pts) with Crohn’s disease (CD).

Methods: Pts with Crohn’s Disease Activity Index (CDAI) scores ≥220 and ≤450 and C-reactive protein (CRP) levels ≥2.87 mg/L were randomized 1:1 to receive 300 mg NAT (n = 259) or placebo (pbo) (n = 250) infusions at Weeks (wks) 0, 4, and 8. The Inflammatory Bowel Disease Questionnaire (IBDQ) and Short Form-36 (SF-36) were used to measure QoL at baseline and wk 12. Higher scores indicate better QoL.

Results: Baseline scores were comparable between the 2 groups. Pts in the NAT group had a mean CDAI score of 303.9 and a mean IBDQ total score of 123.6 vs 299.5 and 122.5, respectively, in the pbo group. At Wk 12, improvement in mean total IBDQ score was greater for pts in the NAT group compared to pbo (26.7 vs 15.1, respectively; p < 0.001), as well as improvement in all 4 dimensions of the IBDQ (p ≤ 0.002). Improvement in 6 of the 8 individual scale scores of the SF-36 (p ≤ 0.013), as well as the physical score component (PCS) score (p < 0.001), was greater in pts receiving NAT.

Conclusions: Pts receiving NAT induction therapy had significantly greater improvements in QoL than those receiving pbo, as measured by both disease specific (IBDQ) and global (SF-36) measures of QoL. Greater improvements were seen in the total IBDQ, all IBDQ subscale scores, 6 of 8 SF-36 scales, and the PCS scale of the SF-36.
a lower proportion of CD patients in the pred group (3/17) than in the non-P group (12/15, \( p = .001 \)). All women were premenopausal. Patients in both groups had similar baseline disease activity. Pred patients had higher t scores for both LS and hips at baseline. Values for baseline t scores, and 3 month changes in t score and% BMD are shown in the Table below. p values are for differences between the pred and non-P groups. There was also a higher proportion of pred patients with a clinically significant, i.e. > 5%, decline in BMD at the hips, than in the non-P group (5/17 vs. 0/14, \( p = .04 \)).

**Conclusions:** In this prospective, controlled study, a < 3 month course of prednisone, led to a significantly greater decline in BMD at the hips (but not at the spine) compared to control patients at 3 months. Significant bone loss at the hips, as defined by a greater than 5% decline in BMD, can be seen as early as 3 months in these patients with active IBD being treated with a tapering course of prednisone, despite concurrent supplemental calcium and vitamin D.

<table>
<thead>
<tr>
<th>Baseline LS t score</th>
<th>Baseline hip t score</th>
<th>( \Delta t ) score at LS</th>
<th>( \Delta t ) score at LS</th>
<th>( \Delta t ) score at hips</th>
<th>( \Delta t ) score at hips</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pred</td>
<td>−0.19</td>
<td>−0.51</td>
<td>−0.17</td>
<td>−1.4</td>
<td>−0.31</td>
</tr>
<tr>
<td>Non-P</td>
<td>−1.1</td>
<td>−1.52</td>
<td>−0.06</td>
<td>−0.6</td>
<td>−0.02</td>
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</table>

**1152**

**Natalizumab Maintains Remission for 2 Years in Patients with Moderately to Severely Active Crohn’s Disease and in Those with Prior Infliximab Exposure: Results from an Open-Label Extension Study**


**Purpose:** Natalizumab has been demonstrated as effective therapy for moderately to severely active Crohn’s disease (CD) in both induction and long-term maintenance trials. Fifty-five percent of patients who responded to natalizumab induction therapy were in remission (Crohn’s Disease Activity Index [CDAI] score < 150) after 15 months of continuous natalizumab therapy in the ENACT trials, compared with 22% in the placebo group (\( p < .001 \)). This analysis was undertaken to assess the ability of natalizumab to maintain remission for up to an additional year (>2 yrs total).

**Methods:** Patients who completed the ENACT-2 trial were eligible to enroll in an open-label extension (OLE) study. The primary objective of this 2-year study was to examine the long-term safety and tolerability of natalizumab. Secondary efficacy endpoints included evaluation of the ability of natalizumab to maintain remission. This analysis includes patients who were in remission after 15 months of continuous natalizumab therapy in the ENACT trials who enrolled in the OLE study and received an additional 12 months of natalizumab therapy. Eighty-seven patients met the criteria for analysis, 22 of whom had previous exposure to anti-TNF. Remission rates were calculated using last observation carried forward.

**Results:** Patients in this analysis had a mean CDAI score of 151 (median, 150) after a single natalizumab infusion in ENACT-1. Ninety-three percent (81/87) of patients who were in remission at Month 12 of ENACT-2 were in remission following 6 additional natalizumab infusions in the OLE study. After 12 additional infusions, 86% (75/87) were in remission. In the subpopulation of patients with prior exposure to infliximab, 91% (20/22) were in remission after an additional 6 and 12 infusions of natalizumab in the OLE study. Similarly, 82% (9/11) who had previously failed therapy with infliximab were in remission at the same timepoints.

**Conclusions:** Natalizumab maintained remission for >2 years (27 months) when administered as continuous therapy. Patients who entered remission with natalizumab induction therapy were highly likely to maintain long-term remission, including patients who had previously failed therapy with infliximab.

**1153**

**Fecal ASCA Measurements in the Assessment of Pediatric Patients with Known or Suspected Crohn’s Disease**


**Purpose:** To examine the utility of measuring fecal ASCA levels as a non-invasive screening measure for CD in children with known or suspected IBD.

**Methods:** 105 patients aged ≤18 years, including 86 patients with CD, 17 with UC, 2 with acute colitis, and 16 healthy controls submitted stool and serum specimens for ASCA analysis. Diagnosis of IBD was based on endoscopic, radiologic, and histologic findings. Fecal samples were diluted 1:10 and analyzed using a qualitative ASCA ELISA immunoassay. Fecal ASCA samples were measured blinded of a subject’s diagnosis.

**Results:** 52% (45/86) of patients with CD and 30% (5/17) patients with UC tested positive for fecal ASCA. None of the healthy controls tested positive for fecal ASCA. The sensitivity and specificity for fecal ASCA testing was 52% and 62%, respectively. Serum ASCA results were available from 71 subjects. The sensitivity and specificity of serum ASCA measurements in these subjects was 86% and 55%, respectively.

**Conclusions:** The prevalence of antibodies to ASCA appears to be comparable in stool or serum. The specificity of serum ASCA testing is superior to that measured in the feces. However, fecal ASCA testing offers the advantage of being inexpensive and noninvasive. When combined with other fecal diagnostic assays, such as lactoferrin, fecal ASCA testing may prove useful for the assessment of children suspected of having IBD.

**1154**

**Low Grade Dysplasia Preceding Neoplasia in Inflammatory Bowel Disease**

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**Purpose:** Prior studies have shown that flat low grade dysplasia (fLGD) progresses to advanced neoplasia (high grade dysplasia or adenocarcinoma) in approximately 30% of patients with ulcerative colitis (UC). We present the first case control study investigating the relationship between developing cancer and having fLGD in patients with UC and Crohn’s colitis (CC).

**Methods:** 23 UC and CC patients with advanced neoplasia (AN) were identified from the inflammatory bowel disease (IBD) database at an urban academic medical center. These patients were matched for date of birth, gender, and disease type to a control group without AN. Medical records were reviewed for disease location and behavior, medications, number of colonoscopies, total number of months under surveillance, and presence of fLGD during surveillance period. Characteristics and outcomes were compared. A subgroup analysis by disease type was performed. Paired t-tests and Chi-square test were used for continuous and dichotomous variables, respectively.

**Results:** There were no significant differences in demographics and disease characteristics (Table 1). No differences in disease location (\( p = 0.96 \)) or disease behavior (\( p = 0.66 \)) were observed. 48% of the study group vs. 9% of controls had fLGD (\( p = 0.012 \)). In patients with UC, 64% of the study group and 14% of the controls had fLGD (\( p = 0.02 \)). In patients with CC, 22% of cases and 0% of controls had fLGD (\( p = 0.453 \)).
Conclusions: AN was preceded by LGD at an impressive rate of 48%, further supporting the idea that there is a clear relationship between LGD and AN. While there appears to be a definitive progression from LGD to AN in UC, patients with CC have a propensity to develop AN without preceding LGD. Further studies are needed to define the pathogenesis of neoplasia and surveillance strategies in patients with CC.

Demographics & Characteristics

<table>
<thead>
<tr>
<th>Variables</th>
<th>Cases</th>
<th>Controls</th>
<th>p-value</th>
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<tr>
<td>N (%)</td>
<td>14 (61)</td>
<td>14 (61)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>9 (39)</td>
<td>9 (39)</td>
<td></td>
</tr>
<tr>
<td>CD</td>
<td>14 (61)</td>
<td>14 (61)</td>
<td></td>
</tr>
<tr>
<td>UC</td>
<td>23 (100)</td>
<td>21 (91)</td>
<td>0.47</td>
</tr>
<tr>
<td>Steroids</td>
<td>5-ASA</td>
<td>14 (61)</td>
<td>9 (39)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>Age Dx</td>
<td>39.1 (16.4)</td>
<td>42.6 (19.0)</td>
</tr>
<tr>
<td>Total # CF during f/u</td>
<td>12 (3–36)</td>
<td>7 (2–30)</td>
<td>0.22</td>
</tr>
<tr>
<td>Total # months under surveillance</td>
<td>132 (2–324)</td>
<td>74 (3–378)</td>
<td>0.45</td>
</tr>
<tr>
<td>Interval between CF</td>
<td>8 (1–43)</td>
<td>9 (1–76)</td>
<td>0.65</td>
</tr>
</tbody>
</table>

CF = Colonoscopies

1155

Cytomegalovirus (CMV) Infection Masquerading as Fulminant Colitis and Low-Grade Dysplasia in Steroid Dependent Ulcerative Colitis

Michael J. Gilbert, MD, Arthur J. DeCross, MD, Ashok Shah, MD, Richard G. Farmer, MD, M.S., M.A.C.P,* Gastroenterology and Hepatology, University of Rochester, Rochester, NY.

Purpose: We report a 49-year-old woman with long-standing steroid dependent colitis, who developed transfusion dependent hematocrit. Her history was significant for Ulcerative Colitis for 17 years with no re-sections. She had been steroid dependent for over a year and had previously been diagnosed with low-grade dysplasia. She presented with 3 days of abdominal pain and hematochezia with fever. She presented with a HCT of 24 despite transfusion and was transferred to our institution for emergent colectomy. Her stool culture and Clostridium difficile were negative. Preoperative colonoscopy revealed mild acute inflammatory colitis with chronic inflammatory changes and numerous punched out ulcers. Biopsies showed viral inclusions and serologic studies all suggested recent CMV infection. Low-grade dysplasia was also found on biopsies throughout the colon. The patient was started on intravenous gancyclovir, was slowly tapered from steroids and started 6-MP. Over six weeks her symptoms improved with intravenous gancyclovir and a colectomy was avoided. Repeat colonoscopy at 8 weeks showed near total eradication of the CMV and complete resolution of the low-grade dysplasia. The patient had no further episodes of hematocrit and had normalization of her HCT. Cytomegalovirus (CMV) colitis has been reported in patients with underlying inflammatory bowel disease. Previous prospective studies have shown higher rates of CMV infection in steroid resistant ulcerative colitis. CMV colitis and ulcerative colitis can both present clinically with hematocrit and can be difficult to differentiate by endoscopic evaluation. Inflammatory changes secondary to CMV infection can confuse the diagnosis of low-grade dysplasia on biopsy. CMV colitis is a potentially treatable cause of colitis and should be excluded in patients contemplating colectomy for low-grade dysplasia or refractory hematocrit in steroid dependent ulcerative colitis. CMV infection should be excluded prior to advancing immunosuppressive therapy in steroid refractory cases. Analysis of blood for cytomegalovirus culture and serology should be obtained to corroborate biopsy results.

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Do Sequential CT Enterography Exams for Assessing Crohn’s Disease Activity Correlate with Physician Global Assessment and Endoscopic Findings?

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Purpose: CT enterography (CTE) is an excellent non-invasive imaging test for evaluating Crohn’s disease (CD). It is not yet known if sequential CTE changes over time correlate with the physician global assessment (PGA) and/or endoscopic findings in patients with CD.

Methods: A retrospective review of the imaging archive from 3/2002–3/2006 identified 23 patients (16M,7F, avg age = 51.3y) with known or suspected CD with at least 2 CTE exams. Using electronic chart review, PGA (based on history, physical exam, and laboratory studies) at the time of each CTE&results of endoscopic exams performed within 6 months of CTE were recorded. A single radiologist blinded to patient history&endoscopic results reviewed all CTE exams&recorded the presence or absence of CD in the small bowel and/or colon (mucosal hyper-enhancement and/or wall thickening > 3 mm)&if findings worsened, improved or remained stable between exams. Imaging results were compared to PGA and endoscopic findings when available.

Results: Mean time between CTE exams was 10.7 mos (1–26 mos). 14 colonoscopies with ileoscopies in 13 patients and 2 capsule studies (CE) in 2 patients were performed. 5 patients had multiple endoscopic exams. Observed agreement between imaging changes on CTE and PGA was 22/23 (96%). Estimated kappa (95% CI) was 0.92 (0.78,1.00). In 13/14 (93%) comparisons, worsening PGA correlated with disease progression by imaging findings at CTE. In 4/4 comparisons, improvement in PGA correlated with improved imaging findings at CTE. In 5/5 comparisons, PGA&CTE findings remained stable. Overall, 13/14 (93%) colonoscopy with ileoscopy results matched CTE findings. Findings which did not correlate included 1 patient with erosions in the ileum but no GI symptoms&negative CTE. Both CE studies correlated with PGA and imaging findings. In a subgroup of patients with sequential endoscopies, observed agreement between endoscopic changes&CTE was 4/5 (80%). In 1/5 patients, PGA & endoscopic findings showed disease progression while CTE findings improved.

Conclusions: These results suggest that sequential CTE exams appear to be an excellent tool for assessing changes in CD activity. CTE appears to have high correlation with PGA and endoscopic findings. Large prospective studies are needed to confirm these results.

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Dramatic Rise in the Incidence of Ischemic Colitis (IC) in Two Metropolitan Hospitals over a 10 Year Period


Purpose: The purpose of this study was to determine the following:
1. If the incident of IC had been increasing over time
2. If IC was occurring with increasing frequency in patients 59 and younger
3. What the ratio of women to male patients affected was

Methods: The incidence of IC as determined by colonoscopy and was evaluated retrospectively from 1992 through 2001 at two large metropolitan hospitals in Indianapolis, IN. Patients were categorized into two groups:

- Age < 60 and Age > 60.

Results: 221 colonoscopically confirmed cases of IC were diagnosed in the 10 year period.

Distribution as follows:

- Age < 60 (n = 80)
- Age > 60 (n = 141)
Symptoms and signs, which include abdominal pain (85.5%), abdominal tenderness (76%), hematochezia (81.9%), and leukocytosis (62%), were similar for both age groups. No clear association with any of the following comorbid conditions was seen: atrial fibrillation, anemia, renal failure, coagulopathy, pregnancy, hypercholesterolemia, prior abdominal surgery, PVD, constipation, prior IC, CHF, CAD, IBS, malignancy, hypertension, DM, vasculitis, tobacco use. No clear association with any of the following medications was seen: lipid lowering agents, diuretics, BCP, antidepressants, opiates, herbs, illicit drugs, NSAIDs, steroids, antiplatelet agents.

The incidence of IC from 1992 to 2001 was statistically significant at the $p < 0.0001$ level.

Conclusions: The incidence of IC has increased significantly over the past 10 years for no apparent reason.

IC is not just a disease that predominates in individuals over age 60: 36% of our patients were < 60 y/o.

Women are more likely affected than men: Ratio: Women/Men = 4/1.

Antibodies to Flagellin: Clinical Significance in Inflammatory Bowel Disease

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Purpose: In inflammatory bowel disease, the primary structural component of bacterial flagellae – Flagellin, activates the innate and the adaptive immunity as well. Aim: to analyze the relationship between immune responses and clinical phenotype.

Methods: In 264 patients (157 Crohn’s disease (CD), 56 ulcerative colitis (UC), 21 infectious (IC), and 43 healthy controls (HC)) we measured (ELISA) flagellin-antibodies (FAB). We investigated the crossreactivity to other IBD antibodies (ASCA, PAB, p-ANCA). A clinical database allowed correlation with location, severity (CDAI or MA YO score) and therapy (medication and/or surgery).

Results: FAB were found in 59% of patients with CD, 33% with UC, 38% with IC but only in 2% of HC. Frequency of FAB was higher in patients with CD than in patients with UC ($p = 0.001$), IC ($p = 0.077$) and HC ($p < 0.001$). ASCA and/or PAB positive CD patients expressed more frequently FAB than ASCA and/or PAB negative CD patients ($p = 0.017$). FAB were slightly more frequently found in CD patients who had CD-related surgery ($p = 0.066$). FAB were not associated with location of disease (colon vs small bowel), fistula and extraintestinal manifestations. Serological detection rate of CD improved when ASCA was combined with FAB (sensitivity $71\%$ vs $66\%$; specificity $63\%$).

Conclusions: Flagellin is an important antigen in CD but not in UC. Serum reactivity to flagellin is associated with immunoreactivity to other antibodies (ASCA, PAB). The combined testing of ASCA with flagellin has a sensitivity of $71\%$ for the detection of CD and may therefore be a useful diagnostic tool.

Capsule Endoscopy in Patients with Suspected and Known Crohn’s Disease: Correlation with IBD Serology

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Purpose: The diagnosis of Crohn’s disease (CD) is challenging, and requires the combination of clinical findings, inflammatory markers, serology, radiologic, endoscopic, and histologic findings. Wireless Capsule Endoscopy (WCE) provides direct visualization of mucosal abnormalities throughout the entire small intestine and may be the most sensitive means of diagnosing CD.

Methods: A retrospective analysis of 125 patients who underwent WCE with the PillCam Sb (Given Imaging, Yoqneam, Israel) for suspected CD between January 2003 and May 2006. 5 groups of patients were identified: 52 with abdominal pain, diarrhea, guaiac + stools, and iron deficiency anemia (Group-1); 31 with abdominal pain and diarrhea (Group-2); 14 with abdominal pain (Group-3); 21 with indeterminate colitis (Group-4); 7 with known Crohn’s (Group-5). All underwent pan-endoscopy, most ileoscopy, and small bowel series. Findings were classified as definite or possible for CD, non-specific, or normal; Definite: greater than 3 ulcers, edema, nodularity, and stricture; Possible: 1–2 aphthous ulcers, erythema, edema, and nodularity; Non-specific: erythema, edema, nodularity, and mucosal breaks. IBD serology (ASCA IgA, IgG, p-ANCA) was obtained from 85 patients.

Results: There were 70 females, 55 males; average age 46.8 (range 11–82), 12/52 (23%) patients in Group-1 had definite findings, 9 possible, 26 non-specific. 4/31 patients in Group-2 had definite findings, 7 possible, 15 non-specific. 1/21 patients in Group-3 had definite findings, 3 possible, 10 non-specific. 4/21 (19%) patients in Group-4 had definite findings, 5 possible, 6 non-specific. 3/7 patients in Group-5 had definite findings. 74% (28/38) of patients with + IBD serology had definite or possible capsule findings; 16/19 patients with definite findings had + markers; 12/19 with possible findings had + markers; 12/38 with non-specific findings had + markers; 2 with normal findings had + markers.

Conclusions: + WCE findings for CD were highest for patients with abdominal pain, diarrhea, guaiac + stools, and iron deficiency anemia. + WCE findings for CD strongly correlated with + IBD serology. The clinical suspicion, combined with WCE findings and + serology, may be the best way to diagnose early CD. The significance of non-specific findings on WCE remains to be determined.

Adalimumab Safety in Crohn’s Disease and Rheumatoid Arthritis Clinical Trials, Reduced Mortality in Rheumatoid Arthritis

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Purpose: Evaluate adalimumab safety in clinical trials for rheumatoid arthritis (RA) and Crohn’s disease (CD).

Methods: Safety data were routinely collected in all adalimumab clinical trials. Rates of serious adverse events (SAE) of interest to physicians prescribing anti-TNF therapy were assessed per 100-patient-years (E/100-PY). Rates in CD clinical trials [4 Phase II/III multicenter RCT trials and an OL extension] and RA clinical trials [the early RA trial excluded, all Phase I-III randomized controlled trials (RCTs), open-label (OL) extensions, and OL Phase IIIb clinical trials] were compared with previously reported rates in adalimumab.

Results: As of April 15, 2005, the adalimumab RA clinical trial safety database included data for 10050 patients, representing 12506 PY of adalimumab exposure. The serious infection rate (5.05/100-PY) was comparable to that reported on August 31, 2002 (4.9/100-PY) and to published reports of anti-TNF naïve RA populations. SAE rates of interest in RA and CD clinical trials are summarized in the table.

In adalimumab RA clinical trials, the calculated standardized mortality ratio of 0.64 (95% CI 0.52–0.79) was lower than previously reported for the RA population prior to the advent of anti-TNF therapy. Adalimumab therapy showed consistent safety profiles in clinical trials for RA and CD. SAE rates of interest were generally similar in clinical trials in RA and CD. Evidence suggests a decrease in mortality in...
adalimumab-treated patients with RA compared with a gender- and age-matched general population.


1161 Are IBD Patients Who Are Intolerant to 6-MP Able To Tolerate Treatment with Azathioprine?

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Purpose: It has been suggested that pts with inflammatory bowel disease (IBD) who are intolerant to azathioprine (AZA) can be treated with 6-mercaptopurine (6MP) (Scand J Gastro 2005 40:52–55). We investigated whether pts with IBD can safely be treated with AZA if they are intolerant to 6MP.

Methods: Records of 300 sequential pts with IBD were examined to categorize both exposure and intolerance to 6MP. Intolerance was defined as abdominal pain, nausea, rash, significant fatigue or other symptom with normal labs. Once identified, pts were counseled on different treatment modalities. Potential risks and benefits were reviewed, and pts were offered AZA as a treatment option. Data collected included: age, gender, age of diagnosis, surgical history, distribution of disease, concurrent medications, daily dose of 6MP, nature of adverse effects, onset of reaction and duration, daily dose of AZA, and clinical efficacy of AZA.

Results: Seven pts were identified (6 male, 1 female) who were previously intolerant to 6MP and agreed to AZA use. Six pts had Crohn’s disease and one had ulcerative colitis. The mean age of the pts was 35 ± 14.9 years, range of 23–64 yrs. The mean disease duration was 11 ± 87.9 yrs, range of 3–25 yrs. All pts had steroid dependency as the primary indication for immunosuppressive therapy. The maximal dose of 6-MP used was 50 mg/day for 6 of the 7 pts due to intolerance; exact dosing was not clear in the seventh pt. The most common symptoms were nausea and vomiting in 5 of 7 pts. No patients developed pancreatitis. Symptoms related to 6MP use developed in all pts within 2 months of starting 6MP. Four of 7 developed symptoms within one hour to within one week of administration. Four of 7 were challenged with 6MP and developed the same exact side effects. All pts were cautiously started at a low dose (50 mg) of AZA and gradually titrated up to a goal of 2.5 mg/kg. The mean final dose of AZA was 1.93 mg/kg ± 0.74, range 1.25–3.2 mg/kg. Five of 7 pts did not have any adverse reaction to AZA; one pt developed leukopenia which resolved with dose reduction; another developed fatigue which limited dose escalation. No pts needed to discontinue the medication. Five of 7 pts were able to completely withdraw from steroids; one continued to use hydrocortisone enemas and one required further courses of prednisone.

Conclusions: Azathioprine can be safely used for treatment of IBD pts who had prior intolerance to 6MP.

1162 Elevated Prevalence of Colorectal Cancer and Effects of Obesity and Metabolic Disorders in Veterans Patients Diagnosed with Inflammatory Bowel Disease: A Retrospective Cohort Study

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Purpose: The etiology of inflammatory bowel disease (IBD) is complex. Risk factors can be genetic, environmental, or behavioral. The US Veterans Administration (VA) population represents a unique patient characteristics. Published studies suggested that adipocytokines play an important role in the IBD pathogenesis. Chronic obesity may have an effect on the age of onset for IBD. Subsequently, IBD patients could have a higher risk for colorectal cancer (CRC). This study examined the effects of race and chronic obesity on the age of disease onset, and the prevalence of CRC and other chronic diseases in VA IBD patients.

Methods: VA patients with ICD-9 diagnoses for Crohn’s disease (CD) and ulcerative colitis (UC) were identified. The age of disease onset, demographic, weight, and other clinical characteristics were collected. Df from the National Center for Health Statistics (NCHS) were used to compare CRC prevalence data.

Results: Between 1985 and 2005, 659 CD and UC patients were identified (CD: 39.2% and UC: 60.8%). 96.2% were male and 91.5% were Caucasians. The median age of onset for CD was 63.7 years and 68.7 years for UC. Compared to CD patients, UC patients had higher prevalence of chronic obesity (9.76% vs. 5.43%, p = 0.04), metabolic disorder (51.95% vs 35.66%, p < 0.0001), and diabetes (25.61% vs. 14.34%, p = 0.0001). UC patients on average had more comorbid conditions compared to CD patients (10.0 vs. 8.7, p = 0.01). Chronic obese patients had earlier disease onset compared to non-obese patients when adjusted for other covariates. The VA IB patients also had a much higher rate of CRC compared to the general population from NCHS data (2.9% vs. 0.1%, p = 0.0001).

Conclusions: The VA patient population with IBD is unique compared to the general population. In the study, VA patients with UC had higher prevalence of diabetes, metabolic disorders and obesity compared to patients with CD. Patients with UC or CD were generally older and had a much higher rate of CRC. Our findings also demonstrated the significance of obesity status. This study illustrates the need for further evaluation on the etiology of IBD, the effects of obesity and other metabolic disorders, and the subsequent elevated risk for CRC in this specific subset of IBD patients.

1163 Pravastatin Decreases Ileal Inflammation in a Murine Model of Ileitis: A Potential New Treatment for Crohn’s Disease

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Purpose: In addition to their lipid lowering properties, HMG CoA reductase inhibitors (statins) have been reported to have immunomodulatory properties primarily mediated by the inhibition of Th1 cytokines. Statins have been proposed as a potential therapy for a number of Th1-mediated chronic inflammatory diseases. Statins would be an intriguing therapy for Crohn’s disease given their overall safety and tolerability. The aim of this study was to evaluate the effects of pravastatin on the severity of disease in a murine model of ileitis that closely resembles Crohn’s disease (SAMP1/YitFc strain).

Methods: We performed both a prevention and a treatment study using SAMP mice. In the prevention study, 4-week old mice received either pravastatin (10mg/kg, N = 6) or placebo (N = 6) as daily intraperitoneal injections for 6 weeks. In the treatment study, 12-week old mice with established ileitis received either pravastatin (10mg/kg, N = 6) or placebo (N = 6) as daily intraperitoneal injections for 2 weeks. Mice were sacrificed at the end of the

### SAE of Interest (E/100-PY)

<table>
<thead>
<tr>
<th>Indication</th>
<th>RA</th>
<th>CD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure, PY</td>
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<td>1,506</td>
</tr>
<tr>
<td>Patients, N</td>
<td>10,050</td>
<td>1,459</td>
</tr>
<tr>
<td>Serious infections</td>
<td>5.08</td>
<td>5.98</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>0.27</td>
<td>0.20</td>
</tr>
<tr>
<td>Lymphomas</td>
<td>0.12</td>
<td>0.07</td>
</tr>
<tr>
<td>Demyelinating disease</td>
<td>0.08</td>
<td>0.13</td>
</tr>
<tr>
<td>SLE/Lupus-like syndrome</td>
<td>0.10</td>
<td>0.07</td>
</tr>
<tr>
<td>CHF</td>
<td>0.28</td>
<td>0.00</td>
</tr>
</tbody>
</table>
study and ileal histology was graded on acute, chronic, and total inflammation by a blinded pathologist.

Results: In the prevention study, mice receiving pravastatin had significantly lower acute (2.75 v. 4.2; p < 0.02), chronic (2.75 v. 4.2; p < 0.02), and total (5.5 v. 8.4; p < 0.02) ileal inflammatory scores compared to mice receiving placebo. In mice with established ileal disease, the group receiving pravastatin had significantly lower chronic ileal inflammation (1.17 v. 4.17; p < 0.002) but no significant differences in acute (4.42 v. 4.5; p = 0.94) or total (5.59 v. 8.07; p = 0.10) inflammatory scores than mice receiving placebo.

Conclusions: Pravastatin prevents both acute and chronic inflammation, and significantly reduces chronic inflammation in SAMP1/YitFc mice. Since chronic inflammation in this model is mediated by Th1 cytokines, our results are consistent with the possibility that pravastatin suppresses Th1 cytokine production during chronic intestinal inflammation. Given the overall safety and tolerability of statins, the results of our preclinical study provides the proof of concept for testing statins in clinical trials with patients with Crohn's disease.

Endoscopic Features of Inflammatory Bowel Disease in Patients with Primary Sclerosing Cholangitis

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Purpose: An increased prevalence of pancolitis, rectal sparing, and backwash ileitis has been described in inflammatory bowel disease associated with primary sclerosing cholangitis (PSC-IBD), which may represent a distinct phenotype of IBD. This study characterizes the endoscopic features of IBD in a group of patients with PSC-IBD and compares them to a matched group of patients with chronic ulcerative colitis (UC) without PSC.

Methods: All patients with both PSC and IBD evaluated at St. Louis University (SLU) from 1995–2005 were identified through a retrospective review of the medical record. Cases were required to have PSC diagnosed by cholangiography (ERCP and/or MRCP) at SLU. Both cases and controls were required to have had at least one prior colonoscopy with biopsies or a colectomy at our institution. A control group of patients with chronic ulcerative colitis (UC) without PSC was matched for sex, calendar year of first visit to SLU, duration of IBD, patients with PSC are more likely to develop dysplasia.

Results: Twenty-five patients with PSC-IBD and 30 matched controls with chronic UC were identified. The PSC-IBD group was diagnosed with UC, 3 Crohn's disease (CD), and 2 indeterminant colitis (IC). The endoscopic features of IBD in the PSC-IBD group were characterized in the table below. Compared to matched controls with chronic UC, the PSC-IBD patients were no more likely to have pancolitis, rectal sparing, backwash ileitis, or fistulae. Despite being matched for duration of clinical IBD, PSC patients were more likely to have dysplasia than patients with Ulcerative colitis. (24% vs 4%, p < 0.05).

Conclusions: The incidence of pancolitis, rectal sparing, backwash ileitis, and fistulae in our population of patients with PSC and IBD was comparable to that of matched controls with UC alone. Despite being matched for the duration of IBD, patients with PSC are more likely to develop dysplasia. This may reflect the unique natural history of dysplasia in the PSC-IBD subpopulation, longer subclinical inflammation or increased use of mesalamine in patients with only UC.

Seizures and Neuropathy from Inflammatory Bowel Disease

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Purpose: Inflammatory bowel disease (IBD) can rarely present with neurological complications. I report a patient with IBD who presented with seizures and peripheral neuropathy.

Case Report: A 28 y/o black male presented with two witnessed tonic-clonic seizures and post-ictal confusion. He had no loss of bowel or bladder function and no tongue biting. His past medical history was positive only for fistulous Crohn’s disease diagnosed four years prior that was poorly controlled with variable compliance with medications. Social history was negative. On physical exam he was afebrile with other vital signs normal. He was cachectic, bed ridden, and ill appearing. He did not have any cranial nerve deficits, but he did have noticeable bilateral foot drop with reduced strength (2/5) in both lower extremities. He also had reduced light touch
sensation in both legs but good proprioception. His laboratory data showed normal electrolytes, a normal B12 level, and a negative urine drug screen. He had a normal cranial MRI and EEG. EMG/NCV studies demonstrated lower extremity polyneuropathy. No obvious cause was found for the new seizure disorder or peripheral neuropathy other than his Crohn’s disease.

He was started on phenytoin and sent home in stable condition with close follow-up by Neurology and Gastroenterology. Reportedly he has had no further seizures, but his neuropathy has not improved on IBD therapy with azathioprine.

Discussion: IBD is a well-documented entity, but its pathogenesis is poorly defined. Twenty-five percent of individuals with IBD develop some form of extraintestinal manifestations of the disease. Most commonly, the eyes, skin, joints, and biliary tract are involved. Of the 25% that have complications outside the GI tract, 3% of these individuals will develop neurological problems. Most commonly, these complications include peripheral neuropathy (31%), myopathies, cerebrovascular disease, and myelopathies. Seizures are another documented problem associated with IBD. Neurological problems often correlate with disease activity, but they may also be evident during disease inactivity. Thus, it is difficult to determine if these complications are responsive to treatment. An extensive work up for a primary neurological pathology should always be done.

Conclusions: This case demonstrates severe neurological complications that occasionally accompany IBD. It is unclear if prompt diagnosis and treatment of IBD will alter their incidence or severity.

Ulcerative Colitis Is Associated with a Paucity of Colonic T Regulatory Lymphocytes
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Purpose: Previous investigations into the role of FoxP3+ T regulatory lymphocytes (Tregs) in the pathogenesis of inflammatory bowel disease have been hampered by inadequate identification of Tregs and the inclusion of immunomodulated subjects. These studies were also limited by using bulk quantification methods for Tregs, not accounting for altered histologic distribution. Since the immune system first interfaces with luminal antigens at the epithelium, we hypothesize that subjects with treatment-naïve Crohn’s disease and ulcerative colitis might have a paucity of Tregs specifically in the subepithelial space, as identified by a new FoxP3 intracellular antibody, compared to control subjects.

Methods: A case-control study included pediatric patients receiving endoscopy for suspected inflammatory bowel disease and excluded patients taking immunosuppressants. Tissue sections from 23 subjects with Crohn’s colitis, 22 subjects with ulcerative colitis, and 19 control subjects with normal endoscopic and histologic exams were stained with anti-FoxP3 antibody (nFoxo, ebioscience). Slides were reviewed by a blinded pathologist and a blinded non-pathologist.

Results: Colonic mucosa of control subjects consistently demonstrated a lining of FoxP3+ lymphocytes just under the epithelial cells. However, subjects with ulcerative colitis consistently lacked this lining. Crohn’s colitis completely lacked Tregs or showed significant gaps or paucity more often than controls. Blinded pathologists correctly identified the ulcerative colitis tissue, based on FoxP3 distribution alone with sensitivity of 77% and specificity of 94%. Positive predictive value of 94% and negative predictive value of 94% (p < 0.001). Intraobserver agreement was nearly complete. Similar results were found by the non-pathologist. 3/5 subjects with a clinical diagnosis of ulcerative colitis but no acute changes on histology showed a lack of Tregs. Inflammatory controls all showed normal Treg staining.

Conclusions: The immune disregulation of IBD and particularly ulcerative colitis may be related to a paucity of Tregs. FoxP3 staining may be a clinical adjunct for early cases of ulcerative colitis that do not yet have chronic changes.

Beneficial Effects of Eprodisate (NC-503) for Patients with Amyloid A (AA) Amyloidosis: Results of a 2-Year, Multi-Center, Randomized, Placebo-Controlled Trial
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Purpose: AA amyloidosis is a relatively rare but potentially life-threatening complication in patients with long standing chronic inflammatory conditions such as inflammatory bowel diseases. Although insoluble amyloid deposits may be found systemically, renal and gastrointestinal (GI) tract involvement dominates the clinical picture. Currently there is no approved drug for the treatment of this disease. Eprodisate is a member of a new class of agents that inhibit amyloid fibril formation and deposition.

Methods: This trial was conducted to assess efficacy and safety of eprodisate in AA amyloidosis patients. It is the first, large, therapeutic trial of an anti-amyloid compound and provides information about the course of this disease, as well as the efficacy of a novel, specific treatment. 183 patients from 27 centers were enrolled. The primary outcome defined worsened disease as a 50% decrease in creatinine clearance (CrCl), doubling of serum creatinine, progression to dialysis/ESRD, or death. Secondary endpoints included several parameters measuring kidney and GI tract function, including loss of body weight and chronic diarrhea.

Results: Crohn’s disease and ulcerative colitis were the underlying inflammatory conditions in 5% and 0.5% of patients, respectively. Overall, chronic diarrhea was present in 11%, abdominal pain in 11%, vomiting or nausea in 9%, chronic constipation in 7%, hepatomegaly in 6%, splenomegaly in 4%, GI bleeding in 1%, and steatorrhea in 1%. Nephrotic syndrome was present in 40%, proteinuria ≥ 1 g/day in 79%, and mean ± SD CrCl was 76 ± 4 ml/min/1.73 m². There were no statistically significant differences between groups at baseline. The primary endpoint (Cox proportional hazards regression analysis) showed that eprodisate reduced the risk of worsened disease by 42% (HR: 0.58, 95% CI 0.37–0.93, p = 0.025). The adverse event profile was comparable to placebo.

Conclusions: This first multi-center trial of an anti-amyloid agent found that eprodisate had clinically meaningful beneficial effects on the progression of AA amyloidosis.

Remission and Clinical Response to Adalimumab at 4 Weeks in Patients with Active Luminal Crohn’s Disease Who Had Lost Response to or Were Intolerant of Infliximab Therapy
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Purpose: To evaluate the efficacy and tolerability of adalimumab (ADA), a fully human, anti-TNF-α monoclonal antibody, in the induction of remission and clinical response in patients with active luminal Crohn’s disease (CD) and history of intolerance (INT) or loss of response (LR) to infliximab (INF).

Methods: In the first 4 wks of this 52-wk, open-label, multicenter study, ADA was administered sc 160 mg at BL, 80 mg at Wk 2, and 40 mg at Wk 4. This subset of patients had moderately to severely active CD (CDAI≥220) and a history of unsatisfactory response to INF. Patients were assessed after 4 wks for clinical remission (CDAI < 150), clinical response of ≥Δ70 or
Remission and Clinical Response to Adalimumab in 4 Weeks

<table>
<thead>
<tr>
<th>N at Week 4</th>
<th>Luminal Only, No Fistulce</th>
<th>Luminal, Fistulizing CD</th>
<th>All Luminal CD</th>
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</thead>
<tbody>
<tr>
<td>N=25</td>
<td>25</td>
<td>10</td>
<td>35</td>
</tr>
<tr>
<td>N=10</td>
<td>18/26 (77%)</td>
<td>30/36 (65%)</td>
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<tr>
<td>N=11</td>
<td>19/26 (73%)</td>
<td>27/36 (75%)</td>
<td></td>
</tr>
</tbody>
</table>

Intention to treat analysis.

Conclusions: Adalimumab was effective and well-tolerated in inducing clinical remission and response in this subset of patients with moderately to severely active luminal CD who had lost response or developed intolerance to IFN. No new safety concerns were identified compared with ADA-treated RA population.

Impact of Infliximab History on the Efficacy of Adalimumab in Patients with Moderately to Severely Active Luminal and/or Fistulizing Crohn’s Disease — Week 4 Results of an Open-Label Study

Purpose: To examine the efficacy and tolerability of adalimumab (ADA), a fully human, anti-TNF-α monoclonal antibody, in the induction of remission and clinical response (CR) in patients with luminal and/or fistulizing Crohn’s disease (CD) and history of intolerance (INT) or lost response (LR) to infliximab (INF).

Methods: In this continuing, 52-wk, open-label, multicenter study of ADA for inducing remission (CDAI < 150) and perianal fistula closure, ADA was administered sc 160 mg at BL, 80 mg at Wk 2, and 40 mg at Wk 4. Eligible patients had fistulizing CD (CDAI < 220) or moderately to severely active (CDAI ≥ 220) luminal (mucosal) CD, with or without fistulce, and a history of loss of response (LR) or intolerance (INT) to INF. CDAI and complete or partial (≥ 50% decrease in number of draining fistulae) fistula closure, Perianal Disease Activity Index (PDAl) fistula scores, and adverse events (AE) were routinely assessed. Remission, CR70 or CR100 (decrease of > 70 or > 100 in CDAI from BL), fistula closure at Wk 4 were compared for discontinuing (d/c) INF. The impact of smoking behavior on efficacy was assessed.

Results: Of 48 patients enrolled, 12 had fistulizing CD only, 26 had luminal CD only, and 10 had luminal CD and fistulce at BL. Two patients withdrew with AE: 1 with luminal CD only, 1 with fistulizing CD only. Results at Wk 4 by reason for d/c INF are presented here (table). Non-smokers (25%) tended to respond better to ADA than smokers (35%) or ex-smokers (45%). No serious AE occurred.

Conclusions: Adalimumab was efficacious and well-tolerated in patients with luminal and/or fistulizing CD irrespective of reasons for discontinuing prior INF therapy.

<abstract ref="S546"

Adalimumab Efficacy at Week 4 by Reason for Discontinuing Infliximab

<table>
<thead>
<tr>
<th>Reason</th>
<th>Luminal Only, N=25</th>
<th>Luminal + Fistulce, N=10</th>
<th>Fistulizing Only, N=11</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>13</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>CDAI &lt; 150, %</td>
<td>39</td>
<td>23</td>
<td>100 (75)</td>
</tr>
<tr>
<td>CR100 CDAI, %</td>
<td>77</td>
<td>62</td>
<td>0 (0)</td>
</tr>
<tr>
<td>CR70 CDAI, %</td>
<td>85</td>
<td>69</td>
<td>67 (70)</td>
</tr>
<tr>
<td>∆ΔPDAI (Fistulae)</td>
<td></td>
<td>-6.5</td>
<td>-4.5</td>
</tr>
</tbody>
</table>

Conclusions: Adalimumab was efficacious and well-tolerated in patients with luminal and/or fistulizing CD irrespective of reasons for discontinuing prior INF therapy.

Adalimumab Induced and Maintained Clinical Remission in Patients with Crohn’s Disease Independent of Baseline CRP Concentration: Subanalysis of the CHARM Study

Purpose: To evaluate the association of baseline CRP concentrations with induction and maintenance of clinical remission with anti-TNF adalimumab (ADA) therapy in patients with active Crohn’s disease (CD) in the CHARM study.

Methods: In CHARM, a Phase III, double-blind, placebo-controlled study of remission and safety of ADA therapy in patients with active moderate to severe CD (CDAI 220–450), all patients received open-label induction dosages of ADA, 80 mg at Wk 0 (BL) and 40 mg at Wk 2. At Wk 4, all patients were randomized to receive placebo (PBO) or 40 mg ADA sc, every other week (EOW) or weekly (W), through Wk 56. Those randomized with a clinical response of ≥ 70% decrease from BL CDAI (CR70) at Wk 4 were classified as randomized responders. Patients in clinical remission (CDAI < 150) at Wks 26 and 56 were stratified by baseline CRP concentrations (<1 mg/dL vs. ≥ 1 mg/dL).

Results: Baseline characteristics were similar across treatment arms, with mean CDAI = 313 and median CRP = 0.9 mg/dL. Of 854 patients who received induction therapy, 778 were randomized. Of these, 449 (58%) had achieved CR70 at Wk 4. Clinical remission in randomized responders by baseline CRP concentration is presented in the table.

Remission Rates by Baseline CRP, n/N (%)

<table>
<thead>
<tr>
<th>CRP (mg/dL)</th>
<th>PBO</th>
<th>ADA</th>
<th>ADA EOW</th>
<th>ADA W</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wk 26</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 1</td>
<td>15/85 (18)</td>
<td>68/177 (38)*</td>
<td>37/95 (39)</td>
<td>31/82 (38)</td>
</tr>
<tr>
<td>≥ 1</td>
<td>14/85 (17)</td>
<td>73/151 (48)**</td>
<td>31/76 (41)</td>
<td>42/75 (56)</td>
</tr>
<tr>
<td>Wk 56</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 1</td>
<td>11/85 (13)</td>
<td>61/177 (35)*</td>
<td>34/95 (36)</td>
<td>27/82 (33)</td>
</tr>
<tr>
<td>≥ 1</td>
<td>9/85 (11)</td>
<td>66/151 (44)**</td>
<td>28/76 (37)</td>
<td>38/75 (51)</td>
</tr>
</tbody>
</table>

*p < 0.001, **p < 0.0001, both vs. PBO.

Conclusions: Adalimumab induced and maintained remission over 1 year in patients with CD independent of CRP concentrations, with clear separation of adalimumab-treated groups from placebo. The small, nominal differences...
in absolute remission rates for adalimumab between the CRP-elevated and CRP-normal groups are without clinical significance.

1172

Perianal Fistula Closure with 4 Weeks of Adalimumab Therapy in Patients with Fistulizing Crohn’s Disease and a History of Intolerance or Loss of Response to Infliximab

Joaquín Hinojosa, MD, G. Bastida, MD, N. Vázquez, MD, P. Guererro, MD, B. Castro, MD, F. Fernández, MD, M.A. Gassull, MD* Digestive, Hosp. de Sagunto, Valencia, Spain; Digestive, Hosp. La Fe, Valencia, Spain; Digestive, Hosp. General Univ. Elche, Alicante, Spain; Digestive, Hosp. Nuestra Señora de Valme, Sevilla, Spain; Digestive, Hosp. Marqués de Valdecilla, Santander, Spain; Digestive, Hosp. Costa del Sol, Málaga, Spain and Digestive, Hosp. Germans Trias I Pujol, Barcelona, Spain.

Purpose: To examine the efficacy and tolerability of adalimumab (ADA), a fully human, anti-TNF-α monoclonal antibody, in the closure of perianal fistulae in patients with fistulizing Crohn’s disease (CD) and history of intolerance (INT) or lost response (LR) to infliximab (INF).

Methods: In the first 4 weeks of this ongoing, 52-week, open-label, multicenter study, ADA was administered se 160 mg at BL, 80 mg at Week 2, and 40 mg at Week 4 to patients who had discontinued previous INF therapy. The subset of patients either had fistulae only with CDAI < 220, or moderately to severely active (CDAI>220) luminal (mucosal) and fistulizing CD. Patients were assessed for complete or partial (≥50% decrease in the number of draining fistulae compared to BL) fistula closure, Perianal Disease Activity Index (PDAI) score, and adverse events (AE).

Results: Of 22 patients with fistulae, all had previously discontinued INF: 23% (n = 5) for LR, 77% (n = 17) for INT. Ten (45%) patients had luminal and fistulizing CD, 12 (55%) had fistulae only. The mean BL PDAI score overall (n = 22) was 10.5 ± 2.8; the mean number of fistulae at BL was 2.5 ± 1.2 in patients with fistulizing CD only and 3.8 ± 5.5 in patients with both luminal and fistulizing CD. Week 4 results are presented (table). Treatment-related AE were mild to moderate in severity and similar to those observed in studies of ADA in patients with rheumatoid arthritis (RA). The most common AE were erythema, nausea/dizziness, weakness, and myalgia. One patient with fistulizing CD dropped out due to non-pruritic erythema. No serious AE were reported.

PDAI Scores and Fistula Closure at Week 4 of Adalimumab Treatment

<table>
<thead>
<tr>
<th>Week</th>
<th>Therapy</th>
<th>PBO</th>
<th>ADA, EOW</th>
<th>ADA, W</th>
</tr>
</thead>
<tbody>
<tr>
<td>26</td>
<td>Concom. IMM</td>
<td>15/131 (12)</td>
<td>50/136 (37)*</td>
<td>47/121 (39)*</td>
</tr>
<tr>
<td></td>
<td>No concom IMM</td>
<td>5/39 (13)</td>
<td>12/36 (33)**</td>
<td>18/36 (50)*</td>
</tr>
<tr>
<td></td>
<td>Prior anti-TNF</td>
<td>13/81 (16)</td>
<td>28/86 (33)*</td>
<td>30/71 (42)*</td>
</tr>
<tr>
<td>56</td>
<td>Concom. IMM</td>
<td>1/21 (11)</td>
<td>53/136 (39)*</td>
<td>53/121 (44)*</td>
</tr>
<tr>
<td></td>
<td>No concom IMM</td>
<td>8/39 (21)</td>
<td>15/36 (42)**</td>
<td>20/36 (56)**</td>
</tr>
<tr>
<td></td>
<td>Prior anti-TNF</td>
<td>8/81 (10)</td>
<td>26/86 (30)**</td>
<td>24/71 (34)*</td>
</tr>
<tr>
<td></td>
<td>No prior anti-TNF</td>
<td>12/89 (14)</td>
<td>36/86 (42)*</td>
<td>41/86 (48)*</td>
</tr>
</tbody>
</table>

*Intention to treat analysis.

Conclusions: Adalimumab induced complete or partial fistula closure in these patients and was well-tolerated. No new safety concerns were identified compared with ADA-treated RA population.

1173

Sustained Clinical Remission in Patients with Moderate to Severe Crohn’s Disease with Adalimumab, Regardless of Anti-TNF History or Concomitant Immunosuppressant Therapy

Stephen B. Hanauer, MD, G.R. D’Haens, MD, J.F. Colombel, MD, W.J. Sandborn, MD, P. Rutgeerts, MD, J.D. Kent, MD, P.F. Pollack, MD,* Medicine, Univ. of Chicago, Chicago, IL; Gastroenterology, Imelda Research Center, Bonheiden, Belgium; Gastroenterology, CHU Lille, Lille, France; Research, Mayo Clinic, Rochester, MN; Gastroenterology, Univ. of Gathuisberg, Leuven, Belgium; Immunology Development, Abbott, Abbott Park, IL and Immunology Development, Abbott, Parsippany, NJ.

Purpose: To evaluate the efficacy of adalimumab (ADA) in sustaining clinical remission in patients with CD with concomitant immunosuppressant (IMM) therapy or history of anti-TNF treatment.

Methods: In CHARM, a Phase III, double-blind, placebo-controlled study of the maintenance of clinical remission (CDAI<150) and safety of ADA, pts with active CD (CDAI 220–450) received open-label induction ADA 80 mg at Wk 0 (BL) and 40 mg at Wk 2. At Wk 4, all pts were randomized to placebo (PBO) or 40 mg ADA, every other week (EOW) or weekly (W), through Wk 56. Patients with clinical response, a decrease in CDAI ≥70 from BL (CR70), when randomized at Wk 4 were classified as randomized responders (RR). The% of pts with CDAI<150, stratified by concomitant IMM use and anti-TNF history, were calculated at Wks 26 and 56.

Results: Of 854 pts receiving induction therapy, 778 were randomized. Of these, 499 (58%) were RR. BL characteristics were similar across the 3 arms: mean CDAI = 313; concomitant IMM use (such as AZA, 6-MP, or MTX), 47%; history of anti-TNF therapy, 30%. The proportions of RR with CDAI<150 at Wks 26 and 56 by prior anti-TNF or concomitant IMM therapy are in the table.

Randomized Responders in Remission by Concomitant/Prior Therapy

<table>
<thead>
<tr>
<th>Week</th>
<th>Therapy</th>
<th>PBO</th>
<th>ADA, EOW</th>
<th>ADA, W</th>
</tr>
</thead>
<tbody>
<tr>
<td>26</td>
<td>Concom. IMM</td>
<td>15/131 (12)</td>
<td>50/136 (37)*</td>
<td>47/121 (39)*</td>
</tr>
<tr>
<td></td>
<td>No concom IMM</td>
<td>5/39 (13)</td>
<td>12/36 (33)**</td>
<td>18/36 (50)*</td>
</tr>
<tr>
<td></td>
<td>Prior anti-TNF</td>
<td>13/81 (16)</td>
<td>28/86 (33)*</td>
<td>30/71 (42)*</td>
</tr>
<tr>
<td>56</td>
<td>Concom. IMM</td>
<td>1/21 (11)</td>
<td>53/136 (39)*</td>
<td>53/121 (44)*</td>
</tr>
<tr>
<td></td>
<td>No concom IMM</td>
<td>8/39 (21)</td>
<td>15/36 (42)**</td>
<td>20/36 (56)**</td>
</tr>
<tr>
<td></td>
<td>Prior anti-TNF</td>
<td>8/81 (10)</td>
<td>26/86 (30)**</td>
<td>24/71 (34)*</td>
</tr>
<tr>
<td></td>
<td>No prior anti-TNF</td>
<td>12/89 (14)</td>
<td>36/86 (42)*</td>
<td>41/86 (48)*</td>
</tr>
</tbody>
</table>

*p < 0.001, **p < 0.05, ***p < 0.01, all vs. PBO.

Conclusions: Adalimumab was significantly superior to PBO for the long-term treatment of CD irrespective of concomitant IMM therapies. Prior anti-TNF therapy resulted in slightly lower remission rates, but ADA significance vs. PBO was maintained.

1174

Indications for Proctocolectomy and Surgical Outcomes in Patients with Inflammatory Bowel Disease and Primary Sclerosing Cholangitis

Timothy Smith, MD, Prabhakar Swaroop, MD,* Division of Gastroenterology and Hepatology, St. Louis University, St. Louis, MO.

Purpose: Inflammatory bowel disease associated with primary sclerosing cholangitis (PSC-IBD) may represent a distinct phenotype of IBD. PSC-IBD carries an increased risk of dysplasia and colorectal cancer as well. The unique natural history of PSC-IBD may be reflected in indications for proctocolectomy and surgical outcomes in these patients. This study characterizes a group of patients with PSC-IBD who underwent colectomy and compares them to matched patients with UC alone.

Methods: Patients with IBD who underwent proctocolectomy with ileal pouch-anal anastomosis (IPA) at St. Louis University from 1995–2005 were identified retrospectively. Cases were required to have PSC confirmed by cholangiography. Controls with UC alone were matched for sex, year of diagnoses, and prior history of cholangitis (PSC-IBD) may represent a distinct phenotype of IBD. PSC-IBD carries an increased risk of dysplasia and colorectal cancer as well. The unique natural history of PSC-IBD may be reflected in indications for proctocolectomy and surgical outcomes in these patients. This study characterizes a group of patients with PSC-IBD who underwent colectomy and compares them to matched patients with UC alone.

Results: Five patients with PSC-IBD who underwent colectomy/IPAA were identified and matched with ten controls. There was no difference between
the groups in time to colectomy following the diagnosis of IBD. Dysplasia was an indication for colectomy in 3/5 patients with PSC-IBD, compared to none of the controls. Refractory disease was an indication for colectomy in 3/5 cases and 10/10 controls. There was no significant difference in rates of pouchitis between the groups. The percentage of patients alive at most recent follow-up was lower in the PSC-IBD group. Both deaths in the PSC-IBD group were from sepsis. Interestingly, among patients with PSC, the presence of backwash ileitis appeared to increase the risk of colectomy.

Conclusions: Dysplasia is a more common indication for colectomy in patients with PSC-IBD. This is true despite a high prevalence of pancolitis in both groups and a similar time to colectomy, suggesting that colitis in PSC-IBD is associated with an increased risk for dysplasia. PSC-IBD patients may also have higher morbidity following colectomy. Backwash ileitis appears to be risk factor for colectomy in patients with PSC.

Characteristics of patients undergoing Proctocolectomy

<table>
<thead>
<tr>
<th></th>
<th>PSC-IBD (n = 5)</th>
<th>IBD (N = 10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to colectomy after diagnosis (yrs)</td>
<td>4.6±7.0**</td>
<td>4.3±4.7</td>
</tr>
<tr>
<td>Backwash ileitis</td>
<td>3 (60%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Dysplasia*</td>
<td>3 (60%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Refractory Disease</td>
<td>3 (60%)</td>
<td>10 (100%)</td>
</tr>
<tr>
<td>Age IBD Diagnosis (yrs)</td>
<td>24.6±5.9</td>
<td>33.0±15.7</td>
</tr>
<tr>
<td>Age at Colectomy (yrs)</td>
<td>29.4±3.2</td>
<td>37.6±17.5</td>
</tr>
<tr>
<td>Pouchitis</td>
<td>3(60%)</td>
<td>4(40%)</td>
</tr>
<tr>
<td>Alive at last followup</td>
<td>3(60%)</td>
<td>10(100%)</td>
</tr>
</tbody>
</table>

* (p = 0.06), ** Mean ± 1 S.D

1175

Rectal Strictures in Crohn’s Disease and Co-Existing Perirectal Complications

Susan W. Fields, MD, Burton I. Korelitz, MD,* Georgia Panagopoulos, PhD. Division of Gastroenterology, Lenox Hill Hospital, New York, NY and New York University School of Medicine, New York, NY.

Purpose: The significance of the presence of rectal strictures in Crohn’s disease has not been well studied. The aim of this study was to examine patients diagnosed with Crohn’s disease associated with rectal strictures and to describe co-existing manifestations of perianal disease (perianal abscesses, fistulae, or skin tags) and strictures located elsewhere in the colon or small intestine.

Methods: A cohort of 105 Crohn’s disease patients with rectal strictures was identified. A thorough retrospective chart review was undertaken for demographic and clinical characteristics. Data were collected on gender, age, duration of disease, location of disease, and on the presence of perianal disease or strictures located elsewhere. Data were analyzed using descriptive statistics.

Results: The average age of our Crohn’s disease patients with rectal strictures was 58 years (15.7) and the average duration of disease was 29 years (13.3). 52.4% of patients were women. The majority of these patients (56.2%) had isolated Crohn’s colitis, whereas 34.3% of patients had ileo-colonic involvement and 9.5% had strictly ileal involvement. 54% of these patients with rectal strictures also had perianal fistulæ. Perianal abscesses and anal skin tags were less common (46.7% and 7.6%, respectively). 33% of patients had colonic strictures in addition to the rectal strictures and 17% had small bowel strictures.

Conclusions: This observational study of Crohn’s disease patients suggests that the majority of patients with rectal strictures have colonic involvement and increased perianal fistulæ. Only a minority of patients was observed to have ileal or ileo-colonic disease, perianal abscesses, skin tags, or strictures elsewhere. A future study with a control group matched for age, gender, and duration of disease is currently underway to help elucidate the significance of the presence of rectal strictures in Crohn’s disease.

1176

Adalimumab Maintains Clinical Remission and Response in Patients with Active Crohn’s Disease: Results of the CHARM Trial

William J. Sandborn, MD, J.F. Colombel, MD, P Rutgeerts, MD, R. Enns, MD, S.B. Hanauer, MD, R. Panaccione, MD, S. Schreiber, MD, K.G. Lomax, MD, P.F. Pollack, MD,* Research, Mayo Clinic, Rochester, MN; Gastroenterology, CHU Lille, Lille, France; Gastroenterology, University Hospital of Gathuisberg, Leuven, Belgium; Pacific Gastroenterology Assoc., St. Paul’s Hospital, Vancouver, BC, Canada; Medicine, University of Chicago, Chicago, IL; Inflammatory Bowel Disease Clinic, University of Calgary, Calgary, AB; Canada; Medicine, Christian-Albrechts University, Kiel, Germany and Immunology Development, Abbott, Parsippany, NJ.

Purpose: To evaluate the efficacy and safety of adalimumab (ADA), a fully human anti-TNF monoclonal antibody with demonstrated efficacy in the induction of remission in Crohn’s disease (CD), in the maintenance of clinical remission and response.

Methods: In this double-blind (DB), placebo-controlled, multicenter study in pts with moderately to severely active CD (CDAI ≥220–450), pts received open-label (OL) induction doses of ADA, 80 mg at Wk 0 (BL) and 40 mg at Wk 2. All pts were randomized at Wk 4 to receive placebo (PBO) or 40 mg ADA sc, every other wk (EOW) or weekly (W), through Wk 56. Clinical response was defined as a decrease in CDAI from BL ≥70 or 100 (CR70/100). Co-primary endpoints were remission (CDAI<150) at Wk 26 and WK 56 in Wk 4 responders (randomized responders). Pts were routinely assessed for adverse events.

Results: Characteristics at BL were similar across treatment arms, with a mean CDAI of 313. Of 854 pts enrolled, 778 pts were randomized at Wk 4. Of these, 499 (58%) pts were stratified as randomized responders (primary endpoint cohort). In this cohort, significantly higher rates of remission and response were maintained with ADA vs. PBO at both Wk 26 and Wk 56 (table).

Efficacy of ADA at Wks 26 and 56

<table>
<thead>
<tr>
<th>Endpoint, %</th>
<th>Wk</th>
<th>PBO (n = 170)</th>
<th>ADA EOW (n = 172)</th>
<th>ADA W (n = 157)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remission</td>
<td>26</td>
<td>17</td>
<td>40*</td>
<td>46*</td>
</tr>
<tr>
<td></td>
<td>56</td>
<td>12</td>
<td>36*</td>
<td>41*</td>
</tr>
<tr>
<td>CR100</td>
<td>26</td>
<td>26</td>
<td>52*</td>
<td>52*</td>
</tr>
<tr>
<td></td>
<td>56</td>
<td>16</td>
<td>41*</td>
<td>48*</td>
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<tr>
<td>CR70</td>
<td>26</td>
<td>28</td>
<td>54*</td>
<td>56*</td>
</tr>
<tr>
<td></td>
<td>56</td>
<td>18</td>
<td>43*</td>
<td>49*</td>
</tr>
</tbody>
</table>

*p < 0.001 vs. PBO.

In the 4-wk OL induction period, serious adverse events (SAE) were reported in 3% of pts. In the 52-wk DB period, significantly lower rates of SAE were reported in the ADA 40 mg EOW/W treatment groups, 9% and 8% respectively, vs.15% in the PBO group (p < 0.05).

Conclusions: Adalimumab, either 40 mg EOW or W, was more effective than PBO in maintaining ADA-induced clinical remission and response in pts with moderately to severely active CD. Adalimumab was well-tolerated, with significantly lower rates of SAE with ADA maintenance compared with PBO.

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Induction, Maintenance, and Sustainability of the Healing of Draining Fistulæ in Patients with Crohn’s Disease Treated with Adalimumab: Results of the CHARM Study

David Schwartz, MD, P Rutgeerts, MD, J.F. Colombel, MD, W.J. Sandborn, MD, S.B. Hanauer, MD, J.D. Kent, MD, P.F. Pollack, MD,* Gastroenterology, Vanderbilt Univ. Medical Center, Nashville, TN; Gastroenterology, Univ. Hospital of Gathuisberg, Leuven, Belgium;
Purpose: To evaluate the efficacy of adalimumab (ADA), a self-injectable, fully human monoclonal antibody that targets TNF, in the healing of draining fistulas in patients with active Crohn's disease (CD).

Methods: In CHARM, a Phase III, double-blind, placebo-controlled study of the long-term maintenance of clinical remission and safety of ADA in patients with active moderate to severe CD (CDAI 220–450), all patients received open-label induction dosages of ADA, 80 mg at Wk 0 (BL) and 40 mg at Wk 2. At Wk 4, all patients were randomized to receive placebo (PBO) or ADA 40 mg sc, every other week (EOW) or weekly (W), through Week 56. Patients were assessed for fistula drainage at each study visit. Complete healing was defined as no draining with gentle compression of all fistulas present at BL. Patients with draining fistulas at both screening and BL visits were evaluated for healing at Wks 26 and 56 and at their last 2 blinded study visits. Based on a prespecified analysis plan, data from both ADA treatment arms were combined to obtain a more robust sample size and statistical power.

Results: Clinical characteristics at BL were similar across treatment arms: age, 37 yrs; female, 62%; Caucasian, 93%; mean CDAI, 313; median CRP, 0.9 mg/L; and immunosuppressant use, 47%. Of 854 patients enrolled, 778 were randomized at Wk 4. Of these, 499 were stratified as randomized responders (RR (CR70)). Results for patients with draining fistulas are shown, ADA EOW and W arms combined (table).

| Complete Fistula Healing in CHARM: Patients With Draining Fistulas |
|-------------|--------|--------|
| Randomized pts, n/N (%) | PBO | ADA |
| All | | |
| Wk 26 | 6/47 (13) | 21/70 (30)* |
| Wk 56 | 6/47 (13) | 23/70 (33)* |
| Last 2 visits | 6/47 (13) | 23/70 (33)* |
| Wks 26 and 56 | 6/47 (13) | 21/70 (30)* |
| RR (CR70) | | |
| Wk 26 | 4/28 (14) | 14/36 (39)* |
| Wk 56 | 4/28 (14) | 15/36 (42)* |

*p < 0.05 vs. PBO.

Conclusions: In patients with active Crohn's disease, adalimumab therapy was significantly superior to placebo in maintaining complete fistula healing. In patients with fistula healing at Wk 26, healing was sustained at Wk 56.

Adalimumab for Patient's with Crohn's Perianal Fistulas
Leah R. Griggs, MD, Paul Wise, MD, Alan Herline, MD, Roberta Muldoon, MD, David A. Schwartz, MD*. Gastroenterology-IBD, Vanderbilt University, Nashville, TN and Colorectal Surgery, Vanderbilt University, Nashville, TN.

Purpose: Infliximab (IFX) has been shown to be effective for treating perianal Crohn's disease (CD), but some patients develop intolerance or lack of response. Adalimumab (ADA) is a fully humanized anti-TNF antibody that has been shown to be safe and effective in patients (pts) with CD, including those pts who have lost response or are intolerant to IFX. Its utility in pts with perianal CD has not been proven. We report the outcomes of a series of perianal CD pts who were treated with ADA.

Methods: Eight pts with complex fistulizing CD (3 – rectovaginal fistula, 1 – scrotal fistula, 2 – multiple perianal fistulas) who had either an adverse reaction or attenuated response to IFX were placed on ADA. Median pt age was 42, five (62.5%) were female. All pts received an 80mg loading dose of ADA. Seven were then placed on 40mg every other week (qow). One pt was placed on 40mg weekly at the onset of treatment. Immunomodulators were maximized [6MP/azathioprine – 5 pts; methotrexate – 2] and concomitant antibiotics [Cipro-5; Flagyl1] were started in most pts. Two pts were on prednisone at time of presentation. Three pts were ultimately increased to weekly ADA dosing. Setons were placed in three patients (2 setons each). Therapy effectiveness was assessed by pt symptom report, physical examination, and endoscopic ultrasound (EUS).

Results: Of the 8 pts evaluated, one was lost to follow-up. The median length of follow-up was 18 mns (12 – 24 mns). Four (57%) of the seven pts had complete cessation of drainage. Two (29%) pts had a significant decrease in fistula drainage. The median time for cessation of fistula drainage was six months. Of the four pts with cessation of drainage, three (75%) were on 40mg of ADA weekly while one (25%) was on 40mg qow. EUS was used in 7 of the pts at time of initiation of therapy to assess fistula activity. Five (71%) of seven pts had either complete or significant cessation of fistula drainage. In two (66%) of the 3 pts with seton placement, repeat EUS assessments were used to evaluate healing and guide seton removal with complete cessation of drainage.

Conclusions: ADA combined with seton placement may be effective in pts with complex perianal CD who have an attenuated response or intolerance to IFX. Prospective trials are warranted.

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Efficacy of Infliximab in Ulcerative Colitis in a Clinical Practice Setting
Jonathan Potack, MD, Maria Abreu, MD*, Thomas Ullman, MD, Asher Kor屁股, MD, James George, MD, Peter Legnani, MD, Anthony Weiss, MD, Deepthi Deconda, MD, Michele Kissous-Hunt, R.P.A.-C., Lloyd Mayer, MD. Division of Gastroenterology, Mount Sinai School of Medicine, New York, NY.

Purpose: Infliximab has recently been approved for use in moderate and severely active ulcerative colitis (UC) on the basis of two randomized controlled trials. We aim to evaluate the drug in routine practice to ascertain if outcomes are similar in everyday clinical use.

Methods: We reviewed the charts of patients treated with infliximab for UC at one center over 3 years.

Results: We identified 42 patients (20 male, 22 female), with an average age of 36.9 years, who received 146 infusions. The average duration of disease prior to first infusion was 7.5 years (3 months-27 years). The leading indications for infliximab use were steroid refractory or steroid dependent disease. 67% of patients were being treated with concurrent immunomodulators at baseline. 32 patients had sufficient data for follow-up of symptoms after infusion of infliximab and a modified Mayo score measuring stool frequency and rectal bleeding (range 0–6, with 6 being most severe) was calculated from data collected at baseline and follow-up visits. The mean time to follow-up after 1st infusion was 11 weeks. Sigmoidoscopy or colonoscopy was documented in 14 patients within 3 months prior to therapy; 6 had pancolitis, 6 – left sided colitis, 1 – proctitis and 1 – pouchitis. 23 patients were on steroids at time of 1st infusion at a mean dose of 24.7 mg of prednisone. At follow-up, the mean dose of steroids had decreased to 19.9mg of prednisone. 17% of patients were able to discontinue steroids. 71% of patients had a clinical response as measured by decrease in stool frequency and/or bleeding. 22% of patients were in remission as defined by normal stool frequency, absence of rectal bleeding and no use of steroids. The mean modified Mayo score decreased from 3.9 at baseline to 1.4 at follow-up. However, 22% of patients required colectomy at a mean of 43 days after 1st infusion. 12% of patients required dose escalation to maintain response.

Conclusions: Our data show that the majority of patients have some improvement after infliximab. However, the important clinical endpoints of remission or steroid withdrawal occur in less than a quarter of patients. In this short term study 22% of patients required a colectomy. These findings are consistent with data obtained in larger randomized controlled studies and suggests those results can be applied to patients encountered in clinical practice.
The Incidence of Symptomatic, PICC-Related Venous Thrombosis in Hospitalized Patients with Inflammatory Bowel Disease

Conor D. Shea, MD, Gene L. Chang, MD, Robert Rahimi, MD, Mani Mahdavian, MD,* Medicine, Lutheran General Hospital, Park Ridge, IL.

Purpose: Peripherally inserted central venous catheters (PICCs) are placed in hospitalized patients to establish a durable and larger type of venous access. Patients with inflammatory bowel disease (IBD) are often restricted from oral intake when exacerbations require hospitalization and often need PICC line placement. Venous thrombosis (VT) is a known complication associated with central venous catheters (CVCs). Incidence ranges of catheter-related mural thrombosis have been reported up to 90% in those with hypercoagulability states. Inflammatory bowel disease (IBD) is associated with hypercoagulability and a three fold increased risk for developing DVT. The incidence of CVC associated VT among populations with inflammatory bowel disease who receive PICC line access have not been evaluated.

Methods: We performed a retrospective chart review of 575 patients admitted between 1/01/03 and 12/31/04 with a primary or secondary diagnosis of Crohn’s Disease (CD), Ulcerative Colitis (UC), or Inflammatory Bowel Disease/Non-infectious Gastroenteritis at a large community hospital. Inclusion criteria for this study mandated that all individuals were eighteen years of age or older, diagnosed with IBD, and received a PICC line. Exclusion criteria were patients with a known malignancy, pregnancy, anticoagulation use, less than 4 weeks post operative, ICU admission, an inherited or acquired coagulopathy, and receiving hemodialysis. Data collected included presence and location of VT, IBD diagnosis (UC vs CD), age, sex, PICC specifics (size, brand, location), use of anticoagulation.

Results: 15 patients satisfied both inclusion and exclusion criteria. Three patients were found to have developed a PICC-related venous thrombotic event, representing a 20% incidence. PICC line duration spanned up to 26 days. A 2.17% incidence rate of VT per PICC-day was calculated. Factor exact’s test and Mann Whitney test determined no statistically significant difference among the type of IBD, PICC specifics, anticoagulation use, sex, age, or location of VT. The power was limited due to the size of the study.

Conclusions: In our study, there was a 20% incidence of VT among hospitalized IBD patients who received a PICC line, with a 2.17% incidence rate of VT/PICC day. Due to the limited size of the study, this data was underpowered. Prospective double-blind controlled studies could be performed to evaluate the potential need for anticoagulation in patients with IBD requiring PICC line access.

Sustained Steroid-Free Clinical Remission in Patients with Moderate to Severe Crohn’s Disease Treated with Adalimumab

Stephen B. Hanauer, MD, M.A. Kaam, MD, J.F. Colombel, MD, W.J. Sandborn, MD, P. Rutgeerts, MD, J.D. Kent, MD, P.F. Pollack, MD,* Medicine, University of Chicago, Chicago, IL; Medicine, St. Mark’s Hospital, Harrow, United Kingdom; Gastroenterology, CHU Lille, Lille, France; Research, Mayo Clinic, Rochester, MN; Gastroenterology, University Hospital of Galbaisberg, Leuven, Belgium; Immunology Development, Abbott, Abbott Park, IL and Immunology Development, Abbott, Parsippany, NJ.

Purpose: To assess the efficacy of adalimumab (ADA) in the long-term maintenance of remission in patients with Crohn’s disease (CD) without continued corticosteroid use in CHARM, the largest and longest study of adalimumab for the treatment of moderate to severe CD to date.

Methods: In CHARM, a Phase III, double-blind, placebo-controlled study of ADA in patients with CD, patients with active CD (CDAI 220–450) received open-label induction with ADA 80 mg at Wk 0 (BL) and 40 mg at Wk 2. At Wk 4, all patients were randomized to receive placebo (PBO) or ADA 40 mg, every other week (EOW) or weekly (W), through Week 56. Randomized responders were classified as those with clinical response, a CDAI decrease ≥70 from BL (CR70). At the discretion of the investigators, patients in clinical remission (CDAI <150) were permitted to have their steroid dosages tapered beginning at Wk 8. The proportion of patients in clinical remission at Wks 26 and 56 who had been off steroid therapy for ≥90 days were calculated for each treatment arm.

Results: Patient BL characteristics were similar across arms: mean CDAI, 313; corticosteroid use, 44%. Of 854 patients receiving induction therapy, 778 patients were randomized at Wk 4. Of these, 499 (58%) had achieved CR70 (randomized responders). Substantial percentages of randomized responders who were in clinical remission at Wks 26 and 56 had been able to discontinue steroids for ≥90 days.

Randomized Responders with Steroid-Free Remission for >90 Days

<table>
<thead>
<tr>
<th>Week</th>
<th>PBO, N = 66</th>
<th>ADA 40 mg EOW, N = 58</th>
<th>ADA 40 mg W, N = 74</th>
</tr>
</thead>
<tbody>
<tr>
<td>26</td>
<td>2 (3%)</td>
<td>11 (19%)*</td>
<td>11 (15%)*</td>
</tr>
<tr>
<td>56</td>
<td>3 (5%)</td>
<td>17 (29%)*</td>
<td>15 (20%)*</td>
</tr>
</tbody>
</table>

*p < 0.05 vs. PBO.

Conclusions: Adalimumab therapy allowed a significant percentage of patients with moderate to severe CD to maintain steroid-free remission at both Wk 26 and Wk 56.

Crohn’s Disease of a Continent Ileostomy Pouch and Secondary Amyloidosis: A Rare Association

Meredythe A. McNally, MD, Edward V. Loftus, MD,* Division of Gastroenterology and Hepatology, Mayo Clinic College of Medicine, Rochester, MN.

Purpose: Secondary amyloidosis occurs in the background of a chronic inflammatory or infectious disorder and leads to deposition of an abnormal protein and eventual organ dysfunction. It has rarely been reported in association with long-standing inflammatory bowel disease (IBD).

Case Report: A 51-year-old white male was diagnosed with ulcerative colitis 33 years ago. Due to refractory disease, he underwent total proctocolectomy and continent ileostomy pouch formation 29 years ago. He was well until 4 years ago when he was diagnosed with borderline hyperglycemia. Mild proteinuria was noted and an angiotensin-converting enzyme inhibitor (ACEI) was begun. He remained stable until the year of presentation when his ACEI was discontinued due to hypotension. On 24-hour urine collection, his creatinine clearance was 47 mL/minute and his proteinuria had progressed to 915 mg/dL. Monoclonal protein studies of the urine and serum were negative. Renal biopsy revealed interstitial fibrosis, tubular atrophy, and a mononuclear cellular infiltrate. Immunofluorescent staining was negative for β2-microglobulin, kappa light chains, and lambda light chains, but staining was positive for Congo red, SAP, and SAA protein. A diagnosis of secondary amyloidosis was made. Investigations for chronic infections were negative. Flexible pouchoscopy revealed scattered ulcerations within the pouch and biopsies showed severe active chronic pouchitis without granulomas. Small bowel X-ray demonstrated mucosal nodularity, asymmetric rigidity, and diminished distensibility of the pre-pouch ileum compatible with Crohn’s disease. In addition to oral delayed-release budesonide 9 mg once daily, treatment with metronidazole 250 mg by mouth three times daily and ciprofloxacin 500 mg twice daily for 60 days was prescribed. His renal function stabilized and serum inflammatory markers normalized. He has done well maintained on budesonide 6 mg per day and ciprofloxacin twice daily. His renal function gradually continues to decline despite quiescent Crohn’s disease.

Conclusions: IBD is a rare, yet recognizable, cause of secondary amyloidosis. Treatment consists of controlling the underlying inflammation driving the amyloid process. Unfortunately, even when remission of the underlying IBD or chronic inflammatory disorder is well-maintained, many patients continue to experience a decline in organ function and progress to transplant or death.
Normal Acute Phase Response Markers Are Identified in 13% of Hospitalized Ulcerative Colitis Patients Admitted with Severe Flare

Mazen Issa, MD, Dawn B. Beaulieu, MD, Sushrut V Shidham, Lydia R. Weber, David G. Binion, MD,* Medicine, Medical College of Wisconsin, Milwaukee, WI.

Purpose: Acute phase response markers include C-reactive protein (CRP), erythrocyte sedimentation rate (ESR) and platelet count (PLT). These routinely available clinical laboratory tests may reflect ulcerative colitis (UC) inflammatory activity, but patterns of these test abnormalities, alone or in combination, have not been characterized in the setting of fulminant disease requiring hospitalization. We sought to determine the patterns of these inflammatory markers in consecutive UC patients (pts) hospitalized for severe inflammatory flare, and correlate these with clinical outcome.

Methods: This was a retrospective observational cohort study evaluating all consecutive UC pts hospitalized at a single referral center between 8/2001–11/2005. All pts required tx with intravenous corticosteroids. Serologic markers of inflammatory activity included CRP, ESR, PLT and maximal values were recorded during the course of the hospitalization. Clinical outcome, with successful medical therapy or colectomy was also recorded.

Results: Forty-two UC pts in 46 admissions (24 male/18 female) were identified (Table 1). Among the total admitted UC pts, 13.04% had no elevation in any of the 3 inflammatory markers, 8.7% elevated only one marker, 34.78% elevated 2 markers, and 43.5% elevated all 3 markers.

Surgical outcome: 16/46 encounters (34.7%) required colectomy for refractory disease (Table 2). When patterns of serologic markers were investigated, we found that among colectomy pts, 18.75% had no elevation in any of the 3 markers, 6.25% elevated only 1 marker, 25% elevated 2 markers, and 50% of the pts elevated all 3 markers.

Conclusions: Isolated routinely available inflammatory markers fail to identify 13% of UC pts requiring hospitalization for disease flare. Individually, CRP elevation was most commonly found, but still failed to identify 22% of hospitalized UC pts. PLT was elevated most frequently in UC patients requiring surgery for severe disease. When any one of these 3 markers were elevated, the correlation with clinical inflammation was 87%. Identifying the pattern of objective markers of inflammation in an individual pt appears essential to maximize the utility of these tests. These data emphasize the need for improved markers or indices of serologic measures of inflammation for pts with UC.

<table>
<thead>
<tr>
<th>Markers</th>
<th>Elevated</th>
</tr>
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<tbody>
<tr>
<td>CRP 36/46</td>
<td>78.3%</td>
</tr>
<tr>
<td>ESR 32/46</td>
<td>69.5%</td>
</tr>
<tr>
<td>Platelets 29/46</td>
<td>63%</td>
</tr>
</tbody>
</table>

Markers

Table

<table>
<thead>
<tr>
<th>Marker</th>
<th>Elevated</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRP 11/16</td>
<td>68.75%</td>
</tr>
<tr>
<td>ESR 10/16</td>
<td>62.5%</td>
</tr>
<tr>
<td>Platelets 13/16</td>
<td>81.25%</td>
</tr>
</tbody>
</table>

Thromboembolic Complications and Disturbed Coagulation

Parameters in Inflammatory Bowel Disease

Helder Cardoso, MD, Amadeu C.R. Nunes, MD, Armanda Cruz, MD, Carlos C. Santos, MD, Fernando Tavarela Veloso, PhD,* Servico de Gastrenterologia, Hospital S. Joao, Porto, Portugal.

Purpose: About one third of inflammatory bowel disease (IBD) patients without active disease experience thromboembolic events, which may be related to disturbed coagulation parameters (antithrombin III, ATIII; protein C and protein S). The aim of this study was to assess the role of coagulation parameters in the development of thromboembolic complications in IBD.

Methods: 72 IBD patients (37 with Crohn’s disease, 35 with ulcerative colitis) followed at outpatient consultation were included in this prospective study (Jan-Dec 2005). Exclusion criteria: 1) active IBD; 2) associated unstable/neoplastic diseases; and 3) past history of excessive alcohol consumption/tobacco/drug addiction. Coagulation parameters assessed were: protein C, protein S, ATIII, Quick’s time, APTT and fibrinogen. Statistics: Pearson χ2.

Results: Mean duration of IBD was 8.8 ± 8 years; mean age = 43.6 ± 14.3 years; gender: 40F/32M. Extraintestinal manifestations were present in 44.4% of the cases. Thromboembolic complications occurred in 6.9% (5/72) of the cases (deep venous thrombosis = 2, stroke = 2, phlebitis = 1). Coagulation parameters were disturbed in 8.3% of the cases (↑ protein C = 4, ↓ protein C = 1, ↑↑ APTT = 1). There was no relationship between development of thromboembolic complications and disturbed coagulation parameters in IBD patients (p > 0.05). Thrombocytosis was never associated with thromboembolic complications or disturbed coagulation parameters. There was no relationship between the development of thromboembolic complications/disturbed coagulation parameters and IBD type, gender or age of the patients (p > 0.05).

Conclusions: Development of thromboembolic complications in IBD is unrelated to disturbed coagulation parameters or thrombocytosis. Laboratory screening of these patients is therefore not warranted.

Toll-Like Receptor 9 (TLR-9) Polymorphisms and CARD15/NOD-2 Mutations in Hispanics with Crohn’s Disease

Federico Gregory, MD, Roberto E. Mena, MD, Paul Nieves, MD, Esther A. Torres, MD, Ling Mei, PhD, Kent Taylor, PhD, Huaying Yang, MD, PhD,* Jerome Rotter, MD, PhD. Medicine, University of Puerto Rico School of Medicine, San Juan, PR and Genetics, Cedars-Sinai Medical Center, Los Angeles, CA.

Purpose: Crohn’s disease (CD) exhibits phenotypic heterogeneity. The pattern of inheritance is unknown. Variable penetrance and expression support a complex genetic predisposition. CARD15/NOD-2 was described as the first susceptibility gene for CD. TLR-9 is a toll-like intracellular receptor that recognizes muramyl dipeptide motifs derived from bacterial peptidoglycan and acts on the innate mucosal response. TLR-9 participates in the innate response, it controls the immune response to bacterial infections. Particular interest has evolved over the role of NOD-2 and TLR-9 polymorphisms in IBD patients.

The aim of this study was to determine the prevalence of polymorphisms of CARD15 and TLR-9 in Puerto Ricans with Crohn’s and to describe possible phenotypic associations.

Methods: Samples from 113 Puerto Ricans with Crohn’s disease and 107 controls recruited for the IBD Genetics Consortium project were studied for the presence of mutations of, NOD-2,8, NOD-2,13, and TLR 9 rs352140. These polymorphisms were correlated with disease behavior, location and need for surgery.

Results: Polymorphisms in NOD-2 were identified in 18.67% of CD as compared to 9.4% of controls (p = 0.049). The presence of NOD-2,13 was significant for the absence of colorectal disease (p = 0.02), the presence of strictureing disease (p = 0.02), and the absence of perianal disease (p = 0.01). The presence of NOD-2,8 and NOD-2,13 were significant for the absence of perianal disease (p = 0.00). TLR9 rs352140 was more frequent in subjects with no CD-related surgery (p = 0.04).

Conclusions: NOD-2 was found to be more prevalent in Puerto Ricans with CD as compared to racially similar controls. Association of some mutations with specific disease behavior or location support the influence of genetic variants on clinical expression of the disease.
Capsule Endoscopy (CE) in Patients with Known IBD: Frequency of Findings, and Influence on Medical and Surgical Management Are Based upon the Indication for CE
Stephanie Santos, MD, Jonathan Erber, MD, Peter Legnani, MD, Blair Lewis, MD, Simon Lichtiger, MD, James George, MD, William Erber, MD, Asher Kornbluth, MD,∗ Gastroenterology, Mount Sinai School of Medicine, New York, NY; Gastroenterology, SUNY Downstate, Brooklyn, NY and Gastroenterology, Maimonides Medical Center, Brooklyn, NY.

Purpose: The role and utility of CE in IBD remain controversial. The purpose of this study is to determine the frequency of significant findings, and how often they impact changes in medical and surgical management based on the indication for CE in patients with known IBD.

Methods: We reviewed the results and impact on management of CE in IBD, and categorized patients into 3 groups, based on indication:

1) Indeterminate Colitis, rule out small bowel disease (IC)
2) Known CD, unexplained symptoms (CD-Sx)
3) Known CD, obscure bleeding (CD-OB).

Results: 69 patients met one of the above inclusion criteria. Frequency of findings and their influence on management are shown in the Table below. In the combined CD-Sx and CD-OB groups, compared with the IC group, significantly more patients had positive CE findings (p = .04) and changes in management (p = .02) than patients with IC. Both positive and negative findings influenced management. A retained capsule requiring surgery occurred in 5 of 69 (7.3%) of patients: 4 occurred in CD-SX and 1 in CD-OB. Surgery led to a resolution of unexplained symptoms or bleeding in all 5 patients.

Conclusions: CE findings and associated changes in management, were significantly more common in patients with known CD with unexplained symptoms, or obscure bleeding, than in patients with indeterminate colitis. Overall, findings on CE led to a change of management in the majority (59%) of patients, supporting its utility in selected patients with IBD.

CE Findings and Change in Management

<table>
<thead>
<tr>
<th>Group</th>
<th>N (%)</th>
<th>Positive Findings (%)</th>
<th>Change in Management (%)</th>
<th>Medications added to current regimen (%)</th>
<th>Medication regimen decreased (%)</th>
<th>Surgery (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IC</td>
<td>26 (38%)</td>
<td>11 (42%)</td>
<td>10 (39%)</td>
<td>8 (31%)</td>
<td>1 (4%)</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>CD-Sx</td>
<td>24 (35%)</td>
<td>15 (63%)</td>
<td>17 (71%)</td>
<td>11 (46%)</td>
<td>2 (8%)</td>
<td>4 (17%)</td>
</tr>
<tr>
<td>CD-OB</td>
<td>19 (27%)</td>
<td>15 (79%)</td>
<td>14 (74%)</td>
<td>12 (63%)</td>
<td>0 (0%)</td>
<td>2 (11%)</td>
</tr>
</tbody>
</table>

Fibronectin Is Transcriptionally Upregulated in DSS-Induced Colitis in Mice
Rahul Bajaj, MD,* Vasantha Kolachala, PhD, J.D. Ritzenthaler, J. Roman, MD, Shanti Sitaruman, MD, PhD. Division of Digestive Diseases, Emory University, Atlanta, GA.

Purpose: Fibronectin (FN) is an extracellular matrix protein that plays important role in many processes including cellular adhesion, migration and wound healing. We have previously demonstrated that FN is secreted in polarized colonic epithelial cells treated with adenosine in a cellular model of inflammation. FN also potentiates bacterial invasion suggesting it plays a role in intestinal inflammation. The expression of FN during intestinal inflammation is currently not known. The purpose of this study was to evaluate FN expression during colitis in mice.

Methods: FVB/NJ mice were given water (n = 5) or 3% Dextran Sodium Sulfate (DSS) (n = 5) for 5 days. To study the regulation of FN expression, transgenic mice expressing a Luciferase (LU)-FN promoter were fed water (n = 5) or 3% DSS (n = 5) for 5 days. Colitis was determined by clinical and histological scores validated previously. FN expression was determined by Western blot and immunohistochemistry. The LU assay was performed using a standard protocol.

Results: DSS-treated mice developed severe colitis, which mimics human colitis both in terms of clinical symptoms as well as histological appearance. FN levels were upregulated in these mice compared to mice fed with water that had no colitis (water: 0.9±0.2 vs DSS: 2.4±0.1 Densitometry Values). Immunohistochemistry demonstrated that FN was expressed in epithelial cells and is deposited in the ECM similar to observations made in epithelial cell cultures. Luciferase levels were 1.86-fold (45.6±1.1 DSS vs 24.5±6.55 LU/mcg protein) higher in mice given colitis compared to water fed mice suggesting a transcriptional activation of FN during colitis.

Conclusions: FN, an extracellular matrix protein, is increased in DSS-induced colitis and appears to be transcriptionally mediated. Our observations have mechanistic implications in understanding the pathogenesis of colitis given the important role of FN in bacterial-epithelial interaction and wound healing; both of which underlie the inflammatory response in intestinal inflammation.

Correlation of C-Reactive Protein (CRP) Level with Disease Activity and Response to Treatment in Inflammatory Bowel Disease (IBD)
Carlos B. Quintero, MD, K. Shiva Kumar, MD,∗ Gastroenterology, Ochsner Medical Center (OMC), New Orleans, LA.

Purpose: To correlate CRP level with disease activity and outcome following treatment in patients with IBD.

Methods: Study sample:
Patients with Crohn’s disease (CD) and Ulcerative Colitis (UC) evaluated at OMC from 01/01/04 to 07/31/05.

Inclusion criteria:
1. Diagnosis of CD or UC based on clinical, endoscopic findings, compatible histology and exclusion of other causes of inflammation and; 2. CRP level measured within 2 weeks of diagnosis.

Exclusion Criteria
1. Other causes of elevated CRP such as current malignancy, infection, major systemic illness, trauma or surgery, connective tissue disease.
2. Active liver disease.

Results: 457 patients were identified within the specified time period. Of these, 24 CD and 9 UC patients met inclusion criteria. Clinical severity was defined as mild, moderate or severe based on the following clinical findings: fever, weight loss, blood in stools and abdominal pain. Endoscopic and histological severity was classified as mild, moderate or severe after review by an experienced endoscopist and pathologist respectively. Outcome was classified as either successful or unsuccessful depending on response to therapy and need for surgery.

Spearman Correlation Coefficients were used to correlate our data.

Basic Statistical Data

<table>
<thead>
<tr>
<th>Inflammatory Bowel Disease</th>
<th>N</th>
<th>Variable</th>
<th>Mean</th>
<th>Std Deviation</th>
<th>Min</th>
<th>Max</th>
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</thead>
<tbody>
<tr>
<td>Crohn’s Disease</td>
<td>24</td>
<td>Age</td>
<td>51.1</td>
<td>20.57</td>
<td>12</td>
<td>84</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CRP (mg/DL)</td>
<td>5.12</td>
<td>4.75</td>
<td>0.3</td>
<td>19.7</td>
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<tr>
<td></td>
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<td>ESR (mm/hr)</td>
<td>37.74</td>
<td>29.52</td>
<td>5</td>
<td>102</td>
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<tr>
<td></td>
<td></td>
<td>Leukocyte Count (k/uL)</td>
<td>9.64</td>
<td>4.67</td>
<td>3.8</td>
<td>18.65</td>
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<tr>
<td>Ulcerative Colitis</td>
<td>9</td>
<td>Age</td>
<td>43.55</td>
<td>22.69</td>
<td>15</td>
<td>82</td>
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<tr>
<td></td>
<td></td>
<td>CRP</td>
<td>2.64</td>
<td>2.73</td>
<td>0.3</td>
<td>8.4</td>
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<td></td>
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<td>ESR</td>
<td>32.25</td>
<td>23.56</td>
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<tr>
<td></td>
<td></td>
<td>Leukocyte</td>
<td>10.38</td>
<td>1.76</td>
<td>7.56</td>
<td>12.35</td>
</tr>
</tbody>
</table>
sory and Suffering pain experiences during active disease. The findings also

Conclusions:

Interestingly there were no differences between these two groups in the Well

Mean (SEM)

p

Active 1.5 (0.2) 2.0 (0.3) 2.5 (0.2)

Remission 0.7 (0.1) 0.9 (0.2) 2.7 (0.3)

p < 0.03 < 0.04 0.63 (NS)

Sensory Suffering Well Being

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Multidimensional Affect and Pain Survey in Inflammatory Bowel Disease Patients

Deepthi Deconda, MD, Savitha R. Tudi, MD, Sita Chokhavatia, MD, F.A.C.P.,* Susanne B. Clark, PhD, Crawford W. Clark, PhD. Medicine/Gastroenterology, Mount Sinai School of Medicine, New York, NY and Psychiatry, College of Physicians and Surgeons, Columbia University, New York, NY.

Purpose: To determine the weight given by Inflammatory Bowel Disease (IBD) patients to each of the three dimensions, Sensory, Suffering and Well Being, in the Multidimensional Affect and Pain Survey (101-MAPS). Pain is a subjective experience that has profound impact on the quality of life. The 101-MAPS is the only currently available instrument that takes into account all recognized pain dimensions. It classifies 101 items into three dimensions or “super clusters”: Sensory (57 items), Suffering (26 items) and Well Being (18 items). The 101-MAPS questionnaire has been validated for cancer and other chronic illnesses. As such, this survey has been used to measure pain in a variety of conditions. To determine the weight given by Inflammatory Bowel Disease Patients to each of the three dimensions, Sensory, Suffering and Well Being during active disease.

Methods: Twenty two IBD patients from our clinics responded to 101-MAPS questionnaire.

Results: Of the 22 IBD patients, there were 18 patients with Crohn’s disease and 4 patients with ulcerative colitis. Twelve patients were in remission and 10 patients had evidence of active disease. Activity was based on history (diarrhea, blood in the stool, abdominal pain and fever), physical examination, lab data (WBC, ESR and CRP) and the gastroenterologists’ assessment. Active patients scored significantly higher on the Sensory and Suffering super clusters than patients in remission.

Sensory Suffering Well Being

Active 1.5 (0.2) 2.0 (0.3) 2.5 (0.2)

Remission 0.7 (0.1) 0.9 (0.2) 2.7 (0.3)

p < 0.03 < 0.04 0.63 (NS)

Mean (SEM)

Interestingly there were no differences between these two groups in the Well Being super cluster.

Conclusions: The 101-MAPS revealed major differences in patients’ Sensory and Suffering pain experiences during active disease. The findings also suggest that IBD patients maintain coping strategies even during periods of active disease.

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Effect of Teduglutide in Patients with Moderate-Severe Crohn’s Disease after 20 Weeks of Daily Therapy

Alain L. Buchman, MD,* Seymour Katz, MD, Michael Shnaidman, PhD, David Jacobs, MD. Division of Gastroenterology, Northwestern University, Feinberg School of Medicine, Chicago, IL; Long Island Jewish Health Systems, Long Island, NY and NPS Pharmaceuticals, Parsippany, NJ.

Purpose: To examine the safety and efficacy of teduglutide in patients with moderate-severe Crohn’s Disease (CD) after 20 weeks of daily treatment and after discontinuation. Teduglutide is an analog of the naturally occurring human peptide Glucagon Like Peptide-2 (GLP-2). GLP-2 is involved in regeneration, maintenance and repair of the intestine. During the double-blind phase of the study, teduglutide at the highest dose tested, induced remission as early as 2 weeks and in 56% of subjects after 8 weeks of therapy.

Methods: In this open label extension study, patients received teduglutide 0.10 mg/kg/day subcutaneously for 12 wks. Subjects had a history of moderate-severe CD (CDAI score 220 to 450) and completed the 8 wk proof of concept study. In addition to assessing safety, the primary objective of this study was to evaluate remission (CDAI score < 150) in patients after an additional 12 wks of therapy. Patients were evaluated 4 wks after discontinuation of study drug for remission status.

Results: All analyses are presented for the ITT population. Key demographics and outcomes are tabulated below. There were no drug-related serious adverse events (AE). Injection site reactions were the most frequent drug related AE encountered.

Conclusions: Teduglutide was well-tolerated. Subjects who received the highest induction dose of teduglutide appeared to demonstrate a greater likelihood for maintenance of remission. There is significant need for new therapies to induce remission in patients with CD. Additional studies are warranted using higher doses of teduglutide and with larger sample sizes. Future studies will also need to address the optimal frequency of maintenance therapy.

8 Wk Proof of Concept Study

<table>
<thead>
<tr>
<th>Placebo</th>
<th>0.05 mg/kg/day</th>
<th>0.10 mg/kg/day</th>
<th>0.20 mg/kg/day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>25</td>
<td>26</td>
<td>25</td>
</tr>
<tr>
<td>Mean Age</td>
<td>39</td>
<td>41</td>
<td>42</td>
</tr>
<tr>
<td>Baseline CDAI</td>
<td>305</td>
<td>292</td>
<td>280</td>
</tr>
<tr>
<td>Wk 2 Remission</td>
<td>16.7</td>
<td>20.7</td>
<td>21.1</td>
</tr>
<tr>
<td>Wk 8 Remission</td>
<td>33.3</td>
<td>38.9</td>
<td>33.3</td>
</tr>
</tbody>
</table>

12 Wk Extension Study

<table>
<thead>
<tr>
<th>All patients received 0.10 mg/kg/day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
</tr>
<tr>
<td>ITT population with available data</td>
</tr>
<tr>
<td>Outcomes (%)</td>
</tr>
<tr>
<td>Follow Up: 4 Weeks Off Study Drug</td>
</tr>
</tbody>
</table>

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Budesonide Induction and Maintenance Therapy for Crohn’s Disease during Pregnancy

Dawn B. Beaulieu, MD, Lydia R. Weber, Mazen Issa, MD, Julianne R. Newcomer, MD, Randall S. Kuhlmann, MD, PhD, Mary F. Otterson, MD, Jeanne Emmons, R.N., Josh F. Knox, P.A.-C., David G. Binion, MD,* Medicine: Division of Gastroenterology & Hepatology, Medical College of
Lipid Redistribution in Crohn’s Disease

Lan Chi T. Lua, PhD, Bradley Newcomer, PhD, Willem J.S. de Villiers, MD, Michael B. Reid, PhD, Trevor A. Winter, MD,* Nutritional Sciences/Digestive Diseases, University of Kentucky, Lexington, KY and Critical and Diagnostic Care and Human Studies, University of Alabama at Birmingham, Birmingham, AL.

Purpose: Ectopic lipids (EL) are lipids redistributed into skeletal muscles (SM) and liver. In the muscle, these lipids may be intramyocellular (IMCL) or extramyocellular (EMCL). Pathophysiological conditions, including obesity, elevate EL in SM and liver and demonstrate strong association to insulin resistance. Increased inflammation in Crohn’s Disease (CD) may affect adipokine levels, redistributing lipids, and alter metabolism.

Methods: 16 CD patients will be matched to 16 controls based on age, gender, race and BMI. Using proton magnetic resonance spectroscopy (1H MRS), levels of EL in SM and liver are measured. Energy metabolism is measured using indirect calorimetry. Circulating levels of cytokines and adipokines are measured. CD subjects are assessed in both active inflammatory and subsequent quiescent states.

Results: Twelve active and four quiescent CD subjects have been studied in comparison to ten controls. The average age was 36 years (+ 9.34) and the mean BMI was 22 (+ 2.27) kg/m². In active CD subjects, levels of CRP (2.20 mg/dL ± 2.31 vs. 0.48 mg/dL ± 0.03, p ≤ 0.03), TNFα (11.954 pg/ml ± 7.051 vs. 4.610 pg/ml ± 1.914, p ≤ 0.02), neutrophils (4.755 k/uL ± 1.867 vs. 2.756 k/uL ± 0.680, p ≤ 0.004), and monocytes (0.546 k/uL ± 0.162 vs. 0.412 k/uL ± 0.0739, p ≤ 0.03) were increased confirming inflammation; cholesterol levels are decreased (134.41 mg/dL ± 26.12 vs. 189.80 mg/dL ± 19.22, p ≤ 0.001); EMCL are increased (27.096 ± 14.561 vs. 14.567 ± 9.681, p ≤ 0.04). Preliminary analysis show a trend to a reduction in leptin, IMCL, and intrahepatic lipids; and elevation in resistin and respiratory quotients in CD compared to controls.

Conclusions: These data indicate lipid redistribution in CD. The adipokine data suggest a reduction in leptin and a rise in resistin levels which may be associated with this redistribution of lipids. 92% of the active CD cohort demonstrated RQ’s in the range 0.93 to 1.22. Elevated respiratory quotients (>1.0) indicate fat deposition. Insight into the relationship between EL and inflammation may shed new light on the pathophysiology of CD.

Support by: NIH DK07778 & MO1RR02602/CReFF

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Plasmacytoid Dendritic Cells Play a Key Role in the Efficacy of GM-CSF in Murine IBD Models

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Purpose: Crohn’s disease is a chronic inflammatory bowel disorder associated with a loss of tolerance to commensal gut flora. A phase II clinical trial demonstrated that Sargramostim (recombinant hGM-CSF) was effective in the treatment of patients with moderate-to-severely active Crohn’s disease (NEJM 2005; 352:2193–2201). We previously demonstrated that pegylated murine-GM-CSF (pGM) also abrogates colitis in mouse models; effects were blocked by a novel mAb 440c that targets the Siglec-H receptor, unique to plasmacytoid dendritic cells (pDCs). To establish the MOA of GM-CSF in the treatment of Crohn’s disease, we investigated GM-CSF effects on 440c+ pDCs, their location in the mucosa, mAb 440c effects on cytokine expression in DSS colitis, and the dependence on adaptive immune elements.

Methods: Mice were treated IP with pGM (5ug/d for 5 days), saline, or 22E9 fxn-blocking anti-GM-CSF (200ug) for five days. Splenic cells were analyzed by flow cytometry (CD11c+ +, 440c+, and B220+ markers). In situ localization was performed by tissue immunohistochemistry (IHC) using mAb 440c. DSS colitis models were performed in Balb/c mice, or RAG1/−/− mice, lacking B and T cells, using DSS for 7 days. Groups were treated with PEG-rgm-GM-CSF and/or mAb 440c to probe the involvement of the pDC in the response to GM-CSF. Disease activity score, histopathological score, and cytokine expression by real time RT-PCR and protein-arrays were determined.

Results: GM-CSF was a potent regulator of the 440c+ pDC (or B220+), with decreases evident in 22E9 treated animals and increases following pGM treatment. pDCs were easily localized by IHC to the subepithelial region of the small intestine and colon. pGM significantly reduced DSS-colitis associated disease activity. However, the administration of mAb 440c blocked this protective effect. Significant decreases in TNFα and IL-1b expression by pGM were blocked by mAb 440c treatment; data further confirmed by protein-array. pGM was therapeutic in RAG1/−/− mice demonstrating independence from adaptive immune elements.

Conclusions: These data suggest that the pDC may play a central role in GM-CSF’s therapeutic effects in IBD, and further support a key regulatory role for this small cell population in the mucosal immune response.
Is Preoperative Gastritis Associated with Long-Term Outcome after Ileal Pouch-Anal Anastomosis (IPAA)?

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Inflammatory Bowel Disease Center, Cedars-Sinai Medical Center, Los Angeles, CA.

Purpose: Ileal pouch-anal anastomosis (IPAA) has become the standard approach for patients with ulcerative colitis (UC) or indeterminate colitis (IC) requiring colectomy. Despite excellent functional results and high patient satisfaction, a significant proportion of patients develop pouchitis or Crohn’s disease (CD) after surgery. The aim of this study was to assess whether preoperative gastritis is associated with acute pouchitis (AP), chronic pouchitis (CP), or CD after IPAA.

Methods: UC or IC patients undergoing IPAA having preoperative EGD were identified. EGD reports were reviewed for evidence of macroscopic gastritis (erythema, erosions or friability). Gastric histology was classified into the following categories: normal, reactive gastropathy, chronic active gastritis, or focally enhanced gastritis. Patients were prospectively assessed for the development of clinical and endoscopically proven pouchitis (AP, chronic pouchitis (CP), or CD) in UC or IC patients undergoing IPAA.

Results: The 84 patients (UC = 56, IC = 28) who underwent IPAA were followed and the enoxaparin dosage was increased to 60 mg bid prior to discharge. She experienced clinical improvement and increased dosage of LMWH level, and delivered at term.

Conclusions: When traditional tx has failed or is unavailable there are limited options for rescue medical therapy in CD pregnancies, particularly during 2nd trimester. LMWH may be effective in this setting. We report 2 pts that achieved medically induced remission and term gestation with the use of enoxaparin. This preliminary data suggests that LMWH may be considered as an adjunctive treatment option for pregnant pts experiencing CD flare not responding to standard medical management.

Mesenteric Vascular Thromboembolism in Inflammatory Bowel Disease

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Purpose: Mesenteric vascular thromboembolism (MVT) is a rare but potentially devastating complication of inflammatory bowel disease (IBD). Catastrophic mesenteric ischemia followed by development of short bowel syndrome (SBS) may occur. We describe a series of patients with Crohn’s disease (CD) or ulcerative colitis (UC) that developed MVT and SBS.

Methods: A retrospective chart review of patients followed in our IBD and Intestinal Rehabilitation Centers was conducted to identify those with IBD, MVT and SBS. Evaluation for the presence of a hypercoaguable state included the following: testing for the gene mutation in Factor V Leiden, prothrombin and methyltetrahydrofolate, serum protein C and protein S activity, and plasma antithrombin III, homocysteine, antiphospholipid antibody, and lupus anticoagulant concentration. Smoking and use of oral contraceptives history was obtained.

Results: 9 patients developed MVT. Eight had mesenteric venous thrombosis (5 located in the superior mesenteric vein and 3 located in a branch of the portal vein) and one had a mesenteric arterial embolus, located in the splenic artery. 5 patients had CD and 4 had UC. The one patient diagnosed with an arterial embolus had CD. One patient was an active cigarette smoker. Mean time from diagnosis of IBD to thrombosis was 24.6 ± 13.5 years. Though there were no deaths, 4 patients had catastrophic episodes of thromboembolism leading to the development of SBS. An underlying risk for hypercoagulability was identified in 3 of 9 patients (1 with lupus anticoagulant and heterozygocity for Factor V Leiden, another with a previously diagnosed venous DVT and one with heterozygocity for factor V Leiden mutation). 5 of the 9 patients developed MVT while their IBD was clinically in remission. 7 of 9 patients were symptomatic from MVT. 4 of the 5 that developed SBS required an exploratory laparotomy for diagnosis. 7 or 9 patients received anticoagulation.

Conclusion: Patients with IBD are at risk for the development of MVT even in the absence of clinically significant active inflammation. Mesenteric ischemia and infarction leading to SBS may develop. These patients require life long anticoagulation. Further studies are needed to examine the association between IBD and thromboembolic complications such as MVT.
Importance of Serum Cortisol Levels in Inflammatory Bowel Disease
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Purpose: Increased cortisol levels suggest increased secretion of glucocorticoids occurring during severe or acute diseases. Treatment of inflammatory bowel disease (IBD) at acute phase includes corticoid administration which, like hypalbuminemia, influences the levels of cortisol. Therefore we studied the influence that cortisol may have on IBD. The aim of this study was to assess the clinical importance of serum cortisol levels in inactive IBD (Crohn’s disease, CD; ulcerative colitis, UC).

Methods: 72 patients with inactive IBD (37 CD, 35 UC) followed at outpatient consultation were included in this prospective study (Jan-Dec 2005). Exclusion criteria: 1) treatment with corticoids or immunosuppressive drugs; 2) associated unstable/neoplastic diseases; and 3) past history of excessive alcohol consumption/tobacco/drug addiction. All patients were submitted to the same protocol of assessment. Statistics: Pearson $\chi^2$ and Odds Ratio (OR).

Results: Mean duration of IBD = 8.75 ± 8.03 years; gender: 40F/32M; mean age = 43.6 ± 14.3 years. CD and UC groups were similar regarding age, number of acute flares/year and albuminemia. Location in UC: left colitis-17; pancolitis-10; proctitis-8. Location in CD: jejunocolitis-2; ileitis-1; ileocolitis-15; colitis-5. Twenty-one percent (15/72) of the patients were submitted to surgery. Mean cortisol $= 8.75 ± 13.4$ mg/dl (1.0–64.1) with increased levels in 50% of the cases (36/72). There was no relationship between cortisol levels, patient’s age or gender, autoantibodies, albuminemia, colesteroelasma, extraintestinal manifestations or body mass index. The “increased cortisol” group included 62% of CD pts but only 37% of UC pts $p = 0.03$; OR = 2.8 (1.1–7.2). The “increased cortisol” group was also related to the need of surgery – 31% vs. 11% of operated patients with normal cortisol ($p = 0.04$).

Conclusions: In IBD, increased cortisol levels are more frequent in CD and in patients submitted to surgery, which may be related to more severe IBD.

Development and Validation of a Capsule Endoscopy Scoring Index for Small Bowel Mucosal Disease Activity: The Lewis Score
Ian Grulneck, MD, Roberto DeFrancis, MD, Ernie Seidman, MD, Jonathan Leighton, MD, Peter Legnani, MD, Hagit Ephrath, Blair Lewis, * Division of Gastroenterology, Mount Sinai School of Medicine, New York, NY.

Purpose: Capsule endoscopy (CE) has been shown to have the highest yield in diagnosing small bowel (SB) mucosal disease compared to other modalities. However, there is no standardized and validated SB mucosal disease scoring index that can be applied to CE mucosal findings, including inflammation and ulceration. Therefore, the aim of this study was to develop and validate a simple, user-friendly CE scoring index for SB mucosal disease activity.

Methods: Using an iterative process over a 2 year period, a CE scoring index was developed and tested by a working group of CE experts. Seven endoscopic variables were initially evaluated: erythema, edema, nodularity, villous appearance, denuded mucosa, ulceration, and stenosis. The number of lesions were categorized as single, few, or multiple. The distribution of lesions were characterized as local, patchy or diffuse. The longitudinal extent of SB disease was described as short, long, or whole segment. Ulcer shape was judged as circular, linear, or irregular. Ulcer size was judged by the amount of wall circumference involved. Stenosis was judged by whether traversed by the capsule and if ulcerated. Scoring was performed per tertile. The index was prospectively tested in a blinded fashion using four readers (IG, RD, ES, JL) initially on 40 full length CE videos and on 10 thumbnailed studies.

Results: Based upon interobserver agreement, the final proposed scoring index includes 3 endoscopic variables: villous edema, ulceration, and stenosis. Index parameters are measured by number, longitudinal extent and other descriptors (See Table). Initial prospective evaluation of the index showed excellent interobserver agreement for these variables (78.2%, 79.8% and 88.8%).

Conclusions: The Lewis Score CE scoring index may prove useful in measuring SB mucosal disease activity and allow for the objective scoring of small bowel disease states. Additional prospective validation studies are warranted.

Baseline Thiopurine Methyltransferase (TPMT) Activity Combined with 6-Thioguanine (6-TGN) Metabolite Levels Predicts Clinical Response to Thiopurines in Patients with Inflammatory Bowel Disease
Lola Y. Kwan, MD, Shane M. Devlin, MD, James M. Mirocha, PhD, Konstantinos A. Papadakis, MD, PhD,* Medicine, Cedars Sinai Medical Center, Los Angeles, CA; Inflammatory Bowel Disease Center, Cedars Sinai Medical Center, Los Angeles, CA and Biostatistics Research Core Institute, Cedars Sinai Medical Center, Los Angeles, CA.

Purpose: To determine if TPMT enzyme activity and post-therapy 6-TGN levels would predict response to therapy with thiopurines in patients with inflammatory bowel disease (IBD).

Methods: Baseline TPMT enzyme activity prior to initiation of therapy with either 6-MP or AZA was determined in 40 patients with IBD (24 CD, 16 UC). Clinical response to at least 3 months of thiopurine treatment was defined by the treating physician’s global assessment in conjunction with an objective decrease in activity indices (Harvey Bradshaw Index in CD and Simple Clinical Index in UC) and a reduction in the dosage of corticosteroids. Records were reviewed for clinical response and maximal 6-TGN levels (available in 35 individuals).

Results: Eighteen of 40 patients (45%) responded to 6-MP or AZA therapy. The patient cohort was dichotomized based on 6-TGN levels and TPMT enzyme activity: maximal 6-TGN levels above or below 230 pmol/8 × 108 erythrocytes (6-TGN Hi) or (6-TGN Lo), and TPMT enzyme activity above or below the mean of 30.3 U (TPMT Hi) or (TPMT Lo). In the 6-TGN Hi group, 10/16 (62.5%) responded versus 7/19 (37%) in the 6-TGN Lo group ($p = 0.18$). In the TPMT Lo group 12/19 (63%) responded versus 6/21 (29%) in the TPMT Hi group ($p = 0.06$). When combining TPMT enzyme activity and 6-TGN level, 7/7 (100%) responded with the combination of TPMT Lo/6-TGN Hi, 5/11 (45%) with TPMT Lo/6-TGN Lo, 3/9 (33%) with TPMT Hi/6-TGN Hi, and 2/8 (25%) with TPMT Hi/6-TGN Lo ($p = 0.01$).

Conclusions: A 6-TGN level above 230 pmol/8 × 108 erythrocytes was associated with a numerically higher response rate. There was a trend toward TPMT enzyme activity below 30.3 U being associated with clinical response. However, the combination of a baseline TPMT enzyme activity below 30.3 U and 6-TGN levels >230 pmol/8 × 108 erythrocytes was highly associated with clinical response. The combined determination of TPMT enzyme activity at baseline and 6-TGN levels better predicts clinical response to thiopurines in patients with IBD than either alone.
Role of Infliximab in Ulcerative Colitis: A Systematic Review  
Tuhama Rihani, B.S., Mohamed O. Othman, MD, Richard Hoffman, MD, Praveen K. Roy, MD.  
*Department of Medicine, University of New Mexico/NMVAHCS, Albuquerque, NM and Department of Medicine, University of Missouri/HTVAMC, Columbia, MO.

Purpose: Infliximab, a chimeric monoclonal antibody directed against tumor necrosis factor-alpha, is an established treatment for Crohn’s disease. Several recent studies of infliximab in patients with ulcerative colitis (UC) have yielded conflicting results. We conducted a systematic review to assess the efficacy of infliximab in ulcerative colitis.

Methods: MEDLINE (from 1966–2006) and abstracts of gastroenterology scientific meetings in the last 5 years were searched (search date June 2006). Open label and randomized control trials in adult subjects were included. Standard forms were used to extract data regarding study design, duration of study, outcome measures, and adverse effects by two independent reviewers.

Results: 9 studies satisfied our inclusion criteria: 5 randomized control trials (RCTs) [829 pts] and 4 open label trials [47 pts]. Significant heterogeneity was present among the studies. 3 RCTs evaluated pts with moderate to severe UC, while 1 RCT evaluated pts with acute UC. 1 RCT evaluated the role of infliximab as a rescue therapy in severe UC. 4 RCTs involved pts with steroid refractory UC. In the open label trials, 3 dealt with severe UC while 1 dealt with moderate to severe UC. All of the pts in the open label trials had steroid refractory disease. The dose of infliximab was 5mg/kg in all the studies (RCTs and open label trials), but 2 RCTs also used 10mg/kg of infliximab. 4 RCTs administered 2 or more infusions of infliximab, while all the open label trials administered a single infusion of infliximab. A validated scoring system was used to assess disease activity in all the studies. The primary end point in the trials was evaluated at different time points in all the studies. 2 RCTs found 5mg/kg of infliximab was superior to placebo [OR 5.06; 95% CI 3.09–8.30] in patients with moderate to severe UC at 30 weeks. Similar benefit was noted with a higher dose of 10mg/kg (3.78; 95% CI 2.40–5.96). 3 open label trials also found infliximab induced a clinical response, while 1 open label trial did not. 1 RCT showed that infliximab decreased the rate of colectomy in severe UC patients (OR 4.9; 95% CI 1.4–17). Infliximab was well tolerated in all the studies.

Conclusions: Infliximab induces clinical remission in patients with active UC. The optimal dose is 5mg/kg. Additionally, infliximab may also be useful as a rescue therapy in severe UC. However, more studies are needed to verify findings from these smaller studies.

Bacterial Diversity Remains High in Inflammatory Bowel Disease  
Ece A. Mutlu, MD, Patrick Gilleveet, PhD, Masoumeh Sikaroodi, M.Sc., Srinadh Komanduri, MD, Ali Keshavarzian, MD.  
*Section of Gastroenterology, Hepatology and Nutrition, Rush University, Chicago, IL and George Mason University, Manassas, VA.

Purpose: While clinical observations and animal models of inflammatory bowel disease (IBD) suggest that a dysbiosis may exist in IBD, the changes in the mucosal microflora of IBD patients are largely unknown. Amplicon length heterogeneity (ALH) is a sophisticated technology that examines the 16s ribosomal DNA of bacteria. We hypothesized that ALH is a tool to study the changes in the mucosal microflora in IBD. We also hypothesized that ALH can aid in selection of samples for costly cloning and sequencing, in an effort to identify the nature of the much suspected dysbiosis in IBD.

Methods: We have collected colonoscopic stool & mucosal tissue samples from the terminal ileum (I), right colon (RC), transverse colon (TC), left colon (LC) and rectum (R) of patients with inactive and active IBD {n = 19 for Crohn’s disease (CD) and n = 18 for ulcerative colitis (UC)} and healthy controls {n = 9}. The samples were fingerprinted for bacterial patterns using ALH. Three indices derived from information theory were used to compare ALH fingerprint patterns using multivariate regression analyses, SAS v 8.2, SAS Institute, Cary, NC. These were Richness (R) which is equal to the number of peaks in a samples; the Shannon-Weaver Diversity Index (SW) which is equal to sum (Pi/lnPi)) where Pi is the peak area; and Evenness (E) which is equal to SW/InR.

Results: Fitting a mixed model assuming a toeplitz covariance structure, there was a statistically significant interaction between disease and sample site (I, RC, TC, S, R or stool). After adjusting for site, and disease and the interaction between site and disease, mean R, SW, or E diversity indices were not statistically different between the controls and disease cohorts in all parts of the colon except the rectum. In the rectum, SW diversity index and R was reduced in CD and UC compared to the controls (p = 0.043, 0.011) whereas E was not statistically different (p = 0.202). After adjusting for site, and disease and the interaction between site and disease, there was no difference in means of diversity indices: SW, R, E between tissues that appeared endoscopically normal or abnormal (p = 0.569, 0.757, and 0.769, respectively) or between patients with active disease vs. inactive (p = 0.105, 0.054, and 0.169, respectively).

Conclusions: Our results suggest diversity of the ileocolonic flora as assessed by diversity indices remains high in inflammatory bowel disease.

There Is a Shift of Luminal Flora to the Mucosal Surface in Inflammatory Bowel Disease  
Ece A. Mutlu, MD, Patrick Gilleveet, PhD, Masoumeh Sikaroodi, M.Sc., Srinadh Komanduri, MD, Ali Keshavarzian, MD.  
*Section of Gastroenterology, Hepatology and Nutrition, Rush University, Chicago, IL and George Mason University, Manassas, VA.

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Methods: We have collected colonoscopic stool & mucosal tissue samples from the terminal ileum (I), right colon (RC), transverse colon (TC), left colon (LC) and rectum (R) of patients with inactive and active IBD {n = 19 for Crohn’s disease (CD) and n = 18 for ulcerative colitis (UC)} and healthy controls {n = 9}. The samples were fingerprinted for bacterial patterns using ALH. We selected

Cloning results

<table>
<thead>
<tr>
<th>RDP Group</th>
<th>Example</th>
<th>Control tissue</th>
<th>Control lumen</th>
<th>CD tissue</th>
<th>UC tissue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteroides group</td>
<td>Bacteroides vulgatus</td>
<td>38%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bacteroides group</td>
<td>Bacteroides distasonis</td>
<td>8%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Propionibacterium group</td>
<td>Propionibacterium acnes</td>
<td>6%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C.Coccoides group</td>
<td>Ruminococcus gnavus</td>
<td>9%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pseudomonas and relatives</td>
<td>Acinetobacter junii</td>
<td>10%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pseudomonas and relatives</td>
<td>Moraxella osloensis</td>
<td>41%</td>
<td>29%</td>
<td>10%</td>
<td></td>
</tr>
<tr>
<td>Acidovirax group</td>
<td>Comamonas sp</td>
<td>14%</td>
<td>13%</td>
<td>12%</td>
<td></td>
</tr>
<tr>
<td>Acidovirax group</td>
<td>Comamonas terrigena</td>
<td>15%</td>
<td>29%</td>
<td>39%</td>
<td></td>
</tr>
<tr>
<td>Cytophaga group</td>
<td>hryseobacterium balustinum</td>
<td>9%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C.Botulinum group</td>
<td>Clostridium</td>
<td>6%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enterococcus group</td>
<td>Enterococcus hirae</td>
<td>6%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
samples that were diverse on the basis of ALH patterns and cloned and sequenced pooled samples of CD (n = 4), UC (n = 2) patients and healthy controls (n = 4).

Results: An overview shows that the flora found on the mucosal surface of CD and UC tissue resemble the floral composition of fecal matter in healthy individuals, which is significantly different than the mucosal composition of bacteria in these healthy individuals. When the data are examined at RDP phylogenetic level 4, there is a decrease in the Bacteroides group in UC more than CD. Clostridium & Enterococci groups are associated with the mucosal surface of UC and Cytophagia group 1 seems to be associated with CD mucosal surface and stool samples.

Conclusions: Our results suggest that there may be a loss of a “protective biofilm” in IBD that results in easy attachment of luminal bacteria to the tissues. Larger number of cloning experiments are needed in IBD to confirm these results.

1203
Tuberculous Arthritis of Hip in a Patient of Crohn’s Disease Treated with Infliximab
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Purpose: We are reporting a case of Tuberculous arthritis of hip in a patient of Crohn’s disease treated with infliximab.

Case Report: 29 years old white male presented with diarrhea and abdominal pain. He was diagnosed with Crohn’s disease and treated at that time with high dose corticosteroids and one dose of infliximab. A picc line was placed for parenteral nutrition which apparently became infected leading to the development of MRSA endocarditis. About 4 weeks after finishing vancomycin, patient noticed pain in his right hip, he was readmitted. MRI was consistent with right hip septic arthritis and blood cultures were positive for MRSA again. He was discharged home with a picc line and 6 weeks of vancomycin, rifampin and septrin. Patient did not have symptomatic improvement and readmitted after few months with bilateral hip pain and right knee pain. Needle aspiration of right hip was done which showed acid fast bacilli in concentrated smear. Patient was started on 4 drug therapy for tuberculosis arthritis. Till now patient still on therapy and responding to treatment.

Conclusions: Active tuberculosis may develop soon after the initiation of treatment with infliximab. According to one study TB developed after 3 or fewer infections and majority of the patients(56%) had extrapulmonary tuberculosis, and 24 percent had disseminated disease although infliximab is an effective treatment for Crohn’s and Rheumatoid arthritis, physicians should be aware of the increased risk of reactivation of tuberculosis among patients who are receiving infliximab and other immunosuppressive agents and, in particular, of the unusual clinical manifestations of the disease. Before treatment with infliximab is initiated, every effort should be made to determine whether the patient has latent tuberculosis infection. Since tuberculin tests may have false negative results in systemically ill or immunosuppressed patients, a detailed assessment of the risk of tuberculosis should be performed in every case. In our opinion, patients with latent infection should be given prophylactic treatment to prevent active disease before infliximab is administered. Physicians prescribing infliximab should advise patients to seek medical attention if they have symptoms suggestive of tuberculosis while taking the drug.

1204
Intestinal Transplantation for End Stage Crohn’s Disease: Therapeutic Efficacy and Risk of Recurrence
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Purpose: Intestinal transplantation has been recently evolved and more frequently utilized to rescue patients with intestinal failure who failed TPN. End stage Crohn’s disease has been the second leading indication for adult transplantation. This report is the first to address the therapeutic efficacy of intestinal transplantation in this unique population.

Methods: Between May 2, 1990 and March 31, 2006, a total of 196 consecutive adult patients underwent intestinal transplantation. Recalcitrant Crohn’s disease(duration: 20 ± 7 yrs) was the cause of intestinal failure in 38(18%) patients. Male to female ratio was 1:1.5 with a mean age of 43 ± 10 yrs. All patients underwent multiple abdominal operations(mean: 10 ± 6) with protocolectomy in 22(63%). The causes of TPN(duration: 65 ± 48 mos) failure and indication for intestinal transplantation were multiple line infections(90%), limited venous access(60%) and elevated hepatic enzymes(84%). Simultaneous liver replacement was required in 9(26%) patients due to TPN associated liver failure with a serum bilirubin of 12 ± 11mg/dL. Rejection prophylaxis was with tacrolimus and prednison with utilization of induction therapy in the recent 25 recipients.

Results: The cumulative overall survival of Crohn’s disease patients after transplantation was 85% at 1yr and 62% at 3 yrs with a retransplantation rate of 14%. With induction immunosuppression, survival has significantly(p = 0.02) improved with 1 and 3yr survival rate of 92% and 78%, respectively. Leading causes of graft loss were rejection(65%) and infection(34%). All survivors achieved full nutritional autonomy and enjoyed unrestricted oral diet. Disease recurrence was histologically documented in 3(7.5%) allografts at 3, 15 and 18 months from time of transplantation with no significant graft dysfunction. With similar distribution of allograft type and immunosuppression, there was no significant(p = 0.3) difference in survival between Crohn’s and non-Crohn’s patients. However, the cumulative risk of graft loss due to rejection was significantly higher in Crohn’s disease compared to non-Crohn’s disease recipients.

Conclusions: Intestinal transplantation is life saving and effective therapy for patients with end stage Crohn’s disease. Disease recurrence is low and at best histologic with no significant impact on graft function. The later and observed high risk of alloreactivity may help to better understand disease pathogenesis.

1205
Alternate Day Steroid Therapy for Crohn’s Disease: Long Term Effects on Remission and Bone Mineral Density
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Purpose: Corticosteroids have been used to treat patients with active inflammatory bowel disease since 1955 when Truelove and Witts showed that oral cortisone induced remission in patients with active ulcerative colitis. Studies have been done to evaluate the effects of alternate-day prednisone treatment in patients with inflammatory bowel disease, however data on long term follow-up in these patients is lacking. Our study evaluates the effects of alternate day prednisone therapy in adults with CD in a cohort with long term follow-up.

Methods: We conducted a retrospective chart review of 29 patients in our practice at Thomas Jefferson University Hospital who had received long-term alternate day prednisone therapy for treatment of CD from 1965–2005. Data on age, sex, prednisone dosage, duration of therapy, hospital admission history, number of flares/year and BMD measurements were entered into an excel database and analyzed.

Results: The mean age was 54 years (range 29–76) and 62% were males. 17/29 patients (59%) of patients had terminal ileal disease, with 10/29 patients with ileocolonic disease, 8/29 with colonic disease alone and 11/29 with small bowel disease alone. The average number of years patients were treated with alternate day prednisone therapy was 14 years (range 2–38 years) with dosage ranges of 5mg to 10mg. 68% of these patients were on concomitant immunosuppressive therapy with Imuran 50mg daily. There were an average 1.86 (range 0–8) total disease flares per year during the
study period with 0.07 hospitalizations/patient-year. BMD measurements were done in 21/29 patients. Only 2/21(9%) patients had osteoporosis (T-score below −2.5), 9/21(43%) had osteopenia (T-score between −1.0 and −2.5) and 10/21(48%) patients had normal bone mineral density. The risk of progression to osteoporosis correlated with number of disease flares/year rather than years on steroid therapy.

**Conclusions:** 1) Patients on alternate day prednisone therapy have a high rate of remission with a low hospitalization rate of 0.07 hospitalizations per patient-year. 2) There is a low rate of progression to osteoporosis in these patients despite long-term prednisone use and when there is progression to osteoporosis the only predictive factor appears to be disease activity.

### 1206

**Rifaximin and Treatment of Recurrent Clostridium difficile Infection in Patients with Inflammatory Bowel Disease**

**Mazen Issa, MD, Lydia R. Weber, Heather Brandenburg, Jeanne Emmons, R.N.C., Sue Skan, PA-C, Joth F. Knox, PA-C, Dawn B. Beaulieu, MD,* David G. Binion, MD. Medicine, Medical College of Wisconsin, Milwaukee, WI.**

**Purpose:** Clostridium difficile (C. difficile) is increasing in North American medical centers and can negatively impact clinical course in patients with inflammatory bowel disease (IBD; Crohn’s disease, ulcerative colitis). Recent reports suggest a 50% failure rate with metronidazole therapy for C. difficile, while vancomycin is associated with high recurrence rates (DM Musher et al. Clin Infect Dis. 2005;40:1586–90). Rifaximin (Xifaxan, Salix Pharmaceuticals, Raleigh, NC) is a non-absorbable oral antibiotic which has efficacy against C. difficile. We examined rates of recurring C. difficile infection encountered in a cohort of IBD patients and specifically focused on patients with recurrent infection and those who required rifaximin treatment.

**Methods:** This was a retrospective, observational study of IBD patients diagnosed with C. difficile (positive stool ELISA toxin A,B) in a single tertiary referral center during 2005. Initial and recurrent treatment for C. difficile was recorded. Recurrence was defined clinically as a relapse after initial resolution of symptoms which required a 2nd course of antibiotics within 2 weeks after initial therapy with metronidazole or vancomycin. Rifaximin was administered for recurrent C. difficile infection on a scheduled taper consisting of 200mg TID × 2 wks, 200 mg BID × 2 wks, 200 mg QD × 2 wks and 200 mg qod × 2 wks.

**Results:** A total of 46 out of 999 IBD patients (4.6%) tested positive for C. difficile during 2005. Fifty-eight percent (27/46) required treatment for recurrent infection. These included 17 Crohn’s disease and 10 ulcerative colitis patients. All relapsing patients had initially received vancomycin. Among patients with recurrent infection, 52% (14/27) received a rifaximin taper. Colectomy was required in 15% of the C. difficile infected IBD patients (7/46). Two of these patients had experienced recurrent infection. Rifaximin taper was successful for treatment of relapsing infection in all cases.

**Conclusions:** Among IBD pts infected with C. difficile, relapse is frequently encountered in over half of cases. Vancomycin was associated with C. difficile relapse in all cases. A prolonged rifaximin taper over an 8 week period was successful in all relapsing cases. Prospective evaluation of rifaximin in C. difficile infected IBD patients, including those experiencing relapse is warranted.

### 1208

**Budesonide in the Treatment of Antibiotic Refractory Pouchitis: An Open Label, Non-Blinded Trial**

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**Purpose:** Pouchitis is the most common adverse effect in patients who undergo Total Proctocolectomy for Ulcerative Colitis. Its characteristic clinical, endoscopic and histologic findings have been well described. Treatment includes antibiotics, probiotics, and at times topical enemas. However, 30% of patients do not respond to the aforementioned. Budesonide, a targeted, minimally absorbed steroid, is most effective in ileal Crohn’s disease. Its use has been proven in both induction and maintenance of active inflammatory disease. Since pouchitis involves the “terminal ileum,” Budesonide may be effective in its treatment.

**Methods:** Five patients with documented clinical and endoscopic pouchitis who did not respond to either Ciprofloxacin or Metranidazole were treated with 9mgs. of Budesonide daily. No concomitant medication except anti-diarrheals were permitted within 2 weeks of starting Budesonide. A modified PDAI, without the histologic criteria, was assessed at the onset, 2 weeks and 6 weeks after treatment. 9 mgs.of Budesonide was administered for 3 weeks, followed by 6mgs. for 3 weeks. A PDAI score of 6 or greater was necessary for admission into the trial, with a PDAI score of 3 or less needed for successful completion.

**Results:** Three of five patients had complete resolution of clinical symptoms both at three and six weeks. In each patient there was complete endoscopic healing. All three had a decrease in their modified PDAI to a score of less than three. A single patient had a partial clinical response with residual endoscopic activity. One patient had no change in either their clinical or endoscopic score and therefore, no change in the modified PDAI. No significant adverse effects were reported and all five patients completed the full 6 weeks of the trial.
Conclusions: Budesonide, a targeted, minimally absorbed steroid, whose effect is greatest in the terminal ileum and right colon, was effective in 60% of patients with antibiotic or probiotic resistant pouchitis. Larger, controlled trials are necessary in order to further define its role in the treatment of refractory pouchitis.

1209
Escalation of Infliximab Maintenance Therapy in Crohn’s Disease
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Purpose: The chimeric monoclonal antibody infliximab is approved by the FDA for the longterm maintenance of remission in moderate to severe Crohn’s disease (CD), and the label includes escalation in therapy (from 5 to 10 mg/kg) to maintain clinical response in individual patients. Rates of dose escalation (either shortening of the infusion interval or increase in the dosage of drug) has not been described with longterm use of infliximab in Crohn’s patients followed in routine clinical practice. We sought to characterize the rate of infliximab escalation in Crohn’s disease patients receiving longterm treatment beyond 1 year and identify clinical parameters associated with escalation of drug therapy.

Methods: This was a retrospective observational cohort study of all CD pts who were treated with maintenance infliximab for greater than 1 year between 1999 – 2005. Treatment escalation was defined as either a decrease in infusion interval to less than 7 weeks or an increase in dosage to more than 5 mg/kg. Data on clinical variables including pt demographics, disability, duration of disease, smoking status, prior use of immunomodulator therapy (AZA, 6MP, MTX), and intolerance to purine analogs was recorded.

Results: There were 125 CD pts identified who received > 1 year of maintenance infliximab infusions. 62% (n = 77) received a standard regimen (SR) vs. 38% (n = 48) who received an escalated regimen (ER). Among patients with ER, 95.8% (46 of 48) required a shortened infusion interval and 52.1% (25 of 48) required an increase to a 10 mg/kg dose for optimal therapy. Mean age was similar between groups, as was gender and current tobacco use and duration of CD. Use of concomitant immunomodulators was significantly higher in the SR vs the ER (79% vs 58%; p = <0.025 Chi square analysis). Rates of purine analog intolerance were similar between the two groups. The rate of permanent disability was significantly higher in the patients with ER (14%) compared with SR (3%; p = <0.05).

Conclusions: Infliximab escalation is commonly encountered in CD patients treated beyond 1 year, and was required in over 1/3 of patients. Concomitant immunomodulator use appeared to protect patients from requiring dose escalation. However, specific mechanisms leading to infliximab dose escalation during longterm therapy remain to be characterized.

Functional Bowel Disorders

1210
Comprehensive Small Intestinal Bacterial Overgrowth (SIBO) Therapy in Functional Bowel Syndrome (FBS)
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Purpose: SIBO contributes to gastrointestinal (GI) IBS symptoms and is caused by an abnormal migrating motor complex in the small intestine. Intestinal permeability may also play a role in symptoms. This observational study assessed potential benefits of a comprehensive treatment protocol for SIBO in IBS (patients) pts.

Methods: Pts with an abnormal lactulose breath test (LBT) at baseline who met Rome II criteria were eligible for the study. After symptom questionnaire completion, pts received the nonabsorbed antibiotic rifaximin 1200 mg/d for 10 days, followed by intestinal permeability therapy with zinc 220 mg/d and a bifidobacter-based probiotic for 1 mo and prokinetic therapy with tegaserod 3 mg nightly long-term. Follow-up questionnaires were completed regarding symptom improvement after completion of 10-day rifaximin therapy and 2 mo post-baseline. At 2-mo follow-up, pts rated overall symptom improvement as great, moderate, mild, or no improvement.

Results: An abnormal LBT was present in 51 (60%) of 85 pts screened (>20-ppm increase in hydrogen [n = 37], methane [n = 11], and both hydrogen and methane [n = 3]). High-hydrogen producers reported a similar incidence of diarrhea (41%) and constipation (30%) at baseline, and high-methane producers reported a higher incidence of constipation (64%) compared with diarrhea (27%). Of 51 pts with baseline data, follow-up data were available for 20. Baseline symptoms in these 20 pts included flatulence (80%), fullness (65%), bloating (55%), constipation (40%), diarrhea (35%), and abdominal pain (25%). At 10 days, ≥50% improvement in baseline symptoms was reported in 44% (7/16) of pts for flatulence, 31% (4/13) for fullness, 36% (4/11) for bloating, 38% (3/8) for constipation, 43% (3/7) for diarrhea, and 60% (3/5) for abdominal pain. Similar improvements in baseline symptoms were also observed at the 2-mo follow-up. Moderate/great improvements in overall GI symptoms were reported in a majority (63%; 12/19) of pts.

Conclusions: Treatment with adjunctive rifaximin improved GI symptoms in FBS pts (lacking all IBS Rome II criteria) with an abnormal LBT. Benefits of comprehensive SIBO treatment regimen appear to sustain effects for a follow-up period of 2 mo.
Development and Validation of an Instrument To Measure Patient Attitudes towards Antidepressant (ATAD) Therapy in Non-Psychiatric Settings

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Purpose: Visceral pain syndromes may be effectively treated by therapies that modulate the interactions between the central and enteric nervous systems. Antidepressants (AD) may be efficacious for the treatment of these syndromes. Patient’s beliefs and biases may influence clinical outcomes with AD therapies. We developed an instrument to assess patients’ attitudes and beliefs about AD use in a non-psychiatric setting, the Attitudes towards Antidepressant Therapy questionnaire (ATAD). The primary objective of this study was to evaluate the psychometric properties, including validity and reliability in an academic GI clinic.

Methods: Initial items were generated based on patient interview, literature review and professional experience. A 21-item questionnaire was derived from the initial items by consensus and face validity. The questionnaire was administered to 236 out-patients with a diagnosis of functional or organic GI disorders. This dataset was used to assess the psychometric properties of the ATAD. A Principal Component Analysis (PCA) with Varimax rotation and Kaiser Normalization was completed. The number of components was determined by the total explained variance, simple structure, and eigenvalues > 1. The final subscales were comprised of items with loading exceeding 0.50 with a particular component, while minimizing cross-loadings. Internal consistency was assessed according to Cronbach’s alpha.

Results: The initial PCA suggested a five-component solution for the total sample, but simple structure was best derived from 4 components: “Efficacy” (25.9%), “Stigma” (22.6%), “Toxicity” (12.1%), and “Sexual Dysfunction” (6.6%). Three items demonstrated complex interactions with multiple components and were deleted. The final questionnaire included 18 items and accounted for 67% of total variance. Cronbach’s alpha ranged from 0.82–0.91 on the subscales, supporting good internal consistency. Split-half reliability was adequate and ranged from 0.72–0.91. PCA demonstrated acceptable component stability across patient groups.

Conclusions: The ATAD questionnaire demonstrated good validity and reliability in patients with gastrointestinal disorders. The ATAD can be used to assess patient’s pre-existing attitudes and beliefs regarding AD therapies and the potential influence of these attitudes on medication compliance and clinical outcomes.

Racial Differences in Gastrointestinal Symptom Reports, Psychosocial Status and Health-Related Quality of Life (HRQOL) in Patients with In Functional Bowel Disorders (FBDs)

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Purpose: Epidemiologic data evaluating racial/ethnic differences in gastrointestinal symptoms are limited. We evaluated ethnic differences in symptom presentation, psychosocial status, and HRQOL in African American (AA) and Caucasian (C) patients with FBDs. We tested the null hypotheses that: (1) AA patients would exhibit no differences in GI symptoms compared to C patient controls with FBDs; (2) AA patients would exhibit similar HRQOL compared to C patients; (3) AA patients would exhibit similar levels of psychosocial function as C patients with FBDs; and (4) the severity of psychological distress would be associated with an overall reduction in HRQOL regardless of ethnic/racial status.

Methods: The current dataset was abstracted from 281 charts from a tertiary GI motility practice. A case-control design with multivariate and univariate analyses was used. Cases included 74 AA (51F; 49 ± 17 yrs) and 166 C (122F; 48 ± 16 yrs). All patients completed the SCL 90-R, a standardized Bowel Symptom Questionnaire, and a brief assessment of HRQOL.

Results: AA patients reported fewer GI symptoms (p = 0.03), less frequent abdominal pain (p = 0.06) and a fewer abdominal pain sites (p = 0.09) than C patients. The overall frequency of bowel movements reported was not significantly different between C and AA. Fewer AA reported constipation or met the Rome Criteria for IBS. Caucasians tended to report more straining and more frequent incomplete evacuation. Upper GI symptoms were identified in both groups, but were more common in C. Significant elevations were noted on the SCL 90-R for Somatization, Depression, and Anxiety in the C group compared to the AA group. HRQOL was reduced in C patients compared to AA patients. Depression constituted the strongest predictive factor in all models and was inversely correlated with HRQOL.

Conclusions: The current investigation is the first to evaluate racial/ethnic differences in GI symptoms, psychosocial distress, and HRQOL in an academic tertiary referral population of functional bowel patients. We rejected the null hypotheses and found a moderately increased prevalence of GI symptoms, increased psychosocial distress and reduced HRQOL in C patients compared to AA.

The Prevalence of Small Intestinal Bacterial Overgrowth in Irritable Bowel Syndrome

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Purpose: The exact prevalence of small intestinal bacterial overgrowth (SIBO) in patients with irritable bowel syndrome (IBS) is unknown. Various investigators using different methods have reported a prevalence rate of 11 to 78% (Ann J Gastro 2005; 100: S366, Am J Gastro 2000; 95: 3503–3506). We have previously reported (Hepato Gastroenterology 1998; 45: 1023–1025) that orocecal time using lactulose hydrogen breath test in humans is 55 ± 3 minutes. In the present study we evaluated the prevalence of SIBO in IBS patients using the stricter criterion of increase in breath hydrogen if it occurred 60 minutes or sooner after oral lactulose.

Methods: In the period of Dec152005to June 2006, we performed lactulose breath hydrogen test on 52 patients with IBS. The patients after a high protein, low fiber diet fasted overnight. A fasting breath hydrogen was recorded with a EC 60 Gastrolyzer (Bedfont Scientific, Medford, NJ) which has a sealed electrochemical sensor specific for H2. They then ingested 10 g lactulose in 30 ml of water. Thereafter breath hydrogen was recorded every 5 minutes for the next 75 minutes. A rise of 5 ppm over the baseline occurring at 60 minutes or sooner after lactulose was considered positive for SIBO.

Results: There were 52 patients; 18/52 (34.6%) were men. The mean age was 42.5 years (range 17–76). There were 28/52 (53.8%) patients with constipation dominant IBS (IBS–C); there were 24/52 (46.1%) with diarrhoea dominant IBS (IBS–D). SIBO was present in 20/52 (38.4%) of the cases; 9/20 (45%) had IBS–C; 11/20 (55%) had IBS–D which are similar (Chi square p > 0.05). SIBO was present in 9/28 (32.1%) IBS patients which was not different from 11/24 (46%) IBS–D patients (Chi Square p = 0.09).

Conclusions: SIBO by our method was found to be present in 38.4% patients with IBS. The prevalence of SIBO was the same in IBS-Cand IBS–D patients.
Comparative Bioavailability of Balsalazide Tablets and US and UK Formulations of Mesalamine pH-Dependent Delayed-Release Tablets

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Purpose: Mechanisms to deliver 5-aminosalicylic acid (5-ASA) to the colon include a pH-dependent delayed-release enteric coating (mesalamine) or an azo-bonded drug cleaved by colonic bacteria (balsalazide). The properties of enteric-coated tablets may be influenced by the manufacturing process. This study evaluated the relative bioavailability of pH-dependent delayed-release mesalamine US and UK formulations, which are manufactured at different sites, compared with balsalazide in an open-label, 4-arm, parallel-group study.

Methods: Healthy volunteers were randomized to receive balsalazide 2.25 g t.i.d. (n = 12), US mesalamine 800 mg t.i.d. (n = 12) or 1600 mg t.i.d. (n = 12), or UK mesalamine 800 mg t.i.d. (n = 12). Systemic absorption of 5-ASA and the active metabolite N-acetyl-5-ASA (N-ASA) was measured using area under plasma concentration-time curve (AUC) and maximum peak observed plasma concentration (Cmax) values.

Results: The systemic absorption of 5-ASA and N-ASA was highly variable among individuals receiving mesalamine compared with those receiving balsalazide and was more variable among those receiving US versus UK mesalamine. The maximum systemic exposure to 5-ASA and N-ASA was greater with US and UK mesalamine compared with balsalazide. Bioequivalence comparisons could not be made due to extreme variability in AUC values for mesalamine formulations.

Conclusions: Balsalazide, the azo-bonded delivery system, was associated with substantially less systemic exposure (mean Cmax) compared with US or UK mesalamine. Furthermore, the higher dose pH-dependent delivery system of mesalamine resulted in markedly higher systemic exposure to 5-ASA compared with balsalazide. US and UK mesalamine formulations produced greater intersubject systemic 5-ASA absorption variability versus balsalazide, which may be due to inherent characteristics of the pH-dependent enteric coating and its variable dissolution and release of 5-ASA. 5-ASA efficacy depends on colonic mucosal levels, not serum levels. The larger N-ASA:5-ASA ratio observed with balsalazide suggests that more 5-ASA is available in the colon following administration of balsalazide versus mesalamine formulations.

Gastrointestinal Infection with Campylobacter jejuni 81–176 Produces Altered Bowel Function and Bacterial Overgrowth in Rats

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Purpose: The cause of irritable bowel syndrome has been unknown. Recently, the pathophysiologic explanation for IBS has been suggested in one theory to be bacterial overgrowth and in another, the result of an acute gastroenteritis (post-infectious IBS). In this study we attempt to determine whether the toxin-related effects of acute Campylobacter jejuni infection will produce altered bowel function and bacterial overgrowth in rats.

Methods: A group of Sprague-Dawley rats were given a vehicle or vehicle containing $5 \times 10^8$ CFU of Campylobacter jejuni strain 81–176 via gavage orally. In the first two weeks after gavage, stool cultures were performed to confirm infection and to determine time of clearance of infection. Three months after clearance of the infectious agent, fresh stool from the rats were evaluated for stool consistency followed by euthanasia. After euthanasia, self-contained segments of duodenum, jejunum, ileum, cecum and left colon were harvested and placed in anaerobic conditions. The lumenal bacteria counts from these segments were then measured via quantitative real-time PCR.

Results: Of the 60 rats who survived gavage, 30 received Campylobacter jejuni. By 2 weeks, 97% of rats had negative stool cultures for Campylobacter from their stool. At three months beyond Campylobacter infection, 57% of rats had some alteration in stool consistency. This was compared to 7.4% in vehicle-only gavaged controls (p < 0.001). In the rats that received Campylobacter, 27% had bacterial overgrowth by PCR compared to controls. The rats with bacterial overgrowth also had the highest prevalence of altered stool form (p < 0.001) as well as lower body weight (p < 0.05).

Conclusions: Campylobacter jejuni 81–176 infection of the gastrointestinal tract can precipitate altered stool consistency and bacterial overgrowth in rats. This may be a model for understanding the mechanism of post-infectious IBS.

Nurse Practitioners (NPs): Practice Patterns and Attitudes Regarding Constipation

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Purpose: The prevalence of constipation (CON) approaches 20% in adult Americans. CON reduces quality-of-life (QoL) and imposes a significant economic burden. Although NPs provide a large portion of US health care, no information exists on how NPs evaluate patients (Pts) with CON. This study was designed to evaluate the practice patterns and attitudes of NPs with regards to CON.

Methods: A questionnaire assessing the knowledge base, attitudes, and practice patterns regarding CON was sent to 1081 NPs. A reminder postcard was mailed, with a second questionnaire to non-responders. Responses were anonymous; no remuneration was provided. IRB approval was obtained.

Results: Of 1069 deliverable questionnaires, 390 were returned completed (36.5%). The mean age of respondents was 47 (± 8 SD) years, with 12 (± 9 SD) years in practice; 92% were women. The etiology of CON was thought due to inadequate fiber (51%) or fluid intake (14%), medications (8%), learned behavior (5%), lack of exercise (4%), and genetics (2%). The pathophysiology of CON was believed due to slow colonic transit (23%), a generalized motility disorder (22%), IBS (7%), pelvic floor dysfunction (<1%), or a combination of 2 or more factors (39%). 330 NPs saw adult Pts and these responses were analyzed further. For the natural history of CON, 63% of NPs noted it is a chronic intermittent process, 28% stated CON is chronic and persistent, 7% stated CON resolves spontaneously, and 2% stated CON slowly progresses. NPs’ primary concern was excluding or–ing CON, 63% of NPs noted it is a chronic intermittent process, 28% stated CON is chronic and persistent, 7% stated CON resolves spontaneously, and 2% stated CON slowly progresses. NPs’ primary concern was excluding or–ing CON, 63% of NPs noted it is a chronic intermittent process, 28% stated CON is chronic and persistent, 7% stated CON resolves spontaneously, and 2% stated CON slowly progresses. NPs’ primary concern was excluding or–ing CON, 63% of NPs noted it is a chronic intermittent process, 28% stated CON is chronic and persistent, 7% stated CON resolves spontaneously, and 2% stated CON slowly progresses. NPs’ primary concern was excluding or–ing CON, 63% of NPs noted it is a chronic intermittent process, 28% stated CON is chronic and persistent, 7% stated CON resolves spontaneously, and 2% stated CON slowly progresses. NPs’ primary concern was excluding or–ing CON, 63% of NPs noted it is a chronic intermittent process, 28% stated CON is chronic and persistent, 7% stated CON resolves spontaneously, and 2% stated CON slowly progresses. NPs’ primary concern was excluding or–ing CON, 63% of NPs noted it is a chronic intermittent process, 28% stated CON is chronic and persistent, 7% stated CON resolves spontaneously, and 2% stated CON slowly progresses. NPs’ primary concern was excluding or–ing CON, 63% of NPs noted it is a chronic intermittent process, 28% stated CON is chronic and persistent, 7% stated CON resolves spontaneously, and 2% stated CON slowly progresses. NPs’ primary concern was excluding or–ing CON, 63% of NPs noted it is a chronic intermittent process, 28% stated CON is chronic and persistent, 7% stated CON resolves spontaneously, and 2% stated CON slowly progresses. NPs’ primary concern was excluding or–ing CON, 63% of NPs noted it is a chronic intermittent process, 28% stated CON is chronic and persistent, 7% stated CON resolves spontaneously, and 2% stated CON slowly progresses. NPs’ primary concern was excluding or–ing CON, 63% of NPs noted it is a chronic intermittent process, 28% stated CON is chronic and persistent, 7% stated CON resolves spontaneously, and 2% stated CON slowly progresses. NPs’ primary concern was excluding or–ing CON, 63% of NPs noted it is a chronic intermittent process, 28% stated CON is chronic and persistent, 7% stated CON resolves spontaneously, and 2% stated CON slowly progresses. NPs’ primary concern was excluding or–
(76%), migraines (63%), and heart failure (57%). NPs stated CON moderately (59%) affects QoL, or significantly (25%) affects QoL. 25% of CON Pts were referred to a G for further evaluation.

**Conclusions:** Educational efforts should be directed at NPs to improve understanding of the etiology and pathophysiology of this common disorder, resolve inappropriate concerns about the risks of constipation and colon cancer, and to improve appropriate colonoscopy referrals for patients > age 50.

**1218**

**Tegaserod: Rapid Onset of Action in Patients with Chronic Constipation**

Brian E. Lacy, MD,* Jeffrey Kralenstein, MD, Michael Dolker, PhD, Michael Shetzline, MD. Gastroenterology & Hepatology, Dartmouth-Hitchcock Medical Center, Lebanon, NH and Novartis Pharmaceuticals Corp., East Hanover, NJ.

**Purpose:** Tegaserod (T) is approved for the treatment of chronic idiopathic constipation (CC) in both men and women less than 65 years of age. We aimed to evaluate the rapidity of response of chronic constipation patients to T compared to placebo (P) by measuring the time to onset of complete spontaneous bowel movement (CSBM) and spontaneous bowel movement (SBM).

**Methods:** Data from two separate double-blind, randomized controlled clinical trials in CC for T dosed at 6 mg bid and placebo were pooled for analysis. CC was defined as an average of ≥3 SBMs per week, associated with at least one of the following symptoms on ≥25% of occasions: straining, incomplete evacuation, and hard and/or very hard stools. A bowel movement was considered to be complete if it was associated with a feeling of complete evacuation, and hard and/or very hard stools. A bowel movement was assessed by test-retest reliability and alternate form reliability.

**Results:** The time to onset to a CSBM and SBM for T 6 mg bid was superior to placebo as was the% of patients with a CSBM or SBM w/in 24 and 48 hours, as compared with placebo.

<table>
<thead>
<tr>
<th></th>
<th>Median % within 24 Hours</th>
<th>Median % within 48 Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CSBM</td>
<td>SBM</td>
</tr>
<tr>
<td><strong>ITT</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(N = 865) 6 mg bid</td>
<td>62.9</td>
<td>41.2</td>
</tr>
<tr>
<td>(N = 843) placebo</td>
<td>12.0</td>
<td>43.9</td>
</tr>
<tr>
<td>p-value</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>RESPONDERS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(N = 366) 6 mg bid</td>
<td>50.8</td>
<td>70.2</td>
</tr>
<tr>
<td>(N = 221) placebo</td>
<td>27.1</td>
<td>52.0</td>
</tr>
<tr>
<td>p-value</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

**Conclusion:** Tegaserod 6 mg bid provides a rapid response in patients with CC. The majority of responders will have a CSBM within the first 24 hours and over 90% will have a SBM within 48 hours.

**1219**

**To Clot or Not To Clot: Are There Predictors of Thrombosis in Patients with Gastroparesis and Prolonged IV Access?**

Bradley Creel, MD, Anil Monocha, MD, Amy Lobrano, MD, Thomas Abell, MD,* William Johnson, PhD. Digestive Health and Nutrition, University of Mississippi Medical Center, Jackson, MS and Preventive Medicine, University of Mississippi Medical Center, Jackson, MS.

**Purpose:** Many patients with gastroparesis require sustained central IV access for hydration, medication, and/or nutrition. A recent report has shown that over 90% of gastroparetics are hypercoagulable. We studied a group of patients with gastroparesis and prolong IV access to identify factors associated with an increased risk of catheter related thrombosis.

**Methods:** We analyzed serum coagulation studies and autoimmune antibodies in 53 consecutive patients with gastroparesis and central IV access. This patient group fell into two categories: those who formed clinically significant line related thrombosis (CLOT) and those that did not (NOCLOT). Data was then statistically compared between the two groups.

**Results:** We found patients in the CLOT group had higher titers of ScI 70 antibodies than the NOCLOT group. Also, our study revealed that higher titers of Ku 66 antibodies were present in the NOCLOT group as compared to the CLOT group. There was no significant difference between the two groups when comparing other autoantibodies (See Table 1) nor other serum coagulation factors (See Table 2).

**Conclusions:** We conclude that the patients that formed thromboses had significantly higher serum titers of ScI 70 antibodies, and those that did not had higher titers of KU 66 antibodies. These findings suggest autoimmune factors may play a role in thrombosis in patients with gastroparesis and in the future may be used to risk stratify these patients for line-related thrombosis.

<table>
<thead>
<tr>
<th>Autoimmune Markers in the CLOT and NOCLOT Groups</th>
</tr>
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<tbody>
<tr>
<td>Autoimmune Marker</td>
</tr>
<tr>
<td>-------------------</td>
</tr>
<tr>
<td>ScI 70</td>
</tr>
<tr>
<td>ScI 105</td>
</tr>
<tr>
<td>SSB 43</td>
</tr>
<tr>
<td>Sm 16</td>
</tr>
<tr>
<td>Sm 18</td>
</tr>
<tr>
<td>Ku 66</td>
</tr>
</tbody>
</table>

**Coagulation Studies in the CLOT and NOCLOT Groups**

<table>
<thead>
<tr>
<th>Coagulation Study</th>
<th>Clot (n = 14)</th>
<th>No Clot (n = 39)</th>
<th>Reference Range</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticardiolipin</td>
<td>8.07 ± 1.98</td>
<td>7.41 ± 1.29</td>
<td>15–22.9</td>
<td>&gt;0.2</td>
</tr>
<tr>
<td>Antibodies</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thrombin Time</td>
<td>15.73 ± 2.58</td>
<td>14.39 ± 0.57</td>
<td>16.2–21.8</td>
<td>&gt;0.2</td>
</tr>
<tr>
<td>Protein S</td>
<td>64.35 ± 4.64</td>
<td>71.4 ± 3.43</td>
<td>60–159</td>
<td>&gt;0.2</td>
</tr>
<tr>
<td>Lupus</td>
<td>0%</td>
<td>10.2%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anticoagulant</td>
<td></td>
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</tbody>
</table>

**1220**

**Patient Knowledge and Perspective on Irritable Bowel Syndrome: Validation of a Survey Instrument**

Kirsten Weiser, MD, Brian E. Lacy, PhD, MD,* Laura Noddin, MD, Michael D. Crowell, PhD, F.A.C.G., Gastroenterology & Hepatology, Dartmouth-Hitchcock Medical Center, Lebanon, NH and Gastroenterology, Mayo Clinic, Scottsdale, AZ.

**Purpose:** Irritable bowel syndrome (IBS) is a highly prevalent functional gastrointestinal disorder. A reliable and valid questionnaire measuring patient knowledge, concerns, and fears does not currently exist, but could be used to improve IBS patient care and outcomes. The aims of this study were to develop a reliable IBS patient knowledge questionnaire and validate it.

**Methods:** Content validity was established by literature review and expert opinion. Face validity was ascertained through a patient focus group. This resulted in the development of 54 questions to assess domains of patient knowledge and concern. Adult patients (≥18 years) with IBS were identified using ICD-9 codes. Patient records were reviewed to ensure that they met the Rome II criteria for IBS. A questionnaire was mailed to appropriate patients with a second identical questionnaire mailed 4 weeks later. All responses were anonymous. IRB approval was obtained. Reliability of the instrument was assessed by test-retest reliability and alternate form reliability.
Results: 153 Patients with IBS completed the initial survey; 121 were female (79%). 119 patients completed the second questionnaire (77.8%). Test-retest reliability had a mean concordance of 0.8, with a range based on individual questions of 0.45 to 0.95. Alternate form reliability had a mean concordance of 0.97. Inter-item reliability, where applicable, had Cronbach's alpha with a range from 0.57 to 0.86. Questions with high reliability and validity had responses with similar metrics. Reliability was more easily established in questions where the responses had no option for uncertainty. Results of the questionnaire were recently reported (Lacy et al, Am J Gastroenterol 2005; 100: S324; Noddin et al Am J Gastroenterol 2005; 100: S323).

Conclusions: This validated survey instrument is the first to assess patient knowledge, fears, and concerns surrounding the diagnosis of IBS. Questions with Likert Scale and True-False responses were more reliable than multiple choice questions. This questionnaire can be used in the out-patient setting to assess the knowledge base and concerns of patients with IBS.

1221
Effects of Family Size, Child Gender, and Maternal IBS on Child Gastrointestinal Symptoms
Shelby L. Langer, PhD, William E. Whitehead, PhD, Lynn S. Walker, PhD, Sarah J. McDonald, B.A., Rona L. Levy, M.S.W., PhD, M.P.H.* School of Social Work, University of Washington, Seattle, WA; Center for Functional GI & Motility Disorders, University of North Carolina at Chapel Hill, Chapel Hill, NC and Adolescent Medicine and Behavioral Science, Vanderbilt University, Nashville, TN.

Purpose: Prior research has found that Recurrent Abdominal Pain symptoms are more common in large families (Apley & Hale, 1973). However, research has not investigated the precise relationship between family size and GI symptoms, nor potential interactive effects with child gender and maternal IBS.

Methods: Participants were 450 mothers of 631 children; 46% of the mothers had a diagnosis of IBS. Demographics were as follows: child mean age = 11.9 (SD = 2.6), 51% female, 80% Caucasian; maternal mean age = 42.9 (SD = 6.2), 80% Caucasian. Mothers rated the severity of their children’s abdominal pain in the past two weeks, using a 0-4 scale (no pain to a whole lot of pain).

Results: A 3-way ANOVA yielded main effects of maternal IBS status (p = .000) and child gender (p = .001), but no main effect of family size (p > .05). Mothers reported more pain for girls than boys (M ± SD = 96 ± 1.0 and 68 ± .89) and, in line with past research (Levy et al., 2000), IBS mothers reported greater abdominal pain severity for their children than did control mothers (M ± SD = 1.18 ± 1.0 and .50 ± .72). Most interestingly, a maternal IBS status × gender × family size interaction emerged (p = .011). Mothers with IBS reported greater pain severity for girls versus boys when the child had either no siblings or one sibling (M ± SD = 1.46 ± 1.1 and 94 ± 1.1), but not two or more siblings (M ± SD = 1.13 ± 1.0 and 1.15 ± .74). This pattern was reversed for control (non-IBS) mothers, who reported greater pain severity for girls versus boys when the child had two or more siblings (M ± SD = .61 ± .75 and .24 ± .5), but not ± 1 sibling (M ± SD = 61 ± .77 and 47 ± .75).

Conclusions: The acquisition of illness behavior by girls with mothers who have IBS may be intensified in smaller families, where presumably these children have more one-on-one time with their mothers to learn either through observation or other mechanisms. Therefore, in the assessment of children’s GI complaints, child gender, maternal IBS status, and family size should be recognized as important variables to consider together. Supported by grant R01 HD36069.

1222
Altered Intestinal Serotonin Signaling in Opiate-Induced Constipation
Matthew D. Coates, PhD, Meagan M. Costedio, MD, Eric K. Ganguly, MD, Michael J. Callahan, PhD, Gary M. Mave, PhD, Peter L. Moses, MD,* Medicine, University of Vermont, Burlington, VT; Anatomy and Neurobiology, University of Vermont, Burlington, VT; Surgery, University of Vermont, Burlington, VT and Novartis Pharmaceuticals, East Hanover, NJ.

Purpose: Serotonin (5-HT) released from enterochromaffin (EC) cells is an important activator of reflexes in the bowel. The actions of 5-HT are terminated by reuptake into epithelial cells, which express the serotonin-selective reuptake transporter (SERT). We have previously reported that several elements of 5-HT signaling, including SERT expression, are diminished in ulcerative colitis (UC) and irritable bowel syndrome (IBS) with diarrhea or constipation. To test whether these changes represent a pathophysiologic cause and/or a functional effect, we evaluated whether 5-HT signaling is altered in opiate-induced constipation (OIC), which represents a “non-pathological” constipation control for IBS with constipation.

Methods: Human rectal mucosal biopsies were obtained from individuals with OIC (<3 bowel movements/week; n = 14; gender: 7m/7f; age range: 22–56 years) and healthy controls (n = 14; 7m/7f; 42–74 years). EC cells were identified by 5-HT immunohistochemistry, 5-HT content was determined by ELISA. mRNA levels for SERT, TpH-1, and a non-serotonergic system control, the chlordiazepoxide protein 3 (CLCN3-3) were assessed using quantitative real-time PCR. All statistical comparisons involved the student’s t-test.

Results: SERT mRNA expression (normalized to expression of beta-actin) was significantly diminished in OIC (0.005 ± 0.001, n = 8) relative to controls (0.012 ± 0.003, n = 8, p < 0.05). However, the message levels for the chloride channel, CLCN3-3 and TpH-1 were not altered in OIC. EC cell number/mm muscularis mucosa, EC cell number/collarod gland and% 5-HT-positive epithelial cells were not significantly different between the groups. In addition, 5-HT content was not altered in OIC.

Conclusions: These results demonstrate that SERT mRNA expression is diminished in OIC. These findings suggest that specific alterations in 5-HT signaling in the intestinal mucosa may be induced by changes in gut function, but that these changes do not completely reflect the alterations detected in IBS. It is possible that both pathophysiology and altered function contribute to the overall change in SERT expression in disorders involving constipation, and that these changes may in turn contribute to altered function and symptoms. Supported by Novartis Pharmaceuticals Corp, and NIH grants DK62267 & RR16453.

1223
In the Treatment of IBS, the Clinical Response to Rifaximin Is Determined by the Normalization of the Lactulose Breath Test
Hyo-Rang Lee, MD, PhD, Kimberly Low, B.A., Soumya Chatterjee, MD, Janet Yang, MD, Jeffery Conklin, MD, Mark Pimentel, MD, F.R.C.P.,* GI Motility Program, Cedars-Sinai Medical Center, Los Angeles, CA and Medicine, Cedars-Sinai Medical Center, Los Angeles, CA.

Purpose: Previous controlled studies have now demonstrated a clinical improvement in IBS after antibiotic therapy. In the case of neomycin, the improvement in clinical response was most significant in those whose breath test was normalized. In this study, a retrospective chart review was conducted to determine the clinical response to rifaximin and correlate that with the presence or absence of abnormal lactulose breath test after treatment.

Methods: A retrospective chart review was conducted on Rome I positive IBS patients seen between July 1, 2004 and October 31, 2005. Patients with IBD or other GI disease were excluded. Among these, subjects with a positive lactulose breath test were included and had to have at least one follow up visit and a post-treatment lactulose breath test. The presence or absence of clinical improvement (defined as > 50% improvement) was then compared to the after treatment breath test result. This was also done by breath test type with specific attention to methane producing IBS subjects.

Results: After inclusion and exclusion criteria were applied, 84 subjects received rifaximin. Of these, 50 (60%) had a follow up breath test and were eligible for study. Of these 50 subjects, 31 (62%) were clinical responders to rifaximin and 19 (38%) did not improve. In the group of 31 clinical responders, 25 (81%) had a normal follow-up breath test. In contrast, only
1224
Rifaximin Is Superior to Other Antibiotics in Treating and Retreating Bacterial Overgrowth in IBS, Supporting a Lack of Bacterial Resistance Development
Hyo-Rang Lee, MD, PhD, Kimberly Low, B.A., Soumya Chatterjee, MD, Janet Yung, MD, Jeffery Conkin, MD, Mark Pimentel, MD, F.R.C.P.,* GI Motility Program, Cedars-Sinai Medical Center, Los Angeles, CA and Medicine, Cedars-Sinai Medical Center, Los Angeles, CA.

Purpose: We have shown that antibiotics such as rifaximin improve IBS symptoms on the basis of the presence of bacterial overgrowth. However, there is limited data comparing the efficacy of other antibiotics to rifaximin in IBS. In this study, we conducted a retrospective chart review to determine the efficacy of rifaximin, compare this to other antibiotics and determine the effectiveness of re-treatment.

Methods: A chart review was conducted on Rome I positive IBS patients seen between July 1, 2004 and October 31, 2005. Their entire chart was reviewed to evaluate all antibiotic treatments even if they predated July, 2004. Patients with IBD or other GI disease were excluded. Only patients with positive lactulose breath test were included and had to have at least one follow-up visit. In the chart review, the data collected included, breath test results (before and after treatment), antibiotic used and clinical response (defined as >50% improvement) to individual antibiotic treatments before and after treatment.

Results: After inclusion and exclusion criteria were applied, 98 subject charts were eligible (84 of which received at least one course of rifaximin) and summarized. The median duration of patient time in clinical treatment was 11 months (range = 1–36 months). Of subjects given rifaximin for the first time, 69% (58/84) had a clinical response compared to 38% (9/24) for any occasion of neomycin use (p < 0.01) and 44% (27/61) for all non-rifaximin antibiotics (p < 0.01 compared to rifaximin). Of 20 patients who received one or more pre-rifaximin antibiotics with no benefit seen, 75% (15/20) still had a clinical improvement with subsequent rifaximin. Rifaximin was used as re-treatment for recurrence on 16 occasions. All 16 had clinical improvement.

Conclusions: Rifaximin treatment produced higher IBS symptom response rates than other antibiotics. In cases which failed to respond to other antibiotics, rifaximin still demonstrated this high response rate. Unlike conventional antibiotics, re-treatment with rifaximin was universally efficacious suggesting a lack of developing bacterial resistance.

1225
A Cost Analysis of Functional Bowel Disorders in Iran
Delnaz Roshandel, MD, Mohammadreza Rezaalishakjani, MD, Sepideh Shafaei, MD, Mohammad Reza Zali, MD, F.A.C.G.∗. Bioinformatics, Research Center for Gastroenterology and Liver Diseases, Tehran, Islamic Republic of Iran.

Purpose: To evaluate the health care utilization and cost of different types of functional bowel disorder (FBD) in a population of Iranian patients and compare the costs in consultants and non-consultors.

Methods: A consecutive sample of 1023 patients in an outpatient gastroenterology clinic in central Tehran was interviewed using two questionnaires based on Rome II criteria from December 2004 to May 2005 to detect FBD patients and to determine the frequency of health resource utilization (physician visit, hospitalization, laboratory tests, imaging studies, and drugs) and productivity loss (days off work or with low functionality) due to FBD symptoms in the past 12 months. Societal perspective was used and cost per person per year was estimated in purchasing power parity dollars (PPPs).

Results: The direct costs (for consultants, non-consultors -in order) were: IBS: (92.04S, 1.04S), unspecified FBD: (100.94S, 0.39S), functional constipation: (57.23S, 1.04S), and functional abdominal bloating (71.35S, 0.63S). Indirect costs (for consultants, non-consultors) were: IBS: (811.85S, 669.09S), unspecified FBD: (705.85S, 263.47S), functional constipation: (587.48S, 97.49S), and functional abdominal bloating (147.88S, 38.60S). Total yearly costs of IBS and functional constipation for urban adult population of Iran were roughly estimated at 2.94 billion PPP$ and 89.2 million PPP$, respectively.

Conclusions: As proved in developed countries, FBD and especially IBS seem to put a heavy burden on the economy of a developing country like Iran too. Further population based studies are needed for more precise estimations.
Conclusions: Serologic markers of IBD are frequently present in patients without Crohn’s disease or ulcerative colitis, including patients with IBS and asymptomatic controls.

Methods: This prospective, open labeled study included 39 patients who fulfilled the Rome II criteria for D-IBS or FD and who have had at least 6 months of recurrent symptoms. Baseline symptoms were evaluated over a two weeks run-in period following which patients were treated with esomeprazole 40 mg OD for 6 weeks. Patients were seen before, during, and after treatment and were evaluated for responsiveness of each of the study endpoints at mid- (3 weeks) and end-of-treatment (6 weeks). Outcome measures of efficacy included overall well being and satisfaction with treatment as primary outcome measures; and post-prandial urgency, stool consistency, stool frequency, abdominal pain, bloating, and health-related quality of life as secondary outcome measures. A repeated measures analysis of variance was used to compare mean scores between visits accounting for the (non-independence) correlation between the variables.

Results: There were no significant changes in the primary outcome measures. However, secondary analysis showed significant decrease in post-prandial urgency scores from pre-treatment (2.28±0.9) to mid-treatment (1.94 ± 0.94) (p = 0.03) and from pre- to end-of-treatment (2.28±0.9 and 1.81±1.01, respectively) (p = 0.005). Responders’ rates by improvement in urgency were 57.7% from pre- to mid and 44.4% from pre- to end-of-treatment. There were no significant changes in other secondary outcome measures.

Conclusions: This study did not show significant benefit for esomeprazole on overall well-being and satisfaction with treatment in IBS. However, subanalyses suggest a beneficial effect of acid suppression with esomeprazole on post-prandial urgency in patients with D-IBS and FD. Further studies are needed to confirm these preliminary findings and to investigate the mechanism of this effect.

Supported by a research grant from AstraZeneca.

Prevalence of Irritable Bowel Syndrome in Students of a University in Lima – Peru
Ricardo Prochazka, MD, Geraldine Salazar-Vargas, B.Sc., Manuel Ojeda, MD, Sandro Vila, MD, Jose Pinto, MD, Alejandro Bussalleu, MD,* Jorge Huerta-Mercado, MD, Raul De los Rios, MD, Alejandro Piscoya, MD. Gastroenterology, Hospital Nacional Cayetano Heredia, Lima, Peru and Psychology, Universidad Peruana Cayetano Heredia, Lima, Peru.

Purpose: Irritable bowel syndrome (IBS) is one of the most important functional gastrointestinal disorders. 10 to 20% of adults in occidental culture have symptoms of IBS, and this diagnosis causes 20 to 50% of references to gastroenterology clinics, with considerable costs. Studies in Peru have found prevalence rates of IBS in the range from 22% to 37.2% in general population from different geographic and socioeconomic background; 13.23% in physicians of a general hospital, and 6.06% in an outpatient gastroenterology clinic. We performed the present study with the aim to know the prevalence of IBS in students of a university in Lima.

Methods: A questionnaire was applied in order to establish the presence of irritable bowel syndrome according to the Rome II criteria in randomly selected students from Cayetano Heredia University in Lima, Peru. General and sex specific prevalence were determined, as well as the frequencies of the diarrhea predominant and constipation predominant variants of the syndrome.

Results: 197 subjects were evaluated. 127 (64.47%) of them were female. Average age was 18.06 years with a range from 15 to 28 years. 21 cases of irritable bowel syndrome were identified using the Rome II criteria, with a general prevalence of 10.66%. 17 cases were female and 4 were male, yielding prevalences of 13.39% in women and 5.71% in men. According to Rome II criteria 18 of the 21 (85.7%) cases of IBS were constipation predominant, 2 (9.53%) were diarrhea predominant, and 1 (4.77%) had a mixed pattern.

Conclusions: Wide variations exist in prevalence of IBS within Peru as in different regions of the world, probably owing to different methodologies of research and different cultural patterns. We have found in this young population a lower prevalence than the reported in other studies in our country, with
a clear female predominance and a strikingly high frequency of the constipation predominant variant. Little is known in our country about the impact in quality of life or derived costs, which is matter for future investigation.

1230

Gastric and Esophageal Sensory Parameters in Patients with Functional Dyspepsia and Functional Heartburn
Sheila Rodriguez-Stanley, PhD, Ivan Bottoli, MD, Sattar Zabadi, MD, Susan Riley, R.N., Tisha Adams, M.S., Maggie Wolff, Philip B. Miner, Jr., MD,* Clinical Research, The Oklahoma Foundation for Digestive Research, Oklahoma City, OK and Novartis Pharmaceuticals, East Hanover, NJ.

Purpose: In a previous study of 42 functional heartburn patients, we found frequent overlap of with dyspeptic symptoms (CGH 2006; 4:442–450); 48% of functional heartburn subjects also had upper abdominal pain, 74% had upper abdominal discomfort, 48% had early satiety, and 74% had post-meal bloating. Our aims were to assess esophageal and gastric mechanical sensitivity in functional heartburn.

Methods: Patients with dyspepsia and heartburn were eligible. Patients underwent physical exam, lab evaluation, ECG, esophageal manometry, gastric and esophageal barostat balloon sensory testing, esophagogastroduodenoscopy, and 24 hour pH-metry. Balloon distentions were repeated on a separate visit in patients with functional dyspepsia and functional heartburn. Barostat balloon distention protocols were performed with pain as the endpoint. Balloon sensitivity thresholds for the purposes of this study were ≤450 ml in the stomach and <50 ml in the esophagus. Patients rated pain severity on the 5-point Likert (0 = none to 4 = very severe) and 100 mm VAS (0 = none to 100 mm = severe) scales.

Results: Of 44 patients screened, 8 were excluded due to an obvious pathologic disorder, 3 withdrew consent, and 5 could not tolerate the procedures. Of the remaining 28 patients, only 2 (7%) were not sensitive to gastric distention (mean pain at 675 ml, n = 2) however they were sensitive to esophageal distention. Only 3 (11%) patients were sensitive to gastric distention but not to esophageal distention (mean pain at 53 ml, n = 3). 23 patients were sensitive to both distentions (82%). 22 of the 23 patients with sensitivity to both had repeated distentions. Mean volume to pain was 25 ml (esophagus) and 284 ml (stomach). Corresponding maximum pressure to pain was 40 mmHg in the esophagus and 19 mmHg in the stomach. Likert and VAS scores were explained using single step models. PCS was predicted by DSS (r² = 0.16; p = 0.008) while MCS was predicted by the SCL-90 global severity index (GSI) (r² = 0.334; p < 0.0001). NDI was predicted using a 3-step model that included DSS (r² = 0.25; p = 0.001), DSS + WL (r² = 0.33; p < 0.0001) and DSS + WL + DIF (r² = 0.43; p < 0.0001). Physical function and bodily pain scores were predicted by DSS alone (r² = 0.115 and 0.24) while GSI predicted physical role (r² = 0.118), mental health (r² = 0.54), emotional role (r² = 0.15), vitality (r² = 0.29) and general health (r² = 0.16). Social function was predicted by a two-step model including GSI and WL (r² = 0.37).

Conclusions: QOL in FD is largely determined by interactions between symptom severity, psychiatric distress and alexithymic traits. These data highlight the complex nature of QOL as an outcome measure and also demonstrate that symptoms alone are not sole predictors of QOL even for condition specific measures such as the NDI. If QOL is to truly be viewed as an outcome measure in FGID, a broader biopsychosocial approach is needed.

1231

Predictors of Quality of Life (QOL) in Functional Dyspepsia (FD)
Michael P. Jones, MD,* Jason Bratten, B.S., Laurie Keefer, PhD. Division of Gastroenterology, Northwestern University, Chicago, IL.

Purpose: QOL is a commonly used outcome measure in FGID. Perceptions of QOL can be affected by physical health, psychological state, personal beliefs, social relationships and their interactions. Given the complex biopsychosocial nature of FGID, we sought to evaluate the relationship between QOL, physical symptoms, gastric function, and psychosocial characteristics in patients with FD.

Methods: We performed a retrospective analysis of pts with Rome II FD who completed general (SF-36) and dyspepsia-specific (Nepean Dyspepsia Index (NDI)) QOL measures. Pts also completed a 15-item dyspepsia symptom score (DSS), psychosocial battery and a 5-minute water load test (WL). Psychosocial measures included the SCL-90-R, Toronto Alexithymia Scale (TAS-20) and the Somatosensory Amplification Scale (SSAS). 30 pts also completed a 13C-S. platensis solid phase gastric emptying breath test. Dependent variables were the NDI score and the Mental and Physical Composite Summaries of the SF-36 (MCS and PCS). Candidate independant variables that significantly correlated with dependent variables were entered into stepwise regression. Stepwise regression was also performed using entered independent variables to predict individual subscales of the SF-36.

Results: 151 pts were studied and included 117F/34M with a mean(SDEV) age of 39 ± 13years. Variables significantly correlated with QOL included sex, WL, DSS, SCL-90, the Difficulty Identifying Feelings (DIF) scale of the TAS-20 and SSAS scores. Both SF-36 MCS and PCS were explained using single step models. PCS was predicted by DSS (r² = 0.16; p = 0.008) while MCS was predicted by the SCL-90 global severity index (GSI) (r² = 0.334; p < 0.0001). NDI was predicted using a 3-step model that included DSS (r² = 0.25; p = 0.001), DSS + WL (r² = 0.33; p < 0.0001) and DSS + WL + DIF (r² = 0.43; p < 0.0001). Physical function and bodily pain scores were predicted by DSS alone (r² = 0.115 and 0.24) while GSI predicted physical role (r² = 0.118), mental health (r² = 0.54), emotional role (r² = 0.15), vitality (r² = 0.29) and general health (r² = 0.16). Social function was predicted by a two-step model including GSI and WL (r² = 0.37).

Conclusions: QOL in FD is largely determined by interactions between symptom severity, psychiatric distress and alexithymic traits. These data highlight the complex nature of QOL as an outcome measure and also demonstrate that symptoms alone are not sole predictors of QOL even for condition specific measures such as the NDI. If QOL is to truly be viewed as an outcome measure in FGID, a broader biopsychosocial approach is needed.

1232

Are Anti-Endomysial or Anti-Tissue Transglutaminase Antibodies Alone Sufficient To Screen for Celiac Sprue in Patients with the Irritable Bowel Syndrome?
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Purpose: Recent work suggests that celiac disease may provide an explanation for symptoms in a small subset of IBS patients. The optimal means by which to screen IBS patients for celiac disease is unclear. The goal of this study was to determine the optimal means by which to screen for celiac disease in patients with IBS.

Methods: Patients meeting the Rome II criteria for non-constipated IBS with no alarm features and healthy persons scheduled to undergo colonoscopy for colorectal cancer screening from 4 US sites were invited to undergo serological screening for celiac disease. Subjects that agreed to participate underwent testing for IgG and IgA anti-gliadin (AGA), anti-endomysial (EMA), and anti-tissue transglutaminase (TTG) antibodies. Total serum IgA levels were also measured (Prometheus Laboratories, San Diego, CA).

Results: In this ongoing trial, 323 IBS patients and 241 controls have been enrolled. Twenty-four (7.4%) IBS patients and 7 (2.9%) controls had at least one abnormal antibody test result (p = 0.02). IgG AGA was most commonly positive (18 IBS pts and 3 controls). The diagnosis of celiac disease was confirmed by small bowel biopsy in 4 (1.24%) IBS patients and 2 controls (0.8%). Results of antibody tests in subjects with biopsy proven celiac disease are provided in the table. Antibody testing results for one patient with celiac disease were not available. None of the antibody tests identified all patients with biopsy proven celiac disease.

Conclusions: Celiac antibodies were significantly more likely to be positive in IBS patients than controls. However, the prevalence of biopsy proven celiac disease was similar between groups. No single antibody test reliably identified all individuals with biopsy proven celiac disease. As such, if screening for celiac disease is pursued in a patient with IBS, a panel of antibody tests,
rather than EMA or TTG alone, is likely to provide the greatest diagnostic yield.

1233

Tegaserod (T) Is Superior to Placebo (P) in Patients Suffering from Concomitant Bothersome Abdominal Discomfort (A), Bloating (B), and Constipation (C)

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Purpose: We investigated how T improved the bothersomeness of ABC vs P in pts suffering from all three symptoms at baseline (BL) from two chronic constipation (CC) trials.

Methods: Data from 2 T double-blind, randomized, placebo-controlled pivotal studies1,2 were pooled for analysis. Results were presented by treatment group. The patient was asked to answer the question on how bothersome each of the three symptoms were over the past week using the scale 0 = not at all, 1 = hardly, 2 = moderately, 3 = a good deal, 4 = a very great deal. A subgroup with at least a “good deal bothersome” symptoms was defined as patients who had BL values of at least 3 for all symptoms. Symptom improvement was defined based on changes from BL for the average of weeks 1–4 and weeks 1–12. A patient was considered to have improvement if the following was fulfilled:

- There was no deterioration for any symptom AND
- Reduction in bothersomeness (for at least 50% of symptoms):
  - of at least 0.5 ( = at least 12.5% improvement)
  - of at least 1 ( = at least 25% improvement)

The thresholds of improvement were selected to reflect changes above the minimum clinically meaningful threshold of improvement (10%: improvement of 0.5 point on a 5-point scale).

Results: Out of 882 T patients and 863 P patients, 859 and 845 patients, respectively, were available for classification. 397 (46.2%) T patients and 426 (50.4%) P patients were classified with “at least good deal bothersome” symptoms.

Conclusions: T was significantly superior to P and clinically relevant at relieving the ABC symptoms. These results were sustained over 12 weeks.

2. Kamm et al. AIG 2005;100:362–72
This research was funded by Novartis.

1234

Topographical Mapping of Esophageal Motor Function during Liquid and Solid Swallows Using High-Resolution, Solid-State Manometry in Patients with Non-Obstructive Dysphagia (NOD)

Michael D. Crowell, PhD,* Hack J. Kim, MD, Isaac B. Malagon, B.S., Michele Moirano, P.A.C., John DiBaise, MD, Virender K. Sharma, MD. Gastroenterology, Mayo Clinic College of Med, Scottsdale, AZ.

Purpose: High-resolution manometry (HRM) using multiple, closely-spaced, solid-state pressure sensors allows for more detailed assessment and topographical mapping of esophageal motor patterns. Most conventional EM protocols use water swallows only and may fail to elicit motor disturbances and associated symptoms. Including solid swallows may improve the diagnostic yield of HRM. We hypothesized that solid swallows would elicit dysmotility and dysphagia symptoms more often than liquid swallows in patients with NOD. We also compared physiologic parameters during liquid and solid swallows.

Methods: Consecutive NOD patients (n = 20) were evaluated using a solid-state manometric assembly with 36 circumferential sensors spaced at 1-cm intervals (Sierra Scientific, CA). Data were acquired at 35 Hz for each sensor. Prior to the study, the transducers were calibrated at 0 and 100 mmHg using externally applied pressure. The catheter was placed transnasally and pressure transducers were spanned from the oropharynx into the gastric body. The study was completed in a semi-supine position after an overnight fast. The protocol included a period of approximately 30 seconds to assess basal sphincter pressure, 10 water swallows of 5ml each and five solid swallows (cracker) in the same session. Non-parametric comparisons were made between swallow sets at the p < 0.05 level.

Results: Complete HRM data with liquid and solid swallows were available in 19 patients with NOD (11F/8M; 39 ± 13 yrs). Symptom severity was significantly increased during solid swallows (p = 0.005). Abnormal esophageal motor function was noted on 33% of liquid swallows and 94% of solid swallows. Peristalsis was disrupted on 51% of solid swallows and 24% with liquids (p = 0.002). Localized spasticity was noted more often with solids vs liquid swallows (42% vs 63%; p = 0.02). Simultaneous contractions were seen on 57% of solid swallows and 24% of liquid swallows. The onset velocity of contractions was significantly shorter with solid swallows. Contractile amplitudes tended to be lower with solids (p = 0.07).

Conclusions: Solid swallows elicited dysmotility and dysphagia symptoms more often than liquid swallows in patients with NOD. Topographical mapping of esophageal dysfunction using HRM during both liquid and solid swallows can increase the diagnostic yield in patients with NOD.

1235

Fecal Incontinence (FI) in Hospitalized Patients: Who Has It? Who Asks?

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Purpose: Fecal incontinence is a common functional gastrointestinal disorder associated with significant morbidity and impaired health related quality of life (HRQOL). The purpose of this study was to identify the prevalence of FI in patients admitted to the medical service of our hospital, to determine
how often medical residents ask about FI, and whether such information is recorded in the chart.

Methods: Forty-nine consecutive admissions to the medical service were evaluated. Patients were excluded if they were unable to communicate, or were incapable of understanding an informed consent document. All physicians caring for the patients were blinded as to the nature of the study. The study was approved by the IRB of the University of South Alabama. The study sample consisted of 57% males and 61% African-Americans, with the mean age of 49.8 (± 12). Investigators queried each patient as to the presence or absence of symptoms suggestive of fecal incontinence using a validated FI screening instrument. Investigators then reviewed the patients’ charts to document any mention as to the presence or absence of FI.

Results: Of the forty-nine subjects, fifteen (15) (31%) had FI. Only one subject had their FI documented in the medical record. Of the thirty-three (33) patients (67%) who did not have FI, none had any documentation in the chart as to that fact. Using a logistic regression analysis age (p = 0.05; OR 1.07) and female gender (p = 0.037; OR 4.5) were significantly associated with the risk of having FI. There was no significant difference in FI in African-Americans versus Caucasians. The most common medical diagnoses were cardiovascular disease (60%), endocrine disorders (20%), and renal disease (16%). Other diagnoses represented included pancreatitis, HIV infection, liver disease, cancer, and pulmonary disorders.

Conclusions: Fecal incontinence seems to be a common disorder of hospitalized patients. In our sample, physicians made essentially no attempt to query patients regarding the presence or absence of FI, and rarely documented the presence or absence of FI in the medical record. Given the implications of FI for quality of care, i.e. avoidance of pressure ulcers, etc., as well as implications for patients’ HRQOL greater attention needs to be paid in training house officers regarding this important point of the medical history.

1236

Lactulose Hydrogen Breath Testing (LHBT) in Patients with IBS and Controls: Differences in Methane (CH₄) but Not Hydrogen (H₂)

Jason Bratten, B.S., Jennifer Spanier, D.O., Michael P. Jones, MD,* Division of Gastroenterology, Northwestern University, Chicago, IL.

Purpose: Recent reports suggest that abnormalities of LHBT are common in pts with IBS and may represent bacterial overgrowth (BO). This observation requires both validation and confirmation. A recent study found poor concordance between the diagnosis of BO made using ¹⁴C-D-xylene and LHBT in IBS (Walters V, Vanner SJ. Am J Gastroenterol. 2005;100:1566). The present study examines LHBT in pts with IBS and healthy controls.

Methods: We analyzed consecutive LHBT performed in pts with IBS and performed LHBT in controls recruited by advertisement. IBS pts listed their most bothersome digestive symptoms at the time of study. LHBT was performed using 10gm of lactulose with breath samples collected every 20 minutes for a 180 minute period. Both breath H₂ and CH₄ were measured. Because of the confounding effects of CH₄-producing bacteria on H₂ production, CH₄ (+) subjects were examined separately. For CH₄ (+) subjects, LHBT was considered positive if it met any of the previously published criteria: 1. breath H₂ >20ppm; 2. increase in breath H₂ in <90 min; 3. dual peaks (12ppm increase over baseline with a decrease ≥5ppm before 2nd peak). The orocecal transit time (OCTT) was calculated as the earliest time at which a sustained increase ≥3ppm H₂ on more than 3 consecutive measurements was seen.

Results: 175 pts with IBS and 23 controls were studied. 37/175 (21%) IBS pts were CH₄ (+) compared with 2/23 (9%) controls (p = 0.16). CH₄ (+) IBS pts were significantly more likely than CH₄ (+) IBS pts to have constipation (OR = 2.61 [1.24–5.54]; p = 0.01) and significantly less likely to have diarrhea (OR = 0.28 [0.13–0.63]; p = 0.001) but the association did not hold for symptoms of bloating or pain. OCTT (mean ± SEM) did not differ significantly between IBS pts and controls (93 ± 5 vs. 89 ± 13; p = 0.75). Pts and controls did not differ significantly with respect to the frequency of a positive study defined by increase in breath H₂ >90min (78/138 vs. 8/21; p = 0.24); increase in breath H₂ ≥20ppm (65/138 vs. 13/22; p = 0.3) or dual peaks (15/138 vs 4/21; p = 0.28).

Conclusions: CH₄ production was more common in IBS pts than controls and was associated with constipation. IBS pts and controls did not differ significantly with respect to OCTT or any of the previously published criteria for a LHBT diagnostic of bacterial overgrowth. The diagnostic utility and clinical relevance of LHBT in IBS requires further study. Accrual of subjects is ongoing to strengthen these observations.

1237

A Randomized Double-Blind Placebo-Controlled Trial of Imipramine in Patients with Irritable Bowel Syndrome

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Purpose: To study the efficacy of low-dose Imipramine in relieving symptoms associated with the irritable bowel syndrome (IBS). Methods: Randomized double-blind trial of 25 mg imipramine vs. matched placebo for 12 weeks. Doubling the dose was allowed once at week 2 if necessary. Primary efficacy variables were subjective global symptom relief at week 12 and general quality of life questionnaire (SF-36) compared to baseline.

Results: 107 patients were enrolled by advertisement or upon referral by general practitioners and 56 (31 imipramine: 25 placebo) completed the 16-week study. Baseline characteristics were comparable. A high overall drop-out rate was noted in the imipramine and placebo arms (47.5% vs. 47.9%, p = NS) a mean of 25.0 and 37.4 days from enrollment respectively (p = 0.026). Adherence to treatment was less common amongst self-referred patients. At the end of 12 weeks, there was a significant difference in global symptom relief with imipramine over placebo (per-protocol: 80.6% vs. 48.0%; p = 0.01, and intent-to-treat: 42.4% vs. 25.0%, p = 0.06). This improvement was evident early and persisted by week 16 (p = 0.02 and 0.053 for PP and ITT analyses respectively). Mean cumulative and component-specific SF36 scores improved significantly only in the imipramine group (p < 0.01). Drug-related adverse events leading to patient drop-out were more common in the imipramine group (25.4% vs. 12.5%; p = NS).

Conclusions: This study suggests that imipramine is effective in the treatment of IBS patients and is associated with improved quality of life. Careful patient selection, gradual dose escalation and monitoring are likely to result in improved therapeutic response.

1238

Benefits of the Antibiotic Rifaximin as Empiric Therapy in Patients with Irritable Bowel Syndrome

George Barrett, MD,* Gastroenterology/Internal Medicine, Milton Hospital, Milton, MA.

Purpose: Irritable bowel syndrome (IBS) affects ∼58 million individuals in the United States, and data suggest a possible role for intestinal bacteria in the pathogenesis/clinical symptoms of IBS. Rifaximin (Xifaxan®; Salix Pharmaceuticals, Morrisville, NC) is a nonsystemic (<0.4% absorption), gut-selective, well-tolerated antibiotic with broad-spectrum activity against gram-positive and gram-negative aerobic and anaerobic organisms. Due to limited data available on potential benefits of rifaximin treatment in combination with probiotics in patients with IBS, a retrospective chart review was conducted from November 2004 to September 2005 to identify patients with IBS fulfilling Rome II criteria who were treated with rifaximin.

Methods: Eight patients were identified (21 to 73 years of age) with a history of IBS for >1 year. Patients were classified as IBS associated with diarrhea (n = 5) or IBS with alternating diarrhea and constipation (n = 3). Comorbidities included gastroesophageal reflux disease (n = 4), lactose intolerance/peptic ulcer (n = 1), pancreatitis (n = 1), Schatzki’s ring...
(n = 1), and infection with human immunodeficiency virus (n = 1). Previous IBS therapy included probiotics (n = 3) or high-fiber diet (n = 1). Patients were empirically treated with rifaximin 400 mg 3 times daily for a mean of 2.5 months (range, 1 to 5 months) in combination with a probiotic (Flora-Q™, Kenwood Therapeutics, Fairfield, NJ) administered once- (n = 7) or twice-daily (n = 1).

**Results:** Rifaximin use resulted in complete resolution of clinical symptoms in 4 patients, with no IBS relapse (follow-up, 1 to 6 months). Partial symptom improvement was observed in 4 patients, 3 of whom were treated for an additional 2 months with rifaximin 400 mg three times daily cycle therapy (2 weeks on/1 week off; with 1 patient also receiving a probiotic) which resulted in a 50% to 70% improvement from baseline. Rifaximin treatment was well tolerated, with no discontinuations or disruptions in the treatment regimen and no reports of rifaximin-related adverse events. All 8 patients remain on probiotic once-daily maintenance therapy.

**Conclusions:** This chart review suggests that some patients with IBS may benefit from rifaximin and probiotic combination therapy. Given the low risk for clinical resistance and positive rifaximin attributes described above, further studies on the potential benefit of this nonsystemic antibiotic for IBS are warranted.

**1239**

**Alvimopan, a Peripherally Acting Mu-Opioid Receptor (PAM-OR) Antagonist – A Study in Patients with Chronic Idiopathic Constipation (CIC) Not Taking Opioid Medication**

**Dennis Kelleher, PhD, John Johanson, MD*, Bonnie Pobiner, PhD, Eric Carter, PhD, George Dukes, PhD** Gastroenterology, GlaxoSmithKline, Research Triangle Park, NC and Rockford Gastroenterology Associates Ltd., Rockford, IL.

**Purpose:** Alvimopan is an investigational oral PAM-OR antagonist, which has been shown to block the effects of exogenous opioids in the gut. Binding of opioids to mu-opioid receptors in the GI tract results in decreased GI motility and gastric secretions, causing a constellation of GI side effects, particularly constipation. Results from study SB-767905/011 (011) in opioid-treated subjects (n = 522) with persistent non-cancer pain showed a significant increase in mean spontaneous bowel movement (BM) frequency ranging from 3.39 to 4.34 in all alvimopan treatment groups during the 6 wk treatment period vs 1.71 in the placebo group (p < 0.001). Additional bowel symptoms, such as straining, stool consistency, and incomplete evacuation were also improved, while opioid-induced analgesia was unaffected. Study SB-767905/007 (007), presented here, tested the hypothesis that alvimopan relieves bowel symptoms in subjects with CIC by antagonizing endogenous opioids.

**Methods:** This randomized, double-blind, placebo-controlled study evaluated alvimopan 1mg BID, 3mg BID or 5mg BID for 8 wks in 217 subjects ≥18 yrs old with ≥6-month history of CIC (<3 month complete SCBMs per wk plus straining and/or hard stool consistency associated with ≥25% of all BMs) not taking opioids. Primary endpoint was change in mean weekly SCBM frequency from baseline during the first 4 wks of treatment.

**Results:** At baseline, mean weekly SCBM frequency was 0.5–0.7 throughout the treatment groups. During wks 1–4 there were no significant differences in mean weekly SCBM frequency between any alvimopan dose and placebo (Table). Alvimopan did not affect other bowel symptoms including degree of straining or stool consistency. Alvimopan was generally well tolerated, with a safety profile similar to placebo.

**Mean Weekly SCBM Change (Weeks 1–4)**

<table>
<thead>
<tr>
<th>Dose</th>
<th>Change (mean/SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo (n = 53)</td>
<td>0.87</td>
</tr>
<tr>
<td>1mg BID (n = 55)</td>
<td>0.95*</td>
</tr>
<tr>
<td>3mg BID (n = 55)</td>
<td>0.76*</td>
</tr>
<tr>
<td>8mg BID (n = 54)</td>
<td>0.80*</td>
</tr>
</tbody>
</table>

*p = 0.822 vs placebo

**Conclusions:** Alvimopan provided clinical relief of constipation and associated BM symptoms in subjects receiving opioids (study 011), but no clinical effect was seen in subjects with CIC not taking opioids (study 007). Although endogenous opioids may play a role in modulation of GI function, antagonism of this pathway with alvimopan does not relieve constipation unrelated to exogenous opioids.

**1240**

**Cortical Evoked Potentials (CEP) and Transcranial Motor Evoked Potentials (MEP) – A Novel Test of Brain-Gut Axis in Humans**

Jose M. Remer-Troche, MD, Jessica Paulson, Megan J. Miller, Thoru Yamada, MD, Shaheen Hamdy, MD, Sattish S.C. Rao, MD, F.A.C.G.,* Division of Gastroenterology-Hepatology, Department of Internal Medicine, University of Iowa, Carver College of Medicine, Iowa City, IA; Neurology, University of Iowa Carver College of Medicine, Iowa City, IA and Gastrointestinal Sciences, University of Manchester, United Kingdom.

**Purpose:** Recently, the brain-gut axis has been implicated in the pathogenesis of functional colorectal disorders. Although fMRI and PET scans provide invaluable insights, there is no comprehensive technique that characterizes afferent and efferent brain-gut axis. We designed a novel and comprehensive test for assessing both cortical function and brain-gut interactions in humans.

**Methods:** In 12 healthy volunteers (9 F, mean age 37 yrs), cortical evoked potentials (CEP) were assessed by electrical stimulation of the ano-rectum with a novel probe containing 2 pairs of bipolar steel ring electrodes, each 2 cm apart. The proximal electrodes were located at 10 cm and the distal pair at 1 cm from anal margin. The efferent brain-gut function was assessed by recording anal and rectal motor evoked potentials (MEP) with the aforementioned probe after transcranial magnetic stimulation (TMS). CEP’s were sampled at 2000 Hz with an epoch duration of 500 ms. TMS was performed using a 70 mm figure eight coil, positioned over the right and left motor cortex using 80–100% stimulator intensity (2.2 Teslas). The anorectal sensory thresholds for first perception and pain (mA), latencies (milliseconds) and amplitudes (μV) for the CEP and MEP anorectal responses were recorded. The positive CEP potentials were labeled as P1 and P2, and negative potentials as N1 and N2.

**Results:** Anal sensory threshold for first perception and pain were 6 ± 2 mA and 18 ± 3 mA, respectively. Rectal sensory threshold for first perception and pain were 15.5 ± 5 mA and 33 ± 14 mA. The mean latencies (± SD) for onset of P1, N1, P2 and N2 as well as for the MEP response are displayed in Table 1. The average duration of test was 3 hours.

**Conclusions:** Our technique of combined CEP and MEP evaluation provides a novel integrated, comprehensive and objective method of neurophysiological assessment of gut-brain-gut interactions. It is a simple, less costly and alternative method of assessing relationships between the gut and brain.

<table>
<thead>
<tr>
<th></th>
<th>CEP Latencies (ms)</th>
<th>CEP Amplitude (μV)</th>
<th>MEP Latency (ms)</th>
<th>MEP Amplitude (μV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1</td>
<td>51 ± 5</td>
<td>40 ± 5</td>
<td>20 ± 3</td>
<td>5 ± 3</td>
</tr>
<tr>
<td>N1</td>
<td>65 ± 7</td>
<td>33 ± 7</td>
<td>25 ± 5</td>
<td>5 ± 3</td>
</tr>
<tr>
<td>P2</td>
<td>78 ± 9</td>
<td>40 ± 5</td>
<td>23 ± 3</td>
<td>5 ± 3</td>
</tr>
<tr>
<td>N2</td>
<td>96 ± 12</td>
<td>30 ± 4</td>
<td>35 ± 15</td>
<td>5 ± 3</td>
</tr>
</tbody>
</table>

Mean ± SD

**1241**

**Racial Disparities in the Presentation of Irritable Bowel Syndrome**

Srikanth Mudanna, MD, Robert Chehade, MD, Howard Cabral, PhD, Horst C. Weber, MD,* Medicine, Boston University School of Medicine, Boston, MA and Biostatistics, Boston University School of Public Health, Boston, MA.

**Purpose:** Irritable bowel syndrome (IBS) is a common gastrointestinal disorder with major effects on lifestyle and health care burden. Studies of IBS symptom patterns suggested specific, yet widely different frequencies...
of IBS subgroups, including constipation-predominant (IBS-C), diarrhea-predominant (IBS-D) and alternating bowel habits (IBS-A). Because there is a great knowledge gap regarding IBS prevalence rates and sub-typing among different racial groups, this study was aimed to determine IBS subtype patterns among different racial groups.

Methods: A retrospective, cross-sectional study of IBS subtype symptom patterns in a large, multi-racial patient population was performed. Electronic medical records of all patients at Boston Medical Center (BMC) older than 18 years with the diagnosis of IBS were reviewed and a total of 391 patients were enrolled in this study. At the time of this submission, the analysis included data from 70 patients. Statistical analysis of data included cross-tabulations of ethnic group with our primary endpoint, IBS-D, IBS-C, and IBS-A and chi-square and Fisher's exact tests. Multivariable analyses using log-linear models and logistic regression analysis were performed.

Results: In contrast to our general patient population at BMC (42% Whites, 37% Blacks, and 21% Hispanics), our IBS cohort included 78% Whites, 9% Blacks, 3% Hispanics and 10% Asians. There is a female predominance (70%), mean age was 48 years [SD = ±18] and age of IBS diagnosis was 43 years [SD = ±18]. Most patients (n = 37) had unspecified IBS, whereas IBS-D was predominant in others (IBS-D [n = 18], IBS-D [n = 8] and IBS-A [n = 7]). In Whites, 54% had IBS-D, 19% IBS-C and 27% IBS-A. Black patients had 75% IBS-D and 25% IBS-C, whereas in Asians 33% IBS-D and 67% IBS-C was observed. In 50% of this cohort (n = 35) as history of psychiatric disorder was found, 39% had depression and 30% anxiety. Common medication included SSRIs (11%), antidepressants (37%) and antianxiety drugs (20%). Treatment included fiber (15%), stool softener (7%) and dietary modifications (42%).

Conclusions: This preliminary analysis of a retrospective study on IBS in a multi-racial patient population suggests that there might be racial disparities in IBS subgroup distribution. In this cohort the diagnosis of IBS was not based on the presence of accepted symptom criteria in a significant proportion of patients. A majority of IBS patients have significant psychiatric co-morbidities.

1242

Escalated Dosing of Tegaserod for the Treatment of Gastroparesis
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Purpose: Gastroparesis (GP) is a common problem with a relatively poor selection of therapeutic agents. Tegaserod, a selective 5-hydroxytryptamine-4 (5HT4) receptor agonist, is known to stimulate gastrointestinal transit, particularly in constipation predominant irritable bowel syndrome. There are suggestions that tegaserod may likewise be useful in the treatment of GP, however there are few published data describing its use in this disorder. We report here, our experience using tegaserod, by means of a gradual dose escalation strategy, to treat GP.

Methods: GP patients treated with tegaserod were included for review if: (1) they received a diagnosis of GP based on symptoms and abnormal gastric emptying times and (2) they agreed to undergo repeat gastric emptying scans. Tegaserod was initiated at 6mg TID with step-wise dose increases of an additional 6mg TID (max. 24mg TID), as necessary based on persistent symptoms. Gastric emptying studies were performed at the time of the initial consultation, within one week of each dose adjustment, and upon resolution of GP symptoms.

Results: Twenty-three of 33 patients reviewed consisted of 25 women and 8 men with an average age of 45.4 years. GP was identified as idiopathic (n = 23) or secondary to diabetes (n = 6), vagal injury (n = 2), or scleroderma (n = 2). At the time of the initial consultation, 5 patients were receiving tegaserod 6mg TID and 28 were receiving no therapy. Baseline gastric emptying scans found the mean gastric emptying at 60 mins. to be 12.7% (range 0–37%) with estimated T2 1/2 emptying times ranging from 100 mins. to “infinity.” All patients achieved symptom resolution using dose escalation over an average of 3.3 months (range 7 days to 10 months). Doses required to achieve symptom resolution were 6mg TID (n = 19), 12mg TID (n = 12) and 24mg TID (n = 2). Gastric emptying scans at the time of symptom resolution found the mean gastric emptying at 60 mins. to be 53.2% (range 25–100%) with estimated T2 1/2 emptying times ranging from 14 mins. to 110 mins. Normalization of gastric emptying (T2 1/2 < 90 mins.) occurred in 78.8% (26/33) of patients. No significant side-effects were noted during treatment.

Conclusions: Our results suggest that tegaserod can be successfully used in the treatment of GP, a disorder which otherwise has few satisfactory therapies. A strategy of dose escalation, beyond standard doses used for irritable bowel syndrome, resulted in symptom resolution in 100% of patients and normalization of gastric emptying times in 78.8% of patients.

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Risk Factors for Chronic Constipation
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Purpose: Constipation has an estimated average prevalence in the general population of 15%; however, the etiopathogenesis of this condition remains relatively obscure. The objective of this study was to identify potentially novel risk factors for chronic constipation.

Methods: A valid self-report questionnaire that recorded gastrointestinal (GI) symptoms required for a diagnosis of constipation, self-reported measures of potential risk factors, and a somatic symptom checklist (SSC) was mailed to an age- and gender-stratified random sample of Olmsted County, Minnesota residents aged 30–64 yr. A logistic regression model that adjusted for age, gender, and SSC score was used to identify factors associated with chronic constipation and compute Odds Ratios (OR) [95% Confidence Intervals] for chronic constipation. People reporting symptoms of irritable bowel syndrome were excluded from the analysis.

Results: A total of 643 (72%) of 892 eligible subjects returned the survey. Among the 523 subjects not reporting IBS symptoms, chronic constipation was reported by 93 (18%) of the respondents. Chronic constipation was significantly associated with use of acetaminophen (≥7 tablets/week, OR = 2.7[1.6,6.1]); aspirin use (OR = 1.7[1.0,2.7]); the use of nonsteroidal anti-inflammatory drugs (OR = 1.8[1.3,2.0]); and exposure to cats in the household (OR = 1.6[1.0,2.6]). No association was detected for age, gender, body mass index, family history, smoking history, alcohol use, coffee use, education level, food, allergy history, exposure to dogs in the household, stress, emotional support, or water supply.

Conclusions: Chronic constipation is associated with use of acetaminophen and nonsteroidal anti-inflammatory drugs. Chronic constipation is also associated with household exposure to cats. The roles of these factors require further investigation.

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Further Characterization of Painful Functional Constipation (PFC): Clinical Features over One Year and Comparison with IBS
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Purpose: Patients with painful functional constipation (PFC) differ from those with painless constipation in having poorer health related quality of life and more somatic symptoms (Bharucha Am J Gastro, 2006). The aim was to further characterize clinical features of PFC over time and relative to IBS, another painful disorder. We sought to: 1) compare PFC with IBS and its subtypes, 2) determine clinical features of PFC over time, and 3) compare PFC patients with high (HP) and low (LP) pain scores.
Methods: From 231 women in an NIH trial, Rome II moderate to severe PFC (n = 41), IBS-A (n = 55), IBS-C (varies between IBS-C or IBS-mixed over 1 year; n = 80) and IBS-D (between IBS-D or IBS-mixed; n = 55) received diary cards on stool frequency, consistency and pain (VAS) daily for 14 days pre-and post 12-wk treatment and at 3-mo intervals for 1 yr. PFC was characterized into HP and LP groups by a median split of VAS pain scores. Descriptive statistics were calculated, and comparisons performed by χ² for categorical and t-tests for continuous variables. Linear regression and repeated measures tested between- and within-group associations respectively.

Results: a) PFC differs from IBS with: higher pain scores (p = 0.002), lower education (p = 0.02), greater health care use and surgeries (p = 0.05 to 0.003), and poorer daily function (SIP Overall p = 0.004). b) PFC is similar to IBS-C and IBS-A but different from IBS-D for stool frequency and consistency (p < 0.0001), bloating (p = 0.02), laxative/anti-diarrheal use (p = 0.04 and 0.02) and lower education (p = 0.02). c) Over 1 year, PFC: maintained higher pain scores than IBS, had stool frequencies less than IBS-D and between IBS-C and IBS-A, had stool consistency less than IBS-D and similar to IBS-A. d) For HP and LP PFC there was no difference in constipation, and HP switched to LP over time, while LP stayed low. Limitations include the absence of a painless constipation group, and studying moderate to severe symptoms which may not represent all with PFC or IBS.

Conclusions: PFC is clinically similar in stool pattern and bloating to IBS-C and IBS-A, but different from IBS with greater pain, health care utilization and poorer daily function. Over 1 year, stool frequency/consistency of PFC is stable, but HP scores decreased. Supported by NIH: 1R01DK49334 and R24 DK067674, GCRC 000024 and Novartis Pharmaceuticals

1245

Red Flags in the Diagnosis Irritable Bowel Syndrome: Is Proper Documentation Taking Place?
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Purpose: Irritable bowel syndrome (IBS) is a common medical disorder, occurring in 10−15% of the adult US population. The Rome criteria have become the standard for clinical diagnosis of this disorder. The appropriate diagnosis of IBS requires the screening and absence of warning signs, or ‘red flags’. In one study, the positive predictive value for the diagnosis of IBS using the initial Rome criteria and excluding ‘red flags’ over 1-year follow-up was 98% [Vanner, 1999]. Although excluding ‘red flags’ is critical to the diagnosis of IBS, their use in clinical practice has not been studied. Our aim was to assess the frequency with which both primary care physicians and Gastroenterologists appropriately rule out ‘red flags’ in diagnosing IBS.

Methods: The medical records of 52 cases of IBS diagnosed over the past five years at our institution were reviewed. The chart was reviewed for documentation of ‘red flags’ as listed in Table 1. For each case details of IBS diagnosis and co-morbid conditions were recorded from the physicians note. Statistical significance was determined using two sample t-tests.

Results: In only 3 (6%) patients diagnosed with IBS were all 7 ‘red flags’ were excluded. The mean number of documented red flags were 4.2 (range 0−7). The number of red flags excluded was not correlated with diagnosis by primary care or gastroenterology, patient gender, presenting symptom, or co-morbid auto-immune disorder. However, the number of red flags excluded was increased in patients with co-morbid psychiatric disorders, mean 4.8 vs. 3.9, p = 0.03. The prevalence of documentation of individual ‘red flags’ is noted in Table 1.

Conclusions: Despite established guidelines, physicians are incompletely documenting the absence of ‘red flags’ in the diagnosis of IBS. The frequency of documentation for individual signs and symptoms ranged from 94% to 29% and only 6% had all appropriately noted. There was no difference in documentation practices between primary care physicians and gastroenterologists and with the exception of psychiatric disorders, there was no influence of patient characteristics. This suggests the need for improved documentation by all physicians in the diagnosis of IBS.

1246

Tegaserod Is Efficacious in Patients with Chronic Constipation as Measured by SBM
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Purpose: Tegaserod (T) is indicated in the treatment of chronic idiopathic constipation in adult men and women less than 65 years of age. In pivotal trials, tegaserod has been proven effective in patients with chronic constipation (CC) based on the primary endpoint of improvement of at least 1 complete spontaneous bowel movement (CSBM)/wk over wks 1–4. This endpoint assesses the quantity of bowel movements that are spontaneous or non-laxative induced and the quality of bowel movements by assessing the feeling of complete evacuation. However, many trials have used spontaneous bowel movements (SBMs) as an endpoint and many practitioners use a threshold of <3 SBM/wk to diagnose constipation. The purpose of this analysis is to assess T’s efficacy to improve SBM frequency to >3 SBM/wk.

Methods: Data from two 12-wk, randomized, placebo-controlled, double-blind clinical trials in CC, for T 6 mg bid and placebo (P), were pooled. Data were analyzed for the intent-to-treat population with <3 SBM/wk at baseline (BL) (the original trials selected patients based on <3 CSBM/wk). A responder was defined as having a mean value of at least 3 SBM/wk during the treatment phase. Weekly response rate was compared between T and P using the Cochran-Mantel-Haenszel test.

Results: Of 882 T patients and 863 P patients, 481 and 450 patients, respectively, fulfilled the criteria for this analysis. T showed statistically significantly superior response rates vs P at each of the 12 wks (p < 0.001) at increasing stool frequency to >3 SBM/wk.

Conclusions: T 6 mg bid, as compared with P, provided significantly better weekly response rates at increasing SBM frequency above the 3 SBM/wk threshold. This effect was rapid, evident from the first wk, and was also sustained over the 12 wks of the study. This research was funded by Novartis.

1247

Tegaserod Improves GI Symptoms throughout the Menstrual Cycle
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Purpose: Tegaserod (T) is safe and effective for multi-symptom (sx) relief of chronic idiopathic constipation and IBS-C. Women with IBS-C have more

### Table 1: Documentation of Individual ‘Red Flags’

<table>
<thead>
<tr>
<th>Red Flag</th>
<th>Normal Physical Exam</th>
<th>Appropriate Cancer Screening</th>
<th>No Weight Loss</th>
<th>No Fever</th>
<th>Stool Hemoccult Negative</th>
<th>No Recent Antibiotics</th>
<th>No Nocturnal Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Documented</td>
<td>94%</td>
<td>75%</td>
<td>65%</td>
<td>62%</td>
<td>60%</td>
<td>33%</td>
<td>29%</td>
</tr>
</tbody>
</table>
severe GI sx during the menstrual cycle (MC) and the premenstrual period vs. women without IBS. We explored the effect of T on relief of GI-related sx during MC in IBS-C patients (pts).

Methods: Safety and efficacy of repeated treatment with T was assessed in IBS-C pts in a randomized, double-blind, placebo (P)-controlled multicenter study, with a 2-wk baseline (BL), and two 4-wk treatment periods (P1, P2), separated by a treatment-free interval (TFI). Only P1 pts with ≥ partial response entered TFI and when sx recurred were re-randomized to P2.

Pre-menopausal pts were included in a sub-analysis of relief of abdominal discomfort/pain (ADP) and of overall IBS sx during their MC while on 4 wks of treatment for P1 and P2. Start of menstruation was defined as day 1 of MC. ADP was measured by a weekly yes/no question: “Did you have satisfactory relief of ADP during last week?” A similar weekly question was asked for relief of overall IBS sx: “Did you have satisfactory relief of IBS overall sx during last week?” Response rates were compared using a Generalized Estimating Equations Method.

Results: Results showed a higher response rate for T vs. P for all 4 wks of treatment in P1 and P2 for satisfactory relief of ADP. Results were similar for overall relief of IBS sx (contains bloating relief as a major component).

Conclusions: T demonstrated relief of ADP and overall IBS sx over P during each wk of the MC in pre-menopausal IBS-C pts. Results were consistent and sustained over each wk of the MC when partial responders were re-challenged. This research was funded by Novartis.

### 1249

Tegaserod Improves Symptoms in Patients with IBS-C with Severe Baseline Abdominal Pain/Discomfort and Bloating

**Purpose:** Tegaserod (T) has been shown to be safe and effective in the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation. As IBS patients (pts) with severe symptoms at baseline (BL) may be at greatest need for treatment, we explored the effect of T in a subset of pts with severe abdominal pain/discomfort (ADP) and bloating at BL.

**Methods:** In a randomized, double-blind, placebo (P)-controlled multicenter study, we assessed the safety and efficacy of repeated T treatment in IBS-C women: 2-wk BL, and two 4-wk treatment periods (P1, P2), separated by a treatment-free interval (TFI). Only P1 pts with ≥ partial response entered TFI and when symptoms recurred were re-randomized for P2. An ADP responder was a pt who recorded satisfactory relief for ≥ 2 of the first 4 wks in P1 or P2. We measured bloating on a 7-point scale (0–6, severe defined as score ≥4) with a daily question: “How intense was your bloating today?” A bloating responder had an average ≥1-point/wk improvement from BL. A pre-specified sub-analysis evaluated relief of ADP and improvement of bloating symptoms in pts with severe ADP and severe bloating at BL in P1 and P2. Response rate for T and P were compared using logistic regression.

**Results:** Our analysis showed improvement in pts with severe ADP at BL, in both P1 and P2, for relief of their ADP and bloating symptoms. Similar results were seen in severe bloating at BL for relief of ADP and bloating symptoms (Table 2).

**Conclusions:** In pts with severe ADP or bloating at BL, T showed significant improvement as compared with P in pts with IBS-C, in the relief of ADP and bloating symptoms in the first 4 wks of treatment, and when responders were re-challenged. This research was funded by Novartis.

### 1248

Assessing Global Change and Symptom Severity in Subjects with IBS: Qualitative Item Testing

Sheri Fehnel, PhD,* Jeff Johnston, MD, Caroline Kurtz, PhD, Allen Mangel, MD. RTI Health Solutions, RTI International, Research Triangle Park, NC and Development, Microbia, Inc., Cambridge, MA.

**Purpose:** Patient-reported outcome (PRO) measures have become increasingly important in the evaluation of clinical response in IBS treatment trials. The goal of this study was to identify optimal PRO endpoints for use in clinical trials of a new treatment for patients with IBS-constipation predominant (IBS-C) and to investigate patients’ interpretation of these items.

**Methods:** Two iterative sets of interviews were conducted with 16 IBS-C patients to evaluate items addressing global change (8 items), global severity (4 items), and severity of 7 specific symptoms (12 items). All global items utilized a 24-hour reference period, whereas symptom-specific items utilized either a 24-hour reference period or the patient’s last bowel movement. During the interviews, participants verbalized their thoughts while responding to each item and answered follow-up questions to more fully elucidate the response-process. The results of the first set of 8 interviews were presented to an Advisory Board of experts in the area of IBS. A number of items were modified or eliminated; 15 items were evaluated in the second set of 8 interviews.

**Results:** A dichotomous item assessing “adequate” relief of IBS symptoms was easily answered by all participants; responses were typically driven by the symptom(s) most bothersome to the individual. While the alternative construct of global relief or improvement/worsening in items with balanced, ordinal response scales was well understood, some participants had difficulty answering without the specification of a previous time period; others answered easily but compared to different time periods (e.g., prior to initiation of treatment, previous 7 days). Nonetheless, most of the patients preferred the Likert-type response scales, noting that they were more descriptive and specific. Additional findings related to the measurement of symptom severity. For example, “pain” and “discomfort,” historically assessed together as a single construct, were interpreted by 14 of 16 participants as two distinct symptoms.

**Conclusions:** A dichotomous “adequate relief” item was the most consistently interpreted item assessing global change. Although Likert-type items have the potential to be more sensitive, a comparative reference period must be specified to minimize measurement error. The results of this evaluation also support the separate assessment of IBS-related pain and discomfort. Future efforts will evaluate the psychometric properties of the final item set.
Severe bloating at BL (% of pts) | P1 | P2 | p-value | P1 | P2 | p-value
--- | --- | --- | --- | --- | --- | ---
Relief of ADP | 48.7 | 33.7 | <0.0001 | 57.8 | 40.6 | <0.0001
Improvement in bloating (% of pts) | 59.9 | 45.6 | 0.0129 | 68.1 | 51.9 | <0.0001

### 1250

**Differences in Clinical Parameters between IBS with Constipation and IBS with Mixed Bowel Habits**

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**Purpose:** IBS pts are subgrouped by their predominant bowel pattern. Rome II criteria have defined subgroups for IBS with constipation (IBS-C) and IBS with diarrhea (IBS-D), but 30–40% of IBS pts with a mixed bowel pattern (IBS-M) do not fit into these subgroups. Efforts to define IBS-M pts are confounded by ongoing treatment interventions during data collection. This study evaluated the clinical characteristics and natural history of symptoms in IBS-C and IBS-M pts not receiving medications for their IBS.

**Methods:** 332 women (165 IBS-C [Rome II], 167 IBS-M [not IBS-C or IBS-D by Rome II]) randomized to placebo (P) as part of a larger study were included in this post-hoc analysis. Data were collected during a 2-wk baseline (BL) period followed by a 4-wk period where pts received P or P. P had the following features recorded: abdominal discomfort/pain, bloating, bowel movement frequency, stool consistency, straining, and urgency.

**Results:** IBS-C and IBS-M pts had clear differences in bowel habit features (stool frequency, consistency, straining, urgency) likely related to the enrollment criteria used to define the P period. IBS-M pts had a slightly lower weekly mean abdominal discomfort/pain score during BL than IBS-C pts. Abdominal discomfort/pain scores were not different during the 4-wk P period. Bloating scores were similar between groups throughout the study.

**Conclusions:** IBS-M and IBS-C have differences in clinical characteristics that are maintained over 6 wks. Overall, IBS-M pts have greater stool frequency, softer stool consistency, less straining, and more urgency than IBS-C pts. IBS-M and IBS-C pts have similar degrees of abdominal discomfort/pain and bloating. These observations may have important implications when designing treatment trials and outcome measures in pts with IBS. This study was funded by Novartis Pharmaceuticals.

### 1251

**Chronic Constipation Is Associated with Poorer Survival in a U.S. Population**

*Joseph Y. Chang, MD, G.R. Locke, III, MD, Cathy D. Schleck, B.S., Alan R. Zinsmeister, PhD, Nicholas J. Talley, MD, PhD.* Division of Gastroenterology and Hepatology, Mayo Clinic College of Medicine, Rochester, MN and Department of Health Sciences Research.

**Purpose:** We aimed to evaluate the association of reporting constipation symptoms with survival.

**Methods:** Between 1988 and 1993, valid gastrointestinal (GI) symptom surveys were mailed to randomly selected cohorts of Olmsted County, Minnesota residents. Survey responses were used to identify respondents with chronic constipation based on Rome II criteria. At baseline, the medical records were reviewed and those with serious diseases were excluded. Minnesota administrative death records were used to identify which of the survey respondents had died over the follow-up period (through November 2004). The association between survival and chronic constipation was assessed using proportional hazards regression to compute hazard ratios (HR [95% Confidence Intervals]) adjusting for age at time of survey, gender, smoking, gastroesophageal reflux (GER), marital status, and Charlson Comorbidity Index.

**Results:** A total of 3933 (79% response rate) responded to the surveys. Of the 3311 subjects who did not report constipation, the median age at time of survey was 50 years and 50% were female. For the 622 subjects reporting chronic constipation, the median age at survey was 65 years and 60% were female. A univariate association was detected between constipation and survival (p < 0.001, log rank test). The product limit estimate of survival at 10 years was 73% among those reporting constipation, versus 85% in subjects not reporting constipation. With adjustment for age and gender, constipation was still associated with worse survival (HR = 1.20 [95% CI: 1.03–1.40]). This association was not appreciably altered when adjusting for other potential confounders such as smoking, GERD, and marital status. This association was attenuated when adjusting for the Charlson Comorbidity Index (HR = 1.16 [95% CI: 0.99–1.35]). However, even in subjects without any of the Charlson comorbidities, the 10 year survival rates were 85% and 93% for those with and without constipation, respectively (p < 0.001, log rank test).

**Conclusions:** Constipation is associated with significantly poorer survival. This association remained impressive even when adjusting for age, gender and comorbidities. The etiopathogenesis for this association requires further investigation.

This research was supported in part by an unrestricted grant from Novartis.

### 1252

**Epidemiology of Slow and Fast Colonic Transit in a Community**

*Rok Seon Choung, MD, G.R. Locke, III, MD,* Cathy D. Schleck, B.S., Alan R. Zinsmeister, PhD, Nicholas J. Talley, MD, PhD. Division of Gastroenterology and Hepatology, Mayo Clinic College of Medicine, Rochester, MN and Division of Biostatistics, Department of Health Sciences Research, Mayo Clinic College of Medicine, Rochester, MN.

**Purpose:** We aimed to estimate, in the general population, the proportions of subjects with slow and fast colonic transit using stool form, and potential risk factors.

**Methods:** Using the data resources of the Rochester Epidemiology Project, a validated self-report GI symptom questionnaire was mailed to 4196 randomly selected members of the community. One question asked the subject to self-report their stool form using the Bristol Stool Scale. Slow colonic transit was defined by reporting stool form of 1 or 2 and fast colonic transit by reporting stool form of 6 or 7 on this scale. The associations between predictors and colonic transit by stool form were determined in a logistic discriminant analysis.

**Results:** A total of 2270 (54%) subjects returned a survey and completed the stool form question. Overall 18.1%, 8.7% and 73.2% met stool form...
criteria for slow colonic transit, fast colonic transit, or normal colonic transit, respectively. Those with slow colonic transit, fast colonic transit and normal colonic transit had a mean age of 63 (± 13) years, 60 (± 12) years, and 62 (± 12) years, while female were 62%, 57%, and 50%, respectively. Increased odds for slow colonic transit relative to normal colonic transit were observed for higher somatic symptom checklist (SSC) score, while decreased odds for slow transit were observed with greater BMI and male gender (table). An increased odds for fast colonic transit was observed with smoking history, higher SSC score, greater BMI, and a history of cholecystectomy (table).

**Conclusions:** Nearly one in five in the community have slow colonic transit, while one in 12 have fast colonic transit based on stool form assessment. Fast transit is linked to obesity, somatization, smoking and past cholecystectomy. Supported by Novartis.

Predictors of transit Groups: Odds ratios (OR [95%CI], adjusted for other variables listed)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Slow colonic transit</th>
<th>Fast colonic transit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (per 10 years)</td>
<td>1.07 [0.99,1.18] *</td>
<td>0.88 [0.77,1.102]</td>
</tr>
<tr>
<td>Male gender</td>
<td>0.59 [0.46, 0.76] *</td>
<td>0.90 [0.64, 1.27]</td>
</tr>
<tr>
<td>BMI</td>
<td>0.97 [0.95, 0.99] *</td>
<td>1.03 [1.01, 1.05] *</td>
</tr>
<tr>
<td>High SSC score</td>
<td>1.59 [1.25, 2.01] *</td>
<td>2.23 [1.68, 2.96] *</td>
</tr>
<tr>
<td>Cholecystectomy</td>
<td>0.95 [0.64, 1.39]</td>
<td>1.76 [1.2, 2.75] *</td>
</tr>
<tr>
<td>Smoking</td>
<td>0.89 [0.55,1.44]</td>
<td>1.89 [1.14,3.13] *</td>
</tr>
</tbody>
</table>

* p < 0.05

**1253**

**Atypical GERD and Women: Reflux vs. “Irritable Esophagus”**

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**Gastroenterology, Hepatology and Nutrition, Winthrop University Hospital, Mineola, NY.**

**Purpose:** Gastroesophageal reflux disease is often classified as typical or atypical. The role of gender and GERD symptoms has previously been described.[i]. The relationship between functional disorders and atypical GERD remains unclear.[ii]

**Aim:** To study the relationship of atypical GERD and functional gastrointestinal disease.

**Methods:** A total of 157 patients referred to a tertiary care center underwent 48 hour wireless esophageal pH monitoring between 7/1/2003 and 6/2/06. Ninety-eight pts were female, 59. Of these patients, 49 (31%) presented with typical GERD symptoms; and 108 (69%) presented with atypical symptoms. Typical reflux symptoms were defined as heartburn and regurgitation, while atypical symptoms included non-cardiac cardiac chest pain, chronic cough, asthma, laryngitis, hoarseness, and globus. A positive study was defined as the fraction of the time pH <4 for > 5.5% over a twenty four hour period.

**Results:** Figure 1 shows male and female atypical and typical patients. Figure 2 are atypical patients with a negative 48 hour pH monitoring evaluation. [figure1]

**Conclusions:** This study reveals that although men and women experience typical and atypical GERD, a greater proportion of women had negative pH monitoring. Future prospective studies are underway to evaluate if these atypical symptoms are related to a functional disorder via a Rome III based questionnaire. One approach may be to target treatment toward visceral hypersensitivity in lieu of acid suppression in this specially defined population.


**1254**

**Can Pain Intensity Reporting during Sigmoidoscopy Identify IBS Patients with Visceral Hypersensitivity?**


**Purpose:** Visceral hypersensitivity in the form of lower rectal and colonic pain thresholds is a hallmark of IBS and has even been proposed as a reliable biological marker of IBS. Since visceral pain threshold testing is a complex procedure, we sought to determine whether pain reporting during sigmoidoscopy can reliably identify IBS patients with visceral hypersensitivity. We also assessed what variables predict sigmoidoscopy pain intensity in IBS.

**Methods:** 141 IBS patients (Rome II criteria; mean age 34.9 years; 83% females) and 16 healthy subjects (mean age 35.7 years; all female) underwent unsedated sigmoidoscopy for motility catheter placement as a part of a research study. Subjects rated (0–5) their sigmoidoscopy pain intensity immediately after the procedure. All subjects completed barostat pain threshold testing by ascending method of limits (AML). They also completed the IBS Severity Scale (IBSS), the Brief Symptom Inventory (BSI) 18, the Coping Strategies Questionnaire, the Sexual Abuse History Questionnaire and the NEO personality Inventory.

**Results:** IBS patients had lower AML pain thresholds (mean: 24 vs. 39mmHg; p < .001), and higher mean pain ratings (3.17 vs. 2.44; p < 0.05) compared to controls. IBS patients with visceral hypersensitivity (AML pain threshold < 30 mm Hg) rated their sigmoidoscopy pain higher than those without hypsersensitivity (3.25 vs. 2.82; p < 0.05). High (3–5) vs. low (0–2) ratings of sigmoidoscopy pain identified hyperalgesic IBS patients with 81% sensitivity but only 33% specificity. Significant correlations of sigmoidoscopy pain are given in the table. There were no significant correlations with BSI global score, somatization, depression, anxiety, neuroticism, or catastrophizing. (Table 1)

**Conclusions:** Pain reporting during sigmoidoscopy is only modestly correlated with, and unlikely to be a useful predictor of visceral hypersensitivity in IBS. Greater sigmoidoscopy-related pain appears to be associated with current IBS symptom severity and abuse history, but contrary to popular belief, it does not seem to be influenced by current psychological symptoms. Supported by RO1 DK31369 and RR00046.

**Correlations of pain intensity reporting during sigmoidoscopy**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Correlations (Pearson r)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>AML pain threshold</td>
<td>−0.282</td>
<td>0.003</td>
</tr>
<tr>
<td>Overall IBS severity</td>
<td>0.203</td>
<td>0.017</td>
</tr>
<tr>
<td>Severity in the last 10 days</td>
<td>0.184</td>
<td>0.031</td>
</tr>
<tr>
<td>Sexual abuse</td>
<td>0.180</td>
<td>0.033</td>
</tr>
</tbody>
</table>

**1255**

**Delayed Increase in Urinary Bladder Permeability Parallels Mast Cell Migration in TNBS Colitis**

Rizwan Ahmed, MD, Elena E. Ustinova, PhD, Matthew O. Fraser, PhD, Dmitriy W. Gutkin, MD, Michael A. Pezzone, MD, PhD.* Medicine, University of Pittsburgh, Pittsburgh, PA; Urology, Duke University, Durham, NC and Pathology, Oakland VAMC, Pittsburgh, PA.
**Purpose:** Irritable bowel syndrome, interstitial cystitis, and other chronic pelvic pain disorders often occur concurrently. In our laboratory, we have shown evidence of acute pelvic organ cross-sensitization in a rat model involving intra-rectal administration of trinitrobenzene sulfonic acid (TNBS). Acute cross-sensitization is thought to occur via pre-existing neural pathways as bladder denervation prevents this response. We hypothesize that chronic colitis can likewise stimulate and cross-sensitize bladder afferents but may also produce neurogenic changes in the bladder including the recruitment and sensitization of bladder mast cells and permeabilization of the bladder epithelium, making it more sensitive to injury and afferent sensitization.

**Methods:** Female Sprague-Dawley rats received intrarectal trinitrobenzene sulfonic acid (TNBS) or vehicle, and urinary fluorescein excretion, a measure of bladder permeability, was measured 1 hr and 10 days afterwards. Bladder mast cell counts were quantitated at the 10 day time point.

**Results:** The average plasma fluorescein level was recorded at 0.935 mcg/ml for the TNBS vehicle group (controls). One hour following TNBS, no significant change in plasma fluorescein level and hence bladder permeability was detected (mean = 1.573 mcg/ml) (NS). Ten days following TNBS, however, plasma fluorescein levels were increased significantly (mean = 9.107) \( (p < 0.05) \). Coincident with the increase in bladder permeability in the TNBS-treated group (10days) was an increase in bladder mast cell density (18.02 ± 3.11 ± 0.27 mast cells per 100x field for controls, \( p < 0.01 \)).

**Conclusions:** The development of pelvic organ cross-sensitization and hence the overlap of chronic pelvic pain disorders likely involve afferent mast cell interactions. These interactions not lead to afferent sensitization but may also lead to further susceptibility to injury and/or irritation.

1256

**Characterization of Indications for Endoscopic Procedures That Led to a Diagnosis of Ischemic Colitis in the CORI Database and the Role of Diarrhea**

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**Purpose:** Ischemic colitis (IC) is the most common form of intestinal ischemia. It covers a spectrum of injury from transient self-limited ischemia involving the mucosa and submucosa to acute fulminant ischemia with transmural infarction that may progress to necrosis and death. Therefore, the clinical spectrum of IC ranges widely from asymptomatic patients (pts) to the typical presentation of hematochezia, contributing to difficulty in determining true incidence. This study characterized indications that led to the endoscopic diagnosis of suspected IC in the CORI (Clinical Outcomes Research Initiative) database, the role of diarrhea alone and with rectal bleeding.

**Methods:** CORI identified all cases of suspected IC and their indications in the database (1/1/2000 and 12/31/2003) and all cases of diarrhea that led to an endoscopic examination during this period. These data were summarized:

- % of all indications; pts may have >1 (primary) indication per procedure (total of all indications >100%)
- data split by PRIMARY indication (total = 100%)

**Definition of GI bleeding:** + FOBT, melena, and hematochezia.

**Results:** Overall, 560 cases of suspected IC were identified. 29918 pts with diarrhea received a lower endoscopy, and 83 (0.29%) were diagnosed with suspected IC. Table 1 reports the PRIMARY indications, table 2 the 5 most common indications (primary and non) for the 560 cases of suspected IC.

**Conclusions:** This study confirms GI bleeding as the most characteristic symptom in IC pts. Diarrhea, especially in absence of additional signs of bleeding, is less frequently associated with IC.

1257

**Linaclotide Significantly Improves Post-Operative Ileus and Opiate-Induced Constipation in Rats**

Alexander P. Bryant, PhD,* Eichell A. Cordero, PhD, Jenny V. Tobin, Samuel Rivers, Caroline B. Kurtz, PhD, Mark G. Currie, PhD. Pharmacology, Microbia, Inc., Cambridge, MA.

**Purpose:** Linaclotide acetate (MD-1100) is currently in Phase 2 clinical trials for the treatment of irritable bowel syndrome with constipation (IBS-C), chronic constipation and other gastrointestinal (GI) disorders. Linaclotide, a 14 amino acid peptide, acts by stimulating guanylate cyclase-C located on the intestinal epithelial surface and has been found to be minimally absorbed and well tolerated at the doses of up to 3 mg/day tested in Phase 1. Additionally, linaclotide has been found to exhibit the expected dose-related intestinal pharmacodynamic activity in normal healthy subjects. In the current study, linaclotide was assessed for efficacy in rat models of post-operative ileus and opiate-induced constipation.

**Methods:** Female, CD rats (130–180g) were used in these studies. Post-operative ileus was induced by manual manipulation of the intestines following laparotomy. Opiate-induced constipation was produced following intraperitoneal dosing with morphine at 2.5 mg/kg. Animals were dosed orally with linaclotide or vehicle before receiving a charcoal meal used to track transit within the small intestine. Group numbers for each of the studies ranged from 8 to 10 rats.

**Results:** In an in vivo model of post-operative ileus, linaclotide at a dose of 10ug/kg significantly accelerated transit \( (p < 0.01) \) compared to animals receiving vehicle alone. In the opiate-induced constipation model, linaclotide at doses of 25 and 50ug/kg significantly enhanced transit compared to animals receiving morphine \( (p = 0.004 \text{ and 0.002 respectively}) \), while also returning transit to a rate comparable with animals not receiving morphine at doses as low as 12.5ug/kg \( (p = 0.426) \).

**Conclusions:** In two different models of decreased intestinal transit, linaclotide treatment was associated with accelerated transit compared to control animals that received vehicle alone. These data support potential utility of...
linaclootide for the treatment of both post-operative ileus and opiate-induced constipation.

1258
A Double Blind, Randomized, Placebo-Controlled, Parallel Group Study To Evaluate the Effects of Itopride Hydrochloride (100 mg and 200 mg t.i.d.) on Gastric Motor and Sensory Function in Healthy Volunteers
Rok Seon Choung, MD, Nicholas J. Talley, MD, PhD,* Michael Camilleri, MD, William S. Harmsen, M.S., Alan R. Zinsmeister, PhD, Jean R. Basque, PhD, Monique Giguerre. Dyspepsia Center and Division of Gastroenterology, Mayo Clinic College of Medicine; Division of Biostatistics, Mayo Clinic College of Medicine, Rochester, MN and Axcan Pharma Inc, Mont-Saint-Hilaire, QC, Canada.

Purpose: To compare the effects of two doses of itopride (100 mg and 200 mg t.i.d.) and placebo on gastric accommodation, gastric emptying and small bowel transit, and postprandial symptoms in healthy volunteers.

Methods: Randomized, double-blind, placebo-controlled study evaluated gastric function before and after 7 days of itopride 100 mg (n = 16) or 200 mg (n = 15) t.i.d., or placebo (n = 15) in healthy volunteers. Validated methods were used to study gastric emptying and small bowel transit, gastric accommodation (SPECT) and satiation post-nutrient challenge.

Results: The 3 arms were comparable with regards to age, gender, or BMI. There were no statistically significant effects of itopride on gastric emptying. Small bowel transit was somewhat faster on itopride (200 mg) than placebo or itopride 100 mg (p = NS). Maximum tolerated volume and aggregate symptom score with nutrient challenge on placebo were 1006 mL (± 51) and 163 (± 21), versus 1050 mL (± 85) and 140 (± 17) on itopride 100 mg, and 1069 mL (± 75) and 138 (± 24) on itopride 200 mg, respectively (p = NS for both). Smaller values of postprandial change in total gastric volume by SPECT were observed with increasing dose of itopride in healthy volunteers compared to placebo (p = 0.036, table). A similar pattern for postprandial change in proximal gastric volumes was observed but this was only borderline significant (p = 0.094, table). As compared to placebo, itopride was well tolerated.

Conclusions: While itopride decreased total (and to a lesser extent, proximal) gastric volume change after a meal, it does not appear to have significant effects on gastric motor and sensory function in healthy individuals. Supported by Axcan Pharma.

Gastric volumes during fasting and after 300 mL of Ensure by SPECT

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>Itopride 100 mg (n = 16)</th>
<th>Itopride 200 mg (n = 15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Gastric Volume (mL) (postprandial-fasting)</td>
<td>625 (± 28)</td>
<td>555 (± 26)</td>
<td>512 (± 33)</td>
</tr>
<tr>
<td>Overall</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Males</td>
<td>597 (± 46)</td>
<td>517 (± 42)</td>
<td>474 (± 59)</td>
</tr>
<tr>
<td>Females</td>
<td>653 (± 32)</td>
<td>593 (± 32)</td>
<td>551 (± 30)</td>
</tr>
<tr>
<td>Proximal gastric volume (mL) (postprandial-fasting)</td>
<td>516 (± 25)</td>
<td>467 (± 23)</td>
<td>449 (± 29)</td>
</tr>
<tr>
<td>Overall</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Males</td>
<td>509 (± 41)</td>
<td>441 (± 37)</td>
<td>453 (± 52)</td>
</tr>
<tr>
<td>Females</td>
<td>522 (± 29)</td>
<td>493 (± 29)</td>
<td>445 (± 26)</td>
</tr>
</tbody>
</table>

1259
Real-World Treatment Effect of Tegaserod: IBS Longitudinal Outcomes Study (ILOS)
J. Kurland* D. Camiscoli, K.H. Kahler, N. Lesnikova, R. Balshaw. Department of Gastro, Naval Medical Ctr, Bethesda, MD; Shore Health Grp, Brick, NJ; Novartis Pharmaceuticals Corp, East Hanover, NJ and Syreon Corp, Vancouver, BC, Canada.

Purpose: Clinical trials have shown that tegaserod is effective in treating patients with irritable bowel syndrome (IBS) with constipation; however, little evidence is available regarding tegaserod’s real-world treatment effect. We explored the 6-month effect of tegaserod in patients with non-diarrhea-predominant IBS.

Methods: The IBS Longitudinal Outcomes study (ILOS) was a 6-month, prospective, observational study that enrolled 380 patients from 46 centers across the United States. Disease history, demographics, health-related quality of life (SF-36 and IBS-QOL), and prior IBS-related resource use were recorded at baseline. Total symptom severity (TSS = sum of frequency, intensity and bothersomeness of constipation, gas, abdominal pain/discomfort and bloating) scores were recorded at baseline and monthly for 6 months (6M). Patients were classified according to 3 baseline treatment cohorts: TEG = treatment including tegaserod; OTR = other treatment (excluding tegaserod); and NONE = no treatment reported. Patients in the NONE cohort were included, but differences were not tested due to the small sample size. Change in TSS from baseline to 6M was assessed by paired Kruskal-Wallis and exploratory multivariate linear regression, with important covariates identified by a backward elimination algorithm. Predictors with P < 0.20 were considered important covariates; p < 0.05 was considered significant.

Results: Baseline and 6M assessments were provided by 61% (231 of 380) of patients. Of these, 96% were women and 89% were white; median age was 44 years. Treatments reported at baseline were: TEG 29%, OTR 65%, NONE 6%. TSS improved significantly for both TEG and OTR (P < 0.01 for each cohort) with mean changes of −8.0 (TEG) and −3.7 (OTR). Backward elimination identified 11 important covariates (P < 0.20). Of these, 4 were significant in the final regression model: ethnicity (P = 0.036) and the baseline scores for total pain (P = 0.009), total bloating (P = 0.007), and overall IBS-QOL (P = 0.003). After adjusting for these using the model, TEG users had significantly greater improvement than OTR users (adjusted mean change, −4.4 vs −1.3; P = 0.042).

Conclusions: In this real-world observational study, we found a significant treatment effect, indicating that patients reporting tegaserod use at baseline showed greater improvement in symptom severity from baseline to 6M than patients reporting other baseline treatments.

1260
Familial Aggregation of Functional Dyspepsia: A Case-Control Study
Smita L.S. Hulder, M.R.C.P, Meredithythe A. McNally, MD, G.R. Locke, III, MD, E.A.C.G.,* Kristine A. Otto, R.N., Prabin Thapa, William S. Harmsen, Alan R. Zinsmeister, PhD, Nicholas J. Talley, MD, PhD, E.A.C.G., Dyspepsia Center, Enteric Neuroscience Program (ENSP), Mayo Clinic College of Medicine, Rochester, MN and Division of Biostatistics, Department of Health Sciences Research, Mayo Clinic College of Medicine, Rochester, MN.

Purpose: Functional dyspepsia (FD) is common, impacts on quality of life and is very costly. The etiopathogenesis is uncertain. While in irritable bowel syndrome there is evidence that genetic and intra-familial factors may be involved, this has not been studied in FD. We hypothesized that if there is familial aggregation, there would be an increased frequency of FD in first-degree relatives of FD patients compared with relatives of controls (the patient’s spouse).

Methods: The study design was a case-control study. Cases had undergone a negative esophagogastroduodenoscopy at the Mayo Clinic for assessment of dyspeptic symptoms; 455 were randomly selected from the endoscopy database using the relevant diagnostic codes. A self report bowel disease questionnaire (BDQ) that recorded symptoms, the somatic symptom checklist, and a family information form (FIF) to collect the names and addresses of all first-degree relatives were mailed to all cases and their spouses. A BDQ was then mailed to all first-degree relatives of study subjects identified from the FIF. FD diagnosis was based on the Rome II criteria.

Results: The study design was a case-control study. Cases had undergone a negative esophagogastroduodenoscopy at the Mayo Clinic for assessment of dyspeptic symptoms; 455 were randomly selected from the endoscopy database using the relevant diagnostic codes. A self-report bowel disease questionnaire (BDQ) that recorded symptoms, the somatic symptom checklist, and a family information form (FIF) to collect the names and addresses of all first-degree relatives were mailed to all cases and their spouses. A BDQ was then mailed to all first-degree relatives of study subjects identified from the FIF. FD diagnosis was based on the Rome II criteria.
database using the relevant diagnostic codes. A self report bowel disease questionnaire (BDQ) that recorded symptoms, the somatic symptom checklist, and a family information form (FIF) to collect the names and addresses of all first-degree relatives were mailed to all cases and their spouses. A BDQ was then mailed to all first-degree relatives of study subjects identified from the FIF. FD diagnosis was based on the Rome II criteria.  

**Conclusions:** This study suggests familial aggregation of FD occurs, supporting a genetic or intra-familial environment component.  

GRANT SUPPORT: Dr. Halder is the recipient of an ACG Clinical Research Award.

### 1261

**Failure To Detect Association with Irritable Bowel Syndrome (IBS) and Small Intestinal Bacterial Overgrowth (SIBO)**  
Kevin C. Ruff, MD, Yuri A. Saito-Loftus, MD, G. Richard Locke, MD, W. Scott Harmsen, Alan S. Zinsmeister, PhD, Nicholas J. Talley, MD,*  
Gastroenterology and Hepatology, Mayo Clinic College of Medicine, Rochester, MN and Biostatistics, Division of Health Science Research, Mayo Clinic, Rochester, MN.

**Purpose:** An association of SIBO with IBS has been proposed. We aimed to determine the proportion of patients with IBS who have SIBO, and to examine whether there are clinical features that are associated with SIBO.

**Methods:** A retrospective chart review was performed using an institutional database to identify all patients who had a duodenal aspirate and culture between January 1 and December 31, 2003. Clinical information including diagnosis of IBS, medication use, co-morbidities, and symptoms was also obtained. The association between abnormal aspirate (predictor) and symptom presence or medication use (dependent variable) was estimated using logistic regression, reporting odds ratio (OR) and 95% confidence interval, adjusting for age, gender, proton pump inhibitor (PPI) and antibiotic use.

**Results:** A total of 690 patients had duodenal aspirates sent for culture. Of the 680 with information about IBS, 22% had a diagnosis of IBS. The proportion of abnormal aspirate results (defined as bacterial count > 100000 cfu/ml) in patients with IBS was 6%. Of those with information about bloating, 72% had bloating. The proportion of abnormal aspirate results in those with bloating was 11%. Overall, 11% of all aspirates were abnormal for SIBO. Co-morbid gastric cancer and narcotic use were both positively associated with an abnormal aspirate result. No other factor measured was significantly associated with a normal or abnormal aspirate result. (See Table)

**Conclusions:** No association between IBS or bloating and SIBO was detected based on duodenal aspirates.

Association of Clinical Factor with Aspirate Results

<table>
<thead>
<tr>
<th>Normal Aspirate (N = 615)</th>
<th>Abnormal Aspirate (N = 75)</th>
<th>OR† (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IBS 142/606(23) 9/74(12) 0.6(03.1.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastric Cancer 51/613(8) 17/74(23) 3.2(1.7.6.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bloating/Distention 204/281(73) 26/40(65) 0.6(03.1.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PPI 223/613(36) 33/72(46) 1.3(0.8.2.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Narcotic 114/613(19) 23/73(32) 1.9(1.1.3.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antibiotic 76/615(12) 11/72(15) 1.2(0.6.2.4)†</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

† Odds ratio for clinical factor adjusting for age, gender, PPI use, and antibiotic use.  
† Odds ratio for clinical factor adjusting for age, gender, and antibiotic use.  
† Odds ratio for antibiotic use adjusting for age, gender, and PPI use.

### 1262

**Work Productivity and Activity Impairment in Patients with Common Gastrointestinal Motility and Sensory Disorders**  

**Purpose:** To assess work productivity and activity impairment in patients with irritable bowel syndrome (IBS), chronic constipation (CC), functional dyspepsia (FD), and gastroesophageal reflux disease (GERD) in a primary care setting.

**Methods:** The validated Work Productivity and Activity Impairment (WPAI) index, adapted for GI diseases, was administered to 400 patients in the US between April and October 2005, with one of the following: IBS with constipation, CC, or FD (Rome II criteria), or GERD, as confirmed by their primary care physician. Patients were excluded if they had organic GI disease, underwent surgery that disrupted normal GI anatomy, or were ≤18 years of age. Scores were expressed as percent of impairment/productivity loss resulting from GI symptoms (higher scores indicated greater impairment and less productivity) and were compared between cohorts using Kruskal-Wallis and paired t-tests.

**Results:** This study included 86 IBS, 39 CC, 36 FD, and 239 GERD patients. Mean age was 51 years, 69% of patients were women, 82% were white, and 67% worked at least part-time. IBS patients reported the greatest (30.9%) and GERD patients reported the smallest (16.8%) loss in overall work productivity attributed to GI symptoms, equivalent to losses of 1.5 and 0.8 days in a 40-hour workweek, respectively. All conditions caused significantly more presenteeism than absenteeism (18.3% vs 6.1%, p < 0.001). Overall, GI patients reported the greatest impairment in daily activities.

**Conclusions:** Patients who visit primary care physicians with symptoms of IBS, CC, FD, or GERD experience considerable productivity loss and activity impairment. Patients with GERD reported the least impairment from their symptoms.

### 1263

**Increased Bowel Movements Are Highly Correlated with Improvements in Secondary Efficacy Assessments in Constipated Patients Treated with Lubiprostone**  
 Ryuji Ueno, MD, PhD,* Aimee Wahl, M.S., Medical and Scientific Affairs, Sucmapo Pharmaceuticals, Inc., Bethesda, MD.

**Purpose:** Lubiprostone is a novel type-2 chloride channel (CIC-2) activator. In double-blinded studies of patients who suffer from chronic idiopathic constipation, lubiprostone at 24 mcg BID has been shown to increase spontaneous bowel movement (SBM) frequency rates as well as to improve other related symptoms such as stool consistency, bowel straining, and abdominal bloating and discomfort. The purpose of this analysis was to examine the relationship between SBM frequency rates and various subjective endpoints to determine if improvements in these endpoints correlate with increased SBM frequencies.

**Methods:** Data from three double-blinded studies of 3 to 4 weeks’ duration were combined. Weekly SBM rates were rounded to SBM weekly counts (integer values) and were used as an independent classification factor in
Generalized Estimating Equations (GEE) models. Models were developed for the changes from baseline and the absolute values. Least-squares means for weekly SBM counts were calculated from these GEE models for each of the secondary endpoints.

Results: Relationships between SBM rates and assessments of bowel straining, stool consistency, abdominal bloating, abdominal discomfort, constipation severity, and treatment effectiveness were all highly statistically significant (P < .0001) for the absolute values and changes from baseline values.

Conclusions: With lubiprostone treatment of chronic idiopathic constipation, there is a strong, positive correlation between increased SBM frequency and improvements in bowel straining, stool consistency, abdominal bloating, abdominal discomfort, and global assessments of constipation severity and treatment effectiveness.

Least-squares Means for Weekly SBM Counts

<table>
<thead>
<tr>
<th>Secondary Endpoints</th>
<th>0</th>
<th>3</th>
<th>6</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal bloating</td>
<td>1.82</td>
<td>1.64</td>
<td>1.18</td>
<td>1.12</td>
</tr>
<tr>
<td>Abdominal discomfort</td>
<td>1.68</td>
<td>1.41</td>
<td>1.06</td>
<td>0.85</td>
</tr>
<tr>
<td>SBM stool consistency</td>
<td>2.00</td>
<td>1.79</td>
<td>1.49</td>
<td>1.49</td>
</tr>
<tr>
<td>SBM straining</td>
<td>1.56</td>
<td>1.45</td>
<td>1.15</td>
<td>1.15</td>
</tr>
<tr>
<td>Constipation severity</td>
<td>2.67</td>
<td>2.10</td>
<td>1.35</td>
<td>1.08</td>
</tr>
<tr>
<td>Treatment effectiveness</td>
<td>0.90</td>
<td>1.40</td>
<td>2.39</td>
<td>2.50</td>
</tr>
</tbody>
</table>

*0 = Absent to 4 = Very severe; |0 = Very loose to 4 = Very hard; †0 = Not at all effective to 4 = Extremely effective

1264

Pooled Analysis of the Most Frequent Adverse Events Associated with the Use of Lubiprostone
Ryuji Ueno, MD, PhD, Aimee Wahle, M.S., Edwin Rivera, MD. Medical and Scientific Affairs, Sucampo Pharmaceuticals, Inc., Bethesda, MD.

Purpose: Lubiprostone, a novel CLC-2 activator, has been shown to be efficacious and well tolerated by patients with chronic constipation in short- and long-term clinical trials. To better characterize the most frequent adverse events (AEs) associated with the use of lubiprostone 24 mcg BID, we examined pooled results of patients enrolled in Phase 2 and 3 trials of 3 to 48 weeks’ duration.

Methods: Data for all safety-evaluable patients were pooled and compared between treatment groups (placebo vs. lubiprostone 24 mcg BID). Nausea, headache, and diarrhea AEs were analyzed for severity, duration, frequency, action taken (eg, drug withdrawn, dose reduced), and outcome. In addition, nausea-related variables were explored in subpopulations of elderly (≥65 years of age) and male patients.

Results: The pooled population included 1113 lubiprostone and 316 placebo patients. Approximately 16% were elderly and 13% were male. At least 1 AE occurred in 79.1% of lubiprostone patients, which included 31.1% with nausea, 13.2% with headache, and 13.2% with diarrhea. At least 1 AE occurred in 39.6% of placebo patients, which included 5.2% with nausea, 6.6% with headache, and 0.9% with diarrhea. Of those lubiprostone patients who experienced nausea, 88.7% reported nausea to be mild or moderate in severity. Overall, 74.5% of nausea events reported by lubiprostone patients were intermittent, and the median durations of nausea events were 12 and 7.5 days for lubiprostone and placebo patients, respectively. Notably, mean incidences of nausea per patient were 1.3 and 1.0 for lubiprostone and placebo patients, respectively. With regard to action taken, 64.1% of nausea events required no change in treatment regimen, and 9.6% of events resulted in dose reduction. Nausea was less prevalent in subpopulations, occurring in only 18.8% and 8.2% of lubiprostone elderly and male patients, respectively, compared with 34.5% of female patients. Similarly, the majority of lubiprostone patients experiencing headache and diarrhea had mild to moderate symptom severity (89.8% and 82.3%, respectively). Furthermore, headache and diarrhea events in lubiprostone patients were mostly intermittent (64.2% and 74.0%, respectively), and the median duration of these events were 9 and 4 days, respectively. Discontinuation rates due to nausea, headache, and diarrhea were 8.7%, 3.7%, and 2.2%, respectively.

Conclusions: Nausea, headache, and diarrhea associated with lubiprostone use are generally mild to moderate in severity, intermittent, and limited in duration.

1265

A Comparison of a Portable Breath Hydrogen Analyzer with the Quintron SC Breath Analyzer in Measuring Small Intestinal Bacterial Overgrowth
John K. DiBaise, MD, F.A.C.G., Isaac Malagon, B.S., Marie Haywood, R.N., Jeannie Stoa, R.N., Michael D. Crowell, PhD, F.A.C.G.. Gastroenterology, Mayo Clinic College of Medicine, Scottsdale, AZ.

Purpose: The measurement of hydrogen in expired air has received renewed interest in recent years as a simple, noninvasive, inexpensive yet indirect method of diagnosing small intestinal bacterial overgrowth (SIBO). A portable breath analyzer would be advantageous given its lower cost and ability to be used in the field. Commercially available portable breath analyzers have not been properly validated for use in the detection of SIBO. Our aim, therefore, was to compare a portable breath hydrogen analyzer (E-Z-EM H2 breath analyzer; E-Z-EM, Inc., Lake Success, NY) with a widely used model (Quintron SC breath analyzer; Quintron Diagnostics, Inc., Milwaukee, WI).

Methods: Consecutive patients referred for glucose hydrogen breath testing between 8/1/05 and 5/15/06 underwent duplicate breath sampling using both analyzers. Standardized preparation instructions were provided to all patients prior to the tests. Several definitions of an abnormal test were explored: (a) H2 rise from baseline > 20 ppm, (b) H2 rise from baseline > 12 ppm, and (c) baseline H2 level > 20 ppm. Data were analyzed using the appropriate parametric or nonparametric test. Sensitivity (Sn), specificity (Sp), positive predictive value (PPV) and negative predictive value (NPV) were calculated for each definition of abnormal using the Quintron results as the gold standard. A p-value < 0.05 was considered statistically significant.

Results: A total of 235 studies were completed in 169 women and 66 men with a mean age of 60.9 ± 15.4. The primary indications for the breath test were chronic bloating (39%), chronic diarrhea (30%) and abdominal discomfort/pain (14%). Breath hydrogen values at baseline and across subsequent time points were significantly higher for the EZ EM device than the Quintron (p < 0.001). Furthermore, the values at all time points were highly correlated between the two devices (r-value range 0.87–0.97; p < 0.001). Using definition (a), the Sn, Sp, PPV and NPV were 0.88, 0.95, 0.93 and 0.99, respectively. Similarly, the values were 0.78, 0.98, 0.74 and 0.98 for definition (b) and 1.0, 0.94, 0.48 and 1.0 for definition (c).

Conclusions: The E-Z-EM portable breath analyzer provides generally higher hydrogen values, but are highly correlated with the standard Quintron breath analyzer. Using a H2 rise from baseline > 20 ppm as the definition an abnormal test seems to provide the best test characteristics when the portable device is used.

1266

The Symptoms of Common Gastrointestinal Motility and Sensory Disorders: Data from Patient Registry for Observational GI Research – Epidemiology and Symptom Severity (PROGRESS™)
A. Legorreta, MD*, S. Clark, M.P.H., J. Mareehbain, M.P.H., K. Ryskina, B.A., A. Cerrilli, M.P.H., K. Kehler, PhD, M. Sheteline, MD School of Public Health, UCLA, Los Angeles, CA; Health Benchmarks, Inc., Woodland Hills, CA and Novartis Pharmaceuticals, East Hanover, NJ.

Purpose: The morbidity associated with chronic gastrointestinal (GI) disorders is often assessed at the tertiary care level, however, treatment is most often provided at outpatient primary care facilities. Our aim was to assess the frequency and bothersomeness of symptoms in patients with common GI motility and sensory disorders in a primary care setting.
Methods: A modified version of the Digestive Health Status Instrument (DHSI) was administered in the US between April and October 2005 to 400 patients with one of the following: irritable bowel syndrome (IBS) with constipation, chronic constipation (CC), functional dyspepsia (FD), as per Rome II criteria, or gastroesophageal reflux disease (GERD), all confirmed by the physician. Patients with surgeries disrupting normal GI anatomy, organic GI disease, or ≥18 years of age were excluded. Symptom frequency was estimated for patients who reported having the symptom ≥25% of the time in the previous two weeks; bothersomeness was based on patients who reported being at least “moderately” bothered by the symptoms. P-values were derived from an overall comparison of the four cohorts using chi-square tests.

Results: We identified 86 IBS, 39 CC, 36 FD, and 239 GERD patients. Mean age was 51 years; 69% were women, and 82% were Caucasian. The average duration of symptoms ranged between 4 (FD) and 10 (CC) years. Frequency of GI symptoms by cohort is described below:

<table>
<thead>
<tr>
<th>Symptom</th>
<th>IBS (%)</th>
<th>CC (%)</th>
<th>FD (%)</th>
<th>GERD (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal pain or discomfort</td>
<td>64</td>
<td>50</td>
<td>78</td>
<td>43</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Constipation</td>
<td>72</td>
<td>92</td>
<td>56</td>
<td>41</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>64</td>
<td>43</td>
<td>44</td>
<td>37</td>
<td>0.0005</td>
</tr>
<tr>
<td>Bloating</td>
<td>64</td>
<td>75</td>
<td>56</td>
<td>43</td>
<td>0.0002</td>
</tr>
<tr>
<td>Nausea</td>
<td>20</td>
<td>19</td>
<td>14</td>
<td>11</td>
<td>0.12</td>
</tr>
<tr>
<td>Upper abdominal fullness</td>
<td>36</td>
<td>50</td>
<td>49</td>
<td>33</td>
<td>0.09</td>
</tr>
<tr>
<td>Early satiety</td>
<td>32</td>
<td>46</td>
<td>39</td>
<td>23</td>
<td>0.01</td>
</tr>
<tr>
<td>Heartburn</td>
<td>28</td>
<td>22</td>
<td>31</td>
<td>44</td>
<td>0.007</td>
</tr>
<tr>
<td>Regurgitation</td>
<td>15</td>
<td>26</td>
<td>25</td>
<td>26</td>
<td>0.22</td>
</tr>
</tbody>
</table>

Conclusions: Primary care patients diagnosed with chronic GI disorders (IBS, CC, FD, or GERD) report considerable burden of symptom interference with different aspects of their lives. Physicians should be aware of the impact chronic GI disorders have on patients’ pursuit of daily living.

1267

Symptoms Associated with Chronic Gastrointestinal Disorders

Interfere with Daily Living as Assessed by Patient Reported Outcomes in the Primary Care Setting

A. Legorreta, MD,* S. Clark, M.P.H., J. Mareehian, M.P.H., K. Ryskina, B.A., A. Cerulli, M.P.H., K. Kahler, PhD, M. Shetzline, MD. School of Public Health, UCLA, Los Angeles, CA; Health Benchmarks, Inc., Woodland Hills, CA and Novartis Pharmaceuticals, East Hanover, NJ.

Purpose: Our aim was to assess gastrointestinal (GI) symptom interference with daily living in patients with common GI motility and sensory disorders, including irritable bowel syndrome (IBS), chronic constipation (CC), functional dyspepsia (FD), or gastroesophageal reflux disease (GERD).

Methods: A modified version of the Digestive Health Status Instrument (DHSI) was administered to 400 primary care patients in the US between April and October 2005. Patients had to have one of the following: IBS with constipation, CC, or FD (Rome II criteria), or GERD, as confirmed by the physician. Patients with surgeries disrupting normal GI anatomy, organic GI disease, or ≥18 years of age were excluded. The study measured the impact of GI symptoms on daily living by assessing symptom interference with the patient’s mood, ability to walk or move about, sleep, normal work (including both work outside the home and housework), recreational activities, and enjoyment of life. Responses were recorded on a 5-point scale (not at all, a little bit, moderately, quite a bit, and extremely). Percentages of patients reporting “moderate” interference or greater were aggregated and compared between cohorts using chi-square tests.

Results: We identified 86 IBS, 39 CC, 36 FD, and 239 GERD patients. Mean age was 51 years; 69% were women, and 82% were white. In general, more patients with IBS or CC reported moderate or greater GI symptom interference with daily living than patients with FD or GERD. Except for Sleep, the associations between cohorts and symptoms were statistically significant (see Table).

<table>
<thead>
<tr>
<th>Symptom</th>
<th>IBS (%)</th>
<th>CC (%)</th>
<th>FD (%)</th>
<th>GERD (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mood</td>
<td>57</td>
<td>44</td>
<td>26</td>
<td>36</td>
<td>0.0038</td>
</tr>
<tr>
<td>Ability to walk or move about</td>
<td>37</td>
<td>37</td>
<td>29</td>
<td>19</td>
<td>0.0045</td>
</tr>
<tr>
<td>Sleep</td>
<td>37</td>
<td>40</td>
<td>41</td>
<td>39</td>
<td>0.9873</td>
</tr>
<tr>
<td>Normal work</td>
<td>45</td>
<td>42</td>
<td>29</td>
<td>24</td>
<td>0.003</td>
</tr>
<tr>
<td>Recreation</td>
<td>45</td>
<td>47</td>
<td>31</td>
<td>25</td>
<td>0.0014</td>
</tr>
<tr>
<td>Enjoyment of life</td>
<td>55</td>
<td>58</td>
<td>32</td>
<td>34</td>
<td>0.0008</td>
</tr>
</tbody>
</table>

Conclusions: Primary care patients diagnosed with chronic GI disorders (IBS, CC, FD, or GERD) report considerable burden of symptom interference with different aspects of their lives. Physicians should be aware of the impact chronic GI disorders have on patients’ pursuit of daily living.
Conclusions: In patients with chronic constipation, lubiprostone decreased the time to first SBM and increased the proportion of patients achieving SBMs within 24 and 48 hours compared to patients receiving placebo.

1269 Evaluation of Safety and Efficacy in a Twelve-Month Study of Lubiprostone for the Treatment of Chronic Idiopathic Constipation Ryuji Ueno, MD, PhD, Aimee Wahle, M.S., Raymond Panas, M.P.H., Taryn B. Jasvick, B.S., Edwin Rivera, MD. Medical and Scientific Affairs, Sucampo Pharmaceuticals, Inc., Bethesda, MD.

Purpose: Constipation is a common gastrointestinal condition with limited long-term treatment options. Lubiprostone is a novel type-2 chloride channel (ClC-2) activator that has been shown to be efficacious and well tolerated by patients with chronic constipation in a number of well-controlled clinical trials of 3 to 4 weeks’ duration. The primary objective of this study was to evaluate the long-term safety of lubiprostone 24 mcg BID in patients with chronic idiopathic constipation; efficacy endpoints were also evaluated over the duration of treatment.

Methods: We conducted a 48-week open-labeled trial in 324 lubiprostone-naive patients. The majority of patients were female (84.9%) and the mean participant age was 53.2 years. Patients assessed constipation severity and abdominal symptoms of bloating and discomfort using a 5-point scale (0 = absent to 4 = very severe) at each study visit (approximately every 6 weeks).

Results: Two-hundred seventeen patients (67%) experienced at least one treatment-related adverse event (AE). The most common treatment-related AEs occurring in ≥2% of the population were nausea (30.2%), diarrhea (19.4%), distention (9.3%), headache (8.6%), flatulence (5.6%), abdominal pain (5.6%), vomiting (4.0%), loose stools (3.4%), dizziness (3.1%), dyspepsia (2.2%), and abdominal discomfort (2.2%). Improvements in assessments of constipation severity, abdominal bloating, and abdominal discomfort were statistically significant at all visits compared to baseline (P < .001). Constipation severity was improved by an average of 1.11 points at Week 1 (N = 320), 1.17 points at Week 24 (N = 183), 1.28 points at Week 48 (N = 152), and 0.99 points for the last on-drug measurement (N = 320). Abdominal bloating was improved by an average of 0.70 points at Week 1 (N = 320), 0.80 points at Week 24 (N = 183), 0.88 points at Week 48 (N = 152), and 0.68 points for the last on-drug measurement (N = 320). Abdominal discomfort was improved by an average of 0.65 points at Week 1 (N = 320), 0.66 points at Week 24 (N = 183), 0.78 points at Week 48 (N = 152), and 0.60 points for the last on-drug measurement (N = 320).

Conclusions: These results demonstrate that lubiprostone 24 mcg BID was safe and tolerable. With respect to symptom relief, the results shown in the short-term, double-blinded trials of lubiprostone were similarly observed in this long-term trial and were maintained for at least 48 weeks.

1270 Efficacy and Safety of Lubiprostone in a Subgroup of Constipation Patients Diagnosed with Irritable Bowel Syndrome with Constipation (IBS-C) John Johanson, MD, M.D. * Aimee Wahle, M.S., Ryuji Ueno, MD, PhD. Gastroenterology, Rockford Gastroenterology Associates, Rockford, IL and Medical and Scientific Affairs, Sucampo Pharmaceuticals, Inc., Bethesda, MD.

Purpose: Lubiprostone is a novel type-2 chloride channel (CIC-2) activator that has been shown to be efficacious and well tolerated in a number of well-controlled clinical trials in patients with chronic idiopathic constipation. Pooled results from two Phase 3 constipation trials were examined to evaluate lubiprostone efficacy in patients with a history of IBS-C compared to placebo.

Methods: To create an adequate pool of IBS-C patients, data were combined from two placebo-controlled clinical trials of 4 weeks’ duration. Spontaneous bowel movement (SBM) frequency rates; stool consistency ratings (0 = very loose to 4 = very hard); and bowel straining, abdominal bloating, abdominal discomfort, and constipation severity assessments (0 = absent to 4 = very severe) were compared between treatment groups (placebo vs. lubiprostone 24 mcg BID). Subgroups of constipation patients with and without a prior diagnosis of IBS-C were also evaluated.

Results: The pooled IBS-C subgroup consisted of 45 placebo and 46 lubiprostone-treated patients. Mean SBM rates were significantly greater among lubiprostone IBS-C patients (4.8-6.0/week) compared to their placebo counterparts (2.8-4.0/week) at all four weekly evaluations (P ≤ .0027). Mean stool consistency ratings were significantly better with lubiprostone treatment (1.6-1.7) vs. placebo (2.6-2.7) at all four weekly evaluations (P < .0001), and mean bowel straining ratings were also significantly better with lubiprostone (1.3-1.6) vs. placebo (2.1-2.2) at all four weekly evaluations (P ≤ .0119). Additionally, assessments of abdominal bloating and discomfort were significantly improved vs. placebo at Weeks 3 and 4 (P ≤ .0495), and constipation severity ratings were significantly improved vs. placebo at Weeks 1, 3, and 4 (P ≤ .0175) and nearly reached significance at Week 2 (P = .0509). Efficacy results were generally similar for both IBS-C and non-IBS-C patients. Fewer IBS-C patients receiving placebo (50%) experienced adverse events compared with patients treated with lubiprostone (68.9%). The most common AE, nausea, had a slightly higher incidence in lubiprostone-treated IBS-C patients vs. their non-IBS-C counterparts (35.6%) vs. 28.4%, respectively.

Conclusions: In chronic constipation trials with lubiprostone, a subgroup of patients with a history of IBS-C treated with lubiprostone had more favorable symptom resolution compared to placebo.
Prevalence of Bowel Symptoms in HLA-positive/negative First-Degree Relatives of CD cases (%)

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Total (N = 25)</th>
<th>HLA-positive (N = 13)</th>
<th>HLA-negative (N = 12)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;3 BM each day</td>
<td>4</td>
<td>0</td>
<td>4</td>
<td>0.31</td>
</tr>
<tr>
<td>&lt;3 BM each week</td>
<td>8</td>
<td>4</td>
<td>4</td>
<td>1.0</td>
</tr>
<tr>
<td>Loose or mushy stool</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Hard or lumpy stool</td>
<td>20</td>
<td>8</td>
<td>12</td>
<td>0.55</td>
</tr>
<tr>
<td>Fecal Urgency</td>
<td>8</td>
<td>4</td>
<td>4</td>
<td>0.95</td>
</tr>
<tr>
<td>Feeling of abdominal fullness or bloating</td>
<td>20</td>
<td>4</td>
<td>16</td>
<td>0.11</td>
</tr>
<tr>
<td>IBS</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Constipation</td>
<td>12</td>
<td>0</td>
<td>12</td>
<td>0.06</td>
</tr>
<tr>
<td>Dyspepsia</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Unstable: Power change of more than 80% for more than 2 consecutive minutes. Statistically significant differences are denoted with an asterisk*. 

1272

Analysis of Colonic Electrical Activity in Patients with Constipation-Predominant Irritable Bowel Syndrome Using a Multi-Channel Transcutaneous Device

Manuel A. Amaris, MD, Bashar M. Attar, MD, F.A.C.G.,* Melchor V. Domertia, MD, F.A.C.G., Daniel C. Sadowski, MD, F.A.C.G., Martin P. Mintchev, PhD. Gastroenterology, Stroger Hospital of Cook County and Rush Medical College, Chicago, IL; Gastroenterology, University of Alberta, Edmonton, AB, Canada and Electrical and Computer Engineering, University of Calgary, Calgary, AB, Canada.

Purpose: To determine if any specific pattern of colonic electrical control activity (ECA) can be found in patients with constipation predominant irritable bowel syndrome (CPIBS) using transcutaneous electrodes.

Methods: Eleven patients with constipation-predominant irritable bowel syndrome (age 40 ± 10, male/female = 2:9, intestinal habit 1.3 ± 0.6/week), and 20 normal volunteers (age 40 ± 16, male/female = 10:10, Intestinal habit 7.3 ± 3.2/week) underwent a 3-channel bipolar fastening recording of colonic ECA via transcutaneous electrodes. Patients were defined by the Rome II criteria. Bipolar electrode combinations of skin electrodes formed 8 ECA-recording channels following the longitudinal axes of the right, transverse and left colon. Colonic electrical activity was recorded and digitally analyzed using custom-designed software in a frequency band of 0.02 to 0.2 Hz.

Results: Weak or unstable power dynamics were seen in most patients with CPIBS and only in 6/20 normal volunteers. Analysis of the power stability in patients showed statistically significant differences in all colonic segments if compared to normal volunteers (p < 0.025) (Table 1). Spectral analysis showed no significant differences in the mean frequencies from both groups.

Conclusions: There was a consistent pattern of unstable power dynamics in patients with CPIBS. It is unclear if this is a pathologic phenomenon or simply an exaggerated level of the physiological fluctuations of ECA seen in normal volunteers. Further studies are needed to confirm these findings.

Table 1. Power dynamics.

<table>
<thead>
<tr>
<th></th>
<th>Right Colon</th>
<th>Transverse Colon</th>
<th>Left Colon</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Stable</td>
<td>Unstable</td>
<td>Stable</td>
</tr>
<tr>
<td>CPIBS. (n = 11)</td>
<td>2</td>
<td>9*</td>
<td>2</td>
</tr>
<tr>
<td>Normals. (n = 20)</td>
<td>18</td>
<td>2</td>
<td>17</td>
</tr>
</tbody>
</table>

1273

Lubiprostone for the Treatment of Chronic Constipation: Patient Symptom Ratings

Ryuji Ueno, MD, PhD,* Aimee Wahle, M.S., Taryn R. Joswick, B.S., Medical and Scientific Affairs, Sucampo Pharmaceuticals, Inc., Bethesda, MD.

Purpose: Lubiprostone, a novel type-2 chloride channel (CIC-2) activator, has been shown to increase spontaneous bowel movement frequency and was well tolerated by patients with chronic idiopathic constipation in clinical trials of 3 to 4 weeks’ duration. We examined pooled results of symptom assessments from three well-controlled trials to assess the effects of lubiprostone on patient-assessed symptoms of constipation.

Methods: Stool consistency ratings (0 = very loose to 4 = very hard), and assessments of constipation severity, straining, bloating, and abdominal discomfort (0 = absent to 4 = severe) were collected, pooled, and compared between treatment groups (placebo and lubiprostone 24 mcg BID). In addition, mean symptom changes from baseline were compared.

Results: The pooled analysis consisted of 273 placebo and 271 lubiprostone patients. Mean changes from baseline in ratings of stool consistency, constipation severity, and bowel straining were significantly improved among lubiprostone patients compared with their placebo counterparts during all study weeks (P < .0001). Mean changes from baseline in ratings of abdominal bloating were also significantly improved for lubiprostone patients as compared to placebo patients during all study weeks (P < .0072), and mean changes from baseline in ratings of abdominal discomfort were significantly improved for lubiprostone patients compared with placebo patients at Weeks 2 and 3 (P < .0011). Constipation severity ratings were improved, and ranged from 1.69 to 1.89 for lubiprostone patients and from 2.19 to 2.38 for placebo patients (P < .0001 at all weeks). Assessments of stool consistency ranged from 1.77 to 1.82 for lubiprostone patients and from 2.48 to 2.54 for placebo patients (P < .0001 at all weeks). Ratings of bowel straining ranged from 1.40 to 1.52 for lubiprostone patients and from 1.95 to 1.99 for placebo patients (P < .0001 at all weeks). Lubiprostone patients rated abdominal bloating from 1.44 to 1.53, compared with 1.65 to 1.80 for placebo patients (P < .0352 at all weeks). Assessments of abdominal discomfort in lubiprostone patients were also improved significantly from those of placebo patients at Weeks 3 and 4 (P < .0098).

Conclusions: Lubiprostone is efficacious in relieving the symptoms of chronic constipation.
correlation coefficient were used to analyze the data. A p-value < 0.05 was considered statistically significant.

**Results:** A total of 167 studies were completed in 121 women and 46 men with a mean age of 61.3 ± 15.3. The primary indications for the breath test were chronic bloating (39%), chronic diarrhea (29%) and abdominal discomfort (15%). The mean values at baseline before and after the mouthwash were 6.05 ppm and 5.95 ppm, respectively (p = NS), and were highly correlated (r = 0.97; p < 0.001).

**Conclusions:** In addition to other preparatory measures, a mouthwash rinse does not appear to be necessary prior to the performance of hydrogen breath testing for SIBO.

### 1275

**Morphological Assessment of the Anal Sphincters and Puborectalis Muscle Using the 3-D Ultrasound Image Technique**

Sung-Ae Jung, MD, Dolores H. Pretorius, MD, Milena M. Weinstein, MD, Bikram S. Padda, B.S., Charles W. Nager, MD, Debbie den Boer, R.N., Ravinder K. Mittal, MD,* The Pelvic Floor Function and Disorder Group, University of California, San Diego, CA; Department of Internal Medicine, University of California, San Diego, CA; Department of Radiology, University of California, San Diego, CA and Department of Internal Medicine, Ewha Womans University College of Medicine, Seoul, Korea.

**Purpose:** Anal sphincter complex, i.e., external anal sphincter (EAS), internal anal sphincter (IAS) and puborectalis muscle (PRM) were evaluated using the 3-dimensional ultrasound (3D US) technique.

**Methods:** 15 asymptomatic nulliparous women (33 ± 12 years) and 11 asymptomatic multiparous women (49 ± 9 years) were studied. A 3D US volume of the pelvic floor was captured during rest and squeeze by placing a 3–9 MHz transducer on the vaginal introitus with image directed posteriorly (travagalinal), and transducer placed on the perineum with the image directed cranially (transperineal). From the 3D US volumes, 2D US images were viewed at every 1 mm distance to assess IAS, EAS and PRM.

**Results:** The 2D US images in the transverse axis of the anal canal (seen in the transvaginal volume) allowed visualization of the IAS and EAS. The entire length of the PRM sling was seen only in the transverse plane of the PRM axis (a line connecting the lower end of the pubic symphysis and the apex of the anorectal angle) in the transperineal volume. A part of the EAS is located below the IAS (subcutaneous EAS) and a part around the IAS (subpubic EAS). The anterior-posterior (AP) length of the PRM was assessed at rest and squeeze. The AP length of PRM is longer in the multiparous but both groups show significant shortening with the squeeze (∗, p < 0.001).

**Conclusions:** Examination of the closely spaced multiple slices of the 3D US volume of the pelvic floor allows detailed morphological assessment of the anal sphincter complex and has the potential to detect damage to its individual components.

<table>
<thead>
<tr>
<th></th>
<th>IAS</th>
<th>EAS</th>
<th>PRM AP length (rest)</th>
<th>PRM AP length (squeeze)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nulliparous (cm)</td>
<td>2.7 ± 0.4</td>
<td>2.1 ± 0.4</td>
<td>5.2 ± 0.5</td>
<td>4.6 ± 0.4*</td>
</tr>
<tr>
<td>Multiparous (cm)</td>
<td>2.9 ± 0.4</td>
<td>2.3 ± 0.5</td>
<td>5.7 ± 0.5</td>
<td>4.9 ± 1.3*</td>
</tr>
</tbody>
</table>

∗, <0.001 comparing rest vs. squeeze

### 1276

**Therapeutic Implications of Clinical Associations of Functional Gastrointestinal Disorders (FGID) with Other Visceral and Somatic Hypersensitivity Syndromes (VSHS)**

Marcelo A. Barreiro, MD, M.Sc.,* Gary D. James, PhD, Daniel E. Osorio. Disorders of Function Clinic (DFC), Binghamton University, Binghamton, NY and Decker School of Nursing and Institute for Primary and Preventive Health Care, Binghamton University, Binghamton, NY.

**Purpose:** Treatment of pts with FGID can be frustrating as these pts often present with other well-characterized disorders of visceral and somatic hypersensitivity and vague psychosomatic symptoms (VSHS). Traditional medication regimens are largely ineffective and newer therapies have had catastrophic adverse events or did not live up to their promise.

**Aim:** To assess whether FGID are unique disorders or whether they are a manifestation of a systemic syndrome.

**Methods:** A total of 183 pts were evaluated, 167 of which presented with VSHS. All underwent a structured interview. Pain was evaluated using a 10 cmVAS, and was further characterized as visceral or somatic. Physchosomatic symptoms were assessed using the SCL-90-R, and health related quality of life (QOL) through the QOL Inventory (QOLI). The presence of Childhood Stress (CS) was also examined in 106 pts.

**Results:** Of the total pts examined, 78% were female. Irritable Bowel Syndrome (IBS) alone or in association with one other Functional Disorder (FD) occurred in 13% of the cases. In this group, Psychiatric Disorder (PD) and Fibromyalgia (FM) were the most common associations. The remaining 27% of the VSHS pts were affected with more than 3 FD (OR 4.57, 95% CI 4.45–11.35, p < .0001). Chronic Fatigue Syndrome (CFS), PD, FM and IBS tended to group together and formed a cluster separate from other FD. In evaluating the SCL-90-R Global Severity Index, pts with 1–2 FDs had a lower score than those with 3 or more FDs (61.75 vs 67.17, p < .007). They also had a higher QOLI Raw Score (2.07 vs 0.85, p < .013). Pain severity and type were not related to type or number of coexisting FD. Pts with CS had a higher number of coexisting FDs and higher scores of every symptom subscale and the Global Severity Index of the SCL 90-R (70.92 vs 65.83, p < .001). Two subscales of the QOLI (Community and Relatives) were significantly lower (p < .05) among those with CS.

**Conclusions:** 1) FGID alone or in association with other FDs may be an infrequent occurrence among pts with FDs. 2) Three or more FDs coexist with a frequency that far exceeds chance, suggesting a common pathogenesis. 3) History of CS worsens the overall clinical picture of VSHS. 4) Systemic-type of therapies may be more effective than organ-targeted therapies in pts with FGID who also present with other VSHS.

**1277**

**Binge Eating Predicts Epigastric Pain in the General Population Independent of Body Mass Index**

Filloreno Cremonini, MD, M.Sc.,* G. Richard Locke, MD, Alan R. Zinmanstein, Michael Camilleri, MD, Nicholas J. Talley, MD, PhD,* Division of Gastroenterology, Mayo Clinic College of Medicine, Rochester, MN and Division of Biostatistics, Mayo Clinic College of Medicine, Rochester, MN.

**Purpose:** Recent data show body mass index (BMI) is associated with upper GI symptoms in normal weight and overweight women (Jacobson et al., NEJM 2006.). The factors behind this association are unknown. We studied the association between binge eating behavior, BMI and GI symptoms in the general population. Our hypothesis was that binge eating is associated with increased reporting of upper GI symptoms.

**Methods:** Mailed survey of the general population of Olmsted County, MN. We used a 48-item questionnaire that included validated descriptors of key upper and lower GI symptoms representative of major functional GI disorders, self-reported body mass index, sleep disturbance, exercise, quality of life and depression. The independent contribution of binge eating to sympoms was tested by multiple logistic regression. We used age, gender, BMI (normal weight versus overweight and obese), and physical exercise as covariates.

**Results:** 4098 subjects responded. 615 participants (15%) reported episodes of binge eating. Overweight and obese status was weakly associated with epigastric pain (OR 1.02, 95% CI 0.98–1.06). Frequent binge eating was associated with increased odds for reporting epigastric pain (OR 2.5, 95%
CI 1.2–5.1 for occasional pain, OR 2.6, 95% CI 1.1–6.0 for frequent pain) independently of BMI, gender, age, levels of exercise.

**Conclusions:** Binge eating episodes are common in the general population. An eating pattern consistent with eating binges is associated with reporting epigastric pain. This association is independent of BMI, gender, age and of levels of physical exercise. Whether this association with GI morbidity reflects more frequent diagnoses of dyspepsia and gastroesophageal reflux in binge eaters remains to be defined.

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**1278**

**Efficacy of Sodium Phosphate (NaP) Tablets in the Long-Term Treatment of Refractory Chronic Constipation**

Craig A. Arochick, MD,* Pennsylvania Hospital, Philadelphia, PA.

**Purpose:** Effective long-term treatments for patients (pts) with chronic constipation are lacking, with tolerance developing after initial response. Given that sodium phosphate (NaP) tablets are an efficacious colon-cleansing agent, the current laxative therapy is inadequate, with intolerance developing after initial response. The purpose of this study was to investigate the efficacy of sodium phosphate (NaP) tablets in patients with chronic constipation.

**Methods:** A prospective chart review was conducted on all pts with chronic constipation (<1 bowel movement/week) who had failed other therapies and were treated with NaP tablets. Pts were treated in an outpatient setting from 2004 to 2006. Efficacy was determined by patient reports of symptom improvement (eg, increase in number of bowel movements and ease of stool passage).

**Results:** Eleven pts (aged 22–87 years) with refractory chronic constipation were identified. The majority of pts reported constipation disorder (n = 2), gastric bypass surgery (n = 1), or other gastrointestinal-related conditions (n = 5). Previous failed therapies included polyethylene glycol 3350, NF powder for solution (n = 1),tagatose maleate (n = 3), and lactulose (n = 1). Six pts (55%) continued current laxative therapy while receiving NaP tablets. Pts were treated with 1 (n = 1), 2 (n = 1), or 3 (n = 1) NaP tablets b.i.d., or 3 tablets t.i.d. (n = 1), with an unknown dose in 1 patient, for up to 6 mo (n = 5), 1.5 years (n = 2), or 2 years (n = 4, mean = 14.5 mo). Improvement in symptoms of chronic constipation was observed in 8 pts (73%), of which 5 were receiving NaP tablets. Two pts (18%) also reported improvement, but clinical symptoms predominantly fluctuated. Measured serum electrolyte levels were available for 9 pts, with no abnormal values observed, including >10 mo (n = 1), >18 mo (n = 3), and >27 mo (n = 2) of daily NaP tablet therapy. No serious adverse events related to NaP tablets were observed. Two pts treated with 3 NaP tablets b.i.d. discontinued therapy after 5 to 6 mo: 1 patient experienced vomiting, considered related to a gastric bypass pouch, and an 8 year old with congestive heart failure experienced leg edema.

**Conclusions:** NaP tablets (2–9 tablets/day) for the long-term treatment of chronic constipation appeared to be efficacious and well tolerated in this small study. Periodic electrolyte measurements (eg, calcium and phosphorus) and serum creatinine and blood urea nitrogen levels, taken >2 years in some pts, indicated no apparent safety issues with low doses of NaP tablets in management of pts with refractory chronic constipation.

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**1280**

**Video Capsule Endoscopy Can Determine Solid Phase Gastrointestinal Motility in Normal Healthy Subjects and in Those with Diabetes Mellitus: A Case Control Study**

Darwin L. Connell, MD, Gregory Zaccaro, MD,* John J. Vargo, MD, Jan Santisi, R.N., Rocio Lopez, M.S.. Section of Endoscopy, Capsule Endoscopy Program, Cleveland Clinic Foundation, Cleveland, OH.

**Purpose:** VCE images allow recognition of transition zones between segments of the bowel that might provide information in regard to gastrointestinal transit times. We reviewed our VCE database and did a comparison of healthy controls to subjects with diabetes mellitus. Overall, the median gastrointestinal transit times were longer when compared to healthy controls. There were no statistical demographic differences between groups in terms of age or gender. The H0 was that subjects with DM have a longer gastrointestinal transit time than HS.

**Methods:** The Cleveland Clinic Endoscopic Capsule Database was reviewed for pts undergoing VCE for obscure bleeding with a concomitant diagnosis of DM and compared to a HS. All study participants underwent standard protocol video capsule endoscopy (Given imaging) with pre-procedural medications of simethicone and metoclopramide. Gastrointestinal transit times were determined by recording time of endoscopic visualization of anatomical transition zones between the various segments of the gastrointestinal tract.

**Results:** Seventy-eight VCE studies were identified for this case control study: 45 healthy controls and 33 diabetes mellitus patients. There were no statistical demographic differences between groups in terms of age or gender. The H0 was that subjects with DM have a longer gastrointestinal transit time than HS. There were no complications or retention of the videocapsules in the study participants.

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**Endoscopy**

**Use of a Novel Endoscopy Biopsy Assist Device Provides a Fully Self Operated Endoscopic Biopsy Technique and Eliminates the Need of an Endoscopy Assistant in Performing Biopsy Thereby Improving Patient Monitoring and Reducing Patient Discomfort.**

Wilson Pais, MD, Wayne Manishen, MD,* Section of Gastroenterology, University of Manitoba, Winnipeg, MB, Canada.

**Purpose:** Flexible fiber optic endoscopes are frequently used in gastroenterology to obtain tissue samples by making use of flexible biopsy forceps. Usually the biopsy forceps are transferred from the endoscopist to the biopsy channel of the endoscope. At this point the endoscopist will ask the assistant to open and close the biopsy forceps, withdraw the forceps to retrieve the specimen obtained, and the assistant will deposit the specimen in to the collection bottles. The endoscopist must use both hands to locate and maintain the distal tip of the endoscope adjacent to the site to be biopsied. Often multiple specimens from multiple sites are obtained. The assistant is responsible for monitoring patient’s vital signs, and assistant’s involvement in biopsy procedure will compromise the monitoring responsibilities. This two operator sequence can prolong the procedure and increase patient discomfort.

**Methods:** We developed a foot operated endoscopy biopsy assist device that is operated and controlled by the endoscopist in its entirety and does not require any intervention from the endoscopy assistant. The device can be applied to any other endoscopic biopsy procedures. The device provides universal connection to any model of endoscopic biopsy forceps to the foot operated actuator prior to commencement of the procedure. The biopsy forceps is thus readily available for use by the endoscopist, who can independently access the forceps, open and close the distal jaws for tissue sampling by using the foot pedal actuator. The endoscopist can then transfer the tissue samples obtained through a guide funnel in to the specimen collection bottles which are pre-loaded on an indexed rotating platform on the biopsy assist device.

**Results:** The device is fully developed and tested in real time by an experienced gastrointestinal endoscopist (author). The device completely frees the endoscopy assistant from any involvement in the biopsy procedure, enabling the assistant to focus on other aspects of patient care. The self operation and freeing of the endoscopy assistant will result in better monitoring of the patient.

**Conclusions:** Our invention, the endoscopy biopsy assist device, will revolutionize the biopsy procedure in gastrointestinal and other endoscopies. The reduced diagnostic procedure time will result in increased patient comfort. The self operation and freeing of the endoscopy assistant will result in better monitoring of the patient.
Conclusions: Gastrointestinal motility can be determined using video capsule endoscopy technology. Video capsule gastrointestinal transit times in patients with diabetes mellitus are prolonged when compared to healthy controls.

Univariable Analysis Comparison of Video Capsule Transit Times Between Controls and Diabetes Mellitus

<table>
<thead>
<tr>
<th></th>
<th>Diabetes (n = 33)</th>
<th>Controls (n = 45)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>68</td>
<td>62</td>
<td>0.55</td>
</tr>
<tr>
<td>CIT</td>
<td>282.1</td>
<td>210.4</td>
<td>0.002</td>
</tr>
<tr>
<td>SBTT</td>
<td>228.2</td>
<td>163.4</td>
<td>0.017</td>
</tr>
<tr>
<td>GET</td>
<td>53.8</td>
<td>24.5</td>
<td>0.009</td>
</tr>
</tbody>
</table>

Statistical Inference data (p-values) determined by Wilcoxon rank sum (GET, SBTT, Age) and Student’s t-test (CIT).

HGF T staging in superficial esophageal tumors has not been definitively established. The aim of this study was to assess our institution’s staging accuracy for superficial esophageal cancers using HFUS, and to determine whether the use of HFUS improves patient management.

Methods: Between December 1999 and December 2004, 42 patients with esophageal cancer underwent preoperative EUS staging without neoadjuvant chemoradiotherapy. Within this group, five patients underwent staging with HFUS, and make up the study subset. Two patients were referred for Barrett’s esophagus with high-grade dysplasia (HGD) on prior endoscopic biopsy, and three patients were referred for Barrett’s esophagus with esophageal nodules found to be at least intramucosal adenocarcinoma on prior endoscopic biopsy. Overall staging accuracy, rate of complications, and impact on clinical management were assessed.

Results: Four of the five patients (80%) had technically adequate HFUS imaging. By surgical pathology, all four patients had T1 disease (confined to the mucosa or submucosa). The accuracy of HFUS T staging in this group was 100% (95% CI 100–100%). No complications occurred as a result of HFUS examination. In both patients referred with HGD in the setting of Barrett’s esophagus, demonstration of at least intramuscular adenocarcinoma changed management, prompting esophagectomy instead of endoscopic ablation with photodynamic therapy.

Conclusions: 1. Use of HFUS at 20MHz frequency appears to be highly accurate in T staging of superficial esophageal cancers. However, larger studies will now be needed to confirm these results. 2. Use of HFUS appears to be safe. 3. HFUS staging has the potential to significantly impact patient management, particularly in its ability to detect intramuscular or more deeply invasive adenocarcinoma in patients with Barrett’s esophagus with known HGD.

Efficacy and Safety of Endoscopic Mucosal Resection with Hydroxy-Propyl-Methyl-Cellulose Compared to Normal Saline

Christopher J. Bacani, MD, Massimo Raimondo, MD, Timothy A. Woodward, MD, Mohammad A. Al-Haddad, MD, Kyung W. Noh, MD, Sarukh Pangpapong, MD, Michael B. Wallace, MD, M.P.H.,* Gastroenterology and Hepatology, Mayo Clinic, Jacksonville, FL.

Purpose: Endoscopic mucosal resection (EMR) is a therapeutic modality that provides an alternative to surgical resection for the treatment of early gastrointestinal neoplasia. EMR with saline is problematic due to rapid diffusion of liquid and loss of the saline “cushion.” Hydroxy-propyl-methyl cellulose (“HPMC,” Gonak, Akorn Pharmaceuticals, Buffalo Grove, IL) is a viscous, inexpensive ocular lubricant which has been previously evaluated in animals as an EMR lifting agent (Feitoza et al. Gastrointestinal Endoscopy. 2003;57:41–7) The goal of this study was to determine the efficacy and safety in humans of EMR with HPMC as compared to normal saline.

Methods: After publication of preliminary safety data, we began routine use of HPMC for EMR. We compared the complication rate and complete resection rate of HPMC EMR to historical controls using saline EMR after controlling for lesion size and location.

Results: EMR was performed in 89 lesions in 88 patients. HPMC-EMR was used in 67 patients and compared to 22 historical control patients treated with saline EMR by the same 5 endoscopists. HPMC provided prolonged lifting of all lesions throughout the duration of EMR (typically 15–20 minutes) whereas saline dissipated within 2–3 minutes in all cases. Lesion size and location was similar in both HPMC and saline groups. Complications were observed in 6 patients; (5/67 (8%) HPMC and 1/22 (5%) saline, p > 0.2) including 1 perforation controlled with endoscopic clips, 3 bleeds controlled endoscopically and 2 unplanned hospital admissions for observation. Long term follow up with repeat endoscopy was available on 43 lesions and identified 35/43 to be completely excised. (20/25 (80%) HPMC-EMR and 15/18 (83%) saline EMR, p > 0.2) Size of the lesion was not associated with success (success mean size 19mm and failure mean size 19mm, p > 0.2) but there was a trend toward greater success in the esophagus (3/4, 75%), compared to duodenum (5/8, 63%), p > 0.2.

Conclusions: EMR with HPMC appears to have similar safety to saline EMR in removal of early gastrointestinal neoplasia. HPMC provides a longer “lifting time” and greater ease of use. Larger studies are needed to determine if the observed increase in successful EMR is statistically significant.

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Staging of Esophageal Cancer Using High-Frequency Ultrasound (HFUS): A Preliminary Analysis

Rahul A. Shimpi, MD, Josh George, MD, Sailaja Yerrabapu, MD, Paul S. Jowell, MD, Frank G. Gress, MD,* Gastroenterology, Duke University Medical Center, Durham, NC.

Purpose: Standard echoendoscopic evaluation of superficial esophageal tumors using frequencies of 7.5MHz and 12MHz has limited ability to optimally visualize the mucosal and submucosal layers. High-frequency catheter-based miniprobes operating at 20MHz permit improved imaging of the superficial layers of the esophagus. The diagnostic accuracy of HFUS staging in superficial esophageal tumors has not been definitively established. The aim of this study was to assess our institution’s staging accuracy for superficial esophageal cancers using HFUS, and to determine whether the use of HFUS improves patient management.

Methods: Between December 1999 and December 2004, 42 patients with esophageal cancer underwent preoperative EUS staging without neoadjuvant chemoradiotherapy. Within this group, five patients underwent staging with HFUS, and make up the study subset. Two patients were referred for Barrett’s esophagus with high-grade dysplasia (HGD) on prior endoscopic biopsy, and three patients were referred for Barrett’s esophagus with esophageal nodules found to be at least intramucosal adenocarcinoma on prior endoscopic biopsy. Overall staging accuracy, rate of complications, and impact on clinical management were assessed.

Results: Four of the five patients (80%) had technically adequate HFUS imaging. By surgical pathology, all four patients had T1 disease (confined to the mucosa or submucosa). The accuracy of HFUS T staging in this group was 100% (95% CI 100–100%). No complications occurred as a result of HFUS examination. In both patients referred with HGD in the setting of Barrett’s esophagus, demonstration of at least intramuscular adenocarcinoma changed management, prompting esophagectomy instead of endoscopic ablation with photodynamic therapy.

Conclusions: 1. Use of HFUS at 20MHz frequency appears to be highly accurate in T staging of superficial esophageal cancers. However, larger studies will now be needed to confirm these results. 2. Use of HFUS appears to be safe. 3. HFUS staging has the potential to significantly impact patient management, particularly in its ability to detect intramuscular or more deeply invasive adenocarcinoma in patients with Barrett’s esophagus with known HGD.

Gastroenterologist-Directed Administration of Propofol Combined with Benzodiazepine and an Opioid: A Prospective Study

Brian W. Sipe, MD,* Mark D. Scheidler, MD, Arthur R. Baluyut, MD, PhD, Gastroenterology, St Vincent Hospital, Indianapolis, IN.

Purpose: The combination of propofol, meperidine, and midazolam has been used successfully by non-anesthesiologists for endoscopic sedation to consistently induce a moderate level of sedation.

Methods: We prospectively enrolled 100 patients(pts) ASA 1–3 undergoing outpatient colonoscopy. Sedation was performed according to an established protocol (Gastrointest Endosc. 2003;58:725). Pts were pre-medicated with midazolam 1mg & meperidine 50mg. Propofol was given in 5–10mg boluses. A nurse administered the sedation under the supervision of a gastroenterologist. Every 2 minutes, blood pressure, heart rate, oxygen saturation, BIS, end-tidal CO2, and levels of sedation as defined by the Modified Observer’s Assessment of Alertness/Sedation (MOAA/S) scale were assessed and recorded. All pts began the procedure on room air. Interventions for hypventilation (O2sat <90%) were recorded. Pts were surveyed by phone 24–48hrs after the procedure.

Results: The pts average age was 50. Female 64% and Male 36%. Pts ASA classification was 1–2. 2–3, 2–7. The mean time for induction of sedation was 3 min. Mean procedure time was 7min. The mean propofol dose was 96 ± 41mg. A total of 86% of the administered sedation was used. The level of sedation was observed to be minimal 234 (27,1%), moderate 628(72.6%), and deep 3(0.3%). Persistent O2 <90% for >30 sec was treated with jaw thrust in 8 patients and one patient was briefly treated with O2 2L by NC. No significant procedural or sedation adverse events were noted. After the procedure was complete, the average time to stand at bedside w/o assistance was 10min, drink fluids 14min, and met discharge criteria 20min. Post procedure satisfaction on a (0–10 scale) was high with an average procedure satisfaction of 9.4 ± 0.8 and sedation satisfaction of 9.4 ± 1.1.
Mild intra-procedure pain was noted by 15%, and no pain was felt by 85% of pts. 5% pts wanted more sedation, 6% wanted less sedation, and 89% “got the right amount.” 88% patients recalled most or all of their post-procedure conversation with the physician. 97% pts were satisfied or very satisfied with the physicians explanation of their test results.

**Conclusions:** This protocol for propofol administration by non-anesthesiologists is safe and effective for patients undergoing elective colonoscopy. The level of sedation was readily titrated to a moderate level of sedation while preserving a high degree of patient satisfaction.

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**Impact of Anticoagulation on Rebleeding Following Endoscopic Therapy for Non-Variceal Upper Gastrointestinal Hemorrhage**

Anne T. Wolf, MD, Sharmee K. Wasan, MD, John R. Saltzman, MD,* Gastroenterology, Brigham and Women’s Hospital, Boston, MA and Medicine, Brigham and Women’s Hospital, Boston, MA.

**Purpose:** Endoscopic therapy for non-variceal upper gastrointestinal hemorrhage achieves hemostasis in greater than 90% of patients, but up to 20% rebleed. The aim of this study was to determine the impact of anticoagulation on rebleeding in patients undergoing endoscopic therapy for non-variceal upper gastrointestinal hemorrhage.

**Methods:** Patients who underwent successful endoscopic therapy for non-variceal upper gastrointestinal hemorrhage between July 1, 1999, and June 30, 2004, at a large, tertiary care teaching hospital were identified. The primary outcome was rebleeding within 30-days. Secondary outcomes were transfusion requirement, length of stay, surgery, and mortality. Baseline data were analyzed using t-tests and χ² tests. Multivariable logistic and linear regression analyses were carried out to calculate the adjusted odds ratios for the primary and secondary outcomes. The multivariable analyses controlled for age, Charlson comorbidity index, antiplatelet agent use, post-procedure heparin use, post-procedure proton pump inhibitor use, hypotension, ulcer as the bleeding source, and active bleeding at endoscopy.

**Results:** The study included 233 patients. Forty-four percent of the patients had an INR ≥ 1.3. Ninety-five percent of the anticoagulated patients had an INR between 1.3 and 2.7. The rebleeding rate was 23% in the anticoagulated patients and 21% in the patients with INRs < 1.3. On multivariable analyses, an INR ≥ 1.3 was not a predictor of rebleeding, transfusion requirement, surgery, length of stay, or mortality.

**Conclusions:** Mild to moderate anticoagulation does not increase the risk of rebleeding following endoscopic therapy for non-variceal upper gastrointestinal hemorrhage, suggesting that endoscopic therapy is appropriate in these patients.

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**Isolated Amyloidosis of the Ampulla: A Rare Presentation of Amyloidosis**

Aran W. Laing, M.B.Ch.B., Ashok Shah, MD,* Division of Gastroenterology and Hepatology, Department of Internal Medicine, University of Rochester, Strong Memorial Hospital, Rochester, NY.

**Purpose:** Rather than defining a single disease entity, amyloidosis is a term which encompasses a group of conditions characterized by extracellular proteinaceous deposition. We present here a case of a man with isolated amyloid of the ampulla of Vater.

**Methods:** This patient is a 42 year old white man with a history of gastroesophageal reflux disease (GERD), who presented with symptoms of heartburn with some bloating and post prandial fullness over a 4–5 month period. An upper GI tract endoscopy showed mild erosive esophagitis, a small hiatal hernia and enlargement of the ampulla of Vater. Liver function tests and amylase/lipase were normal as was ESR. An ERCP showed the ampulla enlarged at approximately 3.5 cm but the common bile duct (CBD) and pancreatic ducts were normal.

**Results:** Biopsies were taken which revealed no neoplastic cells but did contain amorphous eosinophilic material consistent with amyloid. Cholangiogram revealed normal bile ducts. He underwent testing by a hematologist/oncologist including bone marrow biopsy, and hemogenous malignancy and systemic amyloidosis was ruled out. Serum protein electrophoresis, urine protein electrophoresis, urinalysis and renal function were all normal. Spirometry and DLCO were normal as were the cardiac evaluations. Multiple sites were biopsied throughout the GI tract via endoscopy all of which were negative for amyloidosis with the exception of the ampullary mass. The GI tract in some form is involved in up to 60% of patients with reactive or secondary amyloidosis (AA). This compares to only between 1 to 8% of patients with AL having GI tract involvement.

**Conclusions:** This patient has amyloidosis of the ampulla and despite extensive investigation appears to have the disease isolated only to that site. Whilst isolated amyloid tumors are rare, they can lead to significant symptoms and may indicate the presence of a more systemic and sinister underlying condition. Consideration to a possibility of amyloidosis should be given in the event of finding an enlarged ampulla of Vater. We believe this to be the first case ever presented in USA of isolated amyloidosis of the ampulla of Vater.

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**Bowel Preparations and Prokinetics for Small Bowel Capsule Endoscopy**

Cody B. Barnett, MD, Jack A. Di Palma, MD, F.A.C.G.,* Division of Gastroenterology, University of South Alabama College of Medicine, Mobile, AL.

**Purpose:** Current evidence suggests that bowel preparations and/or prokinetics for capsule endoscopy (CE) can lead to shorter transit times, more complete exams, and better mucosal visibility, but there is no standard accepted regimen and there is little experience with combinations. The purpose of this study was to examine our experience with CE bowel preps, prokinetics and simethicone and their effect on transit times and prep quality.

**Methods:** From April 2002 to May 2006, consecutive charts were reviewed recording demographic data, indications, findings and preps and/or prokinetics used for CE. Gastric (GTT) and small bowel transit times (SBTT) were also recorded. CE was judged to be complete if the capsule reached the cecum and if there was adequate prep for mucosal identification of cecum. The quality of prep was determined for each case.

**Results:** There were 274 cases in 176 females (65%) and 98 males (35%). The mean age was 59.5y ±19. Limited bowel preps were given as clear liquids without laxatives (34), bisacodyl (205), or cases performed 1d after...
colonoscopy without additional preparation (4). Full bowel preps used included 4L sulfate-free electrolyte solution (SF-ELS)(1), 2L SF-ELS with bisacodyl (15), oral sodium phosphate (3), or PEG3350 with bisacodyl (2). Prokinetics given 30 minutes prior to CE included metoclopramide 10 mg (34) or tegaserod 6 mg (10). Simethicone 80 mg was also given 30 minutes before CE to those who received prokinetics. The following table illustrates our findings:

<table>
<thead>
<tr>
<th>Preps and prokinetics for capsule endoscopy</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bowel prep</strong></td>
<td>Limited</td>
</tr>
<tr>
<td>Prokinetic prep</td>
<td>None</td>
</tr>
<tr>
<td>n</td>
<td>226</td>
</tr>
<tr>
<td>GTT (min)</td>
<td>35.5 ± 38.5</td>
</tr>
<tr>
<td>SBT (min)</td>
<td>234.5 ± 96.7</td>
</tr>
<tr>
<td>Complete exam</td>
<td>81%</td>
</tr>
<tr>
<td>Prep quality score (avg)</td>
<td>2.5</td>
</tr>
</tbody>
</table>

Conclusions: For CE, improved mucosal visualization, shorter transit times and more complete exams were seen in subjects who had full bowel preps or prokinetics.

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**A Randomized, Double-Blind Study Using Diphenhydramine as an Adjunctive Medication for Conscious Sedation during ERCP and EUS**

Matthew M. Baichi, MD, Razi M. Arifuddin, MD, Asad Ullah, MD, Parvez S. Mantry, MD, Benedict J. Maliaakkal, MD.* Division of Digestive and Liver Diseases, University of Rochester, Rochester, NY.

Purpose: Lengthy procedures such as ERCP and EUS require higher doses of conventional sedatives. The use of droperidol is often limited by cardiovascular toxicity. Propofol is often limited by insurance reimbursement. Diphenhydramine has been used anecdotally as an adjunctive agent for conscious sedation in gastrointestinal endoscopy. Our purpose was to evaluate the efficacy of diphenhydramine as an adjunctive agent for conscious sedation during ERCP and EUS.

Methods: We used a single center, randomized, double-blind, placebo-controlled design. All participants received 50mg intravenous diphenhydramine or placebo followed immediately by 50 mg meperidine and 2 mg midazolam. Further sedation was at the discretion of the endoscopist. Outcomes were doses of meperidine and midazolam, sedation failures, subjective sedation ratings, recovery times, and safety measures.

Results: 54 patients were enrolled (27 in each group). Patient characteristics were similar in both the diphenhydramine and placebo group (table 1). There was no statistical difference between doses of meperidine and midazolam, frequency of sedation failures, subjective sedation ratings, and recovery times (table 2). No sedation complications were observed in either group.

Conclusions: Diphenhydramine is not effective as an adjunctive agent for conscious sedation during ERCP or EUS. A larger cohort of patients would allow subgroup analysis to determine if certain patient populations would benefit.

### Sedation Endpoints

<table>
<thead>
<tr>
<th></th>
<th>Placebo (n = 27)</th>
<th>Diphenhydramine (n = 27)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meperidine dose (mg)</td>
<td>100</td>
<td>98.1</td>
<td>0.8269</td>
</tr>
<tr>
<td>Midazolam dose (mg)</td>
<td>8.7</td>
<td>8.3</td>
<td>0.5839</td>
</tr>
<tr>
<td>Procedure time (min)</td>
<td>42.5</td>
<td>36.4</td>
<td>0.1073</td>
</tr>
<tr>
<td>Inability to complete exam because of poor sedation</td>
<td>n = 1</td>
<td>n = 3</td>
<td>0.6124</td>
</tr>
<tr>
<td>Attending sedation scale (1–5)</td>
<td>3.6</td>
<td>3.7</td>
<td>0.7467</td>
</tr>
<tr>
<td>Nurse sedation scale (1–5)</td>
<td>3.1</td>
<td>3.5</td>
<td>0.2501</td>
</tr>
<tr>
<td>Patient sedation scale (1–5)</td>
<td>4.4</td>
<td>4.7</td>
<td>0.1886</td>
</tr>
<tr>
<td>Recovery time (min)</td>
<td>70</td>
<td>71.2</td>
<td>0.8817</td>
</tr>
</tbody>
</table>

1288

**Initial Experience with Double-Balloon Enteroscopy at a U.S. Center: Technical Aspects, Indications, Findings, and Impact on Care**

Seth A. Gross, MD, Mark E. Stark, MD,* Gastroenterology and Hepatology, Mayo Clinic, Jacksonville, FL.

Purpose: Describe initial experience with double-balloon enteroscopy (DBE) at a single U.S. center.

Methods: We reviewed the first 60 DBE procedures performed at our center between September 2005 and May 2006, using the Fujinon EN-450T5 or PS enteroscopes. DBE was defined as “Helpful” if it showed a convincing explanation of symptoms, guided management, defined an abnormality seen on other tests, or accomplished the desired endoscopic goal (eg hemostasis). DBE was defined as “Possibly Helpful” if lesions of uncertain significance were found.

Results: 60 DBE procedures were performed on 42 outpatients (M 27, F 15; mean age 63yr, range 25–88). 33 DBE were per-oral, 27 per-anal. A single operator controlled the enteroscope or overtube, while an assistant held the other device in position. Per-anal DBE were done with general anesthesia and endotracheal intubation; per-anal DBE with conscious sedation. Indications were gastrointestinal hemorrhage (76% of patients), diarrhea or suspected Crohn’s disease (19%), suspected neoplasm (2.5%), and foreign body (2.5%). Mean procedure time for per-oral DBE was 98 min (range 55–180); for per-anal DBE 103 min (45–173). Mean fluoroscopy time was 4.9 min (0–14.7). Mean length of small intestine examined by per-oral DBE was 220 cm (range 60–480); by per-anal DBE 111 cm (40–250). 32% of procedures were terminated when the target lesion was reached; in all others when no progress was possible. Complete enteroscopy was possible in one of 14 of patients when attempted by combined per-oral and per-anal DBE. Findings were seen in 37 of 42 patients: AVM (19 patients), benign tumors (9), post-op change (2), erosions (2), Crohn’s disease (2), eosinophilic enteritis (2), small bowel varices (1), Dieulafoy lesion (1), lymphoma (1), melanoma (1), metastatic colon cancer (1), blood without source (1). Of 36 patients with findings on capsule endoscopy, 29 (81%) had the finding identified at DBE. Interventions were performed in 90% of DBE: argon plasma coagulation (40% of DBE), biopsy (28%), tattoo (25%), retrieve foreign body (2%), polypectomy (2%). All patients were released with 2 hours of DBE completion. There were no major complications. DBE was judged “Helpful” in 64.3% of patients, “Possibly Helpful” in 14.3%, and “Not Helpful” in 21.4%.

Conclusions: During initial experience, DBE is time-consuming, and does not always allow total enteroscopy. However it is helpful in most patients, it allows tissue sampling and therapeutic interventions, and is safe and well-tolerated.

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**The Effects of a One-Day Hands-On Endoscopic Training Course for Practicing Gastroenterologists**

Mark Osowskiitz, MD,* Afkhamossadat Merikhi, MD, Michael L. Kochman, MD, Asyia Ahmad, MD. Gastroenterology and Hepatology, Drexel...
Double Balloon Enteroscopy in the Private Sector
Kyle P. Etzkorn, MD, * John M. Petersen, D.O., F.A.C.G., Borland-Groover Clinic, Baptist Medical Center, Jacksonville, FL.

Purpose: Double balloon enteroscopy (DBE) is exciting, new technology that often compliments video capsule endoscopy, and has opened the small bowel (SB) to accurate diagnosis and directed treatments. This abstract will review our initial experience with DBE, and examine the indications, findings, efficacy and safety of the procedure, as well as its impact on healthcare providers.

Methods: From Oct. ’05-May ’06, we performed 50 out-patient DBE on 46 patients, 28 males, 22 females, mean age 62 yrs. (range 14–88), at a single 580 bed urban hospital. DBE was done to evaluate obscure GI bleeds and/or unexplained iron deficiency anemia (29), Crohn’s (7), possible neoplasms (28–85 years). Three patients had surgically altered anatomy that eliminated access medically or SB enteroscope (22 patients). Conscious sedation was achieved with Demerol/Fentanyl and Versed. After initial scope passage into the ligament of Treitz, the SL was placed beyond the pylorus in 22/25 patients and locked in place within the C-loop to prevent looping. Thereafter, scope and SL were passed to the limits of the scope length or definable pathology using push and pull maneuvers with and without unlocking and advancement of the SL.

Results: The ShapeLock® was placed beyond the pylorus in 22/25 patients (28–85 years). Three patients had surgically altered anatomy that eliminated the pylorus. The scope was advanced into the terminal ileum in 3 patients, and to mid to distal jejunum in the remaining 22 patients. Bleeding sites were treated in 6/15 patients; a lymphoma in 1, an anastomotic stenosis in 3, and minor pyloric abrasions in 8. An asymptomatic Mallory–Weiss tear was seen in one patient and significant uvala edema in another.

Conclusions: 1) ShapeLock® endoscopy precludes looping in the stomach and potentially improves efficacy when compared to CE and/or conventional SBE in this series of patients. 2) Additional studies are needed to define its role relative to CE and DBE.

The Downstream Economics of Double Balloon Enteroscopy
Andrew Ross, MD, Joel Roth, Charles Dye, MD, Carol Somrad, MD, Irving Waxman, MD, * Section of Endoscopy & Therapeutics, The University of Chicago Hospitals, Chicago, IL.

Purpose: Double balloon enteroscopy (DBE) is an endoscopic technology which allows for endoscopic evaluation deep into the small intestine. In some cases, complete enteroscopy without the need for laparotomy is possible. A variety of endoscopic therapies can be performed using the double

year, we estimate that DBE findings/treatments have saved numerous RBC transfusions, scores of hospital days, ER visits, office returns, labs, contrast and/or nuclear studies, and repeat endoscopies. In 20/29 DBE exams done for avm bleeding, APC cautery eliminated the need for further transfusion in 16, and dramatically decreased the number and frequency of RBC needs in the other 9.

Conclusions: DBE can be performed safely and effectively in the private practice sector, and has significant impact on the diagnosis and treatment of numerous benign and malignant SB disorders, with substantial cost savings to the healthcare system.
balloon enteroscope. Despite its numerous advantages over other endoscopic technologies used to diagnose and treat small bowel disease, DBE is time-consuming, and, at the present time, poorly reimbursed relative to time invested by the gastroenterologist to perform the procedure. This is likely a major factor limiting its wide-spread use in the Gastroenterology community. The aim of this study was to determine the downstream revenue associated with performing large volume DBE in a single tertiary referral center.

**Methods:** A retrospective review of total hospital charges, revenue and cost of providing services associated with DBE between August, 2004 and December, 2005 was performed.

**Results:** 79 patients had undergone DBE during the period of interest. 52 patients were eliminated for hospital activity prior to 2004 or initial hospital encounter outside of Gastroenterology. Of the remaining 27 patients, the payer mix was 58% private third party insurance, 42% Medicare and 0% public aid or self pay. The revenue from DBE and related hospital services was $95000 within the first year of performing the procedure. A total of $260000 in hospital charges was generated from eight patients and 41 inpatient hospital days. Over the next six months, the center billed $900000 on a total of 82 inpatient days with revenue of $100000 for DBE and related hospital services.

**Conclusions:** This conservative analysis suggests that downstream revenue generated by performing DBE in a high-volume referral center is significant. Such economics would favor performing DBE in centers where other services such as inpatient hospitalization and surgery are readily available.

**Predictive Value of Alarm Symptoms in Upper Gastrointestinal Cancer Diagnosis**

Elmufty M. Said, M.B.B.S., Anastasios Koulouzidis, M.R.C.P., Demetris Nicolaides, MD, David Clarkson, B.Sc., Athar Saeed, F.R.C.P.,∗ Department of Gastroenterology, Queen Elizabeth Hospital, Gateshead, Tyne and Wear, United Kingdom.

**Purpose:** The National Institute for Health & Clinical Excellence (NICE) published guidelines (2005) for referral of patients with symptoms suggestive of upper gastrointestinal (UGI) cancer. These guidelines suggest urgent referral/endscopy for patients (regardless age) with dyspepsia who also develop dysphagia, progressive unintentional weight loss, persistent vomiting, iron deficiency anemia (IDA), peptic ulcer or normal barium meal and patients aged 55 years or more suffering from persistent and unexplained dyspepsia. We evaluated the relative predictive value of alarm symptoms for UGI cancer.

**Methods:** Retrospective study; using the computerized endoscopy report register of our hospital (District General Hospital in North-East of England; catchment population of 250000) we identified patients referred under the “Two Week Rule” (TWR) for urgent UGI endoscopy between May 2005 and April 2006 (1 year period). The recorded symptoms were analyzed under the light of positive histology reports (gastric and oesophageal cancers).

**Results:** Patients referred under TWR 342, mean age: 62.95 (range: 17–91), 198 were females (mean age: 63.74) and 144 were males (mean age: 61.86). Number of endoscopies performed: 339 (in 3 cases the test was abandoned). Thirteen (n = 13) UGI cancers found (3.8%). The positive predictive value of all alarm symptoms was 3.49%. Ten esophageal and three gastric adenocarcinomas were found in 8 males (mean age: 68.5) and 5 females (mean age: 65.2). Mean age at diagnosis was 66.2 years for esophageal and 71.6 years for gastric cancers. Reasons for the TWR referrals were: dysphagia in 255(75.2%), weight loss in 40(11.7%), persistent vomiting in 26(7.6%), dyspepsia [patients above 55 years] in 22(6.4%), IDA in 18(5.3%). Of 13 patients who had diagnosis of cancer, 11 had dysphagia (84%), 2 had vomiting, 2 had weight loss, none had anemia. In this cohort, dyspepsia alone at any age did not lead to a diagnosis of cancer. All people with esophageal cancer had dysphagia, so the negative predictive value of this symptom in this cohort was 100%. Also esophageal cancer was 3 times more common as compared to stomach cancer in our series.

**Conclusions:** Dysphagia is the commonest alarm symptom and is found in all patients with esophageal cancer. In our view, dyspepsia alone, in the age group above 55 years, should not be considered an alarm symptom. The positive predictive value of alarm symptoms is 3.49%.
CCD to view the mucosal microvasculature. We hypothesized that NBI might permit improved visualization of the laser light fiber during PDT procedures and thereby improve the accuracy of light application. The aim of this study was to evaluate laser light application during PDT procedures using NBI and then compare the rates of stricture formation with previous PDT procedures performed using conventional white light endoscopy.

Methods: After IRB approval, consecutive patients undergoing endoscopic ablation treatment with Ps-PDT for BE+HGD or IMC were compared for visualization and determination of laser fiber and mucosal location using standard definition white light endoscopy (Olympus GIF-Q180), high definition white light endoscopy (Olympus XGIF-H160Y2), and HD-NBI (Olympus XGIF-H160Y2, 415 and 540 nm). The incidence of post-Ps-PDT stricture formation (dysphagia associated with mucosal scarring or narrowing) was compared with historical controls.

Results: Narrow Band Imaging used to guide poriferon sodium photodynamic therapy in 15 patients (9 BE+HGD pts, 6 IMC pts). All patients were men; mean age 67 yrs, range 59–76 yrs. The mean BE segment was 4 cm; range 1–10 cm. In all cases using a standard white-light endoscope, PDT laser light (630nm, Diomed Inc.) induced CCD video chip “white out” preventing direct visualization and positioning of the laser fiber. HD white light endoscopes (without NBI mode activated) visualized the laser fiber position but not mucosal location. In each case, the use of HD NBI permitted real-time, continuous determination of the laser light fiber position and mucosal location. Strictures occurred in 2/15 patients (13%) after NBI Ps-PDT compared with 22–25% stricture rate in historical controls.

Conclusions: The use of Narrow Band Imaging during PDT for Barrett’s high grade dysplasia or mucosal carcinoma permitted the continuous determination of laser fiber position and mucosal location without the need for a fiber-centering balloon device and may reduce the rate of post ablation stricture.

1296

Diabetes Management Prior to Endoscopy
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Purpose: There is limited available data on the proper management of diabetes in the setting of gastrointestinal endoscopic procedures. The aim of this study was to determine what recommendations physicians gave to their patients concerning their diabetes regimen prior to endoscopy.

Methods: Prior to any endoscopic procedures performed at Beth Israel Medical Center, diabetic patients were given a survey to complete during their initial intake. The survey consisted of 11 questions which sought to determine: type of endoscopic procedure, sex, type of diabetes, doses of insulin or oral agents taken on the day of and the day prior to the exam, instructions given to them by their gastroenterologist and their most recent blood glucose at home and at the hospital. Glucose levels were classified as low (<60), normal (61–200) and high (>200). The inclusion criteria included patients 18 years or older with a diagnosis of diabetes, who underwent an elective endoscopic procedure.

Results: Thirty-two patients filled out the questionnaire during the one month period. Seven were male and 25 were female. Thirteen of the patients took insulin, while 19 took oral agents. Eleven patients received advice from their gastroenterologist, twelve patients received no advice, and nine patients reported that they were unsure if they received any advice. Of the eight insulin dependent patients who did receive advice, 88% of them were told to take their normal dose of insulin the day before the procedure and take no insulin on the day of the test. Of the three patients who were given advice by their doctor and were on oral agents, 66.7% of them were told to take their normal dose of medication the day before the procedure and not to take any medication on the day of the test. Only five patients had a finger stick glucose performed at the hospital, which was classified as outside the normal range. Two patients had glucose levels below 60 and 3 patients had finger sticks above 200.

Conclusions: Our study revealed that a large proportion of diabetic patients undergoing endoscopic procedures received either no instructions or were unsure whether instructions were given to them regarding management of their diabetes. Whether or not they received instructions, the majority of patients seemed to have blood sugars in the normal range on the day of their exams. Further studies need to be conducted to determine what specific instructions, if any, should be given to these patients prior to endoscopy.

1297

Development and Implementation of a Non-Anesthesiologist (Nurse-Based) Propofol Sedation Program for Endoscopy at a Community Hospital
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Purpose: Patients want safe, effective sedation for their endoscopies. The majority of endoscopies in the US are done using midazolam/fentanyl. There are a number of reports showing that propofol can be used to safely produce effective deep sedation for endoscopic procedures. We describe a program for introducing propofol as the primary sedating method at our community hospital.

Methods: The first step was to determine if there were any legal barriers to nurse administered propofol in CO. Next was to generate a preliminary program design, which was presented to the appropriate committees and areas of the hospital that would be impacted (including policies and procedures), and plan a monitoring program to assess the safety and efficacy of the program after initiation. We obtained financial support from the hospital to send 2 physicians and 2 nurses for didactic and observational training with Dr. John Walker in Medford, OR. After training, a pilot program was initiated to collect prospective information for assessment by the hospital credentialing and policy committees. We implemented changes in patient monitoring, setup data collection specific to the new program, designed a patient follow up questionnaire, and developed goals for achievement that included an on site visit by Dr. Walker to assess our program. The final step was to design and implement a local didactic and hands on training program for the other staff nurses and physicians in the GI Lab at the hospital.

Results: 1000 cases have been completed (8/05 to present) by the 2 trained MD’s. We have used only propofol for all of these endoscopies (ASA scores of 1–4). Propofol was used for EGD, therapeutic EGD, colonoscopies, ERCP, EUS and PEG cases. There have been no SAE’s noted to this point. 52 out patients receiving propofol (P) were compared to 52 who received midazolam/fentanyl (MF). P had 6 minor AE’s, while MF had a comparable 7 AE’s. P returned to their baseline Aldrete score in 6.7 min and MF took 14.7 min. A phone survey found that the P felt they were better sedated, tolerated the post-procedure period better, and remembered the post procedure instructions better.

Conclusions: We feel that a nurse administered propofol sedation program can be safely and effectively introduced into a community hospital with the proper cooperation from multiple hospital departments. Patients did better with propofol sedation.
with wall closure have included difficulty in approximating the sides of resection sites and various fistulae and obtaining a tight immediate seal; thereby limiting the application of endoscopic therapy to relatively small openings and defects, and limiting the size of full-thickness resection. To alleviate and overcome these obstacles we hypothesized that wall defects may be able to be effectively bridged and securely closed in two steps with the use of suture placement for closure.

Methods: Animal survival model in 2.25–30 kg swine. Transluminal defects were created with electrocautery in the gastric wall. The openings were 12–15 mm in size, allowing for easy passage of a 2T130 endoscope into the peritoneal cavity. The defects remained easily visible and patent with removal of the endoscope (no spontaneous closure was noted). Using grasping forceps and T-tag sutures the defects were sequentially closed. First the muscularis propria layer was identified and closed with 2 T-tags with a lock. Subsequently the overlying mucosal defect was closed using 2 T-tags with a lock.

Results: The closure was immediately successful with gastric distention with air insufflation and no evidence of subsequent additional pneumoperitoneum. No placement failure occurred. No clinical peritonitis or failure to thrive was noted. No gross peritonitis was noted on post-mortem examination.

Conclusions: 1. Endoscopic 2-layer of gastrointestinal mucosa is feasible. 2. 2-layer closure provides immediate air-tight closure. 3. Closure of iatrogenic GI wall defects, resection sites, and fistulas (e.g. NOTES, CD, wall resection, surgical Anastomotic breakdown, etc.) may be effectively treated.

Shape Memory Alloy (SMA) Controlled Movement of Capsule Endoscope
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Purpose: The introduction of video capsule (VC) technology has allowed for kinetic intraluminal imaging of the GI tract. Currently the capsule is not able to be controlled or commanded to examine specific areas. The VC is unable to remain in a fixed location for serial imaging of an individual target lesion. The next logical extension of this is to allow for movement and aiming of the capsule.

Methods: Video capsules were attached to nylon thread and radio-controlled (RC) car servos on the benchtop. Subsequent porcine in vivo placement of RC servo controlled video capsules was performed via a transgastric pinhole gastrostomy approach with a connecting line passed to the VC servo which remained extracorporeal. In vivo survival experiments were performed to evaluate the longevity of fastening techniques.

Results: RC servos are able to rotate and elevate the VC on the benchtop. In vivo the ability to rotate the capsule was demonstrated with some technical issues in transmitting the requisite torque for activation. Elevation of the VC was easily attained, though declination was difficult due to orientation with gravity and resistance to passage of the servo line through the gastric wall.

Conclusions: 1. RC Control of in vivo capsule endoscopes is feasible. Further development may facilitate serial examination of high-risk bleeding lesions and aid in the development of application of disconnected endoscopy including evaluation of the biliary tree. 2. Radial scanning and up/down control of movement is possible. Further refinement of technique, miniaturization, sealing from bodily fluids and remote on/off of capsule endoscope will be needed.

Open-Access Colonoscopy: Do Patients Know What They’re Getting into?
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Purpose: Surveys from our medical center indicate that patients are satisfied with their experience in an open-access system. However, participation in an open-access system affects patient understanding of endoscopic procedures is currently unknown. We sought to compare patient knowledge levels between patients referred for colonoscopy via an open-access system (OAC) vs. those who had a pre-procedure consultation with a gastroenterologist (CGI) prior to undergoing colonoscopy.

Methods: Prospective cohort study of 84 patients undergoing colonoscopy in our endoscopy lab. Patients were eligible to participate if they were undergoing colonoscopy for CRC screening or polyp surveillance. Upon arrival to the lab, patients completed a survey which evaluated their pre-procedure experience. Questions focused on patient satisfaction, comprehension of pre-procedure preparation instructions, and the informed consent process. Chi-square analysis was performed using SPSS 11.5 (Chicago, IL).

Results: Patient satisfaction rates were similar amongst the groups: 80% of OAC patients and 86% of CGI patients were satisfied with the method by which they were referred. However, the groups differed with respect to their understanding of multiple components of informed consent. OAC patients were less likely to understand the risks, benefits, and alternatives of colonoscopy (43% vs. 85%, X2 = 17.1, p = 0.001) and less likely to know that they were going to receive intravenous sedation (66% vs. 96%, X2 = 13.4, p = 0.001). Only 63% of OAC patients were able to ask questions of their referring physician, while 94% of CGI patients were given the opportunity to ask questions during their office visit (X2 = 10.1, p = .001). There were
no significant differences in sex, race, income, or education level between the groups.

Conclusions: Despite being satisfied with the open-access system, these patients do not receive adequate informed consent with regard to colonoscopy’s risk, benefits and alternatives. Patients are unlikely to cancel their procedure or seek alternatives to it after undergoing a bowel preparation, missing work, and arranging for transportation. Thus, efforts should be directed toward adequately informing these patients prior to their arrival at the endoscopy lab. Potential interventions include distribution of educational materials, calls to patients from the endoscopists in advance of the procedure, and enhanced efforts to educate referring physicians about colonoscopy’s performance, risks, benefits, and alternatives.

1302
How Much Time Does Ileocecal Valvotomy Add to the Colonoscopy Exam and How Successful Are We at Its Performance?
Athan P. Kartsonis, MD,* Kim Howse, R.N., Melbourne ASC, Melbourne Ambulatory Surgery Center, Melbourne, FL.

Purpose: Numerous studies have confirmed that a major reason cancers are missed during colonoscopy is the erroneous documentation of cecum entry. Cannulation of the ileocecal valve and visualization of the ileum clearly prove that the cecum has at very least been identified. The purpose of this study was to determine success rate and time requirements for ileal cannulation during elective colonoscopy.

Methods: The study comprised 102 consecutive patients (60 females 42 males) undergoing elective colonoscopy by one gastroenterologist (AK) from 4/7/06 to 5/16/06. Patients with previous colonic resections were excluded. Diprovan was the major anesthetic agent used in the study. Time to cecal intubation was obtained in all patients with a stop watch. Subsequently ileal cannulation from the cecum was timed with a stop watch with a time cutoff limitation of 5 mins. The method of ileocecal entry (retroflexed or forward) was recorded. Photo documentation of the ileum was obtained in all successful procedures.

Results: Cecal cannulation was accomplished in all 102 patients. Average time to cecal intubation was 3min 42 sec. The ileocecal valve was successfully entered in 89 of 102 patients (87% success rate). Average time to ileocecal cannulation was 1min 38sec. Additional average time added to the entire colonoscopy procedure when employing the 5 min cut off time was 2mins 15secs. Ileocecal cannulation was performed via forward entry rather than retroflexion in the cecum in 84 out of 87 patients. All patients were maintained in the left lateral decubitus position. No complications were encountered during the study.

Conclusions: 1. Ileal cannulation can be performed in a high percentage of elective colonoscopy procedures (87% in this study) in a relatively short period of time. 2. Using a 5 minute cutoff time for attempting ileal intubation added 2min 15sec of additional time to the total colonoscopy procedure. 3. Cannulation by retroflexion in the cecum was rarely necessary. 4. Ileocecal valve cannulation demonstrates unequivocal total colonoscopy to the cecum and should be attempted in elective procedures.

1303
Variables Associated with Complications from Gastrointestinal Endoscopic Procedures
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Purpose: Gastrointestinal (GI) endoscopy is a common and usually low risk procedure. Although rare, complications can be serious, which include complications as a result of instrumentation, cardiopulmonary and neurological. Guidelines from the American Society of Gastrointestinal Endoscopy (ASGE) suggest that patients who are elderly, who have concomitant medical problems, patients who are taking sedatives, opiates, and anxietytics may be at increased risk.

Aim: To identify variables associated with increased risk for complications from gastrointestinal endoscopic procedures and to establish the magnitude of risk.

Methods: We conducted a case-control study from 17289 GI endoscopic procedures comparing 41 cases with complications to 115 controls. We looked at the confidence intervals and odds ratios. Cases and controls were matched by age (± 5 years) and gender. Comorbid conditions, medications, type and duration of the procedure and demographics were obtained from each of the patient’s records. A univariate comparison was done initially using Chi-square test and we checked for interactions between variables with likelihood ratio test. Backward, stepwise, logistic regression analysis was done to control for confounding variables.

Results: Logistic regression analysis yielded significant associations. Comorbid states related to complications included coronary artery disease (CAD) and chronic obstructive pulmonary disease (COPD) combined (OR 21, p = 0.003) and Renal disease (OR 12, p = 0.006). Procedure time (OR 1.1, p = 0.023) by minute showed increased risk, while pre-procedure sedation use (OR 0.007 p = 0.021) had a negative association. The following procedures were associated with low risk: EGD (OR 0.001, p = 0.011), colonoscopy (OR 0.002, p = 0.015) and others like flexible sigmoidoscopy and percutaneous gastrostomy tube placement (OR0.001, p = 0.029).

Conclusions: CAD and COPD combined in a patient, and renal disease with serum creatinine > 2.0 conveyed significant risk for complications during GI endoscopic procedures. Duration of procedure had a direct relation to the occurrence of complications. EGD and colonoscopy along with other procedures are considered to have low risk for complications. Surprisingly, patients who take sedatives as outpatient are at low risk. This might be secondary to their tolerance to the sedation during the procedure. Obesity did not appear to have any significance.

1304
Prophylactic PEG Placement Prevents Exacerbation of Weight Loss during Chemo-Radiation for Head and Neck Cancer Patients
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Purpose: In addition to generalized risk factors of anorexia and cachexia, head and neck cancer patients receiving chemo-radiation therapy are at risk for significant weight loss secondary to mucositis and the odynophagia/dysphagia caused by radiation injury to the esophagus. It is routine practice to prophylactically place a percutaneous endoscopic gastrostomy tube prior to the initiation of chemo-radiation in this population. The value of prophylactic placement has been questioned as some patients never require to utilize the PEG after it has been placed. Outcome parameters of PEG placement were studied in head and neck cancer patients referred routinely for a PEG prior to chemo-radiation. Specifically, we were focused on whether patients utilized the PEG at all for maintenance of hydration or nutrition, and if so, whether utilization of the PEG allowed patients to maintain their weight compared to patients who did not use the PEG.

Methods: A retrospective chart review was performed on 34 consecutive patients who underwent PEG placement prior to beginning combination chemo-radiation for head and neck cancers. Use of the PEG tube and body weights were assessed 12 to 16 weeks after initiation of therapy. The same attending gastroenterologist supervised PEG placement and follow up of each patient.

Results: 5 patients were lost to follow-up, allowing for analysis of 29 patients. 6/29 (20.7%) patients did not end up using the PEG at all for hydration or nutrition. 7/29 (24.1%) patients used the PEG exclusively, due to severe limitations of oral intake. 16/29 (55.2%) patients used the PEG to supplement limited oral intake. Over all average weight loss was 8.0 kg per patient; a reduction in usual body weight (UBW) of 9.9%. Among the patients who never used their PEG the average weight loss was 8.7 kg; a reduction in
Amyloidosis of the Gallbladder Diagnosed after Laparoscopic Cholecystectomy

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Purpose: Amyloidosis is characterized by the extracellular extracellular amyloid deposits in various tissues, which compresses and replaces normal tissue and leads to organ dysfunction. Although, amyloidosis is a rare disease, the localization of amyloid deposits in the gallbladder is extremely rare.

Methods: Case report: We report a rare case of amyloidosis of the gallbladder in a 63-year-old woman with a history of primary amyloidosis. She had physically examined at our hospital and pointed out a elevation of gamma-GTP; however had no complaints. Other blood chemistry, hematologic laboratory tests, and he values of tumor markers were unremarkable. Ultrasoundography (US) of the abdomen showed a focal echogenic lesion in the body of the gallbladder and contrast-enhanced US indicated moderate enhancement. Abdominal computed tomography showed nodular wall thickening in the body of the gallbladder which was enhanced by contrast material. Although this patient was asymptomatic, the existence of the gallbladder cancer could not be totally denied. Therefore, laparoscopic cholecystectomy was performed for total biopsy of the gallbladder. An intraoperative frozen-section examination revealed evidence of mild chronic cholecystitis with the appearance of hyalinal stroma and there was no malignant lesion. Final diagnosis, amyloidosis of the gallbladder, was obtained with staining by alkaline alcoholic Congo red.

Results: Discussion: To our knowledge, this is the first case of amyloidosis of the gallbladder mimicking gallbladder cancer which was diagnosed after laparoscopic cholecystectomy. It is extremely difficult to diagnose preoperatively. Especially in our case, we could not exclude the existence of the gallbladder cancer. In this setting, we think that laparoscopic cholecystectomy may justify for the diagnostic option for total biopsy.
**Abstracts**

**Antonio, TX: Neurology, University of Texas Health Science Center at San Antonio, San Antonio, TX; GERSA, Gastroenterology Research of San Antonio, San Antonio, TX and Gastroenterology, Methodist Hospital, San Antonio, TX.**

**Purpose:**Amyotrophic Lateral Sclerosis (ALS) is a devastating motor neuron disease. With recent data suggesting that early nutritional intervention delays the need for mechanical ventilation more patients with ALS are referred early in the course of their disease for endoscopic gastrostomy placement. We have observed foregut pathology in a number of patients undergoing endoscopy.

**Methods:**47 patients referred from the University ALS Clinic for percutaneous endoscopic gastrostomy (PEG) underwent preoperative screening that included a medical history, physical exam and pulmonary function tests to assess forced vital capacity. All endoscopic procedures were performed in the Gastrointestinal Endoscopy Laboratory at Methodist Hospital. BIPAP machines were used in all patients requiring such devices at home. Respiratory therapy assisted on an as-needed basis. Endoscopic findings were recorded prospectively for each patient. Erosive esophagitis (EE) was graded according to the Los Angeles Classification.

**Results:**Of the 47 patients presenting for PEG, 27 were male and 20 were female. The age range was from 25 to 84 years with a mean age of 57.6 years. EE was seen in 10 patients (8 were class A or B; 1 had grade C and 1 had grade D); 2 patients had Barrett’s esophagitis; 5 had gastric erosions; 2 had duodenal erosions; 1 had a duodenal ulcer; 1 had a foreign body of the esophagus; 1 had atrophic gastrropy and 2 had submucosal gastric nodules. 4 pts had more than one finding.

**Conclusions:**1. 21.3% of the patients had EE, suggesting the need for:

a. Careful questioning of ALS pts for symptoms of GERD. Many are unable to communicate and may not voice their symptoms if not asked.

b. Consideration of prophylaxis with proton-pump inhibitors for all ALS patients.

c. Avoiding prolonged periods of recumbinancy.

2. The findings of 38.3% (18/47) of the patients having active acid-peptic disease of the foregut, screening for GI blood loss should be routine.

**Table 1309**

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**1310**

Endoscopic Papillary Balloon Dilation after Sphincterotomy for Common Bile Duct Stones

**Niraj K. Ajmere, MD, Ronald Ste. Marie, MD, Kanishka Bhattacharya, MD.** Gastroenterology, University of Massachusetts, Worcester, MA.

**Purpose:**Large bile duct stones can be difficult to remove with sphincterotomy and established balloon and basket techniques. Additionally, tapering of the distal common bile duct increases the technical challenge of large stone extraction. Endoscopic papillary balloon dilation without sphincterotomy has been associated with an increased rate of post-procedure pancreatitis. Endoscopic papillary balloon dilation after sphincterotomy has been employed in difficult cases involving large stones and tapering of the distal common bile duct. We sought to describe a case series employing this combined technique.

**Methods:**We retrospectively reviewed ERCP reports from our institution between December 2004 to May 2006. Nine patients with large bile duct stones underwent biliary sphincterotomy; however, stone removal was unsuccessful with standard balloon and basket techniques. Subsequently, dilation of the distal common bile duct was performed with a 12 mm. to 15 mm. diameter balloon for 30 seconds to one minute. Following dilation, standard balloon or basket extraction was performed to remove large stones.

**Results:**Stone removal was successful in all nine patients. In one patient removal was unsuccessful after dilation with a 10–11.2 mm. diameter balloon. In this patient, repeat ERCP and dilation with a 12–13.5–15 mm. diameter was performed with complete removal of stones. Stone diameter ranged from 9 mm. to 18 mm. with average stone size of 12.2 mm. Number of stones in each patient ranged from one to greater than three. Pancreatic stents were placed in the first two patients for pancreatitis prophylaxis. There were no complications including bleeding, perforation, and pancreatitis.

**Conclusions:**Endoscopic balloon dilation after sphincterotomy can be a useful and safe technique for the removal of challenging common bile duct stones.

**1311**

Novel Spiral Overtube Device (Endo-Ease Discovery SB™) for Advancement of the Enteroscope through the Small Bowel

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**Purpose:**Small bowel enteroscopy presents significant challenges. A variety of methods for endoscopic visualization of the small bowel have been proposed including Sonde, push, push w/overtube, capsule and double balloon.
All current methods have significant limitations. After success advancing a novel spiral overtube through the ileum during colonoscopy, we postulated a method to advance the enteroscope through the small bowel using the spiral (helical) raised element at the distal end of the overtube to plicate the small bowel onto the enteroscope and therefore advance through the small bowel perorally. Previous work has shown successful rotational advancement of colonoscopes with the Endo-Ease Endoscopic Overtube.

Methods: Enteroscopy was performed on 9 pts with obscure GI bleeding. Sedation was IV Propofol and Versed. The Endo-Ease Discovery SB specifications were 130 cm in length, internal diameter 12.7 mm and external diameter 17.5 mm. The raised helical thread is 5 mm in height. A collar on the proximal end locks the device on the insertion tube of the enteroscope. The Endo-Ease Discovery SB device was placed over the pediatric colonoscope (PCF-140L). The Discovery SB and PCF-140L were advanced to the ligament of Treitz. The Discovery SB collar was unlocked and the PCF-140L was advanced through the Endo-Ease Discovery SB to approximately 20 cm past the ligament of Treitz. The Endo-Ease Discovery SB was then advanced using rotation back to the bending section on the PCF-140L and re-locked. Using rotation of the Endo-Ease Discovery SB, advancement continued. Depth of insertion was estimated by fluoroscopy and endoscopic criteria.

Results: All 9 pts. tolerated the procedure with no intraprocedure complications. Mild post-procedure sore throat resolved by 72 hrs in 3 pts. Two patients had AVM’s identified as a possible source of GI bleeding. Depth of insertion past the ligament of Treitz averaged 102 cm with a range of 60 to 140 cm. Average time of procedure was 34 minutes. Ease of advancement was excellent in 5 pts and good in 4 pts. A thorough visual examination of the lumen during withdrawal indicated no significant tissue trauma.

Conclusions: The first peroral use of the Endo-Ease Discovery SB device through the small bowel was successful and safe. Rotational advancement of the endoscope proved to be an effective means of visualizing the small bowel.

1312

EUS-Guided Antegrade Approach for Visualization and Therapeutics within the Pancreatico-Biliary System

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Purpose: EUS-guided antegrade access of the pancreatic and biliary ducts in failed ERCP cases has been described. We report our experience with antegrade endoscopic intervention using a rendezvous procedure combining EUS with ERCP.

Methods: Five patients (pts) who failed ERCP were offered an EUS-guided antegrade approach. Pts gave informed consent, understanding the unusual nature of the procedure. Using a 19 gauge needle through a linear array echoendoscope, transmural puncture of the desired duct was done, proximal to the obstruction. Contrast ductography was performed. Through the needle, a standard 0.035 guidewire was then introduced into the targeted duct and an adequate wire length was advanced across the papilla into the duodenum. The EUS scope was removed, leaving the guidewire in place. A duodenoscope was next introduced alongside the guidewire. A snare or biopsy forceps was used to grasp the tip of the wire extending out of the papilla and to pull the wire into the scope channel. With appropriate ERCP position now obtained and access established within the duct, diagnostic and therapeutic maneuvers were performed.

Results: All pts had undergone a previously failed ERCP. Indications for therapeutic intervention were obstructive jaundice (2), occluded biliary wall stent (1), recurrent pancreatitis (1), and pancreatic ductal dilatation (1). EUS-guided antegrade ductal access and ductography was successful in all patients (100%). Traaversal of the obstruction, followed by rendezvous ERCP was successful in 4 out of 5 cases (80%). In 1 patient, who had a previously placed wall stent and enteral stent, a new wall stent pushed into position could not be deployed. Therapeutic interventions were successful in the remaining 4 pts. The procedure was well tolerated and there were no immediate or late complications.

Conclusions: When ERCP fails and ductal access is crucial to confirm significant diagnoses or to relieve obstruction, EUS-guided transmural access of the pancreatic or biliary duct with guidewire placement from an antegrade direction, followed by a rendezvous ERCP, is a novel, promising, and less invasive approach, offering an attractive alternative to percutaneous or surgical intervention for ductal decompression. This endoscopic technique is possibly a more optimal method of accessing an obstructed pancreatico-biliary system; however, controlled trials comparing this technique to alternative modalities are needed.

1313

Safety and Efficacy of Fospropofol Disodium Versus Midazolam Hydrochloride for Sedation in Elderly Patients Undergoing Colonoscopy

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Purpose: This study assessed the efficacy and safety of fospropofol disodium (AQUAVAN® injection, AQ) compared with midazolam hydrochloride (MD) in elderly patients undergoing colonoscopy.

Methods: This was a phase 2, multicenter, randomized (stratified by age and center), open-label study. Patients aged >65 years with ASA status I/II/III were randomized to receive an intravenous bolus of AQ (525, 595, or 735 mg) or MD (0.5, 0.75, or 1.0 mg); dosing was based on patient weight. All patients received pretreatment with fentanyl citrate (0.5 μg/kg). Supplemental dosing of AQ/MD and fentanyl were permitted for inadequate sedation and analgesia, respectively. The protocol and informed consent form were approved by a central Institutional Review Board. Sedation success was defined as 3 consecutive Modified Observer’s Assessment of Alertness/Sedation (MOAA/S) scores ≤4 and completion of the procedure without the need for alternative sedatives or manual/mechanical ventilation. Summary statistics were provided for all endpoints.

Results: Fifteen patients received AQ and 5 patients received MD. Mean age was 70 years (range, 65–76 years). All 15 patients in the AQ arm achieved sedation success, as defined under Methods, compared with 0 patients in the MD arm (P < 0.001). A single dose of study drug was sufficient to initiate and maintain sedation for 13/15 AQ-treated patients. AQ and MD were well tolerated. Hypoxia (AQ, 6/15; MD, 1/5) and paresthesias (AQ, 4/15; MD, 0/5) were the most frequently reported adverse events (AEs). Hypoxia was defined as SpO2 of <90% OR a 3% decrease from baseline. Sedation-related AEs were minimal and were managed without difficulty (3 resolved spontaneously and 3 resolved with increased oxygen flow). There were no serious AEs or deaths. No patients required manual ventilation or intubation. Efficacy results are summarized below. [figure1]
Conclusions: Although interpretation of results is limited by the sample size, AQ appears to be safe and effective for moderate sedation in elderly patients undergoing colonoscopy procedures.

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Does Previous Abdominal Surgery Effect the Transit Time or Safety of Capsule Endoscopy
David Ramsay, MD, Michael Frist, MD, Christopher Entwisle, MD, David Jager, MD, Steven Zeddun, MD, Marie Borum, MD, F.A.C.G.* Division of Gastroenterology and Liver Diseases, George Washington University Medical Center, Washington, DC.

Purpose: There is limited research exploring the safety of capsule endoscopy in patients who have had abdominal surgery. Physicians have expressed reluctance in using this widely used technology in patients who have had previous abdominal surgery. This study evaluates the safety of capsule endoscopy in patients with previous abdominal surgery and the effect upon small bowel transit times (SBTT).

Methods: This retrospective study evaluated the endoscopy records of consecutive patients who underwent small bowel capsule endoscopy at a university practice during 2004–2006. The medical records were reviewed to determine if the patient had previous intestinal or non-intestinal abdominal surgery. All patients who had previous abdominal surgery were included. No patient was excluded. A database was created using Microsoft Excel. Comparison of transit times, capsule retention, and complications were conducted. Statistical significance was determined using t-test. The study was approved by the university IRB.

Results: Medical records of 186 patients were reviewed. Sixty-five (35%) had a history of abdominal surgery. Twenty-four (37%) of the surgical patients had intestinal surgery, and 41 (63%) had non-intestinal surgery. There were no reported capsule retentions or complications in the patients who had had abdominal surgery. The average SBTT of patients who did not have abdominal surgery was 253 minutes. The average SBTT of patients with intestinal surgery was 292 minutes. The average SBTT of patients with non-intestinal surgery was 228 minutes. There was no statistically significant difference in the SBTT of patients who had a history of intestinal (p = 0.09) or non-intestinal (p = 0.17) surgery compared to patients without a history of abdominal surgery.

Conclusions: There are no published reports on the capsule endoscopy-determined SBTT in patients with a history of abdominal surgery. This study revealed a history of abdominal surgery had no significant effect on the SBTT. There were also no reported incidents of capsule retention, and there were no complications associated with capsule endoscopy in patients who have had abdominal surgery. This study suggests previous abdominal surgery in patients who do not have evidence of obstruction should not impact upon the decision to use capsule endoscopy. Further capsule endoscopy research may eliminate physicians’ reluctance to use this technology in patients who have had previous surgery.

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Do Motility Disorders Effect the Gastric Emptying or Small Bowel Transit Times of Capsule Endoscopy
David Ramsay, MD, Michael Frist, MD, Christopher Entwisle, MD, David Jager, MD, Steven Zeddun, MD, Marie Borum, MD, F.A.C.G.* Division of Gastroenterology and Liver Diseases, George Washington University Medical Center, Washington, DC.

Purpose: Capsule endoscopy is utilized to evaluate the small bowel mucosa. There is presently little information available evaluating this technology in patients with known motility disorders. This study evaluated the gastric emptying time (GET) and small bowel transit time (SBTT) of capsule endoscopy in patients with diabetes, hypothyroidism, and irritable bowel syndrome (IBS).

Methods: This retrospective study evaluated the medical records and capsule endoscopy reports of consecutive patients who underwent small bowel capsule endoscopy at a university gastroenterology practice in 2004–2006. The medical records were reviewed to determine if the patient had a diagnosis of diabetes, hypothyroidism, or irritable bowel syndrome. A database was created using Microsoft Excel. The GET and SBTT of patients with disorders that can affect motility and patients without these disorders were compared. Statistical analysis was performed using t-test.

Results: In the 197 patients in whom capsule endoscopy was performed, 39 had a diagnosis of diabetes, 16 had a diagnosis of hypothyroidism, and 7 had a diagnosis of IBS. In patients with diabetes, the average GET was 71.87 minutes and the average SBTT was 236.24 minutes. In patients with hypothyroidism, the average GET was 56.82 minutes and the average SBTT was 238.88 minutes. In patients with IBS, the average GET was 69.86 minutes and the average SBTT was 229.19 minutes. There was no statistically significant difference in the GET (p = 0.24) and SBTT (p = 0.33) between patients with and without the diagnosis of diabetes. There was no statistically significant difference in the GET (p = 0.88) and SBTT (p = 0.64) between patients with and without the diagnosis of hypothyroidism. There was no statistically significant difference in the GET (p = 0.70) and SBTT (p = 0.92) between patients with and without the diagnosis of IBS.

Conclusions: There are no published reports on capsule endoscopy determined transit times in patients with a disorder known to effect motility. Diabetes, hypothyroidism, and IBS are known to impact upon intestinal motility. However, this study revealed these conditions had no significant impact on GET or SBTT. Further studies should be performed in these disorders to determine their impact upon transit times and capsule endoscopy interpretation.

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Retrospective Evaluation of Capsule Endoscopy: Indications and Diagnostic Yield
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Purpose: Traditional endoscopic evaluation of the small bowel can be difficult. Capsule endoscopy has emerged as an effective diagnostic tool in the evaluation of obscure gastrointestinal bleeding and anemia; the yield for other indications is under investigation. This study evaluated indications and diagnostic yield of capsule endoscopy.

Methods: A retrospective evaluation of endoscopy reports and medical records of consecutive patients who underwent small bowel capsule endoscopy at a university gastroenterology practice between 2004 and 2006 was performed. Data collected included indication, age, sex, and capsule endoscopy findings. A database was created using Microsoft Excel. Statistical analysis was performed using chi-square test with significance set at p < 0.05.

Results: The medical records of 206 patients (average age of 54, 137 female and 69 male) were evaluated. 166 of the reports indicated that the cecum was identified and technical difficulties were reported in 9 patients. Indications included: anemia (n = 98), obscure gastrointestinal bleeding (n = 31), unspecified (n = 18), Crohn’s disease (n = 16), occult blood positive (n = 9), abdominal pain (n = 7), celiac (n = 4), diarrhea (n = 4), IBS (n = 4), and weight loss (n = 4). history of small bowel obstruction (n = 2), abnormal CT scan (n = 2), evaluation for malignancy (n = 1), curettage (n = 1), history of FAP (1), and history of angiectasia (n = 1). Overall diagnostic yield was 35.4%; including 33.6% for anemia, 54.8% for obscure gastrointestinal bleeding, and 56% for Crohn’s disease. Overall diagnostic yield was statistically greater in males (45%) than in females (30%) (p < 0.05).

Conclusions: Capsule endoscopy is an effective diagnostic tool for evaluating the small bowel. Previously reported diagnostic yield for capsule endoscopy has ranged from 56–75%. The overall diagnostic yield in our population was lower than past studies; however it was comparable to other
studies for both obscure gastrointestinal bleeding and Crohn’s disease. The decreased overall yield may be related to the indications for performing the capsule endoscopy or related to the large number of patients in the study. It is unclear why males had a significantly higher diagnostic yield than females. Further evaluation of the differences in diagnostic yield between male and female patients is warranted.

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Capsule Endoscopy: Bowel Preparation and Diagnostic Yield, Transit Time and Completeness of the Examination

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Purpose: Studies have suggested that capsule endoscopy may be diagnostically superior to other modalities by increasing diagnostic yield by up to three times. There remains no standard regarding whether a bowel preparation is required prior to the examination. Studies evaluating these issues have involved limited number of patients and have offered conflicting results. This study evaluated the effect of bowel preparation prior to capsule endoscopy on the diagnostic yield, transit time and completeness of the examination.

Methods: This is a retrospective analysis of consecutive patients who underwent capsule endoscopy at a university practice between 2004–2006. 122 of the patients did not receive preparation while 83 patients did. Indications for the examination, gastric emptying times, small bowel transit times, findings and completeness of the examination were extracted from the records. A database was created using Microsoft Excel. Examinations were considered positive if any pathology was noted on the report. Studies performed with preparation and those without were compared. Statistical analysis was performed using chi-square and two-tailed t-tests. This study was approved by the university IRB.

Results: The medical records of 205 patients were reviewed. There were 83 patients who received preparation and 122 who did not. The mean gastric emptying times were 66.48 minutes and 54.60 minutes in the two groups respectively, which was not statistically significant, p = 0.279. The small bowel transit times were 231.73 minutes and 266.21, which was statistically significant, p = 0.02. There was no statistically significant difference in either the rate that the Cecum was reached (n = 12 and n = 19) nor in the diagnostic yield of patients who received preparation (n = 35) and those who did not (n = 54).

Conclusions: Capsule endoscopy is performed with and without preparation. It has been speculated that bowel preparation will cleanse the colon and release the colonic block on small bowel transit, therefore emptying the small bowel of food particles and bile. Some investigators suggest that a bowel preparation will increase small bowel transit time and potentially compromise the capsule endoscopy’s visualization of the small bowel and decrease diagnostic yield. This study reveals that while small bowel preparation increases small bowel transit, it does not appear to impact upon diagnostic yield.

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Capsule Endoscopy: Demographics Predicting Transit Time Variability, Age and Gender

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Purpose: Capsule Endoscopy is relatively new technology, which allows direct visualization of small bowel mucosa. Completeness of the exam is occasionally limited to the eight-hour battery life of the camera. Prior to capsule endoscopy, studies investigating gastrointestinal transit have used indirect methods of assessing orocecal transit times, including hydrogen breath tests, pH telemetry, and scintigraphic methods. The aim of this study is to identify any variability in capsule transit times based on gender and age.

Methods: This is a retrospective review of capsule endoscopy reports of consecutive patients between 2003 and May 2006, at a university gastroenterology practice. Gender, age, gastric emptying times, small bowel transit times, and completeness of the study were extracted from the record. A database was created using Microsoft Excel. Age was categorized into two groups, < 50 years and ≥ 50 years. Statistical significance between mean transit times of the groups was determined using two-tailed t-tests. The study was approved by the university IRB.

Results: The medical records of 194 patients were reviewed (mean age 54; 63 males, 131 females). Males averaged 54.05 years and the females averaged 54.49 years. There were 67 patients ≤ 50 years old and 127 patients > 50 years old. There was no statistical difference in gastric emptying times based on gender or age. There was no statistically significant difference between small bowel transit times of patients ≤ 50 years (263.72 minutes) and patients > 50 years (243.97 minutes), p = 0.20. However, there was a statistically significant difference between small bowel transit times of males (276.19 minutes) compared to females (238.33 minutes), p = 0.016.

Conclusions: It has been proposed that bowel motility slows with age and can therefore affect intestinal absorption. This study revealed that there was no difference in small bowel transit based on age. However, there was a significant difference in small bowel transit based on gender. Females had a more rapid small bowel transit time. Factors influencing intestinal motility are complex and likely multifactorial. Further study is necessary to gain improved understanding of gender influence upon motility.

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Complications after Percutaneous Endoscopic Gastrostomy Placement in a Gastroenterology Fellowship Program

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Purpose: To assess the safety of percutaneous endoscopic gastrostomy (PEG) placement in a gastroenterology fellowship program.

Methods: Design: Retrospective review of all PEG placements performed at a tertiary medical center from January 2005 through December 2005. Review of the electronic medical record was done to determine fellow involvement in case, indication, and follow up.

Results: Retrospective chart review identified a total of 86 patients who underwent PEG placement. Two patients were excluded because of pre-existing PEG. A standard guide wire pull through technique was used for all procedures using 20 French gastrostomy tube following endoscopic localization of the stoma. Endoscopic confirmation of gastrostomy was at the discretion of the endoscopist. Fellows assisted in 75 PEG placements. The remaining 9 were completed by endoscopist alone (8) or with assistance by a surgical resident (1). Indication for PEG placement included CVA in 35 patients (41.6%), head and neck cancer in 28 patients (33.3%), progressive neurological disease in 11 patients (13.1%), respiratory failure-ventilatory dependent in 3 patients (3.6%), and miscellaneous causes in 7 patients (8.3%). The complications observed included 4 bacterial infections (4.8%), 2 yeast infection (2.3%), 2 cases of excessive bumper tightness (2.3%), 1 persistent gastrostomy leakage (1.1%), and 1 buried bumper requiring endoscopic removal (1.1%). There was 1 case of anterior abdominal wall separation from anterograde gastric wall requiring surgical repair (1.1%). 1 post PEG gastrointestinal bleed occurred related to gastric ulcer successfully treated endoscopically (1.1%). There were no deaths related to PEG placement. However, 24 of the 84 patients (28.6%) were deceased at the time of the retrospective study review. The number of gastrostomy tubes placed by each fellow was not an accurate reflection of volume because the study reviewed PEG placement over a 12 month cycle which did not correspond with the academic training year. For this reason the complication rate determined by year of fellowship training was not calculated.
Conclusions: To date no good published data exists specifically looking at complication rates for PEG placement within a gastroenterology fellowship training program. Our data suggest that overall the incidence of PEG related complications in this setting is relatively low. The most commonly observed complication was site infection requiring oral antibiotic therapy.

Method: Post placement wound complications, primarily infections, are becoming less common with the widespread use of PEG tubes. The most common complications include site infection, gastrostomy tube migration, and drainage oozing from the site. Some authors report that complications are directly related to PEG placement and others state that complications are significantly from previously reported literature. Newer anti-platelet drugs were identified in use by 68 patients (23 aspirin, 36 heparin, 3 clopidogrel, and 3 enoxaparin) with these drugs stopped a mean/median of 2 days prior to procedure in 38 patients. No increased risk of bleeding was noted in patients receiving anti-platelet drugs less than 7 days. At time of placement, 6 patients were noted to have anatomic alterations. Most common post-operative complications noted in descending order: 15 – PEG site infection (3 patients did not receive prophylactic antibiotics), 10 – inadvertent removal of PEG, 9 – aspiration, and 6 – excessive leakage around PEG. The PEG was successfully removed in 36 patients. Death was noted in 63 patients (none directly related to PEG placement) and 54 patients did not have an outcome determined due to lack of documentation of disposition.

Conclusions: Complications of PEG tubes do not appear to have changed significantly from previously reported literature. Newer anti-platelet drugs do not appear to significantly increase risk of bleeding associated with placement of PEG.

Results: A total of 192 patients were located in the hospital database using the CPT code for PEG placement. Included in the analysis were 146 patients. Exclusions were made for age < 18, PEG already in place, and no data. The male to female ratio was 81.65 and mean age was 67.5 years. Racial makeup consisted of 89 Caucasian; 42 Black; and 12 patients of other racial background. The pull or Ponsky technique was used in 133 patients. Antibiotics were administered to 126 patients prior to the procedure. Anti-platelet drugs were identified in use by 68 patients (23 aspirin, 36 heparin, 3 clopidogrel, and 3 enoxaparin) with these drugs stopped a mean/median of 2 days prior to procedure in 38 patients. No increased risk of bleeding was noted in patients receiving anti-platelet drugs less than 7 days. At time of placement, 6 patients were noted to have anatomic alterations. Most common post-operative complications noted in descending order: 15 – PEG site infection (3 patients did not receive prophylactic antibiotics), 10 – inadvertent removal of PEG, 9 – aspiration, and 6 – excessive leakage around PEG. The PEG was successfully removed in 36 patients. Death was noted in 63 patients (none directly related to PEG placement) and 54 patients did not have an outcome determined due to lack of documentation of disposition.

Conclusions: Complications of PEG tubes do not appear to have changed significantly from previously reported literature. Newer anti-platelet drugs do not appear to significantly increase risk of bleeding associated with placement of PEG.

Purpose: Percutaneous endoscopic gastrostomy (PEG) tubes are placed for long term feeding for nutritional support. Long-term complications are vaguely reported in the literature.

Method: A retrospective chart review was conducted evaluating the experience of patients who had received a PEG tube between January 1, 2000 and December 31, 2001 based on the Current Procedural Terminology (CPT) code for upper endoscopy with gastrostomy placement. Charts were reviewed for documentation of any complications (known from review of literature) and also to assess the more extensive use of anti-platelet agents in the past several years in causing complications. In those charts with incomplete information regarding disposition and outcome, a telephone follow-up interview was made to ascertain outcome of the patients.

Results: A total of 192 patients were located in the hospital database using the CPT code for PEG placement. Included in the analysis were 146 patients. Exclusions were made for age < 18, PEG already in place, and no data. The male to female ratio was 81.65 and mean age was 67.5 years. Racial makeup consisted of 89 Caucasian; 42 Black; and 12 patients of other racial background. The pull or Ponsky technique was used in 133 patients. Antibiotics were administered to 126 patients prior to the procedure. Anti-platelet drugs were identified in use by 68 patients (23 aspirin, 36 heparin, 3 clopidogrel, and 3 enoxaparin) with these drugs stopped a mean/median of 2 days prior to procedure in 38 patients. No increased risk of bleeding was noted in patients receiving anti-platelet drugs less than 7 days. At time of placement, 6 patients were noted to have anatomic alterations. Most common post-operative complications noted in descending order: 15 – PEG site infection (3 patients did not receive prophylactic antibiotics), 10 – inadvertent removal of PEG, 9 – aspiration, and 6 – excessive leakage around PEG. The PEG was successfully removed in 36 patients. Death was noted in 63 patients (none directly related to PEG placement) and 54 patients did not have an outcome determined due to lack of documentation of disposition.

Conclusions: Complications of PEG tubes do not appear to have changed significantly from previously reported literature. Newer anti-platelet drugs do not appear to significantly increase risk of bleeding associated with placement of PEG.

Purpose: One of the major criticisms of colonoscopy preparation studies has been the lack of a validated way to assess colon cleanliness. In 2004, the Ottawa bowel preparation rating scale was reported as a valid and reliable tool for this purpose. The authors of this scale advise that before its use in any study, observers should perform a training exercise whereby they familiarize themselves with the scale and ensure that they agree on the ratings. The benefit of this training exercise has never been objectively assessed.

Method: We assessed the need for training by selecting from a teaching database of colonoscopy photos a set of images from 20 patients representing various levels of colon cleanliness. We showed these photos to 8 staff endoscopists and 2 senior fellows who used the Ottawa rating scale to rate the prep of each patient, without any training. We then performed a training exercise where each of the 10 endoscopists was shown sets of pictures that acted as “anchors” or examples of each level of colon preparation. A few weeks after this training exercise, each endoscopist was presented with the 20 sets of photos a second time and their rating of bowel cleanliness was again collected.

Results: In order to assess the agreement among multiple endoscopists before and after training, the calculation of variance components is more appropriate than kappa statistics. The baseline variance in our study was 5.9 (95% CI, 3.4–12.7), representing the inherent variability in the quality of preparations. The variance due to endoscopist measurement error (disagreement) was reduced from 3.1 (2.6–3.8) before training to 1.7 (1.4–2.2) after training. These variances equate to a significant (p < 0.001) increase in the intra-class correlation (reliability) from 0.65 to 0.77.

Conclusions: We have therefore established that the variance between raters is lower in a group of endoscopists trained with the Ottawa rating scale, compared to the same untrained group. We believe that the Ottawa bowel preparation rating scale is the best way to assess colon cleanliness in bowel preparation studies. Our results show that a training exercise would significantly increase the reliability of these studies.
Endoscopic Prevalence of Diverticulosis among Filipino Adult Patients: Right Side or Left?

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Purpose: In Western literature diverticulosis occurs most commonly in the left side, accounting for about 70% of cases. In contrast, right-sided diverticulosis occurs in less than 10% of patients. However, right-sided disease is more common in Asian people, accounting for as many as 75% of cases of diverticulitis in that group, and often with a rather aggressive course. The objective is thus to determine the distribution and prevalence of diverticulosis in the colonic tract among adult patients consulting at the Gastrointestinal Clinic of the Philippine General Hospital noted on endoscopy.

Methods: Records of all adult patients aged 18 years old and above who underwent colonoscopy from 2001–2005 were reviewed. Their age, gender, location of diverticulosis, description of diverticula as to single or multiple, simple or complicated by other findings were tabulated and counted.

Results: Of out 2, 219 patients, 251 (11%) were found to have reports of diverticular disease with 51.8% of which were males. Majority or 55% are in the older age group of 61–95 years old. Diverticula are most frequently seen in the ascending colon (32%). This is followed by the descending colon and sigmoid colon with 18% each. The rectum has the least number of diverticula seen. Out of the 251 reports found, 182 patients or 73% presented with multiple diverticula found in either one site of the colon or on multiple sites. Eighty one percent or 203 patients presented with simple diverticulosis while 19% or 48 patients having diverticular disease complicated by bleeding, presence of polyps, mass, ulcers, and inflammation.

Conclusions: Diverticulosis is common among patients > 60 years old. Right-sided diverticulosis is the most common diverticular lesion seen at our hospital, predisposition of which has still yet to be determined. Simple diverticulosis is more common although multiple diverticula are not uncommon. Bleeding is the most common complication. All findings are consistent with reports from other Asian countries.

Trans-Esophageal Endoscopic Ultrasound for Non-Small Cell Lung Cancer Staging

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Purpose: To assess the utility of endoscopic ultrasound with fine needle aspiration biopsy in detecting mediastinal spread of non-small cell lung cancer.

Methods: Thoracic surgery database at the Minneapolis VA Medical Center was searched from 2000 to 2006 to identify patients with non-small cell lung cancer who underwent a mediastinoscopy or thoracotomy for cancer diagnosis, staging, or treatment. Patients that have undergone EUS staging of the mediastinum prior to surgery were stratified by pre-operative TNM cancer stage into four strata [stage I though IV], and were frequency matched in a 1:3 ratio with those who had not undergone EUS staging prior to surgery. The proportion and location of malignant MLN diagnosed at surgery was computed for both groups. Further analysis was performed to determine the ability of EUS-FNA to detect mediastinal adenopathy depending on its location. MLN located in the subcarinal and para-esophageal mediastinum were designated as locations that were readily accessible by EUS. These were compared with nodes located at other mediastinal locations.

Results: Forty-four patients with non-small cell lung cancer underwent surgery following a negative EUS. These were frequency-matched, as described above with 132 controls. In the EUS group, 44/44 patients [91.1%; 95% CI, 3.0 – 21.7%] were found to have evidence of metastasis to MLN at surgery, compared with 41/132 patients [31.1%; 95% CI, 23.8 – 39.4%] in the control group [p = 0.003]. All cases of missed diagnosis in the EUS group occurred in patients with clinical stage III disease, while in the control group 7.6% of patients with clinical stage I disease, 37.5% with clinical stage II disease, 65.5% with clinical stage III disease and 66.7% with clinical Stage IV disease were found to have evidence of mediastinal metastasis. In the EUS group, no malignant MLN were noted in stations that were readily imaged by EUS [stations 7 or 8], compared with 16/41 in the control group [p = 0.1].

Conclusions: Patients with non-small cell lung cancer with a negative pre-operative EUS have a substantially lower rate of malignant MLN diagnosed at surgery than those who have not undergone pre-operative EUS.

Feasibility Assessment of Computer-Assisted Personalized Sedation: A Sedation Delivery System To Administer Propofol for Gastrointestinal Endoscopy

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Purpose: Computer-Assisted Personalized Sedation (CAPS) is a novel method integrating continuous physiological monitoring and delivery of propofol through a computer interface to provide precise control of sedation. These studies were designed to assess the feasibility of an investigational CAPS device to facilitate propofol sedation by a gastroenterologist/nurse team.

Methods: In two IRB/EC approved studies, 48 subjects (12 colonoscopy and 12 EGD; in both US and Belgium) were sedated with the device by the gastroenterologist/nurse teams.

Results: Forty-eight subjects (13 ASA I; 24 II; 11 III) completed the studies. Subjects received a single fentanyl dose (mean 88.5 ± 23.3 mcg in the US and 67.1 ± 30.5 mcg in Belgium). Three minutes later propofol was initiated at 75 mcg/kg/minute, then titrated to desired clinical effect (mean total dose 65.4 ± 27.4 mg in the US and 72.1 ± 36.6 mg in Belgium). Subjects were calm, comfortable and cooperative at a mean MOAA/S score of 4.4 ± 1.0 in the US and 4.4 ± 0.8 in Belgium. For colonoscopy, 17% of US and 33% of Belgian subjects had polyps removed. Procedure times (scope-in to scope-out) for colonoscopy were 9.5 ± 2.1 min in the US and 11.9 ± 3.9 min in Belgium. For EGD, procedure times were 2.5 ± 0.7 min in the US and 2.7 ± 1.0 min in Belgium. Recovery times (scope-out to Aldrete ≥ 12) for colonoscopy were 29 ± 37 seconds in the US and 10 ± 6 seconds in Belgium. Recovery times for EGD were 28 ± 30 seconds in the US and 10 ± 5 seconds in Belgium. Two US subjects and one Belgian subject experienced a total of 5 oxygen desaturation events below 90% (low 78% US, 84% Belgium). Twelve US subjects and six Belgian subjects experienced apnea ≥ 30 seconds (total of 40 events). Automated device actions in response to apnea resulted in recovery of normal respiratory parameters within a mean of 6 seconds. Validated physician and patient satisfaction with sedation scores showed high satisfaction with this new sedation paradigm.

Conclusions: These studies demonstrated the feasibility of CAPS to facilitate propofol sedation by gastroenterologist/nurse teams to subjects undergoing GI endoscopy.

A Safety and Feasibility Study of Trans Oral Gastroplasty (TOGa™) for the Treatment of Morbid Obesity: Initial Human Experience with Endoscopic Gastric Stapling

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**Purpose:** Morbid obesity represents a significant worldwide health problem that is currently treated with laparoscopic surgical approaches. We have developed a transoral endoscopic stapling system to perform a stapled gastric restrictive procedure for the management of morbid obesity. This study was designed to evaluate the technical feasibility and safety of this novel device in human subjects.

**Methods:** 12 subjects with Morbid Obesity were enrolled in this pilot study. All subjects met established inclusion criteria for standard bariatric surgery, received pre procedure education and counseling, and gave informed consent for participation. TOGa™ (Satietty Incorporated, Palo Alto CA) was performed under general anesthesia using the flexible transoral stapling device under direct endoscopic visualization. A restrictive 4.5 cm sleeve gastrectomy was fashioned in the cardia and fundus of the stomach using the stapler. The distal 2 cm of the formed sleeve gastrectomy was then narrowed using the restriction stapler. All patients were hospitalized overnight for observation and underwent a barium UGI study the following morning. Follow up visits were scheduled for 1 day, 1 week, 1, 3 and 6 months. EGD and UGI were scheduled to be repeated at 1, 3 and 6 months. Post TOGa™ all patients were scheduled to be repeated at 1, 3 and 6 months. Post TOGa™ all patients were placed on a post procedure diet and asked to begin an exercise program.

**Results:** 12 Hispanic subjects (10F, 2M) 22–57 years old with Morbid Obesity (BMI 44.2±5.1 kg/m2) were enrolled in this pilot study. All subjects underwent successful completion of the TOGa™ procedure without serious adverse events (AE’s). Minor device related AE’s included pharyngeal pain, vomiting, TMJ dysfunction and post prandial fullness, each in one subject. Persistent stapled sleeve gastrectomies were seen at 1 month follow up in all subjects. All subjects were on a regular diet at one month. Weight loss was seen in all subjects and ranged from 12 to 28 pounds at one month.

**Conclusions:** Endoscopic guided transoral gastrectomy for morbid obesity can be completed in humans with the TOGa™ system. No serious adverse events were encountered. Initial weight loss was seen in all patients. Additional clinical experience and long term follow up with this technique are underway.

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**Capsule Endoscopy (CE) for Validating the Efficacy of Hyperbaric Oxygen (HBO) Therapy in Radiation-Induced Small Bowel (SB) Injury – A New Indication**

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**Purpose:** To establish whether CE is useful for determining the efficacy of HBO therapy in radiation-induced SB injury associated with refractory GI bleeding.

**Methods:** A 66-year-old female was hospitalized with ongoing hematochezia requiring 29 units of blood transfused over four sequential hospital stays. The use of ASA/NSAIDS was denied. Past medical history was significant for regional metastatic ovarian cancer diagnosed in 1991 followed by TAH/BSO, segmental colon resection, radiation and chemotherapy. In the following years cryogenic cirrhosis developed with chronic portal hypertensive ascites and esophageal variceal bleeding requiring band ligation. Two tagged red blood cell scans were positive for a SB source of bleeding. Initially a patent TIPS failed as primary therapy to control continued GI bleeding but later occlusion was associated with worse bleeding requiring two revisions.

**Results:** CE showed blood throughout the entire SB with punched out ulcers, pale mucosa with loss of the vascular pattern, areas of stricturing and regions with total loss of villi suggestive of radiation injury. Biopsies of the ileum were compatible with radiation changes. These findings suggested that radiation injury with ulceration was at least partly responsible for the prolonged GI bleeding. A CMV IgM titer was negative. HBO is an approved therapeutic modality for radiation necrosis of the SB. Therefore, HBO therapy (90 min. sessions × 20) with 100% oxygen at 2.4 atmospheres of pressure was administered. Following this regimen GI bleeding slowed but continued. Because of the expense of HBO the patient’s insurance carrier wanted objective evidence of mucosal healing before authorizing payment for further treatment. Repeat CE 5 weeks after the first study showed erythematous mucosa in the ileum with areas of strictureing and total loss of villi. There was complete healing of all ulcers and no evidence of luminal blood. Because of distinct clinical and endoscopic improvement the patient had 20 more sessions of HBO. There has not been any recurrence of GI bleeding for over 3 years of follow up.

**Conclusions:** 1. HBO appears to be effective therapy for radiation-induced SB injury with ulcer-associated GI bleeding. 2. CE is clinically useful for determining the efficacy of HBO therapy for radiation-induced SB injury and the findings may influence patient management. 3. Assessment of HBO efficacy in SB radiation-induced injury is a new indication for CE and should be added to the current list of acceptable indications.

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**1328**

**Agreement between Blinded and Non-Blinded Reviewers of Capsule Endoscopy (CE) Rapid Videos**


**Purpose:** Capsule Endoscopy has become the primary diagnostic test for small bowel disease. Its accuracy is dependent upon reader interpretation.

**Aim:** To compare the agreement level between an experienced investigator, non-blinded to the patient medical history and current condition, to a second, less experienced, blinded reviewer.

**Methods:** Capsule studies were identified from Given database of funded studies. Studies were included in this analysis if the study reported a blinded, second reading of CE videos and had at least 10 adult enrollees. CE findings were categorized into major findings including presence of tumors/polyps, bleeding and/or ulceration or minor findings erosions, erythema, celiac, diverticula, hematocysts, etc. Statistics included descriptive (mean STD, range), calculation of 95% CI based normal distribution, and ANOVA.

**Results:** 767 patients, 382 (49.3%) men and 385 (50.2%) women, enrolled in 28 studies were analyzed. There were 883 pathological findings (498 major and 385 minor) in 530 patients and 237 videos were normal. Overall there was agreement in 661 of 767 patients (86.2%, 83.5 to 88.5% CI) comprised of 237 normal’s and 424 abnormal. Calculated kappa for agreement level is 0.706 (p < 0.01). The overall agreement for major findings is 84.1% (CI 80.6 to 87.2%) vs. 53.8% (CI 48.6 to 58.8%) overall for minor findings (p < 0.01). There was disagreement in 106 patients (13.8%, CI 11.5 to 16.5%). There was no significant difference between disagreements regarding presence of a major or minor lesion.

**Conclusions:** 1) Agreement level between experienced, non-blinded reviewer and a less experienced blinded reviewer on the presence of major lesions is high (Kappa > 0.7, p < 0.01); 2) Proportion of agreement between reviewers is significantly higher for major over minor lesions (p < 0.01); 3) Disagreement between reviewers occurred in 106/767 (13.8%) patients with no significant difference between major and minor lesions.

**Summary:** CE interpretation for major lesions shows high reproducibility between experienced reviewers’ non-blinded to patient history and current condition and less experienced, blinded reviewers.

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**1329**

**Is It Possible for the Endoscopists To Create Leak Proof Sealing of Circular Perforations of Colon?**

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**Purpose:** Colonoscopic perforation is a serious problem. Delay in the surgical closure of perforation can precipitate sepsis and death; in addition, anesthesia & laparotomy inflict additional trauma before a closure is accomplished. Endoscopists have a unique opportunity to close colonoscopic perforation immediately after its recognition with clips, thereby avoiding the delay of surgical closure and also eliminating the trauma of surgery. Recently,
we have shown that linear perforations of the colon can be closed through a colonoscope (Raju et al. GIE 2005;62:791–5). Development of endoscopic techniques for closure of circular perforations of the colon would be useful to manage circular defects that develop after snare polypectomy. Therefore, we developed techniques for endoluminal closure of circular full-thickness perforations of colon using clips.

Methods: Animals: Ten pigs – Two perforations in the 1st animal and one perforation in the 2nd to 9th animal were closed with clips. In the 10th animal, 5 perforations were created and the dimensions of the perforation were measured. Interventions: Creation of a circular full-thickness resection of the colon with a band-ligation-resection device, followed by longitudinal or transverse endoluminal closure of the perforation using the first clip opened and applied in the 3–9 O’ clock or the 6–12 O’clock direction in relation to the circular perforation respectively. Outcome Measurements: Necropsy immediately after closure of the perforation was done to examine the closure and confirming the quality of sealing with the Methylene Blue dye leak test on three occasion, in-vivo, in-vitro, and in-vitro under water immersion.

Results: The transverse closure was unsuccessful in the closure of 3 perforations, while the longitudinal closure resulted in a leak proof sealing in 6 of the 7 closures.

Conclusions: Circular perforations of colon can be closed successfully with the endoluminal application of clips. Endoscopist’s ability to close perforations will have far reaching implications.

Outcome of Endoluminal Clip Closure of Circular Perforation of Colon

<table>
<thead>
<tr>
<th>Type of Closure</th>
<th>No. of Clips</th>
<th>Endoscopic Assessment of Closure</th>
<th>Leak-Proof Sealing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transverse Closure (n = 3)</td>
<td>6 (5–7)</td>
<td>1* (33%)</td>
<td>0</td>
</tr>
<tr>
<td>Longitudinal Closure (n = 7)</td>
<td>7 (6–13)</td>
<td>7 (100%)</td>
<td>6 (86%)</td>
</tr>
</tbody>
</table>

* A thread attached to a clip was used to bring the edges together for clip approximation. The size of perforation 1.7 ± 0.075 cm (range: 1.5–2.0 cm).

1330

Third Generation Cholecystectomy by Natural Orifices: Transgastric and Transvesical Combined Approach

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Purpose: Isolated transgastric port raises some limitations in performing transluminal endoscopic cholecystectomy. Transvesical access to the peritoneal cavity has recently been reported to be feasible and safe. We assessed the feasibility and technical benefits of transgastric and transvesical combined approach to overcome these limitations in a porcine model.

Methods: We created a transgastric and transvesical combined approach to perform cholecystectomy in seven consecutive anesthetized female pigs (15–25 Kg). Transgastric access was achieved after perforation and dilatation of gastric wall with a needle knife and 18 mm balloon, respectively. Under cystoscopic control, an open-end ureteral catheter, a 0.355 inch guide-wire and a dilator of ureteral sheath were used to place a transvesical 5 mm overte into peritoneal cavity. Using a two working-channel gastrohepatic positioned transgastrically and a one-working channel ureteroscopic positioned transvesically, we carried out cholecystectomy in all animals. Once the closure of the gastric hole revealed unreliable using endoclips, the animals were sacrificed and necropsy was performed immediately after surgical procedure.

Results: Establishment of transvesical and transgastric accesses took place without complications. Under a CO2-pneumoperitoneum controlled by the transvesical port, gallbladder identification, cystic duct and artery exposure were easily achieved in all cases. Transvesical gallbladder grasping and manipulation revealed particularly valuable to enhance gastroscopy-guided dissection. Excluding two cases where mild liver surface hemorrhage and bile leak secondary to the sliding of cystic clips occurred, all remaining cholecystectomies were carried out without incidents.

Conclusions: The transgastric and transvesical combined approach is feasible and revealed particularly useful to perform cholecystectomy through exclusive natural orifices.

1331

Lidocaine Lollipop as Single Agent Anesthesia in Upper Gastrointestinal Endoscopy

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Purpose: Conscious sedation is usually achieved during esophagogastro-duodenoscopy (EGD) using a combination of intravenous benzodiazepines and opiates; however, these have potential serious adverse effects. The addition of topical oropharyngeal anesthetics such as lidocaine may be useful. Recent data suggest that the administration of topical lidocaine by means of a lollipop is effective for endotracheal intubation and bronchoscopy. The aim of this study is to evaluate the safety and efficacy of a lidocaine lollipop as single-agent anesthesia for EGD, and to determine if its use reduces the need for intravenous sedatives and analgesics.

Methods: A single-blinded, randomized, prospective study including 50 patients undergoing diagnostic EGD. Patients were randomized to either lidocaine lollipop or lidocaine spray. Intravenous meperidine and midazolam were administered during the procedure as needed. The main outcome measure was the success and safety of local anesthesia by lidocaine lollipop in addition to the need for intravenous sedation.

Results: Patients were equally randomized between the lollipop and the spray groups. The lollipop group had less gag reflexes, accommodated scope introduction more, and tolerated the procedure better. Thirty-two percent of patients receiving the lollipop required sedation compared to 96% of patients in the spray group (p < 0.001). The majority in the lollipop group were satisfied with their mode of anesthesia compared to the spray group.

Conclusions: Lidocaine lollipop is a promising form of local oropharyngeal anesthesia for EGD. Its use resulted in sparing the use of intravenous sedation. It is well-tolerated and safe, and may be particularly important in the elderly, patients with comorbidities, and office-based endoscopy.

1332

A Randomized Single-Blind Trial of Standard Diet Versus Fiber-Free Diet with Polyethylene Glycol-Electrolyte Solution for Colonoscopy Preparation

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Purpose: Colonoscopy preparation is usually achieved by the intake of large volumes of polyethylene glycol-electrolyte solution (PEG-ES) along with a clear-liquid diet. The adequacy of the preparation is vital for a successful examination. However, non-compliance with the intake of PEG-ES with the clear-liquid diet is one of the main factors contributing to poor colonic preparations. Liberalizing the diet, in terms of fiber-free diet (FFD), might enhance the tolerability of the PEG-ES without compromising its efficacy.
This study aims to evaluate the efficacy and tolerability of standard versus FFD given in conjunction with PEG-ES for colonoscopy preparation. 

**Methods:** In this single-center, single-blind study, two hundred consecutive patients undergoing colonoscopy were prospectively randomized to take either the standard clear-liquid diet (SD) or a FFD in addition to a maximal amount of 4 liters of PEG-ES. The main outcome measure was the efficacy (assessed as the quality of preparation during colonoscopy), and tolerability (assessed as the amount of PEG-ES ingested, occurrence of side effects or hunger, and willingness to repeat the preparation).

**Results:** Patients who were assigned to the FFD were able to drink more (mean 3.82 L) PEG-ES compared to those assigned to the SD (mean 3.63 L) \( (p = 0.01) \). Evaluations based on quantity of intake of PEG-ES showed no significant difference between the two groups in terms of quality of the preparation. Tolerability and willingness to repeat the preparation were better in the FFD group as compared to the SD group.

**Conclusions:** A FFD given along PEG-ES on the day of preparation is as effective as the standard diet, and is much better tolerated by the patients.

**1333**

**Effect of Omeprazole on the Size and Number of Postbanding Ulcers after Esophageal Variceal Band Ligation: A Randomised Controlled Trial**

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**Purpose:** Endoscopic variceal ligation(EVL) is an effective option in treatment of esophageal varices bleeding or elective ablation. UClceration after EVL is well recognised but the effect of acid suppression on ulcer healing is not determined definitely. In this study we tried to evaluate efficacy of omeprazol as most available ppi on number and size of esophageal ulcers after EVL in patients, elective candidates to this procedure.

**Methods:** We performed a double -blinded randomised, placebo controled trial of omeprazol after elective EVL. Fifty consecutive cirrhotic and non cirrhotic patients who were cadidated for EVL randomly entered in case(25) and control(25) groups. After endoscopy and EVL, case subjects recieved omeprazol 20 mg bid for 2 weeks and control subjects received placebo for the same period. Follow up endoscopy was performed 12–16 days after EVL.

**Results:** Forty two patients (20 caces and 22 controls) completed the study. Number and size of ulcers were evaluated at follow up endoscopy. Number of ulcers was significantly higher in control group \( (3.15 \pm 2.59, p = 0.03) \). The ulcers in omeprazole group were on average half as large as in the placebo group \( (37.08 \text{ mm}^2 \pm 73.74 \text{ mm}^2, p < 0.0001) \).

**Conclusions:** Patients treated by omeprazol after elective EVL had significantly reduction in number and size of post banding ulcers. It seems that omeprazol reduces ulcers number and size after EVL.

**1334**

**Feasibility of Supervised Trainee Involvement in Colonoscopy without Sedation (CWOS) – Experience at a Single U.S. Training Center**

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**Purpose:** In the U.S. sedation for colonoscopy is standard practice. Nursing support required for monitoring and recovery; and fixed resources at public institutions such as VA Hospitals appear to have contributed to prolonged wait time. While depicting feasibility in expert hands, recent U.S. publications do not favor trainee involvement in CWOS. ** Aim:** In preparation for a performance improvement program to reduce wait time without incurring additional nursing support, a retrospective feasibility assessment is performed to review cases of CWOS.

**Methods:** We conduct open access education classes for patients referred for outpatient colonoscopy. Patients are given standard instructions including bowel preparation and escort requirement. Inpatients are evaluated by formal consultations. We perform CWOS at patients’ request (no escort, concern about side-effects of sedation, wish to see procedure); and at discretion of colonoscopists (sedation risk, e.g. severe COPD). The procedure is performed using standard colonoscope with minimal air insufflation on scope insertion. Abdominal compression and positioning of patient are necessary to facilitate passage of the scope. Polyps are removed on withdrawal of colonoscope.

**Results:** From 2000 to 2006, 8608 colonoscopies were performed. 142 (1.7%) were CWOS. Majority of patients requested CWOS because they did not have escort. After excluding patients with poor bowel preparation \( (n = 19) \), the overall cecal intubation rate was \( (105/123) 85\% \) for CWOS (61 screening and 44 diagnostic), and 44 patients had polyposity. In addition, CWOS failed in 5 (3.5%) patients because of pain, in 1 with an abdominal hernia and 1 with redundant colon, respectively; and in 11 patients (7.7%) cause of failure was not recorded. There were no immediate CWOS-related cardiorespiratory complications. After excluding patients with poor preparation, success among GI fellows was 17/21 (81%) versus attendings 88/102 (86.3%). On average, fellows took 26 min (14–52) while attendings took 19 min (4–66) to complete the procedure.

**Conclusions:** The current success rate for CWOS is comparable to data in the literature. Poor bowel preparation accounts for substantial (15%) failures. Involvement of supervised trainees in CWOS appears to be feasible with success rates comparable to attending staff. The implication of inclusion of CWOS in the training curriculum and its impact on wait time for colonoscopy in public institutions deserves further prospective studies.

**1335**

**EKG Changes Associated with Transient Hypotension in Patients Receiving Propofol**

James A. Sinnott, MD,* Edward J. Fricker, MD, Glenn Evans, MD, Tana Macera, N.P., Anita Sinnott, N.P., Gastroenterology, South Georgia Medical Center, Valdosta, GA.

**Purpose:** To determine if the use of propofol is associated with EKG changes when transient hypotension is experienced during the procedure.

**Methods:** Conscious sedation with propofol has distinct advantages over using benzodiazepines, notably a rapid onset of action and a shortened recovery time. In our facility, propofol is administered by a registered nurse under the direct supervision of a gastroenterologist. An intensive program for endoscopic nurses was instituted prior to the use of propofol. Our nurses must achieve ACLS certification, complete a didactic airway management techniques training course given by CRNA’s. We chose to adopt a continuous propofol infusion technique for 3 main reasons. Commercially available pumps allow the patient’s weight to be factored in to the infusion, enabling mg/kg dose for both the bolus and infusion doses. Additionally, with the brief half life of propofol, this provides a controlled level of sedation that avoid the peaks and troughs inherent in using a bolus infusion. And finally, it allows a finer titration of sedation resulting in a gentle patient response to the desired sedation level. We retrospectively reviewed 3500 cases of propofol/meperidine induced conscious sedation. There were 60 cases with episodes of transient hypotension, defined as a systolic blood pressure below 90 mmHg. All episodes resolved by either placing the patient in the Trendelenburg position or with fluid administration. Retrospectively we found pre and post procedure EKG’s were available in 9 of these 60 cases. The EKG’s were conducted as part of their routine health screening rather than precipitated by the procedure. Historical controls with midazolam/meperidine that had experienced transient hypotension and had EKG’s available both pre and post procedure were identified and matched for age and gender. In all retrospective and historical cases, EKG’s were reviewed by a board certified cardiologist.

**Results:** No EKG changes were noted post procedurally in either the propofol/meperidine or the midazolam/meperidine groups.
Conclusions: We believe that we have demonstrated the lack of any long term EKG changes associated with hypotension when propofol/meperidine is used to induce conscious sedation. To address some of the inherent study design limitations, a large prospective study would be necessary to confirm this data.

1336

Role of EUS-FNA in Evaluating Mediastinal Lymphadenopathy: Single Center Experience
Shailender Singh, MD, Jyotsna Talapaneni, MD, Srinivas Pulli, MD, Melissa Oropeza, R.N., Scott Stanley, Faisal Jafri, MD, Mojtaba Olyaei, MD. * Gastroenterology and Hepatology, University of Kansas Medical Center, Kansas City, KS and Baptist Hospital, Kansas City, MO.

Purpose: Endoscopic ultrasound along with fine needle aspiration is a useful imaging modality and is being used to assess mediastinal mass lesions. This is particularly useful in staging lung and other gastrointestinal malignancies along with evaluating unexplained mediastinal lymphadenopathy. The aim of the study was to evaluate diagnostic utility of EUS-FNA in patients with mediastinal lymphadenopathy at our center.

Methods: EUS database at our center from April 2002 to February 2006 was retrospectively reviewed. Patients in whom the primary indication for performing EUS was evaluation of mediastinal lesion as seen on CT scan were selected for this study.

Results: 56 patients were identified and reviewed. Adequate cytology sample was obtained in all patients who underwent EUS-FNA, with a mean number of four passes. Nodal stations sampled included left paratracheal, subcarinal and aortopulmonary window. Indications for EUS included mediastinal adenopathy of uncertain cause (21 patients) and lung cancer staging (21 patients). Other malignancies with mediastinal LAP included: gastrointestinal 2, breast 2, melanoma 4, head and neck 4 and lymphoma in 2 patients. EUS confirmed presence of mediastinal mass lesion in 54 patients, 2 patients did not have mediastinal LAP as reported on CT scan. EUS-FNA revealed malignancy in 34% (18/53), atypical cells 5% (3/53), granulomas 7% (4/53) and benign tissue in another 34% (18/53). Benign paraesophageal spindle cell neoplasm and actinomycosis was found in one patient each. Percutaneous cyst was seen in one patient and confirmed on surgery. There were no complications reported with the procedure.

Conclusions: EUS-FNA appears to be a safe and effective modality for evaluating malignant and mediastinal adenopathy of uncertain origin. It has a significant role, especially in staging lung cancer and hence influencing treatment decisions.

1337

Endoscopic Practice for Patients with Obstructive Sleep Apnea: Results of a Community-Based Study
Srikrishna Vemana, MD, Vikram Boolchand, MD, Gregory S. Cooper, MD, Gerard Isenberg, MD, Amitabh Chak, MD, * Gastroenterology, Case Western Reserve University, Cleveland, OH.

Purpose: Obstructive sleep apnea (OSA) is being increasingly diagnosed and is recognized by anesthesiologists as a risk factor for difficult airway management. Conscious sedation used during endoscopic procedures could place patients with OSA at increased risk for complications. Because the current sedation practices of endoscopists in patients with OSA have not previously been investigated, we performed a study to determine reported practices.

Methods: A two page survey was formulated and mailed to members of the North East Ohio Society of Gastrointestinal Endoscopy (NEOSGE), a 123 member regional organization of gastroenterologists and surgeons. The survey included items on physician demographics and training, and reported practice for sedation during endoscopic procedures in patients with diagnosed or suspected OSA.

Results: A total of 63 endoscopists responded (51.2%), including 61 gastroenterologists and 2 surgeons. Thirty-three percent were in academic practice and 67% were in group or solo practice. Most respondents (71.4%) replied that they performed less than 5 procedures per month on patients diagnosed with OSA and most (80.9%) said that their approach to OSA patients regarding anesthesia for EGD versus colonoscopies was no different. Sixty percent felt that lighter conscious sedation was adequate for all OSA patients. Thirty-six and 41% of physicians respectively chose lighter sedation as the only special precaution taken for those patients known to use CPAP or home oxygen. Twenty percent felt that a hospital endoscopy unit and anesthesia assistance was required for OSA patients who use CPAP. Thirty-three percent of respondents referred patients for OSA evaluation if they had apneic episodes during endoscopy, though the overall frequency of apnea during endoscopic procedures was reportedly low.

Conclusions: Overall, most endoscopists perform only a limited number of endoscopic procedures on patients with recognized OSA. Lighter sedation rather than anesthesiologist administered sedation appears to be the preferred management approach in northeastern Ohio for these patients.

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Lower Gastrointestinal Endoscopic Surveillance and Ablative Therapy for Post Operative Familial Adenomatous Polyposis Patients
Ferga C. Gleeson, MD, Georgios I. Papachristou, MD, Christopher J. Gostout, MD, * Gastroenterology and Hepatology, Mayo Clinic and Medical School, Rochester, MN.

Purpose: Preventative surgery for Familial Adenomatous Polyposis (FAP) aims to minimize colon cancer risk. Yet, post surgical time intervals for endoscopic surveillance are unknown. The aims of this study were 1) To determine the prevalence of adenomatous disease in FAP patients following various types of prophylactic colorectal surgery, 2) To determine the safety and effectiveness of lower GI endoscopic surveillance and ablative therapy.

Methods: Retrospective analysis of clinical, demographic, endoscopic, surgical and histological records of 41 FAP patients (M/F: 18/23) enrolled in a lower GI surveillance and ablative therapy program from 1992 to 2006.

Results: Endoscopic surveillance began at a median of 11 years (Range 0–35) following colectomy, with a presentation age for surveillance of 40 years (Range 13–65). Prior surgical history included: subtotal colectomy (n = 10), ileoanal J pouch anastomosis (n = 10), colectomy with ileorectal anastomosis (n = 6), Brooke ileostomy (n = 5), proctocolectomy with ileostomy (n = 4), Kock pouch ileostomy (n = 3) and colectomy with ileal pull through (n = 3). Patients had a median of 4 procedures of which 2 (Range 0–12) were therapeutic over 49 month follow-up (Range 0–155). Initial endoscopy identified polyps in all patients ranging in number from one to numerous. Polyp location included: residual rectum (16/16), J pouch (9/10), efferent ileal limb (2/10), stoma (8/9), ileo anal anastomosis (3/3), and nipple valve (2/3). Diminutive polyps 17/41 were not sampled. In the remaining 24 patients, histology of larger polyps (up to 40mm) confirmed adenomatous tissue with low and high grade dysplasia in 16/24 and 1/24 respectively. Two patients, 12 and 13 years post subtotal colectomy had evidence of rectal stump cancer. Ablative therapy complications included: YAG laser ulcer induced hemorrhage (n = 1) and rectal perforation post polypectomy (n = 1). One patient (1/41) with a Kock pouch histologically progressed from low to high grade dysplasia despite ablative therapy over 30 months surveillance.

Conclusions: Following prophylactic colorectal surgery, all patients had residual polyp burden. Initial endoscopy detected advanced neoplasia in 7%, leading to surgical intervention. Despite ablative therapy, 3% of patients progressed histologically.

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Endoscopic Surveillance and Ablative Therapy for Familial Adenomatous Polyposis (FAP) Associated Duodenal Adenomas
Georgios I. Papachristou, MD, Ferga C. Gleeson, MD, Christopher J. Gostout, MD, * Department of Gastroenterology and Hepatology, Mayo Clinic and Medical School, Rochester, MN.

Purpose: Obstructive sleep apnea (OSA) is being increasingly diagnosed and is recognized by anesthesiologists as a risk factor for difficult airway management. Conscious sedation used during endoscopic procedures could place patients with OSA at increased risk for complications. Because the current sedation practices of endoscopists in patients with OSA have not previously been investigated, we performed a study to determine reported practices.

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Conclusions: Overall, most endoscopists perform only a limited number of endoscopic procedures on patients with recognized OSA. Lighter sedation rather than anesthesiologist administered sedation appears to be the preferred management approach in northeastern Ohio for these patients.
Purpose: FAP is an autosomal dominant colorectal cancer syndrome. Endoscopic management and surgical intervention aim to reduce polyph burden and maintain favorable histology. Suitable time intervals for endoscopic surveillance and long term effectiveness of ablative therapy are unknown. The aims of this study were 1) To determine the safety and effectiveness of endoscopic surveillance and ablative therapy of FAP associated duodenal adenomas and 2) To determine the incidence and management of ampullary adenoma recurrence and disease follow up.


Results: Endoscopic surveillance began at a median of 10 years (Range 0–33) following prophylactic colorectal surgery, with a presentation age of 42 years (Range 13–65). Forty three (90%) patients had evidence of ampullary and/or distal duodenal polyps with a Spiegleman Classification Stage of 3 (Range 2–4). Duodenal tubular adenomas with low grade dysplasia were identified in 38/43 (88%) of patients. A tubular adenoma with high grade dysplasia was identified in one other (2%). Each patient had a median of 5 upper endoscopic procedures, of which 3 (Range 0–13) were ablative therapies over 69 months (Range 1–256). Polypt recurrence post ablative therapy occurred in 13/43 (30%) at 46 months (Range 20–125). All recurrence was managed endoscopically. One patient experienced histological progression of a non-periampullary duodenal adenoma to high grade dysplasia; otherwise all other adenomas were histologically stable over time. Seven patients (15%) experienced ablative therapy related complications: pancreatitis (n = 4), procedural bleeding (n = 1) and delayed bleeding (n = 2).

Conclusions: Endoscopic surveillance and ablative therapy of FAP associated duodenal adenomas achieved and maintained histological regression in 70%. All recurrence, presenting at 46 months post ablative therapy was managed endoscopically.

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Determining Scope Position during Colonoscopy without the Use of Ionizing Radiation or Magnetic Field: The Enhanced Mapping Ability of the NeoGuide Endoscopy System

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Purpose: Knowledge of the position and shape of the colonoscope could overcome many of the challenges of performing a colonoscopy. Fluoroscopy and magnetic endoscopy imaging systems can provide physicians with information on scope shape but not the shape of the colon. They are limited by cost, cumbersome hardware and the risk of ionizing radiation. A novel computer-assisted colonoscope was designed to avoid loop formation during colonoscopy. The colonoscope utilizes a fully articulated, computer-controlled insertion tube. On manual insertion of the colonoscope, the position and angle of the tip are encoded into a computer algorithm. The system is uniquely capable of creating a real time, three dimensional map of the tip position and insertion tube shape. The map can be displayed on the video monitor to provide the endoscopist with a simultaneous view of the video image of the lumen of the colon, the position of the scope tip, and the three-dimensional shape of the insertion tube representing the shape of the colon.

Methods: Endoscopists (n = 18) of various levels of experience were each shown 50 map images generated from the system. The colonoscope was positioned in various locations within a bench top anatomical colon model, and in various loops. Endoscopists were asked to determine the position of the scope based solely on the map image. For each image, the scope position as determined by the endoscopist was compared to the actual scope position. In the second part, endoscopists (n = 18) were each shown 20 map images and were asked to determine the tip angle based on the map image and the systems novel tip positioning aid. Results were compared to the actual tip position. Interobserver agreement was evaluated using the kappa (kappa) index, intraclass correlation coefficient, and proportion of agreement.

Results: Endoscopists correctly identified the tip angle and the position of the colonoscope with an accuracy of 92.4%. The positive predictive value was 94.9%. Interobserver agreement was excellent for determining the scope position, looping and tip angulation (kappa = 0.75–0.85).

Conclusions: This study demonstrated that three-dimensional map images generated by the NeoGuide system in a simulated bench top model provided accurate and reliable information regarding both tip and insertion tube position.

1341

A New Sodium Phosphate Tablet Bowel Purgative Requires Less Irrigation during Colonoscopy Than 2 L Polyethylene Glycol Electrolyte Lavage Solution Plus Bisacodyl Tablets

David Kastenberg, MD,∗ Sandra Lottes, PharmD, Bill Forbes, PharmD. Gastroenterology, Thomas Jefferson University, Philadelphia, PA and Salix Pharmaceuticals, Inc, Morrisville, NC.

Purpose: The time involved in irrigating the colon to adequately visualize the mucosal lining can greatly affect the efficiency of colonoscopy. This study compared the irrigation requirements during colonoscopy of a new sodium phosphate (NaP) tablet bowel purgative (OsmoPrep), Salix Pharmaceuticals, Inc with a bowel preparation kit consisting of 2 L polyethylene glycol electrolyte lavage solution (PEG) and bisacodyl tablets (HallLyte,® Braintree Laboratories, Inc).

Methods: Patients (pts) ≥ 18 enrolled in a multicenter, investigator-blinded study were randomized to receive 32 (48 g) NaP tablets or 2 L PEG + 4 (20 mg) bisacodyl tablets. NaP tablets were administrated as 4 tablets with 8 oz clear liquid every 15 min the evening before (n = 20) and 3 to 5 h prior to (n = 12) colonoscopy. 2 L PEG + bisacodyl tablets were taken the day prior to colonoscopy as directed in US prescribing information. Irrigation requirements during colonoscopy were scored by investigator from 0 to 3 (0 = none; 1 = 50 mL; 2 = 50–100 mL; 3 = > 100 mL).

Results: 205 pts taking NaP tablets and 206 pts taking 2 L PEG + bisacodyl who took ≥ 1 tablet or sip of study medication and underwent colonoscopy were evaluated. Mean irrigation scores were significantly lower in pts taking NaP tablets compared with 2 L PEG + bisacodyl (0.80 ± 1.12 vs 1.28 ± 1.25; P < 0.0001) and remained significant for the following subgroups: males (0.78 ± 1.13 vs 1.31 ± 1.24; P = 0.0033); females (0.82 ± 1.12 vs 1.26 ± 1.26; P = 0.0050); pts ≤ 64 y (0.75 ± 1.13 vs 1.21 ± 1.22; P = 0.0077); and pts >64 y (0.96 ± 1.10 vs 1.52 ± 1.33; P = 0.0244). Significantly fewer pts in the NaP tablet group required any irrigation during colonoscopy compared with the 2 L PEG + bisacodyl group (39% vs 58%; P < 0.0001). Additionally, fewer pts required >100 mL of irrigation with NaP tablets compared with 2 L PEG + bisacodyl (13% vs 26%; P = 0.0017). The distribution of irrigation scores was significantly different between treatment groups and favored NaP tablets (P = 0.0004). This significant difference in favor of the NaP tablet group was consistent for the following subgroup analyses: males (P = 0.0054), females (P = 0.0488), pts ≤64 y (P = 0.0026); and pts >64 y (P = 0.0067).

Conclusions: Significantly less irrigation during colonoscopy is necessary for NaP tablets compared with 2 L PEG + bisacodyl. Given the lower irrigation requirement and previously established efficacy, NaP tablets may improve the efficiency of colonoscopy.

1342

Physician and Patient Satisfaction for AQUAVAN® in a Randomized, Double-Blind, Multicenter, Dose-Finding Colonoscopy Study

Lawrence B. Cohen, MD,∗ Chao Wang, PhD, James B. Jones, MD. Gastroenterology, The Mount Sinai School of Medicine, New York, NY and Clinical Research, MGI PHARMA, Baltimore, MD.

Purpose: Fospropofol disodium (AQUAVAN® Injection, AQ) a prodrug of propofol, is being developed for use in diagnostic and therapeutic procedures requiring minimal to moderate sedation. To assess physician and
patient satisfaction with sedation during colonoscopy performed during a randomized, double-blind, multicenter dose-finding study of AQ.

Methods: Patients (ASA I–IV, age ≥18 years) undergoing colonoscopy were stratified by age and ASA status and then randomly assigned to receive an initial bolus dose of either fospropofol disodium (2.0, 5.0, 6.5, or 8.0 mg/kg) or midazolam (0.02 mg/kg) following pretreatment with fentanyl citrate (50 μg). Midazolam was included in the study as a safety reference. Upon completion of each procedure, the endoscopist answered a 10-question survey designed to assess satisfaction with the patient’s level of sedation, comfort, anxiety, and ability to move and follow instructions during the procedure. Prior to discharge, patients completed a 7-question survey to assess their satisfaction with the sedation medications.

Results: 127 patients were randomized and completed the study. A general dose-response trend in Sedation Success was observed across the AQ dosing groups. (figure1)

Conclusions: A high level of satisfaction was reported by physicians and patients with the two highest doses of AQ (6.5 and 8.0 mg/kg).

1343

AQUAVAN® for Moderate Sedation during Colonoscopy: Results of a Phase 2, Multicenter, Randomized, Dose-Response Study

Lawrence B. Cohen, MD,* Jackie Kline, PhD, Chao Wang, PhD, James B. Jones, MD. Gastroenterology, The Mount Sinai Hospital, New York, NY and Clinical Research, MGI PHARMA, Baltimore, MD.

Purpose: Fospropofol disodium (AQUAVAN® Injection, AQ) a prodrug of propofol, is being developed for use in procedures requiring minimal to moderate sedation. This randomized, double-blind, multicenter, phase 2, dose-response study was designed to assess the optimal dose of AQ during colonoscopy.

Methods: Patients (ASA I–IV, age ≥18 years) were stratified by age and ASA status and randomly assigned to receive a bolus dose of either AQ (2.0, 5.0, 6.5, or 8.0 mg/kg) or midazolam (0.02 mg/kg) following pretreatment with fentanyl citrate (50 μg). Midazolam was included in this study as a safety reference. Patients were permitted to receive supplemental doses of sedative and anxiolytic. Efficacy endpoints included: sedation success, treatment success, sedation adequacy, safety, measures of clinical benefit, and recovery. Sedation success was defined as 3 consecutive Modified Observer’s Assessment of Alertness/Sedation (MOAA/S) scores of ≤4 after administration of sedative medication, AND completion of the procedure without use of an alternative sedative medication, AND without requiring manual/mechanical ventilation. Treatment success was defined as completing the procedure without requiring alternative sedative medications AND without requiring manual/mechanical ventilation.

Results: 127 patients were randomized and completed the study. Demographic and baseline characteristics were similar in all groups. (figure1) Burning sensation and paresthesia were the most common adverse events. Sedation-related adverse events were noted in 3.8% and 12.0% of patients in the AQ 5.0 and 6.5 mg/kg groups, respectively. No patient required manual/mechanical ventilation. No deaths or serious adverse events occurred.

Conclusions: AQ was safe and effective for colonoscopy at a moderate level of sedation. An initial bolus of 6.5 mg/kg of AQ achieved the optimal combination of sedation and safety.

1344

Importance of Duodenal Biopsies in Patients with Suspected Upper GI Pathology

John Cointepas, P.A.–C., Sheila Rodriguez-Stanley, PhD, Susan Riley, R.N., Philip B. Miner, Jr., MD,* Clinical Research, The Oklahoma Foundation for Digestive Research, Oklahoma City, OK.

Purpose: Emergence of microscopic colitis as a valid gastrointestinal diagnosis confirms the importance of obtaining biopsies of endoscopically normal-appearing gastrointestinal (GI) mucosa. Recent emphasis on the un-

<table>
<thead>
<tr>
<th>Endpoints</th>
<th>AQ 2.0 mg/kg</th>
<th>AQ 5.0 mg/kg</th>
<th>AQ 6.5 mg/kg</th>
<th>AQ 8.0 mg/kg</th>
<th>Midazolam 0.02 mg/kg</th>
</tr>
</thead>
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<tr>
<td>N = 25</td>
<td>N = 26</td>
<td>N = 26</td>
<td>N = 24</td>
<td>N = 26</td>
<td></td>
</tr>
<tr>
<td>Mean cumulative dose ±SD, (mg)</td>
<td>225.8 ± 52.8</td>
<td>572.3 ± 162.5</td>
<td>699.1 ± 219.2</td>
<td>777.6 ± 189.9</td>
<td>4.16 ± 1.72</td>
</tr>
<tr>
<td>Mean dose of fentanyl ± SD, (mg)</td>
<td>83.5 ± 27.5</td>
<td>84.6 ± 36.1</td>
<td>66.0 ± 17.5</td>
<td>62.0 ± 14.8</td>
<td>65.4 ± 15.9</td>
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<tr>
<td>Sedation success (%)</td>
<td>24.0</td>
<td>34.6</td>
<td>69.2*</td>
<td>95.8*</td>
<td>80.8*</td>
</tr>
<tr>
<td>Treatment success (%)</td>
<td>36.0</td>
<td>42.3</td>
<td>80.8*</td>
<td>95.8*</td>
<td>88.5*</td>
</tr>
<tr>
<td>% of patients using alternative sedatives</td>
<td>64.0</td>
<td>57.7</td>
<td>19.2</td>
<td>4.2</td>
<td>7.7</td>
</tr>
<tr>
<td>Median time to ready for discharge [range], (min)</td>
<td>6.0 [0–65]</td>
<td>4.0 [0–43]</td>
<td>7.5 [1–30]</td>
<td>11.5 [1–61]</td>
<td>5.5 [0–58]</td>
</tr>
<tr>
<td>Average % of time patients demonstrated purposeful movement</td>
<td>88.3</td>
<td>90.5</td>
<td>95.5</td>
<td>75.5</td>
<td>96.7</td>
</tr>
<tr>
<td>% of patients with MOAA/S score of ≤1 at any time during procedure</td>
<td>8.0</td>
<td>3.8</td>
<td>3.8</td>
<td>25.0†</td>
<td>3.8</td>
</tr>
</tbody>
</table>

*P < 0.05 (Fisher’s exact test for pairwise comparisons between groups)
†8.3% of these patients had MOAA/S ≤1 for ≥5 minutes
derestimated prevalence of celiac disease further emphasizes the need to obtain biopsies of the duodenum to enhance diagnosis of celiac disease. The aim of this study was to assess the value of duodenal biopsies of normal appearing mucosa for diagnosis of symptomatic GI disease including celiac disease and duodenal Crohn’s that may have been otherwise missed if biopsies had not been performed.

**Methods:** Charts were reviewed for 205 consecutive patients who received an esophagogastrroduodenoscopy (EGD) for a variety of upper GI symptoms such as epigastric pain, nausea, abdominal pain, early satiety and heartburn/reflux. Prior diagnosis, symptoms, EGD findings, and pathology findings are summarized.

**Results:** Of 205 charts reviewed (53 Males, 152 Females; age 15–90 years), duodenal biopsies were performed in 85% (n = 174). In 5 patients (2.4%) with a prior diagnosis of Celiac disease, only 2 (1%) were confirmed by duodenal biopsy, and no unexpected cases were found. Of 24 patients with Crohn’s disease, none had duodenal Crohn’s upon biopsy. Increased mast cells were detected in 26% (45/174) of duodenal biopsy specimens. Symptoms that correlated with increased duodenal mast cells included heartburn/reflux (36%), epigastric pain (29%), nausea (24%), and abdominal pain (20%). Increased eosinophils were detected in 13% of patients (22/174). Predominant symptoms in patients with increased duodenal eosinophils were epigastric pain (36%), nausea (32%) and heartburn/reflux (32%). Symptom presentation of patients with duodenal mast cells and/or eosinophils was typical of functional disorders. Nine cases of duodenitis were noted on pathology, with 6 (67%) appearing visually normal on EGD. Distorted duodenal mucosa was detected in 1 patient that also appeared visually normal. Duodenal tubular adenomas were detected in 2 patients known to have familial polyposis, one of which had high-grade dysplasia.

**Conclusions:** Unexpected celiac disease was not found. Crohn’s disease of the duodenum was not demonstrated by biopsy. The emerging importance of eosinophils and mast cells in functional disease is documented by biopsy. As in microscopic colitis, biopsy of a normal-appearing duodenal mucosa may lead to underlying activation of the immune system in functional diseases.

**Abstract: 1345**

**Importance of Unsuspected Colonic Findings Revealed by Capsule Endoscopy in Patients with Obscure/Occult Bleeding**

_Florin Costea, MD, Alan Barkun, MD, Martha H. Dirks, MD, Ernest G. Seidman, MD,* Division of Gastroenterology, McGill University Health Center, Montreal, QC, Canada and Division of Pediatric Gastroenterology, Sainte Justine Hospital, Univ of Montreal, Montreal, QC, Canada._

**Purpose:** Capsule endoscopy (CE) is now established as the state of the art method to detect disorders of the small bowel (SB) missed by other imaging and endoscopic techniques. All patients referred for obscure or occult GI bleeding, the most common indication for CE, have normally undergone one or more colonoscopies previously. When reading CE studies, images are often thus ignored once the capsule arrives in the cecum, as visualization of the mucosa is usually impared by fecal material. Our aim was to review the prevalence and clinical impact of the systematic viewing of colonic CE images obtained in patients referred for intestinal bleeding.

**Methods:** Retrospective study of consecutive cases referred over a 3 yr period (2003–5) for CE with obscure or occult GI bleeding as the indication. Adult, but not pediatric patients were put on a 24 hr liquid diet and received 2 L of a standard PEG prep. CE was performed after an overnight fast.

**Results:** A total of 166 adult and 105 pediatric patients were studied. Of these, 136 (82%) and 40 (38%), respectively, were referred for bleeding and thus eligible for inclusion. CE exam revealed a potential or definite colonic source of bleeding in 12 cases (4M, 8F), representing 8% of adults and 2.5% of pediatric cases. Mean age was 57.3 yr (range 16–82). In 9 cases, the history was of overt bleeding from an obscure source. Multiple transusions were necessary in 5 of these. The 3 others had iron deficiency anemia and OB± stools. On average, each patient underwent 3.7 negative investigations prior to CE, including at least 1 colonoscopy and EGD (mean 1.4 and 1.1, respectively). CE findings: vascular lesions of the colon were seen in 6 cases, including 3 angiodysplastic and 3 with AVMs. Two cases each of colonic masses or Crohn’s disease were seen. In 2 others, active colonic bleeding was found, but the CE did not determine the precise source. Overall, unique colonic findings were seen in 5 cases where the small bowel was entirely normal. Active colonic bleeding was seen in 5 cases, including 3 of the latter group.

**Conclusions:** CE using the SB Pilecam is able to diagnose a colonic source of bleeding in patients with occult or obscure GI blood loss. Our data suggest that systematic reading of colonic CE images be considered for cases with bleeding where a small bowel source was not found.

**Abstract: 1346**

**Glutaraldehyde Induced Chemical Colitis: Does Disinfected Mean Safe?**

_Nikhil Karanth, MD, Lori Sciortino, R.N., Seth Richter, MD,* Gastroenterology, Albany Medical College, Albany, NY._

**Purpose:** With the growing number of ambulatory surgical centers performing endoscopic procedures, physicians and endoscopy staff need to be aware of the common and not-so-common risk associated with performing these procedures. Physicians are usually accustom to the usual risks associated with performing endoscopic procedures, such as, perforation, bleeding, and adverse reaction to sedation. However, one of the less recognized risks can come from improper disinfecting. Without proper guidelines for disinfecting, the beneficial agents used can lead to substantial complications, such as chemical induced colitis. Our purpose is to raise awareness to physicians and endoscopy staff for the need to be familiar with the risk associated with chemical agents used in cleaning endoscopic equipment.

**Methods:** A retrospective review of colonoscopies performed in our institution revealed three cases within a four month period in 2004 of patients who underwent a colonoscopy and later developed symptoms consistent with colitis. Review of the current established guidelines set forth by the ASGE and SGNA were undertaken to evaluate our own disinfecting process.

**Results:** Three patients developed chemical colitis within twenty four hours of glutaraldehyde exposure. Symptoms were fever (n = 2), abdominal pain (n = 1), and bloody stools (n = 2). Follow-up CT, histologic evaluation of biopsies, and endoscopic evaluation were consistent with ischemic colitis which can mimic a chemically induced colitis. All patients were managed conservatively with intravenous antibiotics and fluids; all recovering within a 4 day time frame. Evaluation of the disinfecting process revealed the rinse time where the glutaraldehyde is flushed out of the endoscope not be sufficient, as well as the thermostat was not set adequately to reach the desired temperature.

**Conclusions:** With the pressure of high volumes due to the increased awareness and demand for endoscopic procedures established in the community has created a need for quick turn-over times to be essential for physicians who perform these procedures. With this the incidence of chemically induced colitis has become more of a concern that needs recognition. The familiarity with every aspect of the endoscopic process puts the responsibility of ensuring a safe procedure to lie not only with the physician, but also with the endoscopy staff who help maintain an efficient working environment.

**Abstract: 1347**

**Quality Control of Wireless Capsule Endoscopy Performance: A Large Single Center Experience**

_Thomas C. Knopp, D.O., Luis R. Pena, MD,* Internal Medicine, University of Kentucky, Lexington, KY._

**Purpose:** The use of wireless capsule endoscopy (WCE) has become widespread for evaluation of gastrointestinal bleeding, abdominal pain, and IBD, among others. There is limited data about the adequacy of bowel preparation and rate of cecal visualization if the standard technique is followed (fasting for 8 hours). The purpose of this study was to analyze a single center experience with capsule endoscopy, including indications for testing,
The use of wireless capsule endoscopy (WCE) has become widespread for evaluation of gastrointestinal bleeding, abdominal pain, and suspected IBD (?%). Among cases with GI blood loss, 57 (22%) were to performing WCE.

More aggressive bowel cleansing may be necessary in these patients prior to performing WCE.

Staging for T and N classification by EUS and CT agreed in 66% and 65% of the cases, respectively. It was not possible to classify the TC findings for T and N staging in 10 and 12% of the cases, respectively. The results were not operator dependent.

Conclusions: On stenosing rectal cancer, the EUS findings are inferior to CT and with questionable value. In our Institution, the flexible EUS for non-stenosing rectal staging has similar results to the report in literature.

### 1350

**Utility of JAVA Based Software for Computer-Aided EUS**

Catarina Brandao, MD, Mario Dinis-Ribeiro, PhD,* Helena Lomba-Viana, MD, Nuno Mesquita, MD, Luis Moreira-Dias, MD. Gastroenterology, Instituto Portugues de Oncologia do Porto, Porto, Portugal.

**Purpose:** Endoscopic ultrasonography (EUS) is well established for the evaluation of mediastinal lymph nodes as a diagnostic or staging modality in patients with lung cancer. Various sonographic criteria have been described for diagnosis of malignant spread but EUS guided fine needle aspiration (FNA) has shown to be superior to lymph node echofeatures. The objective of this study is to determine if computer-assisted analysis of mediastinal lymph nodes can be reliable for predicting malignant spread when EUS-FNA is not feasible due to location or other technical difficulties.

**Methods:** A retrospective IRB approved chart review of EUS was done for the evaluation of mediastinal LNs with the indication of suspected or diagnosed lung cancer from May 2002 to June 2005. The diagnosis was accepted as malignant mediastinal lymph nodes when FNA cytology was positive. When cytology was non-malignant, the results were compared with the final pathological diagnosis of excised lymph nodes. An experienced endosonographer (MSB) selected lymph node images for analysis. JAVA based software (Image J, available at http://rsb.info.nih.gov/ij) was used to analyze the echogenicity of lymph node images obtained by EUS. The mean density of lymph nodes was used as a marker for echogenicity.

**Results:** Out of a total of 58 EUS procedures, 26 patients were included per criteria. 11/26 patients had benign lymph nodes and 15/26 patients had different differentiation.

<table>
<thead>
<tr>
<th>Global validity</th>
<th>Stenosis</th>
<th>Neoadjuvant therapy</th>
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<tbody>
<tr>
<td></td>
<td>Yes n = 34</td>
<td>No n = 67</td>
</tr>
<tr>
<td>T (EUS) (%)</td>
<td>55</td>
<td>47</td>
</tr>
<tr>
<td>T (CT) (%)</td>
<td>47</td>
<td>46</td>
</tr>
<tr>
<td>N (EUS) (%)</td>
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<tr>
<td>N (CT) (%)</td>
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*Abstracts S517*

**Wireless Capsule Endoscopy Indication Predicts Study Quality**


**Purpose:** The use of wireless capsule endoscopy (WCE) has become widespread for evaluation of gastrointestinal bleeding, abdominal pain, and IBD, among others. The visualization of the SB can be sub-optimal in up to one third of the cases due to residual intestinal contents. The purpose of this study was to assess the quality of wireless capsule endoscopy in our institution and investigate if specific indications are associated with poor visualization.

**Methods:** Retrospective analysis was done of 400 WCE studies performed in our institution between 2003 and 2005. Data collected included demographics, indication, findings, bowel preparation quality, and whether the capsule reached the cecum or not. Non-parametric tests and logistic regression models were used to assess the associations, estimate the odds ratio (OR) and 95% confidence intervals (CI) of these associations and to control for potential confounders.

**Results:** Data was available on 176 males and 224 females. Mean age was 53.7 years. Poor visualization was reported in 74 studies (25%). The most common indications for the study were: GI blood loss (including suspected cases) in 261 cases (75%), abdominal pain and/or diarrhea in 76 cases (3%) and suspected IBD (7%). Among cases with GI blood loss, 57 (22%) were reported to show poor visualization compared to 8 (10%) among cases with abdominal pain and/or diarrhea (OR 1.9; 95% CI 1.2–4.8).

**Conclusions:** GI bleeding was associated with higher rate of poor visualization compared to abdominal pain and/or diarrhea. It was not possible to classify the TC findings for T and N staging in 10 and 12% of the cases, respectively. Therefore, a prospective, randomized trial is warranted to evaluate whether bowel preparation, and/or the use of prokinetic agents will decrease the incidence of poor visualization, and increase the rate of study completion.
malignant LNs. The mean density was obtained by the lymph node border-tracing method using Image J. No significant difference was found between the mean densities of malignant LNs when compared with benign LNs ($p = 0.32$).

**Conclusions:** Image J appears not to be a useful study for differentiation of malignant from benign lymph nodes on EUS imaging. We need to use more sophisticated image analysis software for reliable computer aided differentiation of nodal spread of malignancy.

### 1351

**Which Is the Key To Predict the Treatment Response to Definitive Chemoradiotherapy for Esophageal Cancer by Routine Endoscopy, Timing, Biopsy or Endoscopic Findings?**

Naoko Chayahara, Ikuya Miki

**Purpose:** Definitive chemoradiotherapy (CRT) plays an important role in non-surgical treatment of esophageal cancer (EC). An early and accurate assessment of non-complete response (non-CR) at the primary site is very difficult by endoscopy. This study investigated when and how to screen local response to definitive CRT for EC for the early attempt of salvage therapy by routine endoscopy.

**Methods:** Eighty-one patients with esophageal squamous cell carcinoma treated with definitive CRT (60Gy) were examined according to histological results of biopsy (with or without definite viable cancer cells) and endoscopic findings (with or without stenosis). CR at the primary site was defined 6 months after the completion of CRT by all the followings; endoscopically invisible residual tumor, disappearance of ulcer and stenosis, and no cancer cells in successive biopsies. Endoscopy was performed 1 week, 1, 3 and 6 months after the completion of CRT.

**Results:** CR and non-CR at the primary site were found in 42 and 22 patients, respectively, and 17 were not evaluated due to death or massive progressive disease within 6 months. At the point of 1 week, 35 (83%) out of CR patients did not have stenosis, whilst 14 (64%) out of non-CR had stenoses. Of 21 patients with stenosis at this point, 6 obtained natural improvement of ulcer and stenosis, and no cancer cells at the biopsy. Endoscopy was performed 1 week after CRT may be useful to screen poor response. Biopsy was of no use for the early detection of non-CR. Prolonged ulceration and stenosis strongly suggests poor response more than 1 month after CRT, so the other modalities including PET should be immediately considered regardless of histological confirmation.

**Conclusions:** Endoscopic findings 1 week after CRT may be useful to screen poor response. Biopsy was of no use for the early detection of non-CR. Prolonged ulceration and stenosis strongly suggests poor response more than 1 month after CRT, so the other modalities including PET should be immediately considered regardless of histological confirmation.

### 1352

**Clinical Usefulness of Endoscopic Submucosal Resection with Double Ligations for Rectal Carcinoid Tumor in Comparison with Strip Biopsy**

Joon Ho Moon, MD, Jong Hyeok Kim, MD,* Byoung Kwan Yoo, MD, Kwang Hyuk Park, MD, Yong Woon Chung, MD, Kyoungh Oh Kim, MD, Cheol Hoe Park, MD, Tae Ho Hahn, MD, Kyu-Sang You, MD, Sang Hoon Park, MD, Choong Kee Park, MD. Department of Internal Medicine, College of Medicine, Hallym University, Anyang, Kyung-gi, Korea.

**Purpose:** Complete resection of rectal carcinoid tumors is difficult with conventional polypectomy because these tumors extend mainly into submucosal layer. And deeper incision to achieve clean margin can make complications such as bleeding or perforation. In this study, we evaluated the efficacy and safety of endoscopic submucosal resection with double ligations (ESMR-DL) for the treatment of small rectal carcinoid tumors in comparison with strip biopsy.

**Methods:** We performed strip biopsy or ESMR-DL between April 2000 and November 2004. Eleven carcinoid tumors were resected by strip biopsy, and eleven tumors were resected by ESMR-DL. ESMR-DL was carried out with a conventional single channel endoscope with attached band ligator device. The lesion was aspirated into the ligator device, followed by deployment of the elastic band. And then ligation was performed below the elastic band by using a detachable snare. Snare resection was performed above the elastic band. ESMR-DL was compared with strip biopsy regarding complete resection rate, distance of vertical resection margin, and complication rate.

**Results:** Two groups were similar with respect to location, shape, and size of tumors. The rate of complete removal of carcinoid tumors with ESMR-DL (100%) was significantly higher ($p = 0.035$) than that with strip biopsy (55%). The mean vertical resection margin in ESMR-DL (832.3 ± 589.4 μ) also was significantly deeper ($p = 0.001$) than that in strip biopsy (158.6 ± 24.7 μ). The rate of complications with ESMR-DL (0%) was significantly lower ($p = 0.035$) than that of strip biopsy (45%). There was no local recurrence or distant metastases in any patients treated with ESMR-DL during the mean follow-up period of 24 months.

**Conclusions:** Endoscopic submucosal resection with double ligations is a useful and safe method for the treatment of small rectal carcinoid tumors.

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![Image](303x293 to 543x437)

**1353 Management of Variceal Bleeding – Is Multiple Band Shooter Really Effective?**

Susumu Shinoura, MD, Yutaka Yamaguchi, MD, Yoshih Shimaoka, MD, Koori Kikuchi, MD, Yoshihide Keida, MD,* Internal Medicine, Okinawa Chubu Hospital, Uruma, Okinawa, Japan.

**Purpose:** 1. To review cases of gastroesophageal variceal bleeding and to compare the clinical characteristics over time at Okinawa Chubu Hospital, Okinawa, Japan.

2. To analyze Endoscopic Variceal Ligation (EVL) cases resulting in death within one month.

3. To find ways to improve management of gastroesophageal variceal bleeding.

4. To establish an algorithm for management of gastroesophageal varices.

**Methods:** This retrospective study includes a total 255 cases in Period I (1976–1981), Period II (1982–1987) and Period III (2001–2005). We have contrasted 127 cases in Period I and II with 128 cases in Period III. The comparison was of 175 males to 80 females, with an average age of 55.8 years. The underlying disease was liver cirrhosis. Alcoholic cirrhosis accounted for 88.1% in Period I and II, and 57.8% in Period III.
Results: 1. Over the course of Period I and II, and Period III, surgical treatments decreased from 32.3% to 9% while endoscopies + IVR increased from 48.8% to 73.4%. Also, medication as vasopressin or octreotide ± SB tube increased from 18.9% to 25.8%.
2. The recurrence rate of variceal bleeding when treated with EVL in Period III were 12.6% within one year and 21.3% within two years.
3. The following characteristics were relevant in a review of ten cases with death within one month of EVL treatments:
   (1) Alcoholic cirrhosis
   (2) Shock state
   (3) Hct <20%
   (4) No EVL treatment even when fresh blood or clot was seen in the stomach at the initial EGD, given no apparent stigmata of bleeding point as plug on varices, varices on varices or hemocystic spot.
   (5) No prophylactic antibiotics given.
Conclusions: On the basis of results, the following treatment policy was established for gastroesophageal variceal bleeding:
1. In principle, to provide sole EVL treatment for an esophageal variceal bleeding without gastric varices and to securely ligate questionable regions or varices at gastroesophageal junctions (GEJ) even if active bleeding is not found.
2. First to provide EVL in acute phase, then to provide Balloon-occluded Retrograde Transvenous Obliteration (BRTO) following CT scan findings as gastrorenal shunt shunt in cases of gastric varices distant from GEJ.
3. Prophylactic antibiotics must be given before endoscopic procedure, as with vasopressin and propranolol following.
4. Given the high rate of fatalities, attention required when described as follows are recognized on a patient visit; (1) shock state (2)Hct <20% (3) a case caused by alcoholic cirrhosis.

1354
Performance of EGD/EUS for Tissue Diagnosis of Malignancy. The First 100 Procedures Performed by an Endosonographer after Completing Advanced Training in EUS at an Institution Recognized by the ASGE for EUS Training, and Who Has Met ASGE Criteria for EUS Credentialing
Rayburn F. Rego, MD,* Division of Gastroenterology, University of South Alabama, Mobile, AL.

Purpose: To evaluate the performance of EGD/EUS for tissue diagnosis of malignancy in the hands of a “relatively inexperienced” endosonographer.

Methods: The study involved the first 100 procedures performed in 2004 and 2005. Twenty five procedures involved FNA. Two patients were lost to follow up and were not included. These 2 patients had benign disease on cytology. 28 sites were sampled by FNA using a 22 Gauge needle.

Results: The sites were pancreas (15), lymph nodes (6), ampulla (3), sub mucosa (2), esophagus (1) and liver (1).The median number of passes was 3.5. No complications were noted following FNA. 8 of 23 patients were confirmed to have malignancy on EGD/EUS and 1 patient surgically (39%). This patient had a distal common bile duct stricture, but the patient was referred to surgery despite a negative FNA as clinical suspicion for malignancy was high. 2 patients were confirmed to have benign pathology at surgery. The remaining 12 patients found to have benign histology were followed clinically. The median follow up of these patients was 453 days. None of these patients showed evidence of malignancy or clinical deterioration suggesting malignancy during this period. The sensitivity and specificity of EGD/EUS in the histological diagnosis of malignancy were 89% and 100%. The positive predictive value (PPV) and negative predictive value (NPV) were 100% and 93%. The negative likelihood ratio was 0.11 (95% CI, 0.04–0.68).

Conclusions: 1. EGD/EUS performs excellently in the tissue diagnosis of malignancy, even in the hands of a “relatively inexperienced” endosonographer. 2. It is a safe procedure. 3. Patients should be referred for surgical excision when biopsy is negative but clinical suspicion of malignancy is high. 4. No case of malignancy was missed when EGD/EUS was combined with clinical acumen.

<table>
<thead>
<tr>
<th>Malignant disease</th>
<th>Benign disease</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>EGD/EUS pos</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>EGD/EUS neg</td>
<td>1</td>
<td>14</td>
</tr>
<tr>
<td>Total</td>
<td>9</td>
<td>14</td>
</tr>
</tbody>
</table>

1355
Utility of Video Capsule Endoscopy (VCE) in the Detection of Small Bowel (SB) Tumors – A Single Center Experience

Purpose: True incidence of SB tumors is unknown; they are usually diagnosed at an advanced stage or incidentally at laparotomy. This may relate to length of SB and lack of endoscopic modalities. VCE visualizes entire SB & may be useful in detection of SB tumors.

Objective: Determine prevalence of SB tumors in patients undergoing VCE, define endoscopic & pathologic findings, & patient outcomes.

Methods: Retrospective review of patients who had VCE at our institution from 9/6/01 to 1/4/06.

Results: 61/860 (7%) patients who underwent VCE had findings of SB tumor/polyloid lesion. 14/860 (2%) had confirmed tumor by CT scan, endoscopy &/or surgery. Of remaining 47 patients, lipoma (6), negative follow-up endoscopy (push or double balloon endoscopy) (16) & lesions of unclear significance without follow-up (25). Mean age of patients with confirmed tumors was 67 yrs (SD 9.9); 9M/5F. Ten patients (71%) with obscure overt GI bleed (7 melena; 2 hematochezia), (2) (14%) occult GI bleed, 1 (7%) abdominal pain & diarrhea, and 1 (7%) surveillance of FAP. Tumor/polyloid mass on VCE in 9 patients (64%), ulcer in 2 (14%), ulcerated nodules in 1 (7%), extrinsic compression in 1 (7%) and poor visualization in 1 (7%).

Capsule impaction at tumor site occurred in 4 (29%) patients. Proximal SB was involved in 4 (29%), mid SB in 7 (50%) & multiple lesions throughout SB in 3 patients (21%). CT enterography performed in 7 patients confirmed VCE findings. 13 patients (93%) had surgery; successful resection of tumor in 8/12 (62%). Pathology included adenocarcinoma, lymphangioma & carcinoid in 2 patients each (14%), diffuse large B cell lymphoma (7%), enteropathy associated T cell lymphoma (7%), GIST (7%), seranaplastic tumor (ovarian) (7%), endometrial stromal sarcoma (7%) & leiomyoma (7%). Pathology unavailable in 2/1 (7%) with presumed metastases from rectal cancer. Accuracy of tumor location with VCE 82% (9/11 patients). IC valve reached in only 43% patients.

Conclusions: 2% of patients who underwent VCE had SB tumor confirmed by endoscopy or surgery. 85% of tumors were malignant, most common adenocarcinoma, lymphoma & carcinoid. VCE proved to be a useful noninvasive modality that facilitated early detection & successful resection of SB tumors. VCE retention rate was high (29%)with colon reached in only 43% of patients.

1356
The Yield of Capsule Enteroscopy Varies in a Community vs University Hospital Setting
V. Alan Botoman, MD,* Ramona Lim, MD, Jason Zakko, Patricia Hellrung, R.N., Ira Litzenblatt, MD, Wisam Zakko, MD, John Bloom, MD, Gregory Bonner, MD, John Watson, MD, Jack Peicher, MD, Daniel Kosches, MD, Arturo Lopez, MD, Gastroenterology, Holy Cross Hospital, Fort Lauderdale, FL and Gastroenterology, University of Miami, Miami, FL.

Purpose: Capsule enteroscopy (CE) is a widely used diagnostic tool for small intestinal disorders. Initial data for CE came from large academic
medical centers, yet CE is now widely available in the community hospital setting. The aim of this study was to compare indications and findings for CE at Holy Cross Hospital (HC), a large Ft Lauderdale community hospital with those at the University of Miami during a comparable period of time.

**Methods:** We retrospectively reviewed 103 CE cases performed at HC between 2002–2005 and 107 CE cases performed at UM during the same time period, using an identical database for: demographics, indications—unexplained occult bleeding (OGIB) and/or iron deficiency anemia (Fe def); Crohn’s (CD), abnormal small bowel X-ray (SBFT), and findings—AVM’s, CD, gastroduodenal lesions (GDoudu), SB erosions, SB tumors, well as incomplete studies. Both institutions used the same Given® CE system and software. Statistical software (Graph Pad Instat v.3.0) analyzed the data. Failed studies defined as inability to completely examine the SB, either due to gastroparesis, technical failure, or food.

**Results:** Both groups were similar in mean age and gender (50% men HC vs 53% at UM) and indications (p = NS). The CE exam was incomplete in 8% of cases in each group.

**CE INDICATIONS**

<table>
<thead>
<tr>
<th>Indications</th>
<th>OGIB</th>
<th>Fe Def</th>
<th>Crohns</th>
<th>Ablt SBFT</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>HC (n = 103)</td>
<td>53%</td>
<td>24%</td>
<td>14%</td>
<td>3%</td>
<td>6%</td>
</tr>
<tr>
<td>UM (n = 107)</td>
<td>50%</td>
<td>13%</td>
<td>12%</td>
<td>9%</td>
<td>4%</td>
</tr>
</tbody>
</table>

There were some significant differences in findings between the 2 groups:

**CE FINDINGS**

<table>
<thead>
<tr>
<th>FINDINGS</th>
<th>AVM’s</th>
<th>Crohns</th>
<th>GDoudu</th>
<th>SB Erosions</th>
<th>SB Tumor</th>
<th>Other</th>
<th>Normal</th>
</tr>
</thead>
<tbody>
<tr>
<td>HC (n = 103)</td>
<td>24%*</td>
<td>8%</td>
<td>14%</td>
<td>8%</td>
<td>6%</td>
<td>11</td>
<td>22%*</td>
</tr>
<tr>
<td>UM (n = 107)</td>
<td>43%*</td>
<td>12%</td>
<td>7%</td>
<td>8%</td>
<td>7%</td>
<td>7</td>
<td>39%*</td>
</tr>
</tbody>
</table>

*p < 0.005; **p < 0.006

**Conclusions:** Concurrent patients undergoing CE in a community hospital vs university hospital setting, show no statistically significant differences in demographics, indications, and rate of incomplete exams (8% in each group). We confirmed a 7–14% incidence of gastroduodenal findings within EGD range in both groups. There were significantly more normal studies in the HC group and more AVM’s detected in the UM group. The data suggests that these differences were observer related rather than due to selection bias, and point to challenges facing deployment of CE technology in the community hospital setting.

**1357**

**Duration of Screening Colonoscopies: Comparing Sedation with Propofol Versus Meperidine and Midazolam**

**Alan H. Wang, MD, William A. Mourad, MD, Emily Suwack, D.O., Michael J. Komar, MD,* Gastroenterology, Geisinger Medical Center, Danville, PA.**

**Purpose:** The main purpose of our study was to determine if the use of propofol was associated with a significant difference in the time it takes to perform a colonoscopy compared with meperidine and midazolam both with and without biopsy and snare polypectomy.

**Methods:** A retrospective study in an outpatient ambulatory surgical center on patients undergoing colonoscopies between 11/1/2005 and 1/31/2006. Patients with an ASA class ≥2 were excluded. Patients were randomly selected to receive either propofol (N = 243) or meperidine and midazolam (N = 316). 9 gastroenterologists participated in the study and were unaware that procedure times were being documented. A nurse recorded the time of scope insertion and scope withdrawal on all patients. Chi-square and Wilcoxon two-sample tests were used to describe the study population and compare characteristics of both groups. This included a bivariate comparison of the time to perform a colonoscopy. Repeated measures linear regression model was used to control the data per physician and for number of biopsies and polypectomies.

**Results:** Of the 316 patients receiving meperidine and midazolam, 48 had at least one snare and 107 had at least one biopsy and 161 had neither. Of the 243 patients receiving propofol, 29 had at least one snare and 73 had at least one biopsy and 141 had neither. Comparing these two groups, no significant time difference was found (p = 0.15).

Repeated measures linear model to determine if time to do colonoscopy varies between using propofol versus midazolam and meperidine

<table>
<thead>
<tr>
<th>Effect</th>
<th>Estimate</th>
<th>Standard Error</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>12.71</td>
<td>1.13</td>
<td></td>
</tr>
<tr>
<td>Midazolam and meperidine vs. propofol</td>
<td>0.052</td>
<td>0.50</td>
<td>0.92</td>
</tr>
<tr>
<td>Any Snare</td>
<td>6.98</td>
<td>0.69</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Any Biopsy</td>
<td>3.57</td>
<td>0.53</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Using each physician as their own control, procedures with at least 1 snare or 1 biopsy were 6.98 minutes and 3.5 minutes shorter (p < 0.0001 and p < 0.0001, respectively) if using propofol. Colonoscopies without biopsy or snare had a nonsignificant 0.05 min shorter duration if using propofol.

The above results included a physician level adjustment.

**Conclusions:** The use of propofol did not significantly change the duration of colonoscopies compared to meperidine and midazolam, unless biopsies or snares were performed.

**1358**

**A Randomized Controlled Double Blind Trial of Patient-Controlled Sedation for Colonoscopy with Propofol/Remifentanil vs. Midazolam/Fentanyl**

**Jeff E. Mandel, MD,* Jonathan Tanner, MD, Gary R. Lichtenstein, MD, David C. Metz, MD, David A. Katzka, MD, Gregory Ginsberg, MD, Michael L. Kochman, MD. Anesthesiology, University of Pennsylvania and Gastroenterology, University of Pennsylvania, Philadelphia, PA.**

**Purpose:** Sedation improves patient acceptance of colonoscopy (COY), but accounts for 90% of complications [1]. Propofol reduces recovery time and improves patient satisfaction relative to benzodiazepines. Use of propofol by non-anesthesiologists is controversial, as is reimbursement for routine colonoscopy with anesthesia providers. Patient-controlled sedation (PCS) has been investigated for COY [2], but previous studies utilized suboptimal doses of narcotics, and were not blinded. We undertook a prospective, randomized, double-blind comparison of PCS for COY with propofol/remifentanil vs. midazolam/fentanyl.

**Methods:** Sedation was provided via a Graseby 3400 PCA pump with a 60 cc syringe containing either propofol 10 mg/ml + remifentanil 10 μg/ml (group PR) or midazolam 0.5 mg/ml + fentanyl 12.5 μg/ml (group MF). The syringe and tubing were shrouded. Initial bolus was 2.5 ml with demand of 0.75 ml at zero lockout (PR) or 4 ml with 1 ml demand at 1’ lockout (MF). An unblinded anesthesiologist was present to intervene. The 1° safety endpoint was S02<85% for 60.” Endoscopist, RN, and patient were blinded; satisfaction was assessed by Likert scale. Ambulation without assistance was assessed by a blinded observer. Comparison of times was by 2 sided t-test.

**Times (min) (mean ± SE)**

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Time to sedation</th>
<th>Procedure time</th>
<th>Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>MF</td>
<td>14</td>
<td>7.3 ± .89</td>
<td>19.7 ± 2.6</td>
<td>37.9 ± 7.8</td>
</tr>
<tr>
<td>PR</td>
<td>17</td>
<td>3.6 ± 3.1*</td>
<td>18.3 ± 2.5</td>
<td>5.4 ± 9.7#</td>
</tr>
</tbody>
</table>

*p < 0.0002 # p < 0.0001

**Results:** As shown in Table 1, time to sedation and to ambulation were significantly lower for group PR. Time to ambulation for group PR was less
than procedure time \((p < 0.0001)\). The study was underpowered for the safety endpoint, but PR patients were more likely to require stimulation to maintain \(S_\text{PO}_2 \geq 85\%\). Only one patient in group PR required intervention by the anesthesiologist (two breaths of 100% \(O_2\)), but completed the procedure without sequelae. Satisfaction of patients, RN, and endoscopist were high in both groups.

**Conclusions:** PCS with PR significantly reduces sedation and recovery times, improving throughput and permitting reduction in PACU capacity. Respiratory depression was more common in group PR, but was generally managed by low-skill interventions. These results may impact the debate on staffing of sedation for COY and economic viability of such practices.


### 1359

**Knowledge of Indications and Utilization of EUS: Survey of Oncologists in the USA**

Nischita K. Reddy, MD, Avi B. Markowitz, MD, James L. Abbruzzese, MD, Manooj S. Bhutani, MD, F.A.C.G.* Internal Medicine, The University of Texas Medical Branch, Galveston, TX and Gastrointestinal Medical Oncology, MD Anderson Cancer Center, Houston, TX.

**Purpose:** Our aim was to study the utilization of EUS by oncologists in the USA and to ascertain the impact of personalized approaches to manage patients with gastrointestinal and adjacent cancers (ca).

**Methods:** A questionnaire was emailed to 650 practicing medical (1), radiology (2), and surgical (3) oncologists.

**Results:** Data was analyzed from 100 (15.38\%) responses. Across the 3 oncology groups, there was similar EUS utilization and EUS availability during training and in practice. Referral of pts. for EUS was not influenced by its availability during training, practice, or the type of practice (hospital, office or both) \((p > 0.05)\). Overall utilization rate of EUS for staging of NSCLC was significantly low \((19.0\%); p < 0.01\), even when it was available in their practice \((24.2\%); p < 0.05\). When EUS was unavailable, 78.9\% did not use it for staging pancreaticobiliary cancers \((p < 0.01)\). Despite lack of availability of EUS in their practice, oncologists referred patients to other centers for staging of esophageal ca. \((57.9\%); p < 0.01\) and rectal ca. \((73.7\%); p > 0.05\). Availability of EUS did not impact its use in staging gastric ca. \((p > 0.05)\). Majority of the responders opined that EUS made an impact in rectal \((89.5\%\)), esophageal \((84.5\%\)), and pancreaticobiliary ca. \((58.5\%)\) but not gastric \((54.7\%)\) or NSCLC \((61.5\%)\). 27.9\% of oncologists who did not use EUS for staging NSCLC, 41.2\% in esophageal ca., 20.8\% in gastric ca., 31.1\% in pancreaticobiliary and 69.2\% in rectal ca., believed it could have a clinical impact on the management of such patients \((p < 0.01)\). In staging NSCLC, EUS-FNA \((35.7\%)\) and Mediastinoscopy \((34.7\%)\) were reported as the most accurate modalities for tissue sampling of lymph nodes in levels 5 (A-P window), 7 (subcarina) and 8 (parasophageal). 41.9\% responded that EUS was better than PET scanning for detecting mediastinal lymphadenopathy and that the 2 modalities maybe complimentary in staging esophageal \((80.6\%)\) and NSCLC \((56.8\%)\). 42.3\% of the oncologists reported that EUS was better than CT/MRI for detecting small \((< 2-3 \text{ cm})\) pancreatic tumors. Majority of them \((67.7\%)\) have not seen or referred patients for EUS guided celiac plexus neurolysis for palliation of pain in unresectable pancreatic ca.

**Conclusions:** These data highlight the variable utilization patterns of EUS-FNA in the management of gastrointestinal and lung cancers, that do not necessarily follow results of published clinical studies.

### 1360

**The Diagnostic Utility of Endoscopic Ultrasound (EUS) in Evaluating Patients with Submucosal Lesions (SMLs) of the Gastrointestinal (GI) Tract**

Leon S. Maratchi, MD, Henry Beecher, MD, Daniel Gelrud, MD, Sammy Ho, MD.* Division of Gastroenterology, Montefiore Medical Center/Albert Einstein College of Medicine, Bronx, NY.

**Purpose:** SMLs of the GI tract present a diagnostic challenge because their subepithelial location prevents their access by conventional endoscopy and biopsy technique. EUS has become the diagnostic procedure of choice in some medical centers and the aim of this study was to report our experience with EUS in evaluating patients with SMLs.

**Methods:** The records of all patients referred to our institution for EUS evaluation of SMLs between July 2003 and March 2006 were reviewed. Patient demographics, clinical history, endoscopic findings and follow-up were recorded.

**Results:** A total of 59 patients were referred for EUS of which 70% \((41/59)\) were female; the mean age of the total group was 62 years (range 23–88 years). All patients underwent a standard endoscopic exam prior to EUS. Presenting symptoms included abdominal pain \((10\%)\) and weight loss \((7\%)\). 83% \((49/59)\) were asymptomatic. SMLs were found in the stomach in 58% \((34/59)\), rectum 14% \((8/59)\), esophagus 12% \((7/59)\), duodenum 10% \((6/59)\), and colon 7% \((4/59)\). Of the 59 patients, 68% \((40/59)\) had intramural lesions: 12 gastrointestinal stromal tumors (GISTs), 9 inflammatory polyps/thickened folds, 6 carcinoids, 5 lipomas, 4 duplication cysts, 2 leiomyomas, and 2 pancreatic rests. 14% \((8/59)\) of the suspected SMLs were due to extrinsic compression by normal structures. 19% \((11/59)\) had normal EUS. Fine needle aspiration was performed on 43\% \((17/40)\) of lesions. The median follow up was 17 months. Nine patients underwent surgical resection of the SMLs and 100\% \((9/9)\) of the surgical specimens were consistent with the EUS diagnosis. There were no procedural related complications.

**Conclusions:** 1. EUS is a safe diagnostic test that plays a definitive role in evaluating patients with submucosal lesions. 2. Most SMLs are benign. 3. Prospective studies are needed to determine the optimal surveillance strategy for patients with SMLs.
Perception of GI Fellows on the Relationship between Hand Size and Endoscopic Training

Daniel L. Cohen, MD, Jahnavi R. Naik, B.S., Ryan D. Madanick, MD,∗
Department of Medicine, University of Miami Miller School of Medicine/Jackson Memorial Medical Center, Miami, FL; University of Miami Miller School of Medicine, Miami, FL and Division of Gastroenterology, University of Miami Miller School of Medicine/Jackson Memorial Medical Center, Miami, FL.

Purpose: GI endoscopy requires considerable dexterity and training to learn well. Some endoscopists, especially early in training, find it difficult to manipulate the scopes’ dials and buttons, possibly due to small hand size. We hypothesized that GI trainees with smaller hands would perceive more difficulty in learning and performing endoscopy.

Methods: A survey designed to assess the perceptions of GI fellows towards hand size and endoscopy was sent to all fellows currently in adult GI training programs in the US and PR. Variables evaluated included gender; hand size; handedness; height; weight; perceptions of the effect of their hand size on their training and ability to perform endoscopy; and their opinions about smaller-handled endoscopes.

Results: 1295 surveys were sent to 158 GI programs. 207 (16.0%) returned the surveys. 51 (24.6%) respondents were female and 26 (12.7%) were left-handed. Median glove size was 7.5. 81 (39.1%) respondents considered their hand too small for the endoscope’s handle. Of the 34 fellows (16.4%) with glove size under 7, all but one (97.1%) were female, and 23 (67.6%) considered their hands to be too small for the endoscope’s handle. Respondents who considered their hand too small were more likely to be female; shorter; lighter; have performed fewer procedures in the prior 12 months and their entire career; use smaller glove sizes; perceive smaller hand size in general; and perceive smaller hand size compared to other trainees (all p < 0.001).

Handedness and level of training were not significant. 162 (79.0%) believed that hand size affects the ability to learn endoscopy, while 125 (64.9%) felt that it affects the ability to perform endoscopy. Only 16 (7.8%) were aware of smaller-handled endoscopes, and only 2 (1.0%) had used one. 70 (34.1%) reported that they would use one if available, and 87 (42.4%) said that programs should offer them to fellows.

Conclusions: A significant number of GI trainees, especially women, perceive that their hands are too small for standard endoscopes and believe that hand size plays a role in learning and performing endoscopy. The option of using of smaller-handled endoscopes may prove to be beneficial and should be considered by their training programs. Prospective investigation about this topic is warranted.

A New, Simplified Ingestion Protocol for PillCam Eso

Ling Hua, B.Sc., John R. Saltzman, MD, Lyndsey Ide, B.A., Julia J. Liu, MD,* Gastroenterology, Brigham and Women’s Hospital, Boston, MA and Emergency Medicine, Brigham and Women’s Hospital, Boston, MA.

Purpose: PillCam Eso is a new, wireless imaging modality to evaluate the esophagus. The recommended ingestion protocol consists of having the patient ingest the PillCam in the supine position, followed by raising the patient 30◦ every two minutes over a six minute ingestion period until the patient is sitting upright, and is thus cumbersome to perform. We developed a simplified ingestion protocol to facilitate patient care. The aim of this study was to evaluate this new, simplified ingestion protocol for PillCam Eso.

Methods: Patients with suspected gastroesophageal reflux disease ingested the PillCam Eso using the new ingestion protocol for evaluation of the esophago-gastric lesions. In this ingestion protocol, the patient swallows the PillCam Eso at a 30◦ incline with 10 mL of water containing simethicone. The patient then holds 5 mL of water containing simethicone in the mouth without swallowing for 5 minutes. The patient ingests 20mL more water at the 30o position for another 5 minutes. At the end of the 10 minutes, the patient drinks an additional 30 ml of water and is allowed to ambulate. The PillCam Eso images were interpreted by one experienced endoscopist. The PillCam Eso transit time, percentage of the gastroesophageal junction visualized, and the number of satisfactory examinations were evaluated.

Results: Thirty-one patients ingested the PillCam Eso with the new ingestion protocol. The mean age was 47.4 ± 8.7 years. There were 11 males (35%) and 20 females (65%). Eleven were Caucasian (35%), 10 were African American (32%), 9 were Hispanic (29%), and 1 was Asian (3%). The median transit time was 25 seconds (IQR 4–1035 sec; 95% CI of 12–335 sec) compared to medians of 134.5 sec and 245 sec in the published literature. Esophageal transit times were less than 33 seconds in 55%. The median percentage of the gastroesophageal junction visualized was 80% (IQR 60–90%).
The Evaluation of Premenopausal Women with Iron Deficiency Anemia: What Is the Yield of Endoscopy?

Amy Barto, MD, Rebecca Liberman, M.P.H., Kristen Robson, MD,* Gastroenterology, Lahey Clinic Medical Center, Burlington, MA.

Purpose: Iron deficiency anemia (IDA) is not uncommon in premenopausal women and is often attributed to menstrual blood loss. The purpose of this study is to determine the yield of gastrointestinal endoscopy in premenopausal women with IDA.

Methods: We identified and reviewed the medical record of 166 premenopausal women between the ages of 21 and 50 years who underwent upper endoscopy and/or colonoscopy for the indication of IDA. Patients with known etiologies for IDA such as cirrhosis, history of gastric bypass, inflammatory bowel disease and pregnancy were excluded. Women who had a hysterectomy were also excluded.

Results: Of the 166 patients, 99 (59.6%) underwent upper endoscopy and 86 (52.2%) underwent colonoscopy. Eighty six (51.8%) patients underwent both procedures. The mean age was 43.6 (21.5-50.8) years. The mean hemoglobin was 10.1 ± 1.4 g/dL. Eleven of 99 patients (11.1%) who underwent upper endoscopy were taking non-steroidal anti-inflammatory medications. Upper gastrointestinal lesions potentially causative for anemia were found in 10 of 99 patients (10.1%) who underwent upper endoscopy. Significant lesions included peptic ulcer disease, erosive esophagitis, celiac disease, carcinoid tumor and esophageal carcinoma. Significant lower gastrointestinal lesions were found in 8 of 153 patients (5.2%) who underwent colonoscopy, and included ileal ulcers, carcinoma and polyps greater than 1 cm. Patients with a significant lesion on upper endoscopy had lower mean hemoglobin values than those without a lesion (8.7 ± 1.9 g/dL vs. 10.1 ± 1.3 g/dL, p = 0.002). Similarly, patients with a significant lesion on colonoscopy had lower mean hemoglobin values (8.6 ± 1.8 g/dL vs. 10.3 ± 1.3 g/dL, p < 0.001). Older age was not associated with the presence of a significant lesion. Neoplastic lesions were found in 3 of 166 patients (1.8%), and included 1 esophageal carcinoma and 2 colon cancers.

Conclusions: Our data suggest that both upper endoscopy and colonoscopy were useful in the detection of significant gastrointestinal lesions in premenopausal women with IDA. Upper and lower gastrointestinal neoplastic lesions were found in 1.8% of patients. Patients with a lower hemoglobin were more likely to have a significant lesion on both upper endoscopy and colonoscopy.

Reduced Looping with a Computer-Assisted Colonoscope: Initial Experience

Ahmad Kamal, MD, Jacques Vam Dam, MD, PhD,* Gastroenterology and Hepatology, Stanford University, Stanford, CA.

Purpose: Colonoscopy is the gold standard for colorectal cancer screening, and the number of colonoscopies performed has increased greatly in recent years. Repetitive strain injuries are common among endoscopists. A recent study reported that 39% of colorectal surgeons performing colonoscopy have had injury or pain believed to be from performing colonoscopy, mostly to the hands and fingers. Liberman AS, Surg Endosc. 2005 Dec;19(12):1606–9.1 A novel computer-assisted colonoscope (NeoGuide Systems, Inc., Los Gatos, CA) was designed to avoid looping during colonoscopy. On manual insertion of the colonoscope, the position and angle of the tip are encoded into a computer algorithm. Each successive segment is directed to make a similar angle when it reaches the same point in the colon, thus advancing through the colon in a “follow-the-leader” manner. The NeoGuide Endoscopy System also replaces the conventional endoscope handle with a more ergonomic joystick control. The purpose of this study was to determine feasibility of performing colonoscopy with this joystick interface for steering.

Methods: In the first part of the study, endoscopists (n = 5) were trained on the joystick driven endoscopy system; they then attempted to perform a simulated colonoscopy using a bench top training model (Koken, Inc., Tokyo, Japan). The second part of the study examined the ability of the joystick to accurately control the endoscope tip. An experimental apparatus was designed to fixture the endoscope tip and provide the subject with 20 optical targets (Light Emitting Diodes) to locate. These targets were thought the workspace defined by the kinematic limits of an endoscope tip, including full retroflexion. During the study the optical targets were activated one at a time in random order. Endoscopists (n = 10) were instructed to find the active targets and center them in the endoscope camera image using the joystick interface.

Results: In the training model study all endoscopists successfully completed the procedure including cecal intubation and inspection upon withdrawal. In the optical target study all 20 targets were successfully located with the NeoGuide system.
Conclusions: This study demonstrates the feasibility of this novel joystick control of a flexible endoscope. Clinical trials are warranted to determine the usability of this interface in a clinical setting. Additional bench studies to determine potential ergonomic and performance benefits of the Joystick interface are also indicated.

Utility of Double Balloon Enteroscopy (DBE) in the Diagnosis of Small Bowel (SB) Ulcers: Results from a Multicenter Study
Shabana F. Fasha, MD, M.E. Harrison, MD, Simon Lo, MD, Shahab Mehlduzadeh, MD, Carol Semrad, MD, Irving Waxman, MD, Andrew Ross, MD, Lauren B. Gerson, MD, Richard Kozarek, MD, Drew Schembre, MD, Kenneth F. Binnmoeller, MD, Jonathan A. Leighton, MD.

Gastroenterology, Mayo Clinic, Scottsdale, AZ; Gastroenterology, Cedars Sinai Medical Center, LA, AZ; Gastroenterology, University of Chicago, Chicago, IL; Gastroenterology, Stanford University Medical Center, Stanford, CA; Gastroenterology, Virginia Mason Clinic, Seattle, WA and Gastroenterology, California Pacific Medical Center, San Francisco, CA.

Purpose: The true incidence & significance of SB ulcers is unknown due to limited endoscopic tools. Capsule endoscopy (CE) can visualize entire SB but does not allow biopsy/therapeutics & rate of missed lesions is unknown. DBE may overcome these limitations by evaluation of entire SB & biopsy/therapeutic interventions.

Objective: To review utility of DBE in the diagnosis and evaluation of SB ulcers.

Methods: Retrospective review of a prospectively collected database of patients who had DBE at 7 medical centers in USA over a 1 year period.

Results: 237 DBEs in 206 patients from 8/27/04 to 8/26/05. SB ulcers detected on 20 (8%) DBEs (12 anastomotic/8 retrograde) in 17 (8%) patients. Mean age 49.7 years (SD 15.4); 11F/6M. Indications for DBE included obscure GI bleed (13), suspected Crohn’s (4), abdominal pain (1), diarrhea (1), evaluation for neuroendocrine tumor (1) and FAP (1). Multiple ulcers were seen in 11 (65%), 2 ulcers in 1 (6%) and single ulcer in 5 patients (29%). Most common location of ulcers was in ileum (6 each in proximal & distal ileum), followed by distal jejunum (5), midjejunum (5), proximal jejunum (2) & IC valve (1). 13/147(9%) patients with obscure GI bleed had SB ulcers on DBE. Biopsies were performed in 12 patients; pathology available in 9: Crohn’s disease (5), superficial inflammatory reaction (1), nondiagnostic (2) & normal (1). Only 1 patient required endoscopic treatment of ulcer. 5 patients required PRBC; mean 6 units (SD 4). Aspirin/NSAID use reported by 5/15 patients (33%). Prior CE performed in 13/17 patients with SB ulcers on DBE; ulcers seen on CE in 10/13 (77%) patients.

Conclusions: DBE is a useful endoscopic modality in the diagnosis of SB ulcers. The retrograde method may have higher yield given predominant location of ulcers in distal and mid SB. SB ulcers accounted for 8% cases of obscure GI bleed. CE was less sensitive than DBE & detected ulcers in 77% patients. DBE offered the advantage of biopsy & tissue diagnosis in patients with SB ulcers.

EUS for Evaluation of Submucosal Lesions: A Retrospective Study
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Gastroenterology, Penn State College of Medicine, Hershey, PA.

Purpose: Endoscopic ultrasonography (EUS) is important in evaluating gastrointestinal submucosal lesions (SL). We evaluated the outcome in patients (pts) who had EUS for evaluation a suspected SL.

Methods: Data collected from EUS reports and clinical charts of pts who had EUS was analyzed. Pts with cancer, Barrett’s esophagus or ampullary tumor were excluded.

Results: Of the 510 EUS exams 91 were performed (December 02 to July 04) on 74 pts for evaluation of suspected SL. The lesion was esophageal in 17 (23%), gastric in 37 (50%), duodenal in 14 (19%) and rectosigmoid in 6 (8%). In 50 pts the lesion was mass-like (including 7 polypoid) and mucosal in the rest. The masses were < 1 cm in 22.5%, 1–2 cm in 30%, 2–3 cm in 37.5% and > 3 cm in 10%. Of the 17 esophageal lesions, 12 appeared mass-like (EUS finding: 7 cysts, 1 cyst and varices, 1 polyp, 3 solid masses) and 5 mucosal (EUS finding: normal). Among the 37 gastric lesions 26 were mass-like (EUS finding: 14 solid masses, 4 polyps, 2 cysts, 2 varices, 2 bulging livers, 1 extrinsic pancreatic mass and 1 lipoma) and 11 mucosal (EUS finding: 3 thick mucosa/gastritis, 1 thick mucosa/gastric ulcer, 1 gastric atrophy, and 6 normal). Out of the 14 duodenal lesions 12 were mass-like (3 prominent papillae, 3 lipomas, 2 solid lesions, 2 polyps, 1 brunners gland, and 1 varices) and 2 were mucosal (EUS finding: normal). The 6 rectosigmoid lesions were all masses (EUS finding: 3 lipomas, 2 solid lesions, 1 abscess). FNA was performed in 28 pts (6/10 cystic lesions, 4/7 lipomas, 15/21 non-lipomatous solid lesions, 1 extrinsic mass, 1/7 polyps and 1/21 mucosal lesions); 5 had spindle cell neoplasms, 2 benign cystic elements, 2 showed atypia, 6 were inadequate and the remaining were benign. Biopsy in one with atypia showed a gastrinoma. All aspirates from lipomas were negative or unsatisfactory. Endoscopic resection was performed in 5 pts (3 polyps, 1 lipoma and 1 solid mass [specimen lost]). 16 pts underwent surgery including the one with an extrinsic mass. 15 had true masses and 1 had an esophageal cyst noted by EUS. Follow up EGD was planned for 25 pts, 13 of whom also had a repeat EUS (9 pts required 2 EUS and 4 pts required 3 EUS procedures). 36 pts needed no further follow up after the initial EUS exam.

Conclusions: 50% of pts after EUS for a SL require follow up. Most pts (15/21 or 71%) with a solid mass ended up with surgery. Most of the cystic lesions (8/10) were esophageal. Excluding lipomas, FNA provides a positive diagnosis in 43% (9/21). FNA is useless in diagnosing lipomas.

Patients Prefer New Sodium Phosphate (NaP) Tablets vs 2 L Polyethylene Glycol Electrolyte Lavage Solution (PEG) Plus Bisacodyl Tablets for Bowel Preparation
Gary R. Lichtenstein, MD,* Michael D. Brown, MD, Sandra R. Lottes, PharmD, William P. Forbes, PharmD, Kelli Walker, PharmD., University of Pennsylvania, Philadelphia, PA; Rush University Medical Center, Chicago, IL and Salix Pharmaceuticals, Inc, Morrisville, NC.

Purpose: Patient preference and tolerability can play important roles in adherence to bowel preparation regimens. The current study assessed patient preference for a new NaP tablet (tab) (OsmoPrepTM; Salix Pharmaceuticals, Inc) vs 2 L PEG + bisacodyl tabs (HalfLytely®, Braintree Laboratories, Inc) for colonoscopy.

Methods: Patients (pts) ≥18 years were randomized in a multicenter, investigator-blinded study to receive 32 (48 g) NaP tabs or 2 L PEG + 4 (20 mg) bisacodyl tabs. NaP tabs were taken 4 at a time with 8 oz clear liquid on the evening before (20 tabs) and 3 to 5 h prior to (12 tabs) colonoscopy. 2 L PEG + bisacodyl tabs were taken as directed in the US prescribing information. Patient acceptance of the study preparation, a secondary endpoint, was evaluated by patient questionnaire administered prior to colonoscopy. A Fisher exact test was used to compare the results.

Results: 205 pts receiving NaP tabs and 206 pts receiving 2 L PEG + bisacodyl underwent colonoscopy. Significantly more pts taking NaP tabs (94%) vs 2 L PEG + bisacodyl (73%) found it easy or fairly easy to take the study medication (P < 0.0001). Similarly, significantly more pts taking NaP tabs (96%) vs 2 L PEG + bisacodyl (83%) considered it easy to follow all medication instructions (P < 0.0002). Patient preference for NaP tabs was further reflected in that 94% of pts in the NaP group vs 60% in the 2 L PEG + bisacodyl group found it easy or fairly easy to drink the amount of liquid prescribed (P < 0.0001). Moreover, 6% vs 28% of pts (NaP and 2 L PEG + bisacodyl groups, respectively) described the study preparation taste as bad or very bad (P < 0.0001). 96% of pts in the NaP group, but only 74% in the 2 L PEG + bisacodyl group, would take the study preparation again should a future colonoscopy be necessary (P < 0.0001). Similarly, significantly more pts taking NaP tabs vs 2 L PEG + bisacodyl would choose the study preparation over the purgative administered at their last colonoscopy.


**[Abstracts S525](#)**

**1370**

**Impact of Hands-On Simulation Training in GI Hemostasis Skills**

Robert E. Sedlack, MD, Division of Gastroenterology and Hepatology, Mayo Clinic, Rochester, MN.

**Purpose:** Training of GI fellows in the use of GI bleeding therapeutic devices is traditionally taught by patient-based instruction alone. With any skills education that involves patients, there is likely a small but real increased risk to the patient’s health and comfort during the early stages of training. We assess the effects that an ex-vivo simulation curriculum involving the fundamentals of endoscopic bleeding management has on the fellows’ preparedness prior to beginning patient-based training.

**Methods:** 12 second year GI fellows with no hemostatic experience underwent a half-day hands-on course using ex-vivo porcine organs during which they learned the practical theory and practiced the use of various hemostatic devices (Injection Needle, Heater Probe, Gold Probe, Argon Plasma Coagulator, Hemoclip, and Band Ligator). In a pre- and post training survey, fellows rated their knowledge about each tool and their comfort in manual application of each of the devices using a 10-point Likert scale (1 = Very Insecure, 10 = Very Secure). Results of these pre and post-course surveys were compared to determine the degree of change in scores as a result of this hands-on training curriculum.

**Results:** Fellows reported a significant increase ($p < 0.001$) in their knowledge and ability to apply all of the hemostatic devices as a result of participation in the hands-on course. The median difference between the pre- and post course scores for each parameter is shown in the figure below. (See figure 1)

**Conclusions:** A hands-on course in hemostatic devices using an ex-vivo simulation model is shown to have a measurable impact on novices’ self-perceived cognitive and motor skills which improves the trainees’ preparedness prior to beginning patient-based training. Future research will determine if these positive effects also result in improved clinical outcomes and accelerated competency by trainees. [figure1]

**1371**

**Receipt of an Endoscopy Report after an Outpatient Procedure: Affect on Anxiety & Satisfaction**

Maya Spodik, MD, Barbara Alpini, C.G.R.N., Cathy Walker, C.G.R.N., David Kastenberg, MD,* GI, Thomas Jefferson University, Philadelphia, PA.

**Purpose:** Among the measures of success with endoscopy (endo), patient (pt) satisfaction and allaying anxiety are important. We evaluated the affect on satisfaction and anxiety of providing pts with a copy of their endo report at the time of discharge from the endo lab.

**Methods:** This was a prospective, single center, investigator-blind study. Post-procedure, the “Control” (C) group protocol consisted of a review of findings and recommendations with the physician or their designee, and receipt of discharge instructions containing recommendations copied from the endo report. In addition to this protocol, the “Intervention” (I) group received an endo report identical to that retained in the pt chart. The Beck Anxiety Inventory (BAI) was administered prior to entering the endo lab. The total BAI consists of 22 items with scores ranging from 0 to 66; higher scores indicate greater anxiety. The BAI, in addition to a satisfaction survey, was conducted 1 week later by phone. This satisfaction survey had 1 less question than the 9 question Modified Group Health Association of America survey, a questionnaire previously validated by the ASGE to measure pt satisfaction with endoscopy. Total satisfaction scores could range between 8 and 80; higher scores indicate greater satisfaction. To assess the reliability of the two outcomes, anxiety and satisfaction, a test/retest reliability study surveyed the initial 27 pts (16 I; 11 C) on days 7 and 14 post-endoscopy.

**Results:** The 2 study groups were equally matched for type of procedure, gender, and race. However, the Intervention group was older (54.4 vs 50.7; $p = 0.037$). Spearman rank correlations across the two surveys were 0.80 for the anxiety score and 0.79 for the satisfaction score. Satisfaction scores were similar and very high for the Control and Intervention groups (75.2 vs 73.8; $p = 0.417$). When analyzed by age, older pts (>60 yrs) had lower average satisfaction scores by ~6 points ($p = 0.004$). Anxiety scores were not significantly different between the Control and Intervention groups before endo (5.3 vs 5.7; $p = 0.759$). Though the BAI decreased markedly 1 week later in both groups, the scores were significantly lower in the Intervention group (0.8 vs 2.4; $p = 0.001$).

**Conclusions:** Providing an endoscopy report to a patient at discharge results in less anxiety, but no difference in satisfaction, 1 week after a procedure. Patients were highly satisfied with the outpatient endoscopy experience, though those >60 yrs less so than younger patients. This intervention should be adopted.

**1372**

**Computer-Aided-Diagnosis (CAD) in Colonoscopy Using Texture Analysis**

Jia Gu, PhD,* Allen Poirson, PhD. Image Processing Group, STI Medical Systems, Honolulu, HI.

**Purpose:** We apply medical image processing techniques to video colonoscopy data to create a computer-aided-diagnosis (CAD) system that aids the physician. Our automatic, minimally-invasive system aims to improve early cancer detection by identifying suspicious regions using the texture of the tissue surface. STI Medical Systems duplicates the diagnostic process used by colonoscopists to assess the severity of abnormalities.

**Methods:** First, we discard poor quality image data that arise from suboptimal digital camera settings such as focus and shutter speed. Second, we improve the remaining images through glint removal and contrast

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Feeling Blue? Cyanosis/Hypoxia during an ERCP from Methemoglobinemia Precipitated by Topical Benzocaine Pharyngeal Anesthesia
Carmelita J. Colbert, MD, Hareth M. Raddawi, MD,∗ Gastroenterology, University of Illinois/Advocate Christ, Chicago/Oak Lawn, IL.

Purpose: Alert Endoscopists to the rare, albeit potentially life-threatening, complication of Cyanosis and Hypoxia from Benzocaine-induced Methemoglobinemia. Endoscopists should be able to recognize it and effectively treat it.

Methods: A 51 year old man with Cholelithiasis and Choledocholithiasis underwent an ERCP. He was premedicated with 4mgs of Midazolam, 100 mcgs fentanyl and Benzocaine spray for topical pharyngeal anesthesia. The Cholangiogram demonstrated 3 CBD stones, the Pt then became restless and acutely cyanotic, tachycardic and tachypneic but with a normal lung and cardiac exam. His Oxygen saturation was 52% by Pulse oximetry. The Procedure was immediately aborted, pulse oximetry was down to 47% on a 15 Liter non-rebreather. A Chest X Ray was normal but an Arterial blood gas showed a PH of 7.47 PCO2: 35.6, PO2:100, HCO3:25.5, Sat.:47. Hgb 12.5, Carboxyhemoglobin 0.6, Oxyhemoglobin 57.9, Methemoglobin 39.5.

Results: The Patient was transferred to the Medical Intensive Care Unit and Methylene Blue at a dose of 2mg/Kg was administered Intravenously over Five minutes. His Cyanosis regressed within 20 minutes and his hemoglobin normalized in 30minutes.

Conclusions: Topical Anesthetics like Benzocaine used for pharyngeal anesthesia prior to upper Endoscopy or ERCP are believed to have an oxidizing effect that would transform the Iron in the four heme groups of Hemoglobin from the usual Ferrous state Fe++ to the non-oxygen binding Ferric state Fe+++ . Left uncorrected, the Hemoglobin will not be able to bind with Oxygen nor will it allow for Oxygen unloading at the tissue level. Methemoglobinemia should be suspected in patients with hypoxic symptoms who appear cyanotic but have a PaO2 sufficiently high that Hemoglobin should be fully saturated with Oxygen.

1375

EUS-FNA of Mediastinal Lymphadenopathy: A Retrospective Study from an Upstate New York Tertiary Center
Nikhil Kananth, MD, Ali Nawras, MD,∗ Gastroenterology, Albany Medical College, Albany, NY.

Purpose: Endoscopic ultrasound (EUS) with fine-needle aspiration (FNA) has been widely used for the evaluation of a variety of gastrointestinal lesions. As an adjunct to bronchoscopy and mediastinoscopy, the EUS has been utilized in the evaluation of mediastinal lymphadenopathy often when the bronchoscopy is negative or the mediastinoscopy is not feasible. We
1376

Laboratory Predictors of Hospital Length of Stay Following Acute GI Bleed

Sara W Echelmeyer, MD, * Latha G. Stead, MD. Internal Medicine, Mayo Clinic, Rochester, MN and Emergency Medicine, Mayo Clinic, Rochester, MN.

Purpose: To study whether any early laboratory variables after acute GI bleed are associated with increased hospital length of stay (HLOS).

Methods: The study cohort of 231 consecutive patients consisted of adults with a GI bleed that required emergent endoscopy. Routine laboratory studies included electrolytes, CBC, and coagulation studies. Information on current medications and vitals at triage were collected. General linear models were used to evaluate the association between each of the patient characteristics and HLOS. HLOS was modeled as a normally distributed variable after applying the natural logarithm transformation. The transformation decision was based on visual inspection of histograms and normal probability plots. Each patient characteristic was evaluated univariately by fitting separate models. Patient characteristics with more than two levels were handled by defining 2 indicator variables with normal defined as the referent. A multivariate model was obtained using a combination of stepwise and backward procedures and an inclusion criterion of R-squared > 0.15 years were more likely to believe that PEGs decrease nutrition, but less than half believe that PEGs provide other benefits (Table 1). Although over 80% of respondents believe that not placing a PEG or withholding feeding from patients with AD may be acceptable, 34% would opt for a PEG in themselves or a family member with AD; this latter group of doctors is more likely to believe that PEGs provide benefit in AD. Respondents in practice >15 years were more likely to believe that PEGs decrease aspiration risk. While the majority discuss the commonly associated risks of PEG placement with caregivers, few mention other risks such as the need for restraints and decreased social contact.

Conclusions: With the exception of improved nutrition, most respondents do not believe AD patients benefit from PEG and believe it may be acceptable not to place PEGs and/or withhold feeding from AD patients. These findings belie the prevalence of PEGs in this population. Respondents’ willingness to accept a PEG for themselves or a family member with AD correlates with beliefs in the benefits of PEG. The major limitation of this survey is self-selection bias.

Gastroenterologists’ Beliefs about Benefits of PEG in AD

<table>
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<tr>
<th>Improved Nutrition</th>
<th>Increased Longevity</th>
<th>Increased Comfort</th>
<th>Decreased Aspiration</th>
<th>Improved Functional Status</th>
</tr>
</thead>
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<td>42%</td>
<td>41%</td>
<td>44%</td>
</tr>
<tr>
<td>Disagree</td>
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<td>58%</td>
<td>59%</td>
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1377

Gastroenterologists’ Beliefs on Percutaneous Endoscopic Gastrostomies (PEGs) in Patients with Advanced Dementia (AD)

Patricia L. Kosch, MD, Julie Yang, MD, Daniel Gelrud, MD,* Lawrence J. Brandt, MD, M.A.C.G. Div. of Gastroenterology/Department of Medicine, Monmouth Medical Center of the Albert Einstein College of Medicine, Bronx, NY and Div. of Gastroenterology/Department of Medicine, Jacobi Medical Center of the Albert Einstein College of Medicine, Bronx, NY.

Purpose: PEG tubes in patients with AD are common in the US: 34% of nursing home patients with AD have PEGs. Few data support the traditional goals of PEGs in AD, such as improved nutritional and functional status, increased longevity, and decreased aspiration or suffering; further, PEGs pose procedure-related and other risks. The purpose of this study was to better understand gastroenterologists’ beliefs about the benefits and risks of PEGs in AD.

Methods: A one-page survey mailed to non-trainee members of the ACG included demographic questions, Likert-scale items about PEG benefits in AD, personal belief questions, and an open-ended question about PEG risks.

Results: Of 2500 surveys mailed, 466 (18.6%) were returned. Most respondents were white males in non-academic settings; over half were in practice more than 15 years. Two-thirds reported that AD is the indication for PEG placement in less than 30% of cases. 83% agreed that a PEG may improve nutrition, but less than half believe that PEGs provide other benefits (Table 1). Although over 80% of respondents believe that not placing a PEG or withholding feeding from patients with AD may be acceptable, 34% would opt for a PEG in themselves or a family member with AD; this latter group of doctors is more likely to believe that PEGs provide benefit in AD. Respondents in practice >15 years were more likely to believe that PEGs decrease aspiration risk. While the majority discuss the commonly associated risks of PEG placement with caregivers, few mention other risks such as the need for restraints and decreased social contact.

Conclusions: With the exception of improved nutrition, most respondents do not believe AD patients benefit from PEG and believe it may be acceptable not to place PEGs and/or withhold feeding from AD patients. These findings belie the prevalence of PEGs in this population. Respondents’ willingness to accept a PEG for themselves or a family member with AD correlates with beliefs in the benefits of PEG. The major limitation of this survey is self-selection bias.

Gastroenterologists’ Beliefs about Benefits of PEG in AD
Purpose: EUS is performed commonly for evaluation of submucosal lesions (SL) in the gastrointestinal tract. Some of the patients (pts) with an SL end up with surgical treatment. Our aim is to describe characteristics and findings in pts who underwent surgery for an SL.

Methods: Data collected from endoscopy reports and clinical charts of pts who had EUS at The Milton S Hershey medical center, a tertiary care facility was analyzed. Pts with cancer, Barrett’s esophagus or ampullary tumor were excluded.

Results: 91 EUS exams were performed (December ’02 to July ’04). 74 pts had evaluation of suspected SL. 16 pts subsequently underwent surgical resection. 13 of these pts were evaluated by one endoscopist. Lesion size was < 1 cm by EUS in 1 pt (0.2 cm), 1–2 cm in 5 pts, 2–3 cm in 5 pts, 3–4 cm in 2 pts, and > 4 cm in 1 pt (4.3 cm). There was no lesion size recorded in 2 pts. The indication for surgical removal was: FNA pathology of spindle cell or stromal cell neoplasm in 6 pts and atypical cells in 1 pt, suspicion of stromal-type tumor raised by EUS examination in 3 pts, interval increase in mass size in 3 pts, diagnostic excision of a mass in 1 pt, debulking for primary peritoneal carcinoma in 1 pt and pancreatic mass excision in the remaining pt. Review of tumor pathology revealed 7 gastrointestinal stromal tumors (GIST), 2 leiomyomas, 1 malignant melanoma plus leiomyoma, 1 primary peritoneal carcinoma, 1 heterotrophic pancreas with adenomyosis, 1 inflammatory fibroid polyyp, 1 esophageal duplication cyst, 1 rectal abscess. The remaining pt, who was being evaluated for a gastric antral lesion, was found to have a well-differentiated pancreatic endocrine carcinoma with liver metastases, but no gastric involvement. The surgical procedures performed were as follows; 11 partial gastrectomies or wedge resections, 1 total gastrectomy, 1 rectal abscess excision, 1 surgical resection of a duplication cyst, 1 Whipple procedure, and 1 peritoneal debulking surgery for extensive primary peritoneal carcinoma.

Conclusions: Characteristics and findings in pts undergoing surgery after EUS for an SL are described. A partial gastrectomy or wedge resection is the most common surgical procedure performed in pts who are evaluated for a gastrointestinal submucosal lesion. The most frequent diagnosis at surgery is that of GIST. We speculate that multiple factors including pt and physician preferences rather than the size of the lesion affected the decision to proceed with surgery.

1379

The Intra and Inter Observer Variability of String Capsule Endoscopy (SCE) for the Diagnosis of Esophageal Lesions
Richard P. Shaughnessy, D.O., Francisco C. Ramirez, MD, Richard Gerkin, MD, Nooman Gilani, MD, R.N., Paula Erickson, R.N., Suryakanth R. Gurudu, MD,∗ Gastroenterology and Hepatology, Mayo Clinic Scottsdale, Scottsdale, AZ.

Purpose: String Capsule Endoscopy (SCE) uses a standard small bowel video capsule fitted with a sleeve and string to obtain images of the esophagus. Previous studies have demonstrated its feasibility for the diagnosis of Barrett’s Esophagus (BE) and Esophageal Varicies (EV).

Aim: To determine the inter and intra variability of SCE and the effect of training in the diagnosis of esophageal lesions.

Methods: Videos of SCE were reviewed by an experienced endoscopist and the diagnosis was confirmed by EGD and biopsy. Studies were defined as representative of normal, BE, EV, erosive esophagitis, and tumor. Two videos of each diagnostic finding (total of 10) were selected for training purposes. Five different videos of each finding (total of 25) were selected for testing purposes. A 20 sec clip was selected from the video that was most representative of the diagnostic finding. Study participants included 4 endoscopy RN/NP, 6 GI fellows(GIF), and 5 GI attendings(AT). The participants were divided into two groups. Group A received training and then performed the test module. Group B first performed the test module and then received training. Both groups then repeated the test module after at least 8 hours. The effect of training was evaluated with independent and paired nonparametric tests.

Results: The group that received training between testing episodes demonstrated a trend toward significant improvement (p = 0.056). The group that did not get training between testing episodes did not significantly improve (p = 0.652).

Conclusions: Participants with previous endoscopic training demonstrated a substantial agreement (κ score > 0.6) with expert opinion. Endoscopy nurses demonstrated only moderate agreement. Intra-observer agreement ranged from 20–100%. Training demonstrated a trend toward improved diagnostic accuracy. SCE is minimally invasive, negates the need for sedation and carries no risk for capsule retention. This study demonstrates interpretation of images from SCE can be readily learned by trained endoscopists.
obstruction. Capsule retention always occurs at the site of pathology, therefore surgical removal usually leads to identification and treatment of the underlying small bowel disease. Most common cause of retention in our center appears to be diaphragm disease due to NSAIDs followed by small bowel tumors.

Conclusions: The WA colonoscopy is associated with a reduction in withdrawal time without compromising adenoma detection. However, this effect appears to be operator dependent.

Comparison of WA and ST scopes for withdrawal time and mean number of adenomas per colonoscopy

<table>
<thead>
<tr>
<th>Endoscopist</th>
<th>Number of procedures</th>
<th>WA mean withdrawal time</th>
<th>ST mean withdrawal time</th>
<th>p value</th>
<th>Adenoma detection WA</th>
<th>Adenoma detection ST</th>
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</tr>
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</table>


d damages associated to Peutz-Jeghers Syndrome.

Conclusions: DBE is a safe and effective technique for the management of small bowel polyps related to the Peutz-Jeghers syndrome (PJS).

Methods: Retrospective review of patients that had DBE for management of symptomatic PJS from October 2005 until May 2006.

Results: Five patients underwent six DBE procedures (4 antegrade, 2 retrograde). All patients had symptoms of intussusception. All patients had a previous video capsule endoscopy showing polyps in the small intestine. DBE allowed visualization of small intestine polyps in 3 of the 5 patients. One of the patients that had an unsuccessful DBE, subsequently had a polypectomy using snare electrocautery, often in a piecemeal fashion. No complication were associated to the procedures.

Conclusions: DBE is a safe and effective technique for the management of small bowel polyps associated with distinctive mucocutaneous pigmentation. Nearly 50% of patients experience an intussusception in their lifetime, often beyond the reach of conventional endoscopy.

DBE has been FDA approved as endoscopic modality for visualization and therapeutic intervention of the small intestine.

Methods: Eight colonoscopists in 2 institutions participated in the study. Patients were randomized in a 1:1 ratio, so that each colonoscopist performs 50% of the exams with 160 series variable stiffness Olympus colonoscope and 50% with the WA instrument. Insertion and withdrawal times and number of polyps detected were recorded. Endoscopists were asked to withdraw as quickly as they could carefully complete the exams. Analysis of variance was done to compare insertion and withdrawal times and number of polyps detected. Time to perform biopsy, polypectomy and cleaning was subtracted using a stopwatch.

Results: A total of 710 procedures were performed, 355 with ST and 355 with WA colonoscopy. The mean insertion times were similar. The mean withdrawal time with WA colonoscopy was 4.9 min which was significantly shorter as compared to ST colonoscopy which was 5.4 min (p = 0.0001).

Withdrawal time was significantly shorter for three endocopists when using WA as compared to ST colonoscope (p = 0.0001, p = 0.01, p = 0.03). The difference in withdrawal time for the rest of the endoscopists was not statistically significant. There was no difference in the mean number of adenomas detected per colonoscopy with ST (0.6) compared to WA (0.5) (p = 0.12). Two of the endoscopists with shorter withdrawal times with WA had numerically higher detection rates with WA.

Conclusions: Case: A 44 y/o Caucasian male with chronic hepatitis C, constipation, long standing GERD, polysubstance abuse and bipolar disorder was referred to the GI service for evaluation of his GERD. There was no history of NSAID abuse, weight loss, early satiety or dysphagia. His medications included OTC laxatives, ranitidine, antidepressants and multivitamins. He had no family history of any GI malignancy. On exam, vital signs were stable and physical exam was unremarkable. Labs: Normal CBC, BMP and folate level. EGD showed erosive gastroduodenitis and diffuse speckled brownish-black pigmentation in the stomach. Gastric biopsies showed severe chronic gastritis, presence of H. pylori, and pseudomelanosis with negative iron stains. Results of electron microscopy (EM) and X-ray analysis to identify the pigmentation composition are awaited.

Discussion: The literature identified an isolated case focal (2 x 2 cm) pale blue pigmentation in the gastric fundus


d the patients that had DBE, subsequently had a polypectomy using snare electrocautery, often in a piecemeal fashion. No complication were associated to the procedures.

Conclusions: DBE is a safe and effective technique for the management of small bowel polyps related to the Peutz-Jeghers syndrome (PJS).

Methods: Retrospective review of patients that had DBE for management of symptomatic PJS from October 2005 until May 2006.

Results: Five patients underwent six DBE procedures (4 antegrade, 2 retrograde). All patients had symptoms of intussusception. All patients had a previous video capsule endoscopy showing polyps in the small intestine. DBE allowed visualization of small intestine polyps in 3 of the 5 patients. One of the patients that had an unsuccessful DBE, subsequently had a polypectomy using a standard colonoscope with terminal ileum intubation. This polyp was seen intussuscepting into the cecum. In all cases, polypectomy was performed using snare electrocautery, often in a piecemeal fashion. No complication were associated to the procedures.

Conclusions: DBE is a safe and effective technique for the management of small bowel polyps associated with Peutz-Jeghers Syndrome.

Wide-Angle (WA) (170° Angle of View) Versus Standard (ST) (140°) Colonoscopy

Table: Comparison of WA and ST scopes for withdrawal time and mean number of adenomas per colonoscopy

<table>
<thead>
<tr>
<th>Endoscopist</th>
<th>Number of procedures</th>
<th>WA mean withdrawal time</th>
<th>ST mean withdrawal time</th>
<th>p value</th>
<th>Adenoma detection WA</th>
<th>Adenoma detection ST</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>710</td>
<td>4.9</td>
<td>5.4</td>
<td>0.0001</td>
<td>0.5</td>
<td>0.6</td>
<td>0.12</td>
</tr>
<tr>
<td>1</td>
<td>94</td>
<td>5.3</td>
<td>5.5</td>
<td>0.23</td>
<td>0.7</td>
<td>1.1</td>
<td>0.34</td>
</tr>
<tr>
<td>2</td>
<td>49</td>
<td>4.4</td>
<td>4.9</td>
<td>0.35</td>
<td>0.3</td>
<td>0.7</td>
<td>0.19</td>
</tr>
<tr>
<td>3</td>
<td>99</td>
<td>4.6</td>
<td>4.8</td>
<td>0.14</td>
<td>0.5</td>
<td>0.6</td>
<td>0.19</td>
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<tr>
<td>4</td>
<td>99</td>
<td>4.2</td>
<td>4.8</td>
<td>0.01</td>
<td>0.3</td>
<td>0.2</td>
<td>0.32</td>
</tr>
<tr>
<td>5</td>
<td>100</td>
<td>4.9</td>
<td>6.3</td>
<td>0.0001</td>
<td>1.3</td>
<td>1.0</td>
<td>0.25</td>
</tr>
<tr>
<td>6</td>
<td>97</td>
<td>7.4</td>
<td>7.7</td>
<td>0.84</td>
<td>0.1</td>
<td>0.3</td>
<td>0.11</td>
</tr>
<tr>
<td>7</td>
<td>76</td>
<td>4.8</td>
<td>3.6</td>
<td>0.03</td>
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<td>0.6</td>
<td>0.47</td>
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<tr>
<td>8</td>
<td>96</td>
<td>3.4</td>
<td>3.5</td>
<td>0.82</td>
<td>0.5</td>
<td>0.4</td>
<td>0.17</td>
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</tbody>
</table>
and body in a 27 yr old woman abusing laxatives. Histological examination revealed brown granular material within macrophages in the lamina propria with a negative iron stain; however, no electron microscopy or X-ray analysis studies were executed. Case reports of “pseudolamellanos diodensi” suggest an association with GI bleed, advanced age, female gender, chronic renal failure, fusosomial-propanolol use, diabetes mellitus, hypertension and oral iron supplementation. Our patient had none of these conditions except the finding of erosive gastritis. The pigment in pseudolamellanos diodensi resembles lipofuscin and melanin on light microscopy, (positive Fontana-Masson bleaching and Warthin- Starry stains – characteristic of melanin; positive with PAS and Oil Red O – characteristic of lipofuscin). However, EM and X-ray analysis confirmed the pigment to be FeS. Conclusions: The pigment implicated in pseudolamellanos gastrici could be FeS secondary to GI bleed from the erosive gastritis. EM and X-ray studies will identify the pigment composition. [figure1]

1384

Double-Balloon Enteroscopy: Initial Experience at a Referral Center
James Disario, MD,∗ Gastroenterology, University of Utah, Salt Lake City, UT.

Purpose: Describe the initial experience with DBE in a referral center. Methods: Database review of all DBE procedures performed with the Fujinon EN-450P5/20 between March 2005 and May 2006. Complications were defined by adapting modified ERCP consensus criteria based on length of hospital stays and required interventions.

Results: 3 endoscopists performed 38 DBEs on 34 patients (20 women, 14 men) with a mean age of 53 (21–86) years. Indications included 12 (32%) bleeding, 8 (21%) ERCP with surgically altered anatomy, 5 (13%) polyposis syndromes, 5 (3%) suspected Crohn’s, 5 (13%) abnormal imaging, 2 (5%) jejuno/stomy placement, 1 (3%) stricture. Fluoroscopy was employed in all procedures. An oral approach was used in 32 (84%) cases, required a mean of 110 (50–240) minutes, and 30 (94%) had general anesthesia. The depth of insertion was estimated to be proximal 5 (16%), middle 11 (34%) and distal 5 (16%) jejunum, and proximal 6 (19%), middle 1 (3%) and distal 4 (13%) ileum. Anal insertion was done in 6 (16%), required a mean of 89 (55–130) minutes, and all had general anesthesia. Insertion was to distal 1 (17%), proximal 2 (33%) and middle 1 (17%) jejunum, and proximal 1 (17%) and distal 1 (17%) ileum. Tattoos were placed at the extent of insertion in 21 (55%). 3 (8%) patients had tattoos placed at upper DBE and subsequently had lower DBE, but the tattoos were not seen. Detected lesions included vascular malformations in 2 of 34 (6%) patients, polyps in 5 (15%), ulcers in 2 (6%), and stenosis in 1 (3%). Biopsies were performed in 15 (40%) procedures. Therapy included vascular coagulation in 2 (5%); polyectomy/ablation in 5 (13%), jejunostomy in 1 (3%), dilation in 1 (3%), and ERCP interventions in 5 (13%). The primary aim of the procedure was totally achieved in 32 (84%) and partially in 3 (8%), and 3 (8%) were unsuccessful. There were 4 (11%) DBE-related complications including 1 mild and 1 moderate bleeding episode, 1 mild pancreatitis (presumably from transgastric pancreatic compression), and 1 mild bout of pain. 3 of 8 (38%) persons had ERCP-related complications.

Conclusions: DBE is a useful modality for a variety of diagnostic and therapeutic indications. However, the procedures are lengthy, usually require general anesthesia, may not visualize the entire small bowel or find suspected lesions, and have associated complications. Improved technology and accessories will expand the applications DBE.

1386

Incidence and Outcomes of Capsule Endoscopy Retention: An International Study
Andres Sanchez Tague, MD, Andrew K. Roorda, MD, Margaret Allen, L.VN, Cecilia M. Sison, MD, Angel Cauanedo Alvarez, MD, Kanwar R.S. Gill, MD, Christine Pizziote, MD, Javier Romero Vazquez, MD, Juan M. Herrera Gutierrez, MD, Kenneth F. Binnemoller, MD,∗ Interventional Endoscopy Services, California Pacific Medical Center, San Francisco, CA; Endoscopy Unit, Virgen Macarena University Hospital, Sevilla, Spain and St. Mary’s Medical Center, San Francisco, CA.

Purpose: In capsule endoscopy (CE), capsule retention (CR) is defined as non-passage of the device after two weeks from the procedure date. It has been reported to occur in 6.7 percent of patients with known Crohn’s disease. The purpose of this study was to determine the incidence, causes, and outcomes of CR in a large series from two referral academic hospitals in the United States and Europe.

Methods: Reports and charts from subjects that had undergone CE and had documented CR were reviewed. CR was defined as having the capsule remain in the lower GI tract (small bowel or colon) two weeks or more after the examination. The cause of retention was documented. Outcomes included natural capsule passage with or without pharmaceutical treatment or capsule removal either by endoscopy or surgery. Cases of CR in the stomach were excluded.

Results: Of the 1127 subjects included in our cohort, CR was observed in 28 (2.5%) patients (25F/3M; mean age 64 year old). Obscure gastrointestinal bleeding (46.4%) was the main indication for CE followed by anemia (25%) and abdominal pain (17.8%). The cause of capsule retention could be recognized in 14 patients on CE images. The findings were compatible with non-Crohn’s strictures in 10 patients, Crohn’s strictures in 7 and a tumor in 5. Nine patients had a history of chronic NSAID intake. Surgery was...
performed in 19 patients to treat underlying pathology that caused capsule retention and to remove the capsule. Two Crohn’s patients passed the capsule after corticosteroid treatment and in another two the capsule remained in the ileoanal pouch and was removed by endoscopy. Natural passage of the retained capsule occurred in 5 patients.

**Conclusions:** Non-Crohn’s small bowel strictures, Crohn’s strictures and tumors were the three lesions most likely to cause CR. In the majority of cases, surgery was performed to treat the underlying lesion and remove the capsule. A surprisingly high proportion of CR (32%) resolved with non-invasive means.

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**1387**

**Satisfaction Assessment for Endoscopy with Trainee-Participation (SAFE-T)**


**Purpose:** Training future endoscopists is essential to meet increasing demands for colonoscopy. However, it remains unknown if trainee-participation will adversely affect patient satisfaction.

**Methods:** We conducted a prospective, single-blinded, controlled study of consecutive patients referred to a university hospital for open-access colonoscopy (OAC). Primary and secondary aims were patient satisfaction-and pain-scores with and without trainee-participation. Pre-procedure, procedure, and post-procedure questionnaire data was prospectively recorded. Validated scores were used for assessment of satisfaction and pain. The study was designed to achieve an 80% power with an alpha of 0.05 for the multivariate analysis.

**Results:** 369 patients entered the analysis (181 with trainee participation; 188 without). Most referrals were for screening/surveillance (87%). Mean procedure time was 16 ± 6 min for the attending procedures (AP) vs. 22 ± 8 min for the trainee procedures (TP). Primary outcome: There was no significant difference between satisfaction-scores in both groups (**p** = 0.978). Agreement with the statement “I was very satisfied with the care I received” was found in 97% (AP) and 98% (TP). In the multivariate analysis only waiting-time was significantly associated with lower satisfaction-scores (**p** = 0.001). There was no association with other factors (gender, ASA-class, anxiety, etc.). Bowel preparation was poorly tolerated in 21% but did not affect satisfaction-scores (**p** = 0.56). Secondary outcome: Pain-scores were not significantly different in the 2 groups (**p** = 0.28). Of those who remembered the procedure, 73% had mild pain and 17% had moderate discomfort, but were willing to repeat the test at the same level of sedation. 10% of patients would have preferred more sedation. In the univariate analysis pain-scores had a significant association with higher levels of anxiety (**p** = 0.02), female gender (**p** = 0.02), and procedure duration (**p** = 0.0001).

**Conclusions:** Trainee-participation does not affect satisfaction-scores in patients presenting for OAC. In contrast, waiting-time adversely affected satisfaction. Participation of a trainee prolongs the procedure, but does not affect patients’ pain. These findings may help to reassure patients undergoing OAC with trainee-participation.

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**1388**

**Self-Expandable Plastic Stent (SEMS) for Treatment of Benign and Malignant Strictures of the Esophagus and Colon: A US Cancer Center Experience**

Norio Fukami, MD, Alexander A. Dekovich, MD, Yolander L. Hamilton, MD, William A. Ross, MD.∗ Department of Gastrointestinal Medicine and Nutrition, MD Anderson Cancer Center, Houston, TX.

**Purpose:** SEPS are designed to be removed making them suitable for treatment of benign refractory strictures and for early palliation of malignant strictures awaiting response to chemoradiation. We present our experience with SEPS in benign and malignant strictures of the esophagus and colon.

**Methods:** A retrospective database search between July 2004 and February 2006 to identify patients with SEPS placement was conducted. Demographics, nature and location of stricture, dilation history, outcomes and complications were recorded.

**Results:** A total of 29 SEPS were placed in 18 patients: 8 with malignant strictures and 10 with benign esophageal strictures. In malignant stricture (MS) group were 5 primary esophageal, 1 lung, and 2 rectosigmoid cancers. In benign esophageal stricture (BS) group were 3 anastomotic, 1 post chemoradiation, 3 post photodynamic therapy (PDT), and 3 post inflammatory strictures. Median stricture length was 5 cm. Median delays prior to SEPS for BS were 6 (2–16). SEPS placement was successful in all. Dilation prior to SEPS placement was required in 16 patients. Immediate relief of dysphagia occurred in 14 patients. In the BS group, stents were removed no later than 8 weeks. Stent migration occurred in 8 patients (3 in the MS group) in a median of 22 days. Two patients required narcotic analgesics immediately post stent placement. Two patients with benign stricture developed tracheoesophageal fistula at the middle of stent after the multiple stent exchange. In 13 patients, restenosis occurred within a median of 26 days (range 6–286 days). The median days to restenosis was 127 days if the stent was retained more than 42 days. In MS group, all patients had successful palliation of stricture. One patient with esophageal cancer is undergoing chemoradiation with SEPS for 306 days while maintaining oral intake. Two patients with colonic SEPS have had good palliation; one till death at 59 days and the other still living at 173 days post placement.

**Conclusions:** We observed a stent migration rate of 44% in our population and 12% developed tracheoesophageal fistula. Long term success in BS group was limited; time to restenosis of benign strictures seemed to lengthen with retention of the SEPS for greater than 42 days. More study is needed to define the ideal candidate for SEPS placement in those patients with refractory benign stricture.

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**1389**

**Diagnostic Value of Capsule Endoscopy in Community Setting & Its Effects in Altering the Management**

Krishnamury Shivshanker, MD,∗ Shilpa Saxena, MD. Gastroenterology, BCM, Houston, TX.

**Purpose:** To evaluate the diagnostic yield of capsule endoscopy in Patients referred for Anemia & Obscure GI bleeding and how management is altered by this intervention.

**Methods:** Of the 88 study participants 35 males, 53 females, their age ranging from 15–85 yrs.They presented with C/o Obscure GI bleeding(42), anemia(32), Pain in abdomen(17), H/o IBD (8), Diarrhea(7), AVM(3).Some of these patients have overlapping symptoms. Most patients gave negative H/o NSAIDS use even on specific questioning. When they were shown the results many did admit the use of NSAIDS. These study participants were followed for a period of 2yrs.

**Results:** In 88 participants Diagnosis & Management

1) Ulcers/Erosions (NSAIDS use)- 20 (Discontinue NSAIDS + medica-
2) AVL –18 (Enteroscopy+cautery)
3) Ulcers+AVL- 4 (As above)
4) AVL+Other Lesions- 8 (Enteroscopy+cautery +Rx)
5) IBD-16 (Enteroscopy+medications)
6) Diverticulosis- 9 (Rx)
7) Gastritis – 3 (Rx)
8) Normal – 5 (NA)
9) Tumor – 1 (Resection)
10) Celiac sprue-1 (Rx)
11) Others- 3 (Rx).
Conclusions: M2 Capsule endoscopy is very useful for the diagnosis of GI diseases in a community setting. The results altered management and care in most patients, supporting its use. We have found that use of NSAIDS is much more common in this setting. There is equal incidence of AVMs & Ulcers/Erosions (NSAIDS use) as the cause of Obscure GI bleeding & Anemia. Tumors are rare.

1390

Capsule Endoscopy Is Useful in Assessing Intestinal Lesions of Behcet’s Disease
Atrysu Sakuraba, MD, Yasuhiro Takada, MD, Haruhiko Ogata, MD, Toshihiko Hibi, MD.* Internal Medicine, Keio University School of Medicine, Tokyo, Japan.

Purpose: Early diagnosis of gastrointestinal lesions is crucial for therapy of inflammatory bowel diseases. Video capsule endoscopy has improved the diagnosis of small-bowel diseases, but data concerning the role of this technique in detecting small-bowel lesions of intestinal Behcet’s disease is scarce. In the present study, we assessed the usefulness of capsule endoscopy in intestinal Behcet’s disease and compared the results with other diagnostic modalities.

Methods: Three patients with intestinal Behcet’s disease (2 male, 1 female; mean age 33.3 years) underwent video capsule endoscopy and video findings were compared with other diagnostic modalities.

Results: In the 1st patient a deep ulcer was found on the ileocecal valve with capsule endoscopy. This was confirmed by ileocolonoscopy. In the 2nd patient multiple ulcers and erosions with active bleeding were found in the ileum with capsule endoscopy. Small bowel barium radiography showed only small erosions in the ileum and ileocolonoscopy was negative except for tarry stool. The 3rd patient showed scars in the ileum with capsule endoscopy. This could not be detected with ileocolonoscopy.

Conclusions: Video capsule endoscopy is able to detect small bowel lesions of intestinal Behcet’s disease that were undiagnosed by classical procedures. The findings found by video capsule endoscopy were important on decision making, which suggests the usefulness of this modality in intestinal Behcet’s disease.

1391

An Effective 2L Polyethylene Glycol (PEG) Electrolyte Lavage Solution for Bowel Cleansing
David Kastenberg, MD.* Sandra R. Lottes, PharmD., William P. Forbes, PharmD. Thomas Jefferson University, Philadelphia, PA and Salts Pharmaceuticals, Inc, Morrisville, NC.

Purpose: A new 2L PEG electrolyte lavage solution containing ascorbic acid (4.7g) and sodium ascorbate (5.9g) (Moviprep) has been developed for bowel cleansing. Ascorbic acid and sodium ascorbate enhance the flavor and osmotic effect of PEG. This study evaluated the efficacy of the new 2L PEG vs a 4L PEG electrolyte lavage solution (Klean-Prep) using a 4-point Visual Analog Scale (VAS) that was used in clinical trials with NaP tablets.

Methods: In a German multicenter, investigator-blinded study, 360 pts received 2L or 4L PEG solution in two equally split doses for bowel cleansing prior to colonoscopy. The first dose was taken the afternoon or evening before colonoscopy, and the second dose the morning of colonoscopy. Each one L regimen of the 2L PEG prep was followed by 500mL of additional clear liquid. A 4-level scoring system which divided the colon into 5 segments (rectum, sigmoid, descending, transverse, and ascending) was used to assess overall quality of colon cleansing (A = all colon segments clean; B = at least 1 segment with residual amounts of brown liquid/semisolid stool which can be easily removed or displaced; C = at least 1 segment with only partially removable stool preventing complete visualization; D = at least 1 segment which cannot be examined due to the presence of solid stool). A random sample of 100 colonoscopy videos (50 per treatment arm) from the German study were reviewed by a blinded investigator (DK). Overall colon cleansing was graded with the scoring system used in US NaP trials (excellent:>90% mucosa seen, mostly liquid colonic contents, minimal suctioning for adequate visualization; good:>90% mucosa seen w/significant succioning needed; fair:>90% mucosa seen w/mixture of liquid/semisolid colonic contents, could be suctioned and/or washed; inadequate:>90% mucosa seen contents could not be suctioned or washed).

Results: Overall colon cleansing was rated excellent or good for 88% and 96% of patients receiving 2L and 4L PEG, respectively. These results are similar to those found in the German study where overall colon cleansing was rated A or B for 88.9% and 94.8% of patients receiving 2L and 4L PEG, respectively.

Conclusions: Use of an established grading system for colon cleansing confirms the efficacy of a new 2L PEG solution containing ascorbic acid and sodium ascorbate. These results are nearly identical to those from a large, multicenter, investigator-blinded study demonstrating that the new 2L PEG is comparable to 4L PEG solution.

1392

The Value of Upper and Lower Gastrointestinal Endoscopy in Identifying Culprit Lesion in Patients with a Drop in Hematocrit without Overt GI Bleeding in a South Bronx Community Hospital
Bheema S. Singu, MD, David Widjaja, MD, Swapan Muppuri, MD, Alan Bloom, MD, Prospere Remy, MD.* Division of Gastroenterology, Bronx Lebanon Hospital Center, Bronx, NY.

Purpose: The purpose of this study was to evaluate the initial EGD and colonoscopy outcome results in influencing the change in management among hospitalized patients consulted for drop in hematocrit (HCT) without overt gastrointestinal (GI) bleeding.

Methods: Retrospective review of the medical records of all patients older than 18 years referred for a drop in hematocrit between January 1, 2005 and December 31, 2005. Exclusion criteria were hematemesis, melena, hema-tochezia, positive stool guaiac test, severe pre-existing anemia, decompensated liver disease, history of anticoagulation use, known peptic ulcer disease, GI malignancy and prior history of GI bleeding. Inclusion criteria were drop in HCT during hospitalization, mild anemia, and history of non-steroidal anti-inflammatory drugs (NSAIDS) use.

Results: 37 patients (mean age, 63 years; range, 20–90 years) were identiﬁed. 23 (62%) patients were men. These patients had a mean admitting HCT of 36.3 vol% (range 29.9–40.1 vol%). The mean drop in HCT was 6.4 vol% (range 1.3–10.2). Co-morbidities included end stage renal disease (2, 5%), chronic viral hepatitis (3, 8%) and HIV (4, 11%). 7(19%) patients were on NSAIDs. Among the 20 patients who underwent EGD, 6 (30%) had negative findings, 6 (30%) had upper GI polyps, 4 (20%) had erythematous gastropathy or duodenopathy, 3 (15%) had non-bleeding peptic ulcers and 1 (5%) had angiectasia of duodenum. Of the 16 patients who had colonoscopy, 8 (50%) had non-bleeding diverticula, 6 (37%) had polyps, 4 (25%) had non-bleeding hemorrhoids. The mean size of colonic polyps was 6 mm (range 2–10 mm). Of 6 patients with colonic polyps, 2 had hyperplastic polyps, 2 had tubular adenoma and 2 had tubulovillous adenoma. 5 (14%) patients underwent both EGD and colonoscopy. 5 patients refused the procedures and 4 patients were referred for outpatient endoscopy but lost to follow up. Among the patients who underwent EGD, there was no statistically significant difference in the drop in HCT between patients with negative or positive endoscopy (6.3 vol% Vs 5.9 vol%, p ≤ 0.05).

Conclusions: In patients with low risk of GI bleeding, neither EGD nor colonoscopy revealed an identifiable source of bleeding in patients with drop in HCT during hospitalization. Of patients underwent EGD, there was no difference in drop of HCT between patients with normal finding and those with non-bleeding lesions.

1393

Cryo Spray Ablation (CSA) in the Esophagus: Optimization of Dosimetry
Lake R. Johnston, Mark H. Johnston, MD.* Biology, Georgetown University, Washington, DC and Gastroenterology, Lancaster General Hospital, Lancaster, PA.
Purpose: Previously published data indicate that CSA of 20 seconds duration and repeated for 2 cycles is efficacious in the ablation of Barrett’s esophagus ranging from no dysplasia to multifocal high grade dysplasia. However, long durations of spray are associated with gastric inflation. The purpose of this study was to identify and explore the optimal dosimetry for CSA using repeated shorter duration sprays.

Methods: The distal 2 cm of the esophagus of 9 swine were treated circumferentially with varying doses of CSA. Each group was treated with a different number of cycles of CSA. In each cycle a given area was frozen for varying durations followed by a complete thaw between sprays. The doses were as follows: Group 1: 20 seconds times 2 cycles, Group 2: 5 seconds times 4 cycles, Group 3: 5 seconds times 6 cycles, Group 4: 10 seconds times 4 cycles. 8 days later the animals were re-endoscoped and then euthanized. Histologic evaluations of the esophagi were then examined to determine the depth of ablation and extent of injury.

Results: The mean ulcer size (MUS) for group 1 was 2.8 mm with a mean depth of injury (MDI) of 5.3mm. MUS for group 2 was 2mm with a MDI of 4.75. MUS for group 3 was 4.75mm with an MDI of 3.25mm. MUS of group 4 was 6mm with a MDI of 4.75mm. Overall, the tissue reactions to CSA were similar, with differences only in depth and lateral involvement of the reaction. Duration of freeze correlated with depth of injury; the longer the freeze the greater the depth of injury. Shorter sprays resulted in less gastric inflation. While both groups 1 and 4 were treated for a total of 40 seconds, 4 cycles of cryo resulted in greater overall tissue injury than 2 cycles.

Conclusions: These data suggest that a dosage of 10 seconds cycled 4 times is preferable to 20 seconds cycled two times in CSA based on equivalent or superior efficacy but less gastric inflation and warrants further investigation.

Dosimetry Table

<table>
<thead>
<tr>
<th>Group</th>
<th>Cryo Rx</th>
<th>Ulcer size (mm)</th>
<th>Mean Depth of Injury (mm)</th>
<th>Mean Degree of Inflammation</th>
<th>Mean Degree of Hemorrhage</th>
<th>Mean Degree of Necrosis</th>
<th>Cryo size</th>
<th>Degree of Injury</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>20 sec × 2</td>
<td>2.8</td>
<td>5.3</td>
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<td>2</td>
<td>3</td>
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<td></td>
</tr>
<tr>
<td>2</td>
<td>5 sec × 4</td>
<td>2</td>
<td>4.75</td>
<td>4</td>
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<td>2</td>
<td>3.6</td>
<td>2.6</td>
<td></td>
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</tbody>
</table>

Key for degree of inflammation, hemorrhage and cryonecrosis: 0 = none, 1 = mild, 2 = moderate, 3 = severe. These are based on an independent pathologist’s review comparing the 4 groups to each other.

1394

Shorter Waiting Times May Improve Satisfaction of Veterans Undergoing Endoscopy.
Melissa M. Garrett, MD, Shahnaz Sultan, MD.* Division of Gastroenterology, Durham Veterans Affairs Medical Center, Duke University Medical Center, Durham, NC.

Purpose: Patient satisfaction is recognized as an important measure of quality assurance by many health care organizations, including the Veterans Administration (VA) Health System. Higher patient satisfaction has been shown to be associated with increased compliance and better continuity of care. We conducted a prospective cohort study of patient satisfaction among veterans undergoing outpatient endoscopy or colonoscopy at our local VA hospital. To assess satisfaction, a 55-question multidimensional survey was developed and pilot-tested. Four aspects of patient satisfaction were assessed: organizational aspects such as waiting time and clinic location, quality of provider interactions (nurses, physicians), quality of the procedure including adequacy of pain control, and overall satisfaction with care.

Methods: Consecutive outpatients undergoing EGD or colonoscopy from June-August 2005 were given the questionnaire. Patients who did not return the questionnaire were sent an additional copy or were contacted via telephone. Demographic characteristics including gender, race, highest level of education, and employment were also obtained. Frequency statistics were generated for each question.

Results: 30% of patients (34/112) underwent an EGD while the remainder underwent colonoscopy (78/112). The majority of patients were male (87.5%) and 61.6% were White, 29.5% Black, and 0.9% American Indian. 90.2% rated their overall satisfaction as “very good” or “excellent” with regards to care received during the endoscopy visit. Factors previously noted to predict satisfaction with endoscopy are adequacy of pain medications and the interaction with the physician: 91.9% of responders rated adequacy of pain meds as “good” or better, 96% rated the level of reassurance by the physician as “good” or greater, with 92.8% of patients reporting similar results for the adequacy of time spent with the physician. Factors receiving the lowest satisfaction scores were length of time to obtain an appointment and convenience of parking (13.4% and 31.3%, respectively, with some degree of dissatisfaction).

Conclusions: Increasing emphasis is being placed on patient-centered outcomes as an important step towards improving the quality of clinical care. Patient satisfaction with endoscopy is an important outcome especially in ensuring compliance with surveillance recommendations. Process of care measures that may improve satisfaction with endoscopy include reducing waiting times for appointments and improving facility access.

1395

Hydrotherapy Compared with PEG-ES Lavage and Aqueous Sodium Phosphate as Bowel Preparation for Elective Colonoscopy: A Prospective, Randomized, Single Blinded Trial
Joseph J. Fiorito, MD, Joan A. Culpepper-Morgan, MD,* Scott G. Estabrook, MD, Patricia Scofield, L.P.N., Victor Usatii, MD, Jodi Cuomo, Rp.H.. Gastroenterology, Danbury Hospital, Danbury, CT and Hydro Health, INC, Las Vegas, NV.

Purpose: Hydrotherapy is a method of colon cleansing using constant warm water lavage using a contained temperature and pressure controlled device administered by a trained technician. The aim of this study was to compare the efficacy and patient acceptance of same-day hydrotherapy (HYDRO) with polyethylene glycol-electrolyte lavage (PEG-ES) and aqueous sodium phosphate (ASP) in patients undergoing elective colonoscopy.

Methods: Consecutive outpatients referred for elective colonoscopy were randomly assigned to receive 4 L PEG-ES (n = 55), two doses of aqueous sodium phosphate (n = 52), or same day hydrotherapy (n = 53), as bowel preparation. The endoscopists were blinded to the method of preparation. The overall quality of the colon cleansing was evaluated with respect to the adequacy of visualization of the right, transverse, and left colon. Patients were asked to rate the preparation with respect to ease, convenience, and comfort using a structured, validated questionnaire. Results were analysed using the chi square test.

Results: Endoscopist rated the quality of colon cleansing as good for the right colon: 62% ASP, 49% PEG-ES, and 92% HYDRO (p < 0.001). For the transverse colon: 80% ASP, 63% PEG-ES, and 100% HYDRO (p < 0.001). For the left colon: 84% ASP, 67% PEG-ES, and 98% HYDRO (p < 0.001). Patients rated the preparations as easy: 87% ASP, 56% PEG-ES, and 96% HYDRO (p < 0.001). Patients rated for convenience: 61% ASP, 79% PEG-ES, and 98% HYDRO (p < 0.001). Patients rated for comfort: 71% ASP, 36% PEG-ES, and 94% HYDRO (p < 0.001). Patients were asked if they wanted a different preparation for the next colonoscopy: 48% ASP, 60% PEG-ES, and 4% HYDRO (p < 0.001).

Conclusions: The quality of colon cleansing, overall tolerance, comfort, and convenience were significantly better for HYDRO. In this study ASP was better than PEG-ES for the same parameters. Hydrotherapy should be further investigated as a viable alternative to PEG-ES and ASP for bowel preparation prior to colonoscopy.

1396

The Performance of Colonoscopy in a Group Gastroenterology Practice: What Does It Take To Get to the Cecum?
S.L. Hansel, MD, J. Prechel, G.T.S., B. Horn, G.T.S., MD Crowell, PhD, F.A.C.G., J.K. DiBaise, MD, F.A.C.G.*, Gastroenterology, Mayo Clinic College of Medicine, Scottsdale, AZ.
Purpose: Little information exists regarding the use and usefulness of ancillary maneuvers such as the application of abdominal pressure and changing the patient's position to successfully complete colonoscopy. Our aim was to determine the frequency, type and success of ancillary maneuvers used by a diverse group of colonoscopists when performing colonoscopy.

Methods: In an ongoing IRB-approved study, data has been collected during all colonoscopies performed since 4/3/06. Data collection sheets, completed at the time of the colonoscopy, included: gender, age, BMI, previous abdominal surgery, previous failed colonoscopy, endoscopist years of experience, procedure information (type of scope used, time to reach cecum, quality of bowel prep, patient tolerance), maneuvers needed to reach the cecum (abdominal pressure, change patient position, stiffen scope, change scope), and success in reaching the cecum. When a maneuver was performed, additional information obtained included the location of tip of colonoscope, type of maneuver and whether the maneuver was successful in producing forward movement of the colonoscope. Descriptive statistics and parametric and non-parametric analyses were completed. Logistic regression analysis was used to determine factors predictive of successfully completing colonoscopy.

Results: From 4/3/06 to 5/15/06, data from 820 patients was collected (419 women; mean age 62.8 ± 12.3). The most common indications for colonoscopy were colon cancer screening and polyp surveillance. Twenty-six endoscopists participated. The cecum was reached in 770 cases (94%). The mean time to reach the cecum was 10:09 ± 00:14 min. Additional maneuvers to reach the cecum were required in 76% of the colonoscopies and a majority required multiple maneuvers (e.g., stiffen scope and apply abdominal pressure). While a number of factors were predictive of inability to reach the cecum in univariate analysis, only the quality of the bowel preparation and patient tolerance of the procedure remained as predictive factors using the multivariate approach. Patient accrual continues and will be reported at the meeting as will a detailed analysis of the data.

Conclusions: These data from a large group of gastroenterologists at a single institution suggest that ancillary maneuvers are frequently utilized by colonoscopists to aid in the completion of colonoscopy. Patient tolerance during colonoscopy and the quality of the bowel preparation appear to be the main factors predicting a successful outcome.

1397
Endoscopic Diverticulotomy in the Treatment of Symptomatic Zenker’s Diverticulum
Andres Sanchez Yague, Cecilia Sison, Roy Soetikno, Kenneth F. Binmoeller,∗ Interventional Endoscopy Services, California Pacific Medical Center, San Francisco, CA.

Purpose: Endoscopic treatment of Zenker’s diverticulum constitutes an alternative to surgery. Endoscopic diverticulotomy with electrocautery was first described in 1960. Several variations have been developed including the use of the needle knife or the endoscopic stapler. Complete dissection of the septum with extended myotomy of the cricopharyngeus is the determinant factor for a successful diverticulotomy. In this study we present our experience in the treatment of symptomatic Zenker’s Diverticulum by endoscopic means.

Methods: In the past 34 months we treated 12 patients (10 male/2 female; 67 ± 13 years) with symptomatic Zenker’s diverticulum. Dysphagia in several degrees was the main symptom. Endoscopic diverticulotomy was completed after a single or multiple successive sessions with the needle knife (NK). Several variations were used including prior dilatation, insertion of a nasogastric tube and use of a plastic cap. Follow up was performed (mean 19.4 months)

Results: All the patients were treated initially with the needle knife. In 8 cases only one session was necessary. In the other 4, a mean of 2.75 sessions were performed (range 2–5). The patient requiring 5 sessions had a fatty septum that was not amenable to the NK so APC was also used. In 2 patients the septum could not be adequately exposed even after repeated dilatation and nasogastric tube insertion. In those cases a plastic cap was attached to the tip of the endoscope improving visualization of the septum and allowing for a proper treatment. Complete septum dissection with extended myotomy was achieved in all the patients. 2 patients presented with mild bleeding post-myotomy and hemostasis was achieved with the placement of a clip. On follow up, 2 patients presented with dysphagia and 1 of them required dilatation.

Conclusions: Endoscopic diverticulotomy is an adequate and safe alternative for the treatment of Zenker’s diverticulum. The use of the plastic cap improves septum visualization.

1398
Jejunostomy Tube Placement with Transgastric Endoscopic Guidance
Noel B. Martins, MD, John M. Levey, MD,∗ Patrick M. McEnaney, MD. Gastroenterology, UMass Memorial Medical Center, Worcester, MA and Surgery, UMass Memorial Medical Center, Worcester, MA.

Purpose: To evaluate the feasibility of jejunostomy tube placement with transgastric endoscopic guidance.

Methods: After a 48 hour fast, each pig was intubated and sedated with general anesthesia. A pediatric colonoscope was passed to the proximal jejunum, and a location for the jejunostomy tube placement was determined based on transillumination and digital pressure. An opening in the jejunal wall was made using a gold probe. A Jag wire was then passed into the peritoneal space, and the pediatric colonoscope was removed. An upper endoscope was then passed into the stomach and a needle knife was used to create a gastrotomy. The endoscope was then passed into the peritoneal space and the wire was found. A small incision was made in the abdominal wall, and a Kelley clamp was passed into the peritoneal space. Under direct vision, the tip of the wire was grasped by the Kelley clamp and pulled through the abdominal wall. The jejunal tube was passed into place and secured tightly under direct vision. Each pig was euthanized after the procedure.

Results: Jejunostomy tube placement was successful in both of the 35 kg pigs that underwent the procedure. In the first pig, the jejunostomy tube was placed at 65 cm from the mouth and the procedure was completed in 90 minutes. In the second pig, the jejunostomy tube was placed at 60 cm from the mouth, and the procedure was completed in 85 minutes. After the jejunostomy tube was placed, the position was confirmed with contrast injection under fluoroscopy. There was no evidence of extraintestinal leakage of contrast.

Conclusions: Direct percutaneous endoscopic jejunostomy may be problematic because of the mobility of the jejunum and difficulty in obtaining transillumination, while percutaneous gastroscope with jejunal extension of ten requires endoscopic reintervention, and surgical placement of a jejunostomy tube is more invasive. Our preliminary results indicate that jejunostomy tube placement is feasible under transgastric endoscopic guidance. This is a novel technique which allows one to directly observe a procedure from within the peritoneal cavity. Further studies could focus on closure of the gastrotomy and monitoring for leakage after survival surgery. Creating an opening in the jejunum was surprisingly straightforward, and a variant of this procedure could be to pass a narrow lumen endoscope through the jejunal opening into the peritoneal space so the wire can be directly guided into the Kelley clamp without the need for a gastrotomy.

1399
Nasal Briddling of Endoscopically Placed Nasojugal Feeding Tubes: A Safe and Effective Approach To Maintain Post-Pyloric Feeding Tube Position
R. Martin Bashir, MD,∗ Harminder Sandhu, MD, Daniel Herr, MD. Internal Medicine/Gastroenterology, Washington Hospital Center, Washington, DC and Pediatric Gastroenterology, Childrens Hospital National Medical Center, Washington, DC.

Purpose: Post-ampullary, Nasojugal feedings have been shown to be an important component in the management of critically ill patients and patients...
Successful Ablation of Barrett Esophagus (BE) with Dysplasia Using the Halo® Ablation System: A Single-Center Experience

Christopher D. Wells, MD, H. Jae Kim, MD, Michele M. Moirano, P.A., David E. Fleischer, MD, Virender K. Sharma, MD,∗ Gastroenterology, Mayo Clinic, Scottsdale, AZ.

Purpose: Worsening dysplasia in BE is associated with increasing risk of esophageal cancer. Ablation using a circumferential balloon (HALO®) has shown promising results for the treatment of both non-dysplastic BE and BE with dysplasia. We report our experience using HALO® for ablation of BE with dysplasia.

Methods: Patients with either low-grade (LGD) or high-grade dysplasia (HGD) diagnosed after adequate acid suppressive therapy with a PPI and confirmed by two pathologists, without prior ablative therapy were treated with HALO®. Patients underwent repeat ablation at 3 month intervals until endoscopically visible BE and 4-quadrant q 1 cm random biopsies from the ablated segment of original BE were obtained at regular follow-up intervals to assessed for dysplasia and residual BE. Adverse events with the procedure were recorded.

Results: Fifty patients with dysplasia have been treated; 36 patients (men = 35; mean age = 71; median length of BE = 5cm) had at least one follow-up endoscopy with biopsy and are presented here. 27/36 had LGD (men = 24; mean age = 69; median length BE = 4cm) and 9/36 had HGD (men = 9; mean age = 74; median length BE = 6cm).

LGD: Fifteen (27) (56%) patients had complete ablation with no endoscopic evidence of BE, 10 (37%) patients had non-dysplastic BE and 1 (3.5%) patient had BE indeterminate for dysplasia. One (3%) patient developed a 5 mm nodule at 12 months follow-up in an otherwise normal appearing esophagus. The nodule was completely resected with single EMR, found to be HGD with intramucosal cancer (IMC) with submucosal component, patient now is in complete remission for BE and dysplasia.

HGD: Five (9) (56%) patients had complete ablation with no endoscopic evidence of BE. Two (22%) have persistent HGD, 1 (11%) has non-dysplastic BE, and 1 (11%) has BE indeterminate for dysplasia.

One patient with LGD, prior history of a pin-hole stricture, and required single balloon dilation.

Conclusions: Circumferential ablation of BE with dysplasia using HALO® is safe, effective and has excellent patient tolerance. There has been no evidence of “buried Barrett” post-ablation. A single case of esophageal nodule with HGD-IMC with submucosal component was observed and successfully treated using EMR.

1401

Anemia in the Older Adults: Evaluation by Wireless Capsule Endoscopy (WCE)

Adnan Muhammad, MD, Harshit Khara, MD, Sandeep Bhargava, MD, C.S. Pitchumoni, MD, M.A.C.G.,∗ Gastroenterology, Hepatology and Clinical Nutrition, Saint Peter’s University Hospital, New Brunswick, NJ.

Purpose: Anemia in the older adults (age > 65 yrs) is associated with the increase risk for morbidity and mortality. It mostly results from iron deficiency secondary to obscure GI bleeding which may be occult or overt or secondary to Celiac disease. The advent of WCE has provided a new diagnostic modality for diseases of small bowel (SB) that can result in anemia. Aim: The aim of this study is to identify the causes of anemia in the older adults with the help of WCE.

Methods: Consecutive medical records of 469 patients presented for WCE were analyzed. Patients were divided into three age groups.

Results: 1) The most common indication for WCE in the older adults is Anemia (168 out of 229 cases = 73%) followed by GI bleeding (105 out of 229 cases = 46%). 2) The most common finding in the older adults is SB erosions (68 out of 229 cases = 30%).

Conclusions: 1) WCE that provides a valuable tool for the visualization of SB also plays a critical role for the evaluation of anemia in the older adults. 2) SB erosions and ulcersations are the most frequent findings in older adults with anemia. 3) WCE helps to rule out a neoplastic process while also delineating some other treatable diseases such as AVM, bleeding ulcers which can be thrombo coagulated subsequently with push enteroscopy.

Indications for WCE in different age groups. (N = 469)

<table>
<thead>
<tr>
<th>Indications</th>
<th>Age &lt; 50 years (N = 130)</th>
<th>Age 50–65 years (N = 110)</th>
<th>Age &gt; 65 (N = 229)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anemia</td>
<td>40 (31%)</td>
<td>78 (71%)</td>
<td>168 (73%)</td>
</tr>
<tr>
<td>GI bleeding</td>
<td>32 (25%)</td>
<td>43 (39%)</td>
<td>105 (46%)</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>34 (26%)</td>
<td>20 (18%)</td>
<td>6 (4%)</td>
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<tr>
<td>Crohn’s disease</td>
<td>30 (23%)</td>
<td>8 (7%)</td>
<td>1 (0.4%)</td>
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<tr>
<td>Chronic diarrhea</td>
<td>20 (15%)</td>
<td>12 (11%)</td>
<td>6 (3%)</td>
</tr>
<tr>
<td>Unexplained weight loss</td>
<td>0</td>
<td>1 (1%)</td>
<td>2 (0.8%)</td>
</tr>
<tr>
<td>R/O small bowel polyp</td>
<td>2 (2%)</td>
<td>1 (1%)</td>
<td>1 (0.4%)</td>
</tr>
</tbody>
</table>

More than one indication present in few cases

Findings of WCE in different age groups. (N = 469)

<table>
<thead>
<tr>
<th>Findings</th>
<th>Age &lt; 50 years (N = 130)</th>
<th>Age 50–65 years (N = 110)</th>
<th>Age &gt; 65 (N = 229)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastric Ulceration</td>
<td>6 (5%)</td>
<td>5 (5%)</td>
<td>19 (8%)</td>
</tr>
<tr>
<td>Gastric Erosion</td>
<td>9 (7%)</td>
<td>21 (19%)</td>
<td>31 (14%)</td>
</tr>
<tr>
<td>Small bowel Ulceration</td>
<td>28 (22%)</td>
<td>31 (28%)</td>
<td>53 (23%)</td>
</tr>
<tr>
<td>Small bowel Erosion</td>
<td>33 (25%)</td>
<td>40 (36%)</td>
<td>68 (30%)</td>
</tr>
<tr>
<td>Small bowel Polyp</td>
<td>4 (3%)</td>
<td>10 (11%)</td>
<td>18 (8%)</td>
</tr>
<tr>
<td>Small bowel Nodularity</td>
<td>6 (5%)</td>
<td>6 (5%)</td>
<td>10 (4%)</td>
</tr>
<tr>
<td>Celiac disease</td>
<td>5 (4%)</td>
<td>3 (3%)</td>
<td>5 (2%)</td>
</tr>
<tr>
<td>AVM</td>
<td>5 (4%)</td>
<td>14 (13%)</td>
<td>19 (8%)</td>
</tr>
<tr>
<td>Active bleeding without</td>
<td>5 (4%)</td>
<td>11 (10%)</td>
<td>19 (8%)</td>
</tr>
<tr>
<td>Lymphangiectasia</td>
<td>20 (15%)</td>
<td>24 (22%)</td>
<td>66 (29%)</td>
</tr>
<tr>
<td>Normal</td>
<td>2 (2%)</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

More than one WCE finding seen in few cases

Abstracts S535
Utility of a New Oblique-Viewing Endoscope
James A. DiSario, MD,* Gastroenterology, University of Utah Health Sciences Center, Salt Lake City, UT.

Purpose: Describe characteristics of procedures done with this endoscope. Straight-viewing scopes miss lesions between folds, are difficult position en face to papillae, and have no elevator. Side-viewing duodenoscopes have a relatively short insertion tube, are very stiff, are cumbersome to pass deep into the intestine, and instruments exit at an acute angle which impairs function. The Pentax EG3670QK is a prototype oblique-viewing scope with a 60° beveled tip and a 120° degree angle of view. The insertion tube is 12.1 mm in diameter and 125 cm long, has a 3.8 mm channel, and incorporates an elevator. Describe characteristics of procedures done with the oblique-viewing scope.

Methods: Prospective data collection with descriptive statistics.

Results: 26 patients had 34 procedures. 15 push enteroscopies were attempted with jejunal intubation in 14 (93%) to a mean of 11 (5–20) cm. Successful maneuvers included: 15 argon coagulation (APC), 10 ampullary biopsies, 1 injection polypectomy. 7 ERCPs were attempted in 6 patients (5 Roux) that failed duodenoscopes (7) and a colonoscope (1). The afferent limb was reached in 4 Roux patients with 1 successful sphincterotomy, dilation and stone removal, and 1 dilation and stone removal. Ampullectomy, stenting and APC were successful in the normal anatomy patient. 7 had EGD: 3 biliary and/or pancreatic stent removals; 1 injection, polypectomy and clipping; 1 hemostasis with injection and multipolar coagulation; 1 cyst-duodenotomy with needle puncture, dilation and stenting. 4 had ileoscopy (3 anal, 1 stomal) to a mean of 43 (30–60) cm. I had colonoscopy to the transverse. Success was achieved with biopsies (18/18), APC (17/17), snare (4/4), clipping (3/3), balloon dilation (3/3), injection (3/3), stent removal (3/3), stone removal (2/2), stenting (2/2) and amputectomy (1/1). There were no complications. The instrument was maneuverable, viewed the esophagus and stomach, was superior to straight viewing scopes for the small bowel between folds and in the bulb, and had adequate visualization of the papillae. Mechanical devices worked better than through a duodenoscope because the deployment angle was not as acute.

Conclusions: This oblique-viewing endoscope: 1. Was able to be maneuvered by an oral approach into the majority of normal anatomy jejunums, roux afferent limbs, and into the ileum by a caudal approach; 2. Provided superior visualization of the small bowel to straight-viewing scopes and adequate viewing of the papillae; 3. Easily permitted elevator directed catheter maneuvers in most cases; 4. Is useful for a variety of indications.

Four-Point Scaling as a Predictor of Pharyngeal Reflex during Esophago-Gastro-Duodenoscopy (EGD)
Tetsuya Yamagishi, MD,* Takashi Kawai, MD. Endoscopy Center, Tokyo Medical University Hospital, Tokyo, Japan.

Purpose: Pharyngeal reflex (P-reflex) is one of the major causes of undesirable EGD because of examiners’ discomfort, and may be a possible cause of iatrogenic complications (e.g., hypopharyngeal bleeding). Individual variation in P-reflex is often experienced during EGD. From the viewpoint of risk management, it is important to predict P-reflex prior to scope insertion.

Methods: Consecutive 820 cases participated in company mass survey for gastric cancer were prospectively integrated in this study. EGD was performed by conventional trans-oral endoscope (Olympus Q260) without sedation. 1. Ask examinees to cooperate to endure pharyngeal movement or swallowing as long as possible through oral-esophageal intubation. 2. Take endoscopic pictures at 4-point: (a) through mouthpiece (oral view), (b) left side of the uvula, (c) look-down view of epiglottis, (d) it-hypopharynx. 3. In each examinee, appearance of P-reflex (R) was defined as the position (a–d), where the static picture could not be obtained by the influence of oral-pharyngeal movement. 4. After completing EGD, intensity and frequency (I/F) of P-reflex after esophageal intubation was assessed. Correlations between (R) and (I/F) were investigated.

Results: (R): a = 6 (after to a barium meal examination for the safety reason), b = 46, c = 128, d = 222. Strong and persistent (I/F) was found in 76% of b, 32% of c and 8% of d. Remaining 418 examinees, who could control oral-pharyngeal movement until esophageal intubation, (I/F) was none or almost none through entire EGD, except for 2 examinees.

Conclusions: The individual with earlier appearance of (R) tend to stronger P-reflex during EGD. The presented 4-point scaling may offer the possibility of comprehensive and practical pre-estimation of P-reflex.

Administration of Metoclopramide before Capsule Enteroscopy Increases the Percentage of Complete Small Bowel Examinations without Affecting the Diagnostic Yield
Ravikiran Ghanta, MD, Molly Rastogi, Jason Dominguez, P.A.C., Vamsi Kurra, MD, Ravikumar P. Yebaru, MD,* Gastroenterology, Permanent Gastroenterology Associates, Odessa, TX and Internal Medicine, Texas Tech University Health Sciences Center, Odessa, TX.

Purpose: Incomplete clearance of M2A capsule has been one of the problems in examination of the small bowel. Increasing the motility of gastrointestinal tract by administration of Metoclopramide was reported to increase clearance of the capsule and decrease the transit time. Since the number of images being taken per unit time remains a constant, we wanted to examine whether increasing the speed of passage of the capsule would result in decreasing the diagnostic accuracy of the examination.

Methods: A total of 190 patients that have completed capsule Enteroscopy examination in a private practice setting were analyzed. 63 out of these 190 patients had received 10 mg of liquid Metoclopropamide thirty minutes prior to initiation of capsule Enteroscopy. Differences in Gastric emptying time, small bowel transit time; percentage of complete small bowel examinations as well as the overall diagnostic yield was measured between the two groups. Patients with incomplete clearing of the small bowel secondary to obstructive lesions were excluded from the study.

Results: Significant decrease in Gastric emptying time was observed with administration of Metoclopramide (Median 27 Vs 20.5 min, p = 0.038). No appreciable difference in Small bowel transit time was noted with administration of Metoclopramide (Mean 212 ± 96 Vs 190 ± 84 min, p = 0.192). In the absence of obstructive lesions, statistically significant difference was not observed in Small bowel clearance (98.4% [63/64] Vs 92.6% [118/126], p = 0.268). However no significant difference in diagnostic yield was noted with administration of Metoclopramide (49.61% Vs 53.1% with Metoclopropide, p = 0.915).

Conclusions: Administration of Metoclopramide 10 mg, orally, 30 minutes before CE has no significant effect on Small Bowel Clearance and the Diagnostic yield.

Endoscopic Ultrasound-Guided Fine Needle Aspiration: A Dedicated Bedside Pathologist vs the Cytopathologist
Aldo A. Garza, MD,* Juan P. Flores-Gutiérrez, MD, Mayra Cepeda, M.S., Emmanuel I. González, M.S., Wendy K. Ayala, MD, Orlando Barboza, MD, Raquel Garza, MD. Department of Medicine, Gastroenterology Division, School of Medicine/University Hospital. Universidad Autónoma de Nuevo León, Monterrey, Nuevo León, Mexico and Department of Pathology, School of Medicine/University Hospital. Universidad Autónoma de Nuevo León, Monterrey, Nuevo León, Mexico.

Purpose: The importance of a bedside cytopathologist to evaluate specimens obtained during EUS-FNA has been well characterized. However, availability of these specialists is limited. We describe our experience with two non-cytopathologists evaluating EUS-FNAs at our institution.
Methods: All EUS-FNAs obtained at our institution are evaluated by a bedside pathologist. We reviewed all preliminary diagnoses made on EUS-FNA performed between Sept 2002 and May 2006, assessed by two non-cytopathologists, and the correlation with the definitive diagnosis made by our two cytopathologists, as well as the impact on the procedure and outcome of our patients.

Results: A total of 133 patients underwent EUS-guided FNAs. Four FNAs initially assessed by a cytopathologist and one evaluated by an outside pathologist were excluded. The most frequent FNA sites were pancreas (65.6%), submucosal lesions (13.3%), biliary tract (11.7%), and lymph nodes (5.9%). The average number of passes to obtain a preliminary diagnosis was 3.9 (range 1–10). Four FNAs (3.1%) did not have a preliminary bedside diagnosis, but adequacy of the sample was confirmed. The preliminary FNA diagnoses made were adenoCa (55.6%), suspicious for malignancy (8.9%), inflammatory (8.9%), benign (19.3%), non-diagnostic (3.2%), and others (4%). The preliminary diagnosis was confirmed by the cytopathologist in 93.5% of the cases. Follow-up data was available in 108 patients, with confirmation of an accurate diagnosis in 103 (95.4%). Based on these values, the overall diagnostic accuracy for the non-cytopathologists in evaluating EUS-FNAs was 87%. A clinically significant cytologic misdiagnosis occurred in 5 patients: 2 serous cystadenomas, one neuroendocrine pancreatic tumor and two FNA’s falsely positive for malignancy. However, none of these cases had significantly adverse outcomes due to the misdiagnosis.

Conclusions: In the absence of a bedside cytopathologist, a dedicated pathologist can sufficiently achieve adequate results in the preliminary assessment of EUS-FNA diagnoses, especially after exposure to multiple procedures. However, a definitive diagnosis by a certified cytopathologist is still essential to achieve a higher accuracy and optimal outcomes in these patients.

1406

ERCP with the Double-Balloon Enteroscope in Persons with Surgically Altered Anatomy: Preliminary Experience

James Disario, MD,* Gastroenterology, University of Utah, Salt Lake City, UT.

Purpose: Describe the procedures and outcomes of ERCP performed with DBE in persons with REY and Whipple anatomy. ERCP frequently fails in patients with surgically altered anatomy. ERCP following Roux-en-Y (REY) bariatric operations and liver transplantation, and Whipple and other procedures. The double-balloon enteroscope (DBE) is a new system that allows deeper small bowel intubation than previous technologies.

Methods: Review of the consecutive ERCPs performed with DBE. All had failed ERCP with duodenoscopes, coloscopes and push enteroscopes. Complications were stratified by consensus criteria based on length of hospital stay and required interventions.

Results: There were 8 ERCPs done in 7 women with a mean age of 47 (30–67) years. The mean procedure duration was 111 (55–180) minutes. The prior operations included 6 gastric bypasses, 1 cholecdochojejunosotomy (CDJ), and 1 Whipple. Indications included 3 choledocho- or hepatico-lithiasis, 1 CDJ stenoses, 3 acute recurrent pancreatitis, and 1 chronic pancreatitis. All ERCPs were performed in the supine position under general anesthesia. Total success with ERCP was achieved in 3 (38%) patients, partial in 3 (38%), and 2 (25%) failed. Successful to attempted maneuvers included 4/5 cannulations, 3/3 needle-knife sphincterotomies 2/2 balloon dilations, 1/2 stone extractions. Reasons for failure included inability to reach the papilla, or pancreatic/biliary enteric anastomoses (3), inadequate accessories (3), or inability to cannulate (3). Complications occurred in 3 (38%) patients and 2 were due to inadequate accessories. A severe bile duct perforation resulted from dilation of a stenosis of 2mm in diameter with a 10mm balloon – the only balloon compatible with enteroscopes. This required surgical revision. There was a tiny mild jejunal perforation near an hepaticojejunostomy which resolved with 3 days of conservative management. This occurred because of the need for strong traction on the endoscope required to remove stones as the only enteroscope compatible extraction balloon was 18 mm in diameter. This caused the endoscope to sharply snap back as the balloon popped out and perforate the adjacent jejunum. There was 1 mild case of pancreatitis.

Conclusions: ERCP with DBE can be performed in patients with REY and Whipple anatomy who have failed procedures with conventional endoscopes. However, the procedures are long, require general anesthesia, and have associated complications. Better accessories and endoscope designs will greatly expand the utility, and improve the outcomes, of this procedure.

1407

Video Capsule Endoscopy Diagnosis of Small Bowel Crohn’s Disease with Different Clinical Presentations

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Purpose: To assess the frequency of Crohn’s disease (CD) lesions in groups of patients, with different clinical presentations, that performed video capsule endoscopy (VCE).

Methods: 174 patients, 118 female and 56 male, that performed VCE were divided according to the main clinical presentation: A – suspected small bowel CD (n = 60); B – iron deficiency anemia (n = 56); C – occult obscure bleeding (n = 36); D – overt obscure bleeding (n = 22). All patients had been done before upper gastrointestinal endoscopy and total colonoscopy. Patients with previous CD diagnosis, celiac disease, non-steroidal anti-inflammatory drugs therapy and AIDS were excluded. Statistics: Pearson χ².

Results: VCE diagnosed lesions suggestive of CD in 32 patients. Twenty patients of group A (33%), six patients of group B (11%), six patients of group D (27%) and none of group C. The lesions were more frequent in groups A and D, p < 0.001. All lesions were located in jejunum and ileum. 15 patients presented severe lesions with large ulcers or strictures. These severe lesions were more frequent in males (7/9 patients) than females (8/23 patients), p = 0.028.

Conclusions: In the four groups that performed VCE, the frequency of CD lesions was higher in patients with suspected small bowel CD and overt obscure bleeding, that also presented more severe lesions. Overt obscure bleeding is a rare presentation of CD with difficult control of bleeding and high recurrence. In occult obscure bleeding patients there were no lesions suggestive of CD. Males had more severe small bowel CD lesions than females.

1408

Receipt of an Endoscopy Report after an Outpatient Procedure Improves Recall of Findings & Recommendations, and Compliance

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Purpose: The therapeutic impact of outpatient (pt) endoscopy (endo) is enhanced as pt recall of the findings and recommendations, and compliance with these, improves. We evaluated the affect on these endpoints of providing pts with a copy of their endo report at the time of discharge from the endo lab.

Methods: This was a prospective, single center, investigator-blinded study. Post-procedure, the “Control” (C) group protocol consisted of a review of findings and recommendations with the physician or their designee, and receipt of discharge instructions containing recommendations copied from the endo report. In addition to this protocol, the “Intervention” (I) group received an endo report identical to that retained in the pt chart. One week later, a phone interview was conducted and pts were queried regarding their endo findings and recommendations, and whether they were in compliance. This was conducted without the report in front of the pt or interviewer, and “lay” answers were acceptable. Compliance was categorized by: Medications, Follow-up (physician, endo), Biopsy results (call as instructed), and Other (diet, life-style, radiology, etc.).
Results: The two study groups were equally matched for type of procedure, gender, and race. The Intervention group was older (54.4 vs 50.7; \( p = 0.037 \)). Significantly more patients in the Intervention group had complete recall of findings and recommendations. (Table 1) Compliance was superior in the Intervention group for the categories of Medication and Other. Compliance was not significantly different between the groups for Bopsy results and Follow-up. (Table 2) Follow-up compliance may have been underestimated as many required appointments > 3 months out.

Conclusions: Providing patients with an endoscopy report after a procedure improves their recall of findings and recommendations. Furthermore, this intervention increases compliance with physician recommendations. This practice should be routinely adopted.

### Table 1. Recall

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Control</th>
<th>Difference (I-C)</th>
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<td>N(%)</td>
<td>N(%)</td>
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<td>Recalled all findings</td>
<td>37(86)</td>
<td>20(51)</td>
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<td>Recalled all recommendations</td>
<td>30(70)</td>
<td>9(23)</td>
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### Table 2. Compliance

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<th>Intervention</th>
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<tr>
<td>%</td>
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</tr>
<tr>
<td>Medications</td>
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<tr>
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<tr>
<td>Biopsy results</td>
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<tr>
<td>Other</td>
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### 1409

**Is Endoscopic Retrograde Cholangiopancreatography a Safe Procedure in Patients 80 Years of Age and Older?**

**Ali K. Masood, MD, Jeffery St. John, MD, Vinay Sood, D.O., Nikhil Karanath, MD, Ali T. Navras, MD, F.A.C.G.,* Department of Internal Medicine, Albany Medical Center, Albany, NY and Department of Gastroenterology, Albany Medical Center, Albany, NY.**

**Purpose:** To review data on Endoscopic Retrograde Cholangiopancreatography (ERCP) conducted on patients aged 80 and older and determine its safety by evaluating for presence of immediate and early complications.

**Methods:** A retrospective analysis of ERCP's performed at our institution, a tertiary care center, between 2001 – 2005 in patients aged 80 years and older. The reports of ERCP's were reviewed and separated based upon the age of the patient at the date of the procedure. The data used specifically for this study contained patients of age 80 years or older. The number of cases done were considered, even if the patient had multiple procedures on different dates. Each procedure was considered as a single case and independent of one another. The procedures were performed by one gastroenterologist with advanced training in ERCP. The outcome of the procedure was then reviewed to see if there were any immediate or early complications. Complications that developed after the patient left the recovery unit were not considered in this study.

**Results:** Between 2001 and 2005, 28 ERCP's were performed on patients aged 80 years and older (age range 80 – 100; 46 males: 36 females with mean age of 84 and median age of 90 among the whole group). The indications for procedure included jaundice and biliary obstruction, choledocholithiasis, abdominal pain of suspected biliary or pancreatic origin, abnormal CT Scan findings, abnormal abdominal ultrasound findings, abnormal liver function tests (defined as at least one value of AST greater than 45, ALT greater than 60 or Alkaline Phosphatase greater than 115), established pancreatitis, abnormal MRCP, and biliary stent removals. Of the total 82 ERCP's, 15 were done under general anesthesia and 3 immediate complications were observed. One patient developed post sphincterotomy bleeding which was controlled with epinephrine injection. Another patient developed stridor, which was treated with supplementation oxygen and resolved. Both cases were performed to completion. The third complication was hypertensive urgency, in which the procedure was terminated early with the hypertension addressed and treated. There were no direct mortalities as a result of doing the ERCP.

**Conclusions:** ERCP can be performed effectively and safely in elderly patients. However, support from an anesthesia team is recommended during these procedures to enhance safety outcomes.

### 1410

**Is ERCP a Safe Procedure in Pediatric and Adolescent Patients When Performed by an Adult Gastroenterologist?**

**Ali K. Masood, MD, Jeffery St. John, MD, Vinay Sood, D.O., Nikhil Karanath, MD, Ali T. Navras, MD, F.A.C.G.,* Internal Medicine, Albany Medical Center, Albany, NY and Gastroenterology, Albany Medical Center, Albany, NY.**

**Purpose:** Endoscopic Retrograde Cholangiopancreatography (ERCP) for pediatric and adolescent patients are usually performed by pediatric gastroenterologists. However, due to the small number of pediatric gastroenterologists trained in ERCP, an adult gastroenterologist is often asked to perform the procedure in urgent cases. The purpose of this study is to review data of ERCP's conducted on pediatric and adolescent patients performed by adult gastroenterologists to determine its safety and efficacy.

**Methods:** Retrospective analysis of ERCP cases performed between 2001 – 2005 were reviewed and separated based upon the age of the patient. The data used specifically for this study contained pediatric and adolescent patients, 18 years old or younger. The procedures were performed by adult gastroenterologists with advanced training in ERCP with documented consent from the patient's legal guardian. The outcome of the procedure was then reviewed for safety and efficacy. The indications for procedure included biliary or pancreatic abdominal pain, choledocholithiasis, pancreatitis, abnormal MRCP or CT scan, jaundice, abnormal LFT's, and bile leak.

**Results:** Between 2001 and 2005, 28 ERCP's were performed on pediatric and adolescent patients, mean age of (13 males and 15 females). Patients age ranged from 7 and 18 years. Of the 28 ERCP's, 24 cases were performed under general anesthesia and the remainder were done under conscious sedation. The findings included bile leak (n = 2), choledocholithiasis (n = 9), chronic pancreatitis/irregular pancreatic duct (n = 2), papillary/distal CBD stenosis (n = 3), pancreatic pseudocyst (n = 3), sclerosing cholangitis (n = 2), choledochocyst (n = 1), pancreatic divisum (n = 1). Therapeutic modalities included sphincterotomy (n = 10), balloon dilatation (n = 1), stents placement (n = 8), stone and sludge removal (n = 9), pancreatic cystogastrostomy (n = 1), and cyst duodenostomy (n = 2). Complications included mild respiratory depression (n = 1) with conscious sedation, reversed with medication, post-sphincterotomy bleeding (n = 1) treated with epinephrine injection, and mild pancreatitis (n = 1) resolved spontaneously.

**Conclusions:** The safety and the efficacy of having an experienced adult gastroenterologist performing an ERCP in a pediatric and adolescent patient is high. Proper informed consent needs to be obtained, and consideration of anesthesia support is recommended.

### 1411

**Safety and Efficacy of ERCP in Pregnancy**

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**Purpose:** To report our experience with ERCP during pregnancy including safety and efficacy.
Methods: A retrospective review of all consecutive ERCPs performed on pregnant patients from October 2001 to May 2006.

Results: Three ERCPs were performed on pregnant patients. Two patients presented with cholelithiasis, abnormal liver function tests and dilatation of the biliary tree by abdominal ultrasound. One patient had biliary leak demonstrated by intrabdominal fluid collection on ultrasound after laparoscopic cholecystectomy. Two of the three underwent ERCP under general anesthesia and one patient underwent conscious sedation supervised by an anesthesiologist. Techniques to minimize fluoroscopy were used including aspiration of bile to identify correct position of the sphincterotome. All patients with choledocholithiasis underwent sphincterotomy with stone extraction. The patient with biliary leak underwent stent placement without sphincterotomy. The procedures were successful in all cases including the biliary leak which resolved completely in two weeks. No complications related to the procedure were identified in the mother or the babies.

Conclusions: ERCP can be performed safely in pregnancy if precautions are taken to minimize radiation exposure.

 Objective Evaluation of Competence in Flexible Sigmoidoscopy
Mary Anne Cooper, MD,* Jason Pennington, MD, Karen Gayman, R.N., Linda Rabeneck, MD, Mark Dobrow, PhD. Departments of Medicine and Surgery, University of Toronto, Toronto, ON, Canada.

Purpose: Determination of competence in endoscopy is important in any endoscopy training program. While objective assessments have been attempted they have not been standardized. A program to train registered nurses (RNs) to perform flexible sigmoidoscopy (FS) has been developed in Ontario, Canada in order to create increased endoscopy capacity to screen for colorectal cancer. Objectives: To develop a standardized method to determine technical competence based on a simulator experience.

Methods: Simulator training was undertaken before the RNs performed procedures on patients. Checklists and global assessments to assess performance on the simulator were developed incorporating simulator-generated parameters and technical characteristics used in the surgical literature. Checklists included measurement of procedure duration, insertion depth, percent mucosa visualized, and percent of time in red-out.

Results: Six RN trainees each performed 10 FSs using the simulator over two days. The simulator provided 18 different endoscopic scenarios divided by an expert endoscopist into categories for degree of technical difficulty (easy, average, and difficult). Figure 1 shows that the time to perform procedures decreased with trainee experience for the average and technically difficult scenarios. There was no distinction seen for the technically easy procedures. Other trends for improved mucosal visualization, depth of endoscope insertion, and time spent in red-out have also been detected. (Data not shown.)

Conclusions: These observations indicate that objective evaluations of endoscopic competence are possible on simulator experience, although they need to be validated. These tools may predict skill transfer to patients and this will be assessed as the students gain experience performing FS on patients.

Patient Satisfaction as an Endoscopy Training Evaluation Tool for Nurses Performing Flexible Sigmoidoscopy
Mary Anne Cooper, MD,* Jason Pennington, MD, Karen Gayman, R.N., Linda Rabeneck, MD, Mark Dobrow, PhD. Departments of Medicine and Surgery, University of Toronto, Toronto, ON, Canada.

Purpose: A program to train registered nurses to perform flexible sigmoidoscopy (FS) has been developed in Ontario, Canada to create increased endoscopy capacity to screen for colorectal cancer. The nurses initially undertook simulator training and they have begun performing procedures on patients. This represents a new role for nurses in Ontario.

Objectives: To develop standardized evaluation tools to monitor nurses’ performance of FS on patients.

Methods: Evaluation of performance on patients was conducted by checklists and global assessments completed by expert observers and by patients completing a patient satisfaction survey. We modified the Patient Satisfaction Questionnaire III (PSQ-III) to include five domains: interpersonal aspects, communication, technical quality, time spent with provider, and general satisfaction.

Results: Five nurse trainees have performed at least ten procedures each. Figure 1 shows the general satisfaction scores of patients seen by two different trainees. It demonstrates that with increasing experience, an improving profile is seen for one trainee (Figure 1a) but a deteriorating profile is seen for another (Figure 1b). These trends are supported by the evaluations obtained by checklists and global assessments. (Data not shown.)

Conclusions: These preliminary data show that the general satisfaction of patients improves with increasing skill of the nurse trainee and they may help differentiate between endoscopists with good skill level and those with poor skill level. The trainees continue to see patients and further data will be collected and evaluated.
Gastric Findings in Pediatric Wireless Capsule Endoscopy (WCE)
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Purpose: WCE is indicated for the evaluation of suspected Crohn’s Disease (CD) and obscure GI bleeding. WCE enables endoscopy without the adverse effects of sedation on gastrointestinal motility, which may more accurately reflect the true physiologic state. Moreover, the structural detail unique to WCE enables one to see what was previously unrecognized with traditional endoscopy. The aim of this study is to describe gastric findings in children undergoing WCE.

Methods: Retrospective review of WCE performed at our Children’s Hospital from January 2005 to May 2006 in patients < 21 yrs. Preparation for WCE included 24hrs of clear liquid diet and an overnight fast. Patients remained fasting until 2hrs after initiation of the study.

Results: There were 96 WCE studies completed. Twenty-one in which the capsule was endoscopically delivered into the small bowel were excluded. The study group included the remaining 75 studies (M:F = 42:33, Mean age 14yr range 4–19yrs). Indications for WCE included evaluation for suspected CD in patients with chronic debilitating abdominal pain (39) and/or diarrhea (9), unexplained bleeding/anemia(8), and evaluation of known disease (IBD = 15, polyposis = 6, Celiac = 2).

Sixty patients (80%) had at least 1 gastric mucosal abnormality (erosion = 9, gastritis defined as mucosal erythema/breaks = 53, ulcer = 8, nodularity = 17, polyps = 3). Mean gastric transit time (GTT) was 75 mins (range 1–480 mins; 37 patients < 120mins, 14 patients > 120mins).

WCE studies were reviewed for the presence of Duodenal-Gastric Bile Reflux (DGBR). The presence of DGBR and gastric mucosal abnormalities in relation to abdominal pain are shown in Table 1. Mild DGBR was defined as translucent bile, severe DGBR as opaque bile, and moderate DGBR as in between mild and severe DGBR. Fifty-three (70%) patients had DGBR: mild: 30; moderate: 11; and severe: 12.

Conclusions: 1. DGBR is common in patients undergoing WCE. 2. Most patients undergoing WCE had at least 1 abnormal gastric finding. 3. WCE may serve as a useful tool for evaluating gastric motility based on the presence of DGBR, and the GTT. 4. DGBR may be a normal finding in fasting pediatric patients. 5. Further studies including routine application of a diet and symptoms diary during WCE are needed to correlate DGBR and gastric mucosal abnormalities with clinical symptoms.

<table>
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<tr>
<th>+ Abdominal Pain (39)</th>
<th>+ Abnormal Gastric Mucosal Findings</th>
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<td>Abdominal Pain (36)</td>
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<tr>
<td>− Abdominal Pain</td>
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Endoscopic Ultrasound in the Endoscopy Suite: Does It Take Too Long?
Aldo A. Garza, MD,* Aline Ghaleb, MD, Cynthia A. Becerra, MD, Wendy K. Ayala, MD, Gerardo Gaytan, R.N. Department of Medicine, School of Medicine/University Hospital. Universidad Autonoma de Nuevo Leon, Monterrey, Nuevo Leon, Mexico.

Purpose: Endoscopic Ultrasound (EUS) is one of the most recent innovations in the field of gastrointestinal endoscopy. Since its introduction, one of the main limitations (especially in private practice) has been the concept that it is a time-consuming and complicated procedure, especially when performing EUS-FNA. We describe our experience with EUS in regards to time and resource utilization in our GI lab after more than three years of its introduction comparing it to ERCP and colonoscopy.

Methods: We reviewed data obtained from all EUS/EUS-FNA procedures performed in our GI lab from Sep 2002-May 2006. Information with regards to the type of EUS, number of assistants, and time required was obtained. All EUSs were performed by a single endosonographer. The time required for the pathologist to arrive to the GI lab was less than 20 minutes in all but three EUS-FNAs. We obtained the same information for comparison applied to a random sample of 85 ERCPs and 108 colonoscopies performed by either one of our the four therapeutic endoscopists in our group.

Results: All procedures were performed using IV sedation. For EUS and colonoscopy, only one assistant nurse was required. For EUS-FNA a second nurse was needed, and a third one was required for fluoroscopy on ERCP. Duration of 354 EUS was available for the study. Average time of Dx EUS was 41.2 min, EUS-FNAs 73.4 and rectal 30.8 min. Average time for all EUS was 52.4 min. 84 ERCPs were reviewed: Dx ERCPs average 15 min, stone extraction 23.7 min, stent placement 40.9 min, mechanical lithotripsy 50.5 min, failed ERCPs 25.7 min. Average time for all ERCPs was 31.1 min. 108 colonoscopies were timed. The average time required for diagnostic colonoscopy was 20.1 min, polypectomy 25.4 min, chemoendo- daysis 31 min, and chemoendoendoscopy with polypectomy 35.9 min. Average time for all colonoscopies was 25.1 min. Using these times as reference, the total assistant time for EUS procedures was 75 min and for ERCPs 93.4 min.

Conclusions: In contrast with common belief, in experienced hands the average time to perform EUS may approach the one required for ERCP and is only twice the time required for colonoscopy. These differences are less marked when considering nurse-time invested in these procedures. The practice of EUS in an organized GI lab with good support of the pathologists should not have a negative impact in its performance, and rather enhance the quality and reputation of the center where it is performed.

Risk Factors for Gastroesophageal Reflux Disease (GERD) in Children
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Purpose: To investigate the incidence of GERD among children over the age of 2 years presenting to a tertiary care center in Poland and to examine the correlation between pH monitoring and risk factors for GERD.

Methods: Children referred to the Department of Gastroenterology at the Children’s Memorial Health Institute, Warsaw, Poland during 2004 in whom a first diagnosis of GERD was made, underwent 24-hour pH monitoring (abnormal versus normal pH = reflux index > / 4.2). The diagnosis of GERD was based on history and upon endoscopic examination. The number of reflux episodes longer than 5 minutes during the 24 hour observation as well as the children’s weight and height were recorded. Using the growth standards published by the National Polish Center for Health Statistics (M. Krawczynski, 2000), we calculated the gender/age specific weight-for-age Z-score (WAZ), height-for-age Z-score (HAZ) (standard deviation score).

Results: In one year (Jan 2004 to Jan 2005), 3852 children between the ages of 2–18 visited the GI Department; 295 had a first diagnosis of GERD (incidence 8%/year). Abnormal pH tests were present in 50%. The most common symptoms were regurgitation/vomiting; 38% of patients. Abnormal pH studies and the number of reflux episodes longer than 5 minutes were both significantly correlated with Wt/Age Z-score (p = 0.008) (p = 0.001).

Conclusions: GERD symptoms were a common cause for referral to a tertiary care center in Poland. Obesity as assessed by a high Wt/Age Z-score correlated with the presence of GERD in children.
Are Pathologists Accurately Diagnosing Eosinophilic Esophagitis in Children? A 9-Year Single Academic Institutional Experience
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Purpose: Eosinophilic esophagitis (EE) has become a hot topic for gastroenterologists with significant research focused on its etiology, clinicopathologic diagnosis and treatment. The purpose of this study was two-fold: (1) to evaluate whether the incidence of EE has increased at our institution over the past 9 years, and (2) to evaluate whether the histologic diagnosis of EE has been made accurately by pathologists during this 9-year interval using currently accepted criteria.

Methods: From January 1997-December 2005, a total of 1215 pediatric (up to age 18) endoscopic esophageal biopsies were performed. Of these, 292 esophageal biopsies were retrospectively reviewed based on one of the following original histologic diagnoses: EE, reflux esophagitis (RE) or acute/chronic inflammation. On review, a diagnosis of EE was based on finding a single high power field (HPF, x400 original magnification) containing greater than or equal to 20 intra-epithelial eosinophils.

Results: 104 patients fulfilled the criteria for a histologic diagnosis of EE. Based on the number of cases of EE per 100 esophageal biopsies during any given year, the incidence of EE remained relatively stable, and ranged from 5 to 11/100 biopsies. In 36 cases (35%), the pathologist correctly reported a diagnosis of EE and in a further 34 cases (33%), EE was included in the differential diagnosis in the report. In the most recent 2 years, the pathologist either correctly diagnosed EE, or included it in the differential diagnosis in 32 of 37 cases (86%). In 34 cases (33%), EE was misinterpreted as RE. No case of RE was misinterpreted as EE. Of the 292 biopsies reviewed, 58 cases (20%) had reports that quantified the densest number of eosinophils/HPF as did 38 of the 104 cases (37%) of EE.

Conclusions: At our institution, EE is a relatively common condition and the incidence has been stable over the past 9 years. Overall, pathologists recognized EE in about two-thirds of cases. The increase in diagnostic accuracy over the past 2 years (86%) suggests that pathologists may now be more aware of EE. If identified, we recommend that pathologists should quantify the densest number of eosinophils/HPF in the report. Thus, gastroenterologists will be able to improve correlation of clinical and endoscopic findings with the histology and provide appropriate therapy for children with EE.

Improving Outcome of Kasai Porteenterostomy with Use of Steroid and Antibiotics – Case Reports
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Purpose: Early reports suggest that the use of steroids and antibiotics after Kasai portoenterostomy may improve bile flow and outcomes in infants with biliary atresia. Under the guidance of these reports, we use intravenous antibiotics and high dose tapering steroids in our patients with biliary atresia.

Methods: Six infants underwent Kasai portoenterostomy between 2001 and 2005 in our institution. The age range at the time of surgery was 4 to 7 weeks. All patients received ursodeoxycholic acid indefinitely, tapering dose of steroids and intravenous antibiotics for 3 weeks. After 3 weeks the patients either received oral antibiotics or continue intravenous antibiotics depending on their direct bilirubin, GGT and platelet levels. Cholangitis is defined as elevated bilirubin level, GGT or platelet counts as a marker of acute phase reactant. The mean duration of steroid therapy was 15.6 weeks (range 7–35 weeks). The mean duration of intravenous antibiotics was 6.8 weeks (range 3–10 weeks). Most patients had elevated direct bilirubin level after Kasai procedure. Four patients at the end of antibiotic and steroid course had normal bilirubin levels and currently doing well after mean follow-up of 2.9 years ranging 1–5 years. Two patients continued to have progressive disease and underwent liver transplantation. One of these two patients had congenital form of biliary atresia with situs inversus and polysplenia.

Results: It is our observation that prolonged course of antibiotics and steroid use improves the outcome in 4 out of 6 patients. Congenital form is known to have poor outcome and the use of steroids and antibiotics did not make any change in the progression of disease. In our patients, we used wide range of antibiotics and steroids depending on the patients clinical and laboratory evaluation.

Conclusions: More controlled studies are needed to decide the duration and the dosage of antibiotics and steroids and parameters to stop or continue these medications.
Purpose: Acid reflux is a common occurrence in children. pH testing is frequently used to evaluate the role that acid reflux plays in symptom generation. The safety and utility of the Bravo capsule has not previously been evaluated in a pediatric population.

Methods: Consecutive patients referred for Bravo capsule placement were enrolled in this study. Demographic information, symptoms, and medication use were recorded. Bravo capsule placement was performed either in conjunction with upper endoscopy or unassisted in the motility laboratory after esophageal manometry. At the completion of the 48 hour testing period, the results of the Bravo capsule study were categorized as being normal or abnormal according to standard accepted criteria. Patients were followed to determine whether the results of Bravo testing led to a change in patient management.

Results: During a 27 month period 36 BRAVO capsules were placed in children aged 6 to 17 (mean age 14 ± 3 years). 58% were female; 42% were male. Primary symptoms were reported as: GERD (heartburn and regurgitation; 39%), abdominal pain (19%), nausea and/or vomiting (14%), chest pain (11%), ENT issues (8%), dysphagia (3%), symptoms brought on by physical activity (3%), and other (3%). Bravo placement primarily occurred in the endoscopy suite (94%) using propofol. 94% of Bravo studies were performed off of medications used to treat acid reflux while 6% were performed on acid-suppressing medications during the 48 hour study. No complications occurred; 1 capsule detached prematurely. 58% had an abnormal study; 39% were normal. The results of the Bravo capsule lead to a change in patient management in 80% of cases. 39% had therapy initiated, 17% stopped a previous acid-suppressing medication, 14% stopped a previous medication and started a new medication, 3% increased the dose of acid-suppressing medication, and 3% were referred for surgical intervention. 65% of those with abnormal Bravo results had a change in management and 35% of those with normal BRAVO results had a change in management.

Conclusions: This study is the first to prospectively evaluate the safety and clinical utility of the Bravo capsule in a pediatric population. Our data demonstrate that the Bravo capsule is safe to use in the pediatric population. More importantly, results of Bravo testing frequently leads to a change in patient management.

1421 Non-Syndromic Bile Duct Paucity Associated with Subsequent Development of Growth Hormone Deficiency – Report of 3 Patients

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Purpose: Congenital hypopituitarism is a recognized cause of neonatal hepatic failure and their linear growth caught up within 2 years. Three of the three have subsequently required additional pituitary hormone replacement (i.e., first patient thyroxine and third patient thyroxine and cortisol).

Conclusions: In conclusion, growth hormone deficiency/hypopituitarism should be in the differential diagnosis of cholestasis due to non-syndromic paucity of bile ducts. Failure to thrive is not necessarily due to cholestasis related malabsorption. Patients should be followed longitudinally for GH deficiency even after normal initial evaluations. MRI of the brain can be a helpful diagnostic tool and should be considered in patients with non-syndromic paucity of bile ducts.

1422 Genomic Diversity of Rotavirus Strains Infecting Pediatric Patients in Tehran, Iran

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Purpose: Group A rotaviruses are the major cause of diarrhea in young children worldwide. This study investigated the diversity of rotavirus strains recovered from young children in Tehran, Iran.

Methods: From February 2003 to January 2004, 372 children less than 5 years of age, presenting with acute diarrhea to the biggest pediatric hospital in Tehran (Iran), were investigated using enzyme-linked immunosorbent assay (ELISA), polyacrylamide gel electrophoresis (PAGE) and reverse transcription-polymerase chain reaction (RT-PCR).

Results: Ninety-four samples (%25.3) were positive for the presence of rotavirus by using either enzyme-linked immunosorbent assay (ELISA), polyacrylamide gel electrophoresis (PAGE), or both. According to PAGE, the predominant electrophoretic pattern detected was the long profile in 62 of 67 (92.5%) and the short electropherotype in 5 of 67 (7.5%). Nine different electrophoretic patterns, 6 of long and 3 of short profile were detected. The G (VP7 genotype) and P (VP4 genotype) types were successfully determined by reverse transcription (RT) and multiplex PCR in 77 (81.9%) and 68 (72.3%) of the positive samples, respectively. G1 was the most prevalent strain (63.6%), followed by G9 (12.9%), G4 (5.2%), G12 (3.9%) and G2 (1.3%), whereas many could not be typed at all (10.4%). G3 was not identified. Two mixed strains of G1/G4 and G1/G9 have been reported for the first time in Iran. The most prevalent P type was P[8] (94%), followed by P[4] (4.4%). Only one P[10] strain was identified. The common G- and P- type combinations G1P[8] (66.7%) and G9P[8] (16.1%) were detected. Of 63 samples tested for VP6 subgroup epitope, by RT-PCR and sequence analysis of a 378-bp VP6 ampiclon, subgroup II was predominant (93.6%) with only a few subgroup I strains (4.8%). The majority of G1 and P8 strains and all serotype G9 strains that had long electropherotype profiles belonged to subgroup II. G1P[10] possessed long electropherotype and belonged to subgroup I. G2P[4] had a short electropherotype and belonged to subgroup I.

Conclusions: The presence of strains representing nine different E-types and mixed genotype specificities with G1/G4P[8] and G1/G9P[8] demonstrate the prevailing high genomic diversity of rotaviruses in this geographical area.

1423 Clinical Presentation of Diarrhea in Iranian Infants and Young Children during One Year

Naghmeh Jafarinia, MD,* Sven Lofdahl, PhD, Chef Microbio., Babak Noorinayer, Gastroenterologist, Nahid Arjmand, MD, Nazanin Hosseinkhan, Microbiologist, Mohammad Reza Zali, Gastroenterologist. Foodborne Disease, Research Center for Gastroenterology and Liver Disease, Shaheed Beheshti University of Medical Sciences, Tehran, Islamic Republic of Iran and Center for Microbiological Preparedness(KCB), Swedish Institute for Infectious Disease Control(SMI), Stockholm, Sweden.
**Purpose:** Diarrhoea is still the most prevalent and important public health problem in developing countries. An epidemiologic study of this initial step toward the introduction of proper interventions for controlling the disease is necessary.

**Methods:** Between April 2005 and April 2006, children less than five years old admitted to the five referral paediatric hospitals in Tehran, were enrolled in this study. Patient’s characteristics including sex, age, duration of diarrhoea prior to hospital or clinic admission, abdominal pain, vomiting, nausea, anorexia, fever, rate of diarrhoea during one day, stool appearance, travelling, nutritional status, hygiene status, hydration conditions and treatment status were gathered by interviewing the parents. For healthy controls demographic data collected. All stool specimens from patients and controls were cultured on MacConkey agar.

**Results:** Totally 1132 subjects, including 89.3% children with acute diarrhoea, 10.7% with chronic diarrhoea (14 days or longer) and 45.5% healthy controls were enrolled in the study. The primary culture result for 515 healthy control children, and 591 subjects from 617 children controls were enrolled in the study. The primary culture result for 501 subjects from 515 healthy control children, and 591 subjects from 617 children with diarrhoea were positive. Watery form of diarrhoea was the most common manifestation of diarrhoea (62.8%). The highest frequency of watery and bloody diarrhoea was detected in autumn and summer, respectively. Vomiting, nausea and fever were significantly higher at watery form of diarrhoea (p = 0.0001, p = 0.0001, and p = 0.03, respectively) but there were no correlation between these symptoms and mucoid or bloody form of diarrhoea. Significant increase of anorexia in children with diarrhoea was detected during the autumn, mainly at the age of 5, 1.5 and 2 years (p = 0.001). Temperature and child dehydration were significantly higher in children with more frequent diarrhoea during one day (p = 0.03 and p = 0.0001). Most of the outpatients with diarrhoea had a history of raw meat consumption during last week before the onset of symptoms in compare with inpatients (p = 0.01).

**Conclusions:** Although this study answers many questions about clinical characteristics of community acquired diarrhoea among young children in Tehran, it also underscores our lack of understanding the aetiology behind most episodes of this frequent paediatric disease.

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**1424**

**Helicobacter pylori in Children: Clinical and Histopathological Findings in a Tertiary-Care Medical Referral Center, Lima-Peru**

Ana Munez, MD, Alejandro Bussalleon, MD,* Felix Tukami, MD, Delfina Cettano, MD, Aldo Mansy, MD, Jose Pinto, MD, Gastroenterology, Hospital Nacional Cayetano Heredia, Lima, Peru.

**Purpose:** Although the prevalence of Helicobacter pylori infection is high in Peru, information in children is still sparse. This study reports the clinical and histopathological features of Helicobacter pylori (HP) infection in children at Cayetano Heredia University Hospital in Lima, Perú. This is the second similar study in our country that describes HP infection findings in a paediatric population.

**Methods:** Information on endoscopies and biopsies from medical records and biopsy reports from July 2003 to October 2005 were obtained. The study population is mainly composed of children attending the Pediatric Gastroenterology Ambulatory Service.

**Results:** 101 endoscopies and 51 biopsies were done in this period. Main indications for upper gastrointestinal endoscopy were: Upper abdominal pain (21), gastritis (15), abdominal recurrent pain (3), dysphagia (9), esophagitis (15), foreign body ingestion (6), chronic diarrhoea (1), upper gastrointestinal bleeding (24), caustic ingestion (4) and iron-deficient anemia (3). Endoscopic findings were: Esophageal varices (2), nodular gastritis (19), neoplasia (1), gastric ulcer (1), duodenal ulcer (5), gastritis (37), esophagitis (25), foreign body (5) and normal (6). In the 51 biopsies, HP prevalence was 59%/429 out 51 patients). HP-positive patients in average were older (10.7 versus 7.0 years, range 1 to 15 years, p < 0.05). Abdominal pain and upper gastrointestinal bleeding were the most frequent symptoms. Endoscopic nodular gastritis were HP status dependent (48.2 versus 13.6%, p < 0.05). All ulcers were HP positives. Histopathological findings in HP positive included more chronic and active severe inflammation. Dysplasia and intestinal metaplasia were absent in our biopsies, irrespective of HP status.

**Conclusions:** A high prevalence of HP infection among children with gastrointestinal complaints was found. All ulcers were HP positive. Metaplasia and dysplasia were absent. Impact of eradication therapy still needs to be evaluated.

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**1425**

**Percutaneous Endoscopic Gastrostomy Placement in Children: Patient Selection and Outcome**

Anup J. Patel, MD, Howard I. Baron, MD,* Pediatrics, University of Nevada SOM and Pediatric Gastroenterology & Nutrition Associates, Las Vegas, NV.

**Purpose:** Evaluate patient selection and outcome of children who had percutaneous endoscopic gastrostomy (PEG) placement over a five year period.

**Methods:** A retrospective chart review was conducted including all patients in our practice who underwent PEG placement from January 2000 through June 2005. Note was made of procedural indications, past medical history, pre-operative evaluation, PEG change to button gastrostomy, duration of indwelling tube, and complications including eventual need for fundoplication (FP).

**Results:** Eighty-seven patients underwent PEG during the years studied. Eight patients were excluded due to insufficient data, leaving 79 patients (41 males and 38 females). The mean age was 5 years 2 months old (range of 12 days to 17 years 3 months). Indications for a PEG were divided into three categories: inability to swallow (53), inadequate caloric intake despite normal swallowing (15), and special requirements (11). Inability to swallow was related to a neurological impairment in 85% (45 of 53). All of the studied patients underwent upper GI fluoroscopy prior to PEG, while 35% (27 of 78) had a Technetium-labeled gastric emptying study pre-operatively. Subsequent to initial PEG, 85% (66 of 79) had the original PEG converted to a button apparatus, a mean of 13.3 weeks (range 6 to 38 weeks) after PEG. The mean time of an indwelling gastrostomy was 69 weeks (range 2 to 255 weeks). Despite pre-operative assessment measures, 10 of 79 patients (13%) went on to require FP subsequent to the PEG (12 of 79 had a FP prior to PEG). The risk of requiring a FP post-PEG in our population was 15% (10 of 67). Only 7% of the neurologically-impaired group required post-PEG FP, while 80% (4 of 5) patients with maxillofacial defects went on to FP.**

**Conclusions:** PEG is a well-accepted method of long-term feeding tube placement in children, and has a variety of indications. While it is a safe and effective alternative to surgically-placed gastrostomy, potential complications can occur, including accidental dislodgement of the tube, peritonitis, and gastro-esophageal reflux (GER) requiring FP when medical therapy fails. Our study demonstrates that even with stringent pre-operative patient selection criteria, 15% of patients will require FP after PEG. Neurological impairment does not appear to be a statistically significant risk factor for FP after PEG, although patients with maxillofacial malformations may be at higher risk for post-PEG GER requiring FP than other patients needing long-term feeding access.

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**1426**

**Endoscopic Retrograde Cholangio-Pancreatography (ERCP) and Magnetic Resonance Cholangio-Pancreatography (MRCP) in Children with Recurrent Pancreatitis or Cholestatic Jaundice**

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**Purpose:** ERCP and MRCP are increasingly utilized for imaging pancreatobiliary (PB) system in children. The data pertaining to safety, effectiveness, and accuracy of each are still evolving.
Aim: To review our experience with use of MRCP and ERCP in children (<18 yrs age) with recurrent pancreatitis (RP) or cholestatic jaundice (CJ).

Methods: Retrospective review of patients admitted to Loma Linda Children’s Hospital who have undergone both, ERCP and MRCP examinations since Jan. 1, 2000.

Results: A total of 21 patients, 12/9 F/M, average age 10 1/2 yr (range 2 1/2 – 17 1/2) were identified. Indications for the studies were: RP (12), CJ (7), abnormal ultrasound or CT scan (5), and other miscellaneous conditions (1 each of abdominal injury, liver mass, family h/o pancreatic cysts, and evaluation of biliary anastomosis in liver transplant). RP patients were further divided into 1) familial or idiopathic 2) secondary to abnormal anatomy of PB tree (ultrasound or CT scan (5), and other miscellaneous conditions (1 each of familial or idiopathic 2) secondary to abnormal anatomy of PB tree (abnormal angle or site of PB junction, pancreas divisum, abnormal duct of Santorini). Transient pancreatitis was seen in 12/21 (57%) of patients following ERCP. 5 patients had multiple ERCP (2 to 6 times) for therapeutic intervention.

Table 1

<table>
<thead>
<tr>
<th>Final Diagnosis (Number)</th>
<th>ERCP</th>
<th>MRCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>RP (familial) (5)</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>RP (anatomic) (5)</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Cholecystitis</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>CBD stone (2)</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Miscellaneous (6)</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Total (21)</td>
<td>13 (62%)</td>
<td>17 (81%)</td>
</tr>
</tbody>
</table>

*Abnormal finding, suspicious but not diagnostic of final diagnosis

Conclusions: 1. ERCP and MRCP are feasible and safe diagnostic tools in children with RP or CJ.
2. MRCP is a noninvasive diagnostic modality to evaluate PB system in children, but the technique needs to be refined to evaluate distal CBD and PB junction.
3. ERCP seems superior to MRCP in children with RP caused by anatomic abnormality or CJ based on diagnostic accuracy and ability for therapeutic intervention.
4. RP in children may be caused by abnormal PB junction as diagnosed by ERCP.

1427

A New Biobehavioral Treatment Approach for Recurrent Abdominal Pain: Heart Rate Variability Biofeedback

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Purpose: Childhood recurrent abdominal pain (RAP) has been hypothesized to be associated with a deficit in autonomic nervous system (ANS) recovery to stress and an enhanced subjective response to pain. Respiratory sinus arrhythmia, which is positively correlated with heart rate variability, has been shown to be an indicator of ANS functioning. Therapeutic heart rate variability biofeedback (BF) attempts to achieve behavior modification toward pain and has been used in the treatment of RAP. A decrease in pain frequency and intensity along with an improvement in ANS functioning would serve as valid endpoints, marking efficacy of this therapeutic intervention in RAP.

The objective of this study is to determine pain intensity, pain frequency, and ANS functioning of children with RAP after completing BF.

Methods: Children diagnosed with RAP were referred for BF by pediatric gastroenterologists. The children were seen by doctoral interns for an average of 6 weekly sessions. The data was collected prior to BF treatment and post treatment. Outcome measures used included: pain intensity (visual analogue scale, 1 to 10), pain frequency (episodes per week), and ANS functioning as measured by peak to valley differences in respiratory sinus arrhythmia (RSA).

Results: 64 children (70% female, aged 7 to 18 years) had been diagnosed with RAP and undergone BF treatments (6 sessions, range 1–12). Pain intensity and frequency were significantly reduced. RSA was significantly increased (see Table).

Conclusions: In this cohort of children with RAP who were treated with BF, there was a marked decrease in pain intensity and frequency after completing BF in a pediatric medical setting. BF should be considered as a cost effective first line therapy for childhood RAP. Long-term studies need to be performed to see if this positive outcome effect persists into adulthood.

Pain Levels and RSA

<table>
<thead>
<tr>
<th>Pre BF Treatment</th>
<th>Post BF Treatment</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain Intensity (visual analogue scale 1–10)</td>
<td>6</td>
<td>2.5</td>
</tr>
<tr>
<td>Pain Frequency (episodes per week)</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>RSA during rest</td>
<td>13.6</td>
<td>22.5</td>
</tr>
<tr>
<td>RSA during slow paced breathing</td>
<td>22</td>
<td>32.5</td>
</tr>
</tbody>
</table>

1428

Abdominal Pain of Unknown Origin: Does Early Childhood Pain or Female Gender Influence Adult Presentation?

Denesh K. Chitkara, MD, *Nicholas J. Talley, MD, Amy Weaver, Miranda van Tilburg, PhD, Slavica Katusic, MD, G. Richard Locke, MD, Mary Jo Rucker, William E. Whitehead, PhD. Pediatric Gastroenterology, University of North Carolina, Chapel Hill, NC; Gastroenterology, Mayo Clinic, Rochester, MN and Gastroenterology, University of North Carolina, Chapel Hill, NC.

Purpose: Abdominal pain of unknown origin (AP) is a common medical complaint in children and adults. Purpose: To estimate the gender and age specific incidence and number of visits for AP in a population based birth cohort from 5 to <21 years. 2. To evaluate if AP during early childhood (<5 yo) influences presentation to adulthood.

Methods: A birth cohort of all children born between 1976 and 1982 to mothers who were residents of Rochester, MN, and who remained in the community until age 5 years, was considered in this study. Medical visits for AP of unknown origin were identified by HICDA codes. Subjects were followed based on their diagnoses accumulated while <21 yo, and 80% of the population remained in the area until at least age 19. Incidence density estimates were derived based on the number of new AP cases diagnosed being 5 and < 21 years of age, divided by the total “person-time” of observation.

Results: Of the 5347 birth cohort members without presentation for AP prior to age 5, the overall age and sex adjusted incidence was 31 per 1000 person years (py) for females and 17 per 1000 py for males. The incidence was significantly higher in females from 5–8 years and from 13 yo to adulthood (Table; < p < 0.001). Females were more likely to have additional medical visits for AP compared to males from 5- to < 21 years (p < 0.001). Of patients who presented for AP, 24% of females had 3 or more visits compared to 9% of males. Females with an early initial diagnosis for AP (<5 yo) had a significantly higher incidence for a subsequent medical visit for AP after 5 years of age compared to females without an early diagnosis (p < 0.001).

Risk of Gender and Age on AP presentation

<table>
<thead>
<tr>
<th>Age of Diagnosis (yrs)</th>
<th>Risk ratios (Females/Males (95% C.I))</th>
</tr>
</thead>
<tbody>
<tr>
<td>5–8</td>
<td>1.4 (1.1–1.7)</td>
</tr>
<tr>
<td>9–12</td>
<td>1.2 (0.9–1.5)</td>
</tr>
<tr>
<td>13–16</td>
<td>2.4 (1.9–3.1)</td>
</tr>
<tr>
<td>17–20</td>
<td>3.8 (2.9–4.8)</td>
</tr>
</tbody>
</table>
Conclusions: Females have significantly more initial and overall medical visits for AP from 5–<21 year. Early childhood presentation for AP in females but not in males is associated with subsequent medical visits. Females have a substantially higher risk of presenting with AP after adolescence.

1429
Factors Associated with High Mortality in Pediatric Patients Evaluated for Liver/Small Bowel Transplantation
Rebecca Carey, MD, Greg Tiao, MD, Maria Alonso, MD, Frederick Ryckman, MD, Samuel Kocoshis, MD.* Pediatrics, Cincinnati Children’s Hospital Medical Center, Cincinnati, OH and Surgery, Cincinnati Children’s Hospital Medical Center, Cincinnati, OH.

Purpose: Patients awaiting liver-small intestinal transplantation have a survival disadvantage compared to patients requiring isolated liver transplantation. Changes in organ allocation policies allow greater opportunity for transplantation, but prioritization still depends upon liver-dependent risk factors. This study analyzed cause of death for patients evaluated for liver-small intestinal transplantation.

Methods: Retrospective chart review of all patients evaluated for liver-small bowel transplant at our center since 2001.

Results: Forty three patients were evaluated for small bowel transplantation from May, 2001 through May, 2006. Thirty five of them were candidates for combined liver/small bowel transplant. Diagnoses for this subset were short gut with cholestasis (29), pseudo-obstruction with cholestasis (5), and autoimmune enteropathy with cholestasis (1). Only 13 of this subset survived to transplantation; 8 died while listed or after being deactivated as too sick for transplant, 8 died prior to being listed because they were too sick for transplantation, and 1 died after parents refused transplantation. One patient’s family refused transplantation and cholestasis improved, 2 were deferred and cholestasis improved, and 2 remain listed. The mortality rate is 77% (17/22) among all 22 who are no longer active candidates because they were listed and either died or improved, or because they were either too well or too sick to list. Even among the 21 patients who survived long enough to list for transplant, the mortality rate is 38% after initial listing compared to 12% for patients listed for isolated liver transplant. Causes of death included sepsis, hypernatremic dehydration, hemorrhagic pancreatitis, BPD, gastrointestinal hemorrhage, endstage liver disease, multiorgan failure, and cardiopulmonary arrest. Most deaths (15/17) were in patients <18 months of age. Comorbid conditions in these patients included prematurity (11), BPD (2), cardiac disease (2), renal insufficiency (1), cystic fibrosis (1) and hydrenephrosis (1), and renal dysplasia (1).

Conclusions: The mortality of pediatric candidates for liver-small bowel transplant is high and adversely affected by age and comorbidity. Not only should referral be early, but organ allocation schemes should take into consideration other comorbid conditions.

1430
Endoscopic Ultrasound in Pediatric Gastroenterology
Aldo A. Garza, MD*, Wendy K. Ayala, MD. Department of Medicine, Gastroenterology Division, School of Medicine/University Hospital, Universidad Autónoma de Nuevo León, Monterrey, Nuevo León, Mexico.

Purpose: The value of endoscopic ultrasound (EUS) in the evaluation and diagnosis of gastrointestinal disorders in adults is well recognized. Although the number of publications and reports of EUS applications in pediatric patients has been increasing in recent years, the medical literature is still limited. We describe our initial experience with EUS as a diagnostic tool in pediatric patients.

Methods: We reviewed all EUS procedures performed at our institution between Sept 2002 and May 2006. EUS was performed using conventional adult echoendoscopes (Pentax EG-3630 UR and EG-3630 U models) by a single endosonographer (AAG). Patients younger than 18 years of age were included in the study. We obtained demographic data, indications and EUS findings as well as follow-up information and outcomes of these patients.

Results: A total of seven pediatric patients underwent EUS in the period reviewed. The mean age was 11.7 years (range 7–17), 3 male and 4 female. All patients were >18 kg in weight. EUS was performed with a pediatric anesthesiologist providing IV sedation in all cases. All patients had radial endosonography, two undergoing linear array EUS for FNA of abnormal lesions found during the study. The indications for the procedure included recurrent pancreatitis of unknown origin (4 patients), submucosal lesions of the stomach (2 patients), and an apparent rectal adenocarcinoma for staging (1 patient). All procedures were performed safely without immediate or long-term complications. EUS findings included gallstone disease (2 patients), chronic pancreatitis (1 patient), non-obstructive jaundice (1 patient), and UC in the patient with apparent malignancy of the rectum. The two submucosal gastric masses undergoing EUS-FNA were reported as benign lesions. EUS provided valuable information and had a direct impact in the management decisions made for all patients.

Conclusions: In experienced hands, EUS and EUS-FNA can be safely performed in pediatric patients who weigh more than 18 kg using regular adult echoendoscopes, always under assistance of a pediatric anesthesiologist. Our most common indications for EUS in pediatric patients included the evaluation of recurrent pancreatitis of unknown etiology and the presence of submucosal lesions of the GI tract found during routine endoscopy. EUS and EUS-FNA, when indicated, can provide useful information in the decision-making process for the evaluation and treatment of selected pediatric patients.

Colorectal Cancer Prevention

1431
Colorectal Cancer among Hispanics in the United States
Sridhar R. Allam, MD*, D. Michael Hallman, PhD, Lu Ann Aday, PhD, Alexandria T. Phan, MD. School of Public Health, The University of Texas Health Science Center at Houston, Houston, TX and Gastrointestinal Medical Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX.

Purpose: To compare colorectal cancer patterns among Hispanics, African Americans and non-Hispanic Whites in the United States.

Methods: This is a cross-sectional community-based observational study, using U.S. population-based cancer registry data from the Surveillance, Epidemiology, and End Results (SEER) program. Data included 179457 invasive colorectal cancer cases diagnosed among Hispanics, African Americans and non-Hispanic Whites between 1992 and 2002. Average annual age-adjusted incidence rates and stage distributions of colorectal cancer are computed by race, gender and anatomic subsite.

Results: Rates of annual age-adjusted colorectal cancer incidence per 100000 among Hispanics, African Americans and Non-Hispanic Whites respectively are: for men, 47.4, 72.9 and 65.3, and for women, 31.9, 55.9 and 47.2. The percentage of patients diagnosed with colorectal cancer below the age of 50 is 14.12%, 12.01% and 6.4% among Hispanics, African Americans and Non-Hispanic Whites respectively. Compared to distal colon and rectal cancers, proximal colon cancers are less likely to be diagnosed at the localized stage in all groups and proximal colon cancer rates are markedly higher among women and African Americans.

Conclusions: The current recommendations for screening colorectal cancer among average-risk adults make no distinction based on gender and race/ethnicity. The higher incidence rates and lower age of onset of colorectal cancer may warrant decrease of age of initiation of screening in African Americans. In contrast, the lower incidence rates and higher age of onset of colorectal cancer may justify delaying the age of initiation of screening in Non-Hispanic White females. Colonoscopy may be preferred over sigmoidoscopy as screening test of choice among women and African Americans, in whom rates of proximal colon cancer are much higher compared to rates of distal colon and rectal cancer.
Factors Affecting Physician Compliance with Practice Guidelines for Colorectal Cancer Screening in a Large, Urban Community Hospital

S456 Abstracts

1432

Methods: All the patients seen at the VA hospital, Lyons, NJ from January 1, 2000 to January 1, 2001 who had a screening colonoscopy were investigated. These patients had a total of 574 polyps removed which were each analyzed for polyp size, location, and pathology. Patients with colonic masses were excluded.

Results: The clinical and pathological features of the resected polyps are demonstrated in Table 1. Forty eight percent of adenomatous polyps were found in the right side of colon. Furthermore, 44% of all polyps 0–3mm were adenomatous, while 21% were hyperplastic.

Conclusions: Almost half of all adenomatous polyps were found in the right side of the colon, validating the use of screening colonoscopy over screening sigmoidoscopy. A large number of diminutive polyps less than 3mm were adenomatous, validating the need for removal. More than half of all polyps under 6mm are adenomatous indicating the limitation of current virtual colonoscopy imaging modalities.

Table 1. Clinical and pathological characteristics of resected polyps

<table>
<thead>
<tr>
<th>Polyp Size:</th>
<th>0.0–3 mm</th>
<th>4.0–6 mm</th>
<th>7.0–9 mm</th>
<th>&gt;9 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>314</td>
<td>174</td>
<td>34</td>
<td>52</td>
</tr>
<tr>
<td>Sessile</td>
<td>314</td>
<td>174</td>
<td>26</td>
<td>29</td>
</tr>
<tr>
<td>Pedunculated</td>
<td>0</td>
<td>0</td>
<td>6</td>
<td>23</td>
</tr>
<tr>
<td>Age</td>
<td>67.8</td>
<td>69.7</td>
<td>67.7</td>
<td>69.6</td>
</tr>
<tr>
<td>Wt</td>
<td>190.7</td>
<td>192.54</td>
<td>187.6</td>
<td>205.9</td>
</tr>
<tr>
<td>Pathology</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TA</td>
<td>140</td>
<td>44%</td>
<td>96</td>
<td>56.3%</td>
</tr>
<tr>
<td>TV</td>
<td>1</td>
<td>0.3%</td>
<td>2</td>
<td>1.1%</td>
</tr>
<tr>
<td>VA</td>
<td>0</td>
<td>n/a</td>
<td>1</td>
<td>0.6%</td>
</tr>
<tr>
<td>CA</td>
<td>0</td>
<td>n/a</td>
<td>0</td>
<td>n/a</td>
</tr>
<tr>
<td>Hyperplastic</td>
<td>66</td>
<td>21%</td>
<td>23</td>
<td>13.2%</td>
</tr>
<tr>
<td>Inflammatory</td>
<td>25</td>
<td>8%</td>
<td>11</td>
<td>6.3%</td>
</tr>
<tr>
<td>Biopsy Abstract</td>
<td>21</td>
<td>6.7%</td>
<td>11</td>
<td>6.3%</td>
</tr>
<tr>
<td>Insufficient</td>
<td>41</td>
<td>13%</td>
<td>11</td>
<td>6.3%</td>
</tr>
<tr>
<td>Normal Tissue</td>
<td>20</td>
<td>6.3%</td>
<td>17</td>
<td>9.8%</td>
</tr>
<tr>
<td>Location</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cecum</td>
<td>19</td>
<td>6%</td>
<td>20</td>
<td>11.5%</td>
</tr>
<tr>
<td>Ascending</td>
<td>25</td>
<td>7.9%</td>
<td>25</td>
<td>14.4%</td>
</tr>
<tr>
<td>Transverse</td>
<td>60</td>
<td>19%</td>
<td>35</td>
<td>20.1%</td>
</tr>
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<td>Descending</td>
<td>7</td>
<td>2.2%</td>
<td>6</td>
<td>3.4%</td>
</tr>
<tr>
<td>Elapacid</td>
<td>102</td>
<td>32.5%</td>
<td>54</td>
<td>31.2%</td>
</tr>
<tr>
<td>Rectum</td>
<td>101</td>
<td>32.2%</td>
<td>34</td>
<td>19.5%</td>
</tr>
</tbody>
</table>

The clinical and pathological features of the resected polyps are demonstrated in Table 1.
Results: One hundred and eleven eligible patients were contacted by mail. Twenty two patients declined to participate in the study and 29 patients did not respond. Results of first 50 patients analyzed. Thirty four of forty participants preferred NaP tablet preparation over PEG (Table). A majority also indicated that they would use NaP tablet preparation again and would like to have a choice of preparation. Seventy percent of patients had their preparation rated as good or excellent. The most common adverse events are mild nausea, bloating and abdominal pain. None of the patients stopped their preparation because of adverse events.

Conclusions: The majority of patients in this study preferred NaP tablet preparation over PEG preparation for their colonoscopy. Seventy percent of patients had a good or excellent preparation quality with 28 tablets of NaP preparation.

Results:

<table>
<thead>
<tr>
<th>Age</th>
<th>Mean 69.27yrs (48–86)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>21 females, 29 males</td>
</tr>
<tr>
<td>Good or excellent preparation</td>
<td>35/50 (70%)</td>
</tr>
<tr>
<td>Fair preparation</td>
<td>11/50 (22%)</td>
</tr>
<tr>
<td>Poor preparation</td>
<td>4/50 (8%)</td>
</tr>
<tr>
<td>Prefer tablets over PEG</td>
<td>34/50 (68%)</td>
</tr>
<tr>
<td>Would take tablet preparation again</td>
<td>35/50 (70%)</td>
</tr>
<tr>
<td>Would like a choice</td>
<td>39/50 (78%)</td>
</tr>
</tbody>
</table>

1435

Increased Risk of Colon Adenocarcinoma after Lung Transplantation

Douglas H. Weinstein, MD, Luis F. Lara, MD, Randall L. Rosenblatt, MD,* Internal Medicine, The University of Texas Southwestern Medical Center at Dallas, Dallas, TX and Division of Digestive and Liver Diseases, The University of Texas Southwestern Medical Center at Dallas, Dallas, TX.

Purpose: The risk of cancer, especially of the gastrointestinal tract, may be increased in patients with cystic fibrosis (CF). There are no specific recommendations for more diligent screening or surveillance for gastrointestinal malignancy in patients considered at average risk for colorectal neoplasm (CRC) after undergoing lung transplantation for any cause. We report an unusually high incidence of colon cancer in a cohort of patients after lung transplantation.

Methods: A retrospective review was performed on patients with adenomatous polyps excised between July to December 1998. The hospital endoscopy database was used to determine whether these patients were compliant with their follow-up colonoscopy. 34 clinical factors were assessed by univariate analysis in patients grouped into whether they were compliant (n = 60) or non-compliant (n = 59). Factors assessed included demographics, compliance with previous healthcare visits, substance abuse, mental illness, travel distance, and medication history. Significant variables by univariate analysis were included in a multivariate regression analysis model to determine factors predicting early mortality. All values are presented as means ± SE, statistic significance was a p ≤ 0.05.

Results: 119 patients with adenomatous polyps were identified. They were all men (mean age 64.2 yrs). 114/119 (96%) had a documented recommendation for follow up of 5 years or less. 40% (34/119) had previously undergone colonoscopy and 58% (49 of 119) were symptomatic at the time of the colonoscopy. 8% (7/119) had a family history of colorectal cancer. Follow up was available in all 119 of these cases, 60 (50.4%) of which had been compliant with follow up colonoscopy. In a univariate analysis, greater number of polyps (p = 0.04), presence of diabetes (p = 0.003), NSAIDs use (p = 0.002), HMG Co-A reductase use (p = 0.005), first-degree relatives with colon cancer (p = 0.05) and compliance with outpatient clinic follow-up (p < 0.001) were significantly associated with patient compliance with follow up colonoscopy. A multivariate logistics regression analysis revealed HMG Co-A reductase use (p = 0.05) first-degree relatives with colon cancer (p = 0.05) and compliance with outpatient clinic follow-up (p < 0.001) to be independently associated with compliance.

Conclusions: Age, substance abuse, mental illness, or travel distance was not associated with compliance with follow-up colonoscopy. Use of HMG Co-A reductase and having a 1st degree relative with colon cancer are independent predictors of compliance. The strongest predictor with noncompliance can be predicted from noncompliance with other healthcare encounters.

1436

Determinants of Compliance with Colonoscopy in Patients with Adenomatous Colon Polyps

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Purpose: Removal of adenomas with at least a three to five-year follow up reduces incidence of colorectal cancer. The aim of this study was to determine factors which affect compliance of a follow up colonoscopy in patients with previously diagnosed adenomatous colon polyps.

Methods: A retrospective review was performed on patients with adenomatous polyps excised between July to December 1998. The hospital endoscopy database was used to determine whether these patients were compliant with their follow-up colonoscopy. 34 clinical factors were assessed by univariate analysis in patients grouped into whether they were compliant (n = 60) or non-compliant (n = 59). Factors assessed included demographics, compliance with previous healthcare visits, substance abuse, mental illness, travel distance, and medication history. Significant variables by univariate analysis were included in a multivariate regression analysis model to determine factors predicting early mortality. All values are presented as means ± SE, statistic significance was a p ≤ 0.05.

Results: 119 patients with adenomatous polyps were identified. They were all men (mean age 64.2 yrs). 114/119 (96%) had a documented recommendation for follow up of 5 years or less. 40% (34/119) had previously undergone colonoscopy and 58% (49 of 119) were symptomatic at the time of the colonoscopy. 8% (7/119) had a family history of colorectal cancer. Follow up was available in all 119 of these cases, 60 (50.4%) of which had been compliant with follow up colonoscopy. In a univariate analysis, greater number of polyps (p = 0.04), presence of diabetes (p = 0.003), NSAIDs use (p = 0.002), HMG Co-A reductase use (p = 0.005), first-degree relatives with colon cancer (p = 0.05) and compliance with outpatient clinic follow-up (p < 0.001) were significantly associated with patient compliance with follow up colonoscopy. A multivariate logistics regression analysis revealed HMG Co-A reductase use (p = 0.05) first-degree relatives with colon cancer (p = 0.05) and compliance with outpatient clinic follow-up (p < 0.001) to be independently associated with compliance.

Conclusions: Age, substance abuse, mental illness, or travel distance was not associated with compliance with follow-up colonoscopy. Use of HMG Co-A reductase and having a 1st degree relative with colon cancer are independent predictors of compliance. The strongest predictor with noncompliance can be predicted from noncompliance with other healthcare encounters.

1437

Dehydration with Bowel Purgatives: A Risk for Polyethylene Glycol (PEG) and Sodium Phosphate (NaP) Formulations

Charles F. Barish, MD*, Kelli Walker, PharmD., Wake Research Associates, LLC, Raleigh, NC and Salix Pharmaceuticals, Morrisville, NC.

Purpose: Dehydration-related complications from colon preparation have recently emerged as a vital issue in colonoscopy screening. Signs of dehydration include weight loss, postural changes in blood pressure (BP) and pulse rate (PR), dizziness, and headaches. To assess whether multiple classes of purgatives may lead to dehydration, signs were monitored in patients (pts) undergoing colonoscopy in 2 identically designed, randomized, multicenter, investigator-blinded studies.

Methods: Pts scheduled for colonoscopy received either 4-L PEG solution (Cherry Flavor NuLYTELY®; Braintree Laboratories Inc, Braintree, Mass; n = 432) or NaP tablets (Visicol® Tablets; Salix Pharmaceuticals, Inc, Morrisville, NC; n = 427) for bowel preparation. Weight, postural changes in
BP and PR, and adverse events (AEs) were recorded up to 7 days before colonoscopy (baseline), on the day of colonoscopy, and 48 to 72 hours post-colonoscopy. Postural hypotension was defined as a symptom-associated orthostatic increase of 30 beats/min in PR or an orthostatic decrease in systolic (>25 mm Hg) or diastolic (>20 mm Hg) BP.

**Results:** On the day of colonoscopy, weight loss was evident in pts treated with 4-L PEG (2.4 ± 2.8 lb) and NaP tablets (2.1 ± 3.3 lb). Pts regained the majority of lost weight within 3 days postcolonoscopy, but weights were still reduced compared with baseline levels (n = 0.7 ± 3.0 lb, PEG group; 0.3 ± 3.1 lb, NaP group). Fourteen (3.2%) pts in the PEG group and 21 (4.9%) pts taking NaP tablets reported light-headedness or dizziness. Similarly, 2.8% (n = 12) and 3.3% (n = 14) of pts treated with PEG and NaP, respectively, reported symptoms suggestive of postural hypotension but did not reach the predefined criteria. In both groups, slight changes in plasma electrolytes resolved by end of study.

**Conclusions:** Mean weight loss after purgation with either PEG solution or NaP tablets was ~2 lb. Return to baseline weight was not fully achieved 2 to 3 days postcolonoscopy. Data suggest that pts lose a similar amount of stool and fluid during purgation, regardless of the bowel preparation. The prolonged weight reduction, along with AEs such as light-headedness, dizziness, and headaches, suggests that dehydration may be a risk even several days postcolonoscopy. Thus, pts who are scheduling a colonoscopy should be advised of the importance of proper hydration prior to, during, and after bowel preparation. Complications of dehydration can be avoided.

1438

**Long-Term Follow-Up of Patients Noncompliant with Recommendations for Surveillance Colonoscopy**

*John R. Scherer, B.S., Arthur J. DeCross, MD,* Gastroenterology and Hepatology Division of Medicine, University of Rochester Medical Center, Rochester, NY.

**Purpose:** Long term follow up of patients labeled “noncompliant” in a previous study of participation in a colonoscopy surveillance program.

**Methods:** We previously reported two different strategies for recalling patients for a colonoscopy surveillance exam. This was a retrospective chart review of consecutive cases within a defined time period. Patients were asymptomatic, were told after index colonoscopy to repeat the exam in 3 years (usually post-polypectomy), and were not seen clinically in the practice for 3 years. Patients in Group 1 (N = 48) were contacted by the practice to schedule the previously recommended surveillance exam (“physician-initiated recall”). Patients in Group 2 (N = 79) were not contacted by the practice (“patient-initiated recall”), but were considered to be compliant with follow up if they presented within 1 year of the recommended date for the exam. Compliance was 75% for group 1 and 72% for group 2, p = NS. Our current study examines the long-term outcome of those patients labeled “noncompliant” in both groups, 3–5 years after they missed their exams. Outcome was assessed for ultimate participation in colonoscopy, detection of polyps or cancer, or long term loss to follow up.

**Results:** Of 127 total patients, 35 (27.6%) were noncompliant with surveillance colonoscopy within 1 year of the recommended date. 16 of the 35 (29.6%) eventually had a “late” exam 1–3 years after the recommended date [Group I: 4/12 (33.3%), Group II: 6/23 (26.1%), p = NS], but within the 10 patients, only two tiny polyps were detected [Group I: 1/4 – 3mm, Group II: 1/6 – 5mm]. 25 of the 35 (71.4%) originally noncompliant with recommendations to follow up for a surveillance colonoscopy remained noncompliant long-term, >3 years. 13 of the 25 (52%) long-term noncompliant patients could not be located within the entire hospital system [Group I: 4/12 (50.0%), Group II: 7/23 (30.4%)].

**Conclusions:** 27.6% of patients were noncompliant with recommendations for surveillance colonoscopy, and most of these patients (71.4%) remain noncompliant long-term, >3 years. This was not significantly affected by physician-initiated efforts to encourage their participation. Of particular interest, 52% of these long-term noncompliant patients can no longer be tracked anywhere in the hospital system after 3 years, suggesting permanent loss to any regional follow up is a dominant factor in noncompliance with the surveillance recommendation. This information may be of value to physicians from a medical-legal perspective.

1439

**Colorectal Cancer Screening in HIV-Positive Patients in a Major U.S. Metropolitan Hospital**

*Matthew M. McMahon, MD, Jae W. Nam, MD, Charles G. Nesmith, MD, Kamil M. Obideen, MD, Mohammad A. Wehbi, MD,* Internal Medicine, Emory University School of Medicine, Atlanta, GA and Gastroenterology, Emory University School of Medicine, Atlanta, GA.

**Purpose:** Since the introduction of highly active antiretroviral therapy (HAART), patients with human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS) are living longer. This increased life expectancy has implications for the long term care of these patients, including appropriate screening for non-AIDS defining cancers, such as colorectal cancer (CRC). Current guidelines recommend CRC screening starting at age 50 for all patients at average risk for CRC. Most studies suggest the risk of CRC is not increased in HIV infected patients and this population may not be receiving adequate screening for CRC. We designed a study to determine whether or not HIV-infected patients are being screened sufficiently for CRC and to examine the incidence of polyps and colorectal cancer in these patients.

**Methods:** We conducted a retrospective review of all lower endoscopies performed on HIV-positive patients for any indication between January 2001 and October 2005 in Grady Memorial Hospital. For each HIV-infected patient we identified one age- and gender-matched control subject without HIV who underwent lower endoscopy during the same period.

**Results:** Between January 2001 and October 2005, 302 HIV-positive patients underwent lower endoscopic procedures. Of these, 112 were over the age of 50, including 78 males and 34 females with average ages of 59 ± 6.5 and 52 ± 6.3, respectively. The proportion of HIV-infected patients who underwent lower endoscopy for screening purposes was significantly lower than in control subjects (21% vs 41%, p < 0.001). Of the HIV-positive patients who underwent screening lower endoscopy, 6 tubular adenomas (TA), 3 hyperplastic polyps (HP), and 1 tubulovillous adenoma (TVa) were identified. The average CD4 count of those patients with polyps was 396 ± 480 for those without polyps.

**Conclusions:** HIV-infected patients were significantly less likely to undergo lower endoscopy for screening purposes than controls, suggesting that these patients are not being adequately screened for CRC. Additionally, the incidence and proportion of various types of polyps appears similar in HIV patients to that reported in the literature for the general population. Finally, the observed association between low CD4 counts and the presence of polyps needs to be verified as we continue to expand our sample size.

1440

**Patients’ Preferences and Perceptions on Virtual and Conventional Colonoscopy: A Systematic Review**

*Mariana C. Padron, MD, Brenda Jimenez, MD, Daniela Urma, MD, Roger D. Mitty, MD,* Division of Gastroenterology and Internal Medicine, St. Elizabeth’s Medical Center of Boston, Tufts University School of Medicine, Brighton, MA.

**Purpose:** Colorectal Cancer Screening compliance rates remain low and this is due to multiple factors, including poor public awareness and acceptance. No single screening test is unequivocal superiority, but conventional colonoscopy is the most widely used procedure. Virtual colonoscopy has emerged as a promising technique and special attention has been paid to the fact that it is a non invasive method, which translates into a potentially more acceptable examination for patients. Studies have been conducted comparing patients’ preferences and perceptions between conventional and virtual
colonscopy. Our aim was to systematically review the literature and search for these studies.

**Methods:** We conducted an electronic literature search and studies were identified by searches on Medline, PsyicINFO and CINAHL databases through OVID and PUBMed. Three investigators independently reviewed each abstract and eligible articles were retrieved. We also searched the reference lists of retrieved articles and hand searched various gastroenterology journals.

**Results:** The reviewers selected 11 articles that met inclusion criteria. In 9 out of 11 articles the preferred method was virtual colonoscopy with a range of reported preferences from 21% to 72% with a mean of 51% compared to 27% for conventional colonoscopy. Studies were heterogeneous in regard to population included (risk and symptomatology) and virtual colonoscopy methodology. These factors that might have influenced patients’ preferences were studied and no relationship was found between variables. Patients’ experiences and perceptions of these two procedures were also described and analyzed.

**Conclusions:** Virtual colonoscopy is preferred over conventional colonoscopy as a diagnostic procedure. It doesn’t appear that factors such as patient and scanner characteristics and variability in procedure methodology influence patients’ preference for one method over the other. These results should be taken into account since patients’ high acceptance of virtual colonoscopy is a key factor for its potential widespread use for colorectal cancer in the future and might positively impact compliance rates.

**1441**

**Patient Support Program Increases Adherence to Colorectal Cancer Screening**

Jeffrey L. Bagshaw*, William F. Bucher. Vice President, Marketing Support Services, PharmaTech Solutions, Wilmington, NC and Vice President, Marketing & Business Development, Laboratory Corporation of America Holdings, Research Triangle Park, NC.

**Purpose:** Support system limitations to ensure completion of testing or procedure contributes to the lack of colorectal cancer (CRC) screening. Previously a patient adherence and tracking pilot program associated with stool DNA (sDNA) screening was shown to have improved patient adherence (Am J Gastroenterology 2005;100(9):S394). The effect of an enhanced enrollment-based patient support system on test adherence for sDNA—a test intended for patients unwilling, unable, or who were noncompliant with colonoscopy—was studied during the first five months of 2006.

**Methods:** Patients who were prescribed an sDNA test during 2006 were given the option to enroll in a nationwide patient support program titled PreGen-CaresSM (PGC). The enrollment process included patient authorization and enabled the PGC staff to contact the patient directly by phone several days after the office visit to: enhance patient education and reinforce the need for screening, ensure proper at-home stool collection, arrange for specimen transport via overnight mail, provide timely feedback to the clinician, and collect outcomes data. Follow-up contacts were attempted 7–10 days after initial contact to provide patient reminders and facilitate the specimen submission process. A case was considered closed if either the patient submitted a specimen or failed to submit a specimen within 5 weeks of first contact. If the patient failed to submit a specimen, a letter was sent to both patient and clinician to close the case.

**Results:** 1440 patients were enrolled. While 220 of the 1440 patient cases are open pending testing completion, 385 tests out of the 1220 closed cases were completed, yielding an adherence rate of 73%. Twenty-one of the 1220 closed-case enrollees declined the stool DNA test; however, the PGC staff discussed the benefits of CRC screening with these enrollees and the enrollees agreed to recontact their health care providers to schedule the original colonoscopy they were initially unwilling to complete.

**Conclusions:** Patient adherence with CRC screening benefits from an educational and follow-up program, which augments communication between patient and physician, addresses questions that arise before or during testing, increases testing convenience and emphasizes the importance of regular CRC screening. Support system and infrastructure increase compliance with CRC screening recommendations.

**1442**

**Narrow Band Imaging (NBI) vs White Light (WL) for Colorectal Adenoma Detection Using High Definition Wide Angle Colonoscopes**

Douglas K. Rex, MD,*  Gastroenterology, Indiana University School of Medicine, Indianapolis, IN.

**Purpose:** NBI with blue light increases the visibility of mucosal details including vasculature and might enhance the detection of colorectal neoplasia. The purpose was to investigate whether NBI increases detection of colorectal adenomas during colonoscopy.

**Methods:** A randomized controlled clinical trial of NBI vs WL in persons age > = 50 years without surgical resection of the colon, IBDD or polyposis syndromes. A single examiner with a known high adenoma detection rate using WL performed all examinations. Withdrawal time was measured with a stopwatch with subtraction of all time for polypometry, biopsy, washing and suctioning and targeted to at least 6 minutes in both arms. All adenomas were histologically documented.

**Results:** 388 of planned 434 subjects have been enrolled. There was no difference in% male between NBI and WL (52% vs 56%; p = .36), age (61.8 vs 62.7y; p = .36), indication screening (60.8% vs 61.8%) or indication polyp surveillance (37.6% vs 34.5%; p = .41), eccal insertion time (3.3 vs 3.3 min; p = .99), per cent of patients with 1 or more adenomas (61% vs 65%; p = .40), number of adenomas per colonoscopy (1.7 vs 1.7; p = .44), number of flat adenomas per colonoscopy (0.9 vs 0.9; p = .55). Despite efforts to maintain withdrawal time equal in both arms, mean withdrawal time was longer with NBI (7.8 vs 7.3 min; p = .006). Among 238 patients with indication screening, the percent of patients with 1 or more adenomas with NBI vs WL was similar (55% vs 56%; p = .91), as was the number of adenomas per colonoscopy (1.6 vs 1.4; p = .96) and the number of flat adenomas per colonoscopy (0.7 vs 0.7; p = .84). The overall rate of adenoma detection in both arms of the study of 1.7 adenomas per colonoscopy exceeds the historical adenoma detection rate of the same endoscopist as measured in our continuous quality improvement program using high resolution 140 degree angle of view colonoscopes (0.86 adenomas per colonoscopy) and to our knowledge exceeds all adenoma detection rates previously reported, including with pancolonic chromoendoscopy.

**Conclusions:** NBI did not improve adenoma detection by an examiner with known high detection rate using WL. NBI was associated with slightly longer withdrawal time, likely because of image darkness in colon segments with large luminal diameter. Extremely high adenoma detection rates in both arms suggest the need for controlled trials testing whether high definition increases adenoma detection.

**1443**

**Assessment of Patient Compliance and Satisfaction with a Novel Fecal Occult Blood Test**

David T. Rubin, MD*, Mina Sedrak, B.A., Noura Sharabash, MD, John Schumann, MD, Bonnie L. Surana, R.N. Department of Medicine, University of Chicago, Chicago, IL.

**Purpose:** Effective colon cancer screening tests exist, but compliance with them remains inadequate and there is ongoing need for improved acceptability by patients. EZ DetectTM (EZD) (Biomerca, Newport Beach, CA) is a chemically treated tissue that changes color in the presence of blood, requires no dietary modification or stool handling, and is available over-the-counter. We hypothesized that patients would be more likely to comply with EZD than Hemoccult® II Sensa (HS) (Beckman Coulter Inc., Fullerton, CA).

**Methods:** Eligible patients were asymptomatic individuals scheduled for screening or surveillance colonoscopy (CS) without inflammatory bowel disease. With permission of their physicians, subjects were telephoned and
invited to participate in a study assessing fecal occult blood tests but were blinded to study intent. Willing patients were randomized to either EZD or HS. The colonoscopist was blinded to the randomization. The primary endpoint was compliance with the fecal test. Secondary endpoints were accuracy of the fecal test to detect advanced neoplasia compared to CS findings and responses to a survey of the experience with the test. Simple statistics were calculated with Fisher’s exact test and Student’s t-test to assess differences between groups.

Results: 350 eligible patients were contacted, 49 (14%) agreed to participate. The mean age and CS findings were similar between the randomized groups. Of 27 patients randomized to EZD, 18 (67%) were compliant, 5 (18.5%) were non-compliant, and 4 (14.8%) did not show up for their exam; of 22 patients randomized to HS, 13 (62%) were compliant, 6 (27.3%) were non-compliant, and 3 (13.6%) did not show up for their exam (p = NS). EZD was a true negative in 17 of 17 cases, and correctly identified 1 patient who had a 20 mm adenoma; HS was a true negative in 7 of 7 cases but falsely negative in 1 case with 11 mm and 3 mm adenomas (5 HS cases were undeveloped). Surveys revealed similar findings between HS and EZD in test-related anxiety, difficulty, and unpleasantness, as well as reasons for non-compliance. EZD patients agreed or strongly agreed with statements “The instructions were easy to understand” and “I am willing to have this test again” more often than HS patients. 

Conclusions: In this pilot study, patients were equally likely to complete EZD and HS. In the secondary analyses, EZD was 100% accurate at predicting the findings of CS and generally acceptable to patients. Larger studies of this innovative over-the-counter test are warranted.

1444

Enrollment and Education Initiative Dramatically Increases Colorectal Cancer Screening by Colonoscopy in a Predominantly Latino Inner City Population

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Purpose: To assess the impact a colorectal cancer screening (CRCS) enrollment and education initiative had on screening colonoscopy rates among a predominantly inner city Latino population. A secondary aim was to determine the effect of increased CRCS on detection of adenomatous polyps. Underutilization of CRCS is widely reported and is more pronounced among Latinos and those with low socioeconomic status. Our municipal hospital patient population is 70% Latino (majority Spanish speaking), with limited resources.

Methods: This study is retrospective, examining the effect this CRCS initiative had on the number of screening colonoscopies performed at our institution, and the number of patients with adenomatous polyps removed. We reviewed statistics from 2002, the year prior to the initiative, and compared them to 2003 and 2004. In late 2002, our division implemented a program intended to increase rates of CRCS. It contained two principal features:

1. CRCS Clinic: a weekly clinic session, staffed by physician assistants (some bilingual) and supervised by an internist. Our hospital’s primary care physicians (PCPs) referred patients without gastrointestinal symptoms over age 50. There, patients were evaluated, received CRCS counseling, and were directly scheduled for colonoscopy.

2. Saturday Colonoscopy: screening colonoscopies were offered on two Saturdays monthly to accommodate patients unable to attend weekday sessions.

Results: In 2002, 331 screening colonoscopies were performed. The same number of endoscopists performed 658 and 992 in 2003 and 2004, respectively, reflecting increases of 99% and 200%. In 2002, 93 patients had adenomatous polyps removed. This rose to 154 and 215 in 2003 and 2004, corresponding increases of 66% and 131%.

Conclusions: Our CRCS initiative dramatically increased the number of screening colonoscopies at our institution. The CRCS Clinic stimulated PCP referrals for CRCS. This clinic unburdened PCPs and provided a setting better equipped to address cultural, educational, and language barriers to CRCS than a general medical clinic. In addition, Saturday access to colonoscopy provided opportunity for those who could not miss work or had family responsibilities during the week. Our program is reproducible and may benefit other institutions facing comparable challenges in implementing CRCS programs.

1445

Colorectal Cancer: Management of Unrelated Diseases Interferes with Appropriate Screening and Diagnosis

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Purpose: Despite directed efforts at increasing awareness and screening for colorectal cancer, patients with regular medical follow-up for other diseases are routinely diagnosed with advanced colorectal malignancy.

Methods: We reviewed 37 consecutive patients (23 female, 62%) with advanced colorectal cancer treated by three colorectal surgeons over six months (July 2005 – January 2006).

Results: The mean age was 65.5 years. Pre-operative staging was available for 35 patients (II = 6, III = 12, IV = 17). Common presenting complaints were bleeding (n = 23), pain (n = 19), and weight loss (n = 10). Most patients (n = 20) presented to the emergency department with complaints of bleeding (n = 14) or obstruction (n = 4). Mean presenting lab values were: CEA 41.0 ng/ml (range 0.5 – 436), Hematocrit 33.0% (range 22.0 – 50.6), and albumin 3.1 g/dl (range 0.9 – 4.6). Two-thirds had insurance that would have covered cancer screening. 29(78.4%) patients had operations. Five patients were inoperable and three are currently receiving neoadjuvant therapy. Rectal cancers predominated (n = 19) and were more common in males (n = 12). Most patients with rectal cancer required a colostomy (n = 11) or were inoperable (n = 5). Seventeen (58.6%) patients developed post-operative complications; the most common being post-operative ileus (24.1%). Average hospital stay was 10 days. 25 patients received neo-adjuvant chemoradiation therapy, including 5 who received intra-operative therapy. Rectal cancers predominated (n = 19) and were more common in males (n = 12). Most patients with rectal cancer required a colostomy (n = 11) or were inoperable (n = 5). Seventeen (58.6%) patients developed post-operative complications; the most common being post-operative ileus (24.1%). Average hospital stay was 10 days. 25 patients received neo-adjuvant chemoradiation therapy, including 5 who received intra-operative therapy.

Conclusions: These results suggest that comorbid diseases may mask symptoms and signs of colorectal cancer and cause appropriate screening to be ignored. Patients with advanced colorectal malignancy present anemic, malnourished, have frequent post-operative complications, long hospital stays, and require more radical operations. Modern use of advanced multidisciplinary treatment and neo-adjuvant therapy may offer patients with advanced disease more options today.

1446

The Utility of Endoscopic Ultrasound after Endoscopic Polypectomy of Malignant Rectal Polyps

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Purpose: Endoscopic ultrasound (EUS) has become a standard of care for the diagnosis and staging of gastrointestinal mucosal cancers. In rectal cancer, EUS offers high resolution images of the different wall layers and was found to be superior to CT scan or MRI in obtaining accurate staging. The role
of EUS in evaluating the rectum post endoscopic resection of malignant or premalignant polyps remains unclear.

**Aim:** In a retrospective chart review, to evaluate the role of EUS in patients with malignant or pre-malignant rectal polyps resected endoscopically.

**Methods:** Fourteen patients who underwent endoscopic polypectomy were identified from our EUS database. In all cases, malignancy was contained within the polyp with no stalk or submucosal invasion. Patients referred for surgical excision or with extra-polyp disease were excluded. Patients were followed by serial endoscopic ultrasound and flexible sigmoidoscopy examinations on regular basis. Endosonographic recurrence was defined as hypoechoigenicity within the rectal wall with or without perirectal or iliac lymphadenopathy. Local endoscopic recurrence was based on mucosal changes at the site of polypectomy with pathologic confirmation of malignancy.

**Results:** The pathology of resected polyps was carcinoid in 3 patients, high grade dysplasia in 2 patients and adenocarcinoma in the remaining 9 cases. The average size of the polyp was 16.3 mm (range 3–50 mm). The average duration of follow up was 13 months (range 3–60 months). No patient underwent chemoradiation during the duration of follow up. No patients developed recurrence of the malignancy during the same period of time by clinical, endoscopic or endosonographic criteria.

**Conclusions:** In cases of endoscopically resected malignant polyps of the rectum where the disease is contained within the resected polyp, EUS did not offer additional restaging data about recurrence in the absence of endoscopic recurrence. This study suggests that surveillance with standard endoscopic methods should suffice in those patients. Only those with endoscopically visible disease should be referred for endosonographic evaluation.

### 1447

**Analysis of Miss Rates for Colonoscopy, Barium Enema, and Flexible Sigmoidoscopy in 379 Patients with Colorectal Cancer**

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**Green Cancer Center, The Scripps Research Institute, La Jolla, CA.**

**Purpose:** Miss rates for colonoscopy (C), barium enema (BE), and flexible sigmoidoscopy (FS) have been reported using large databases of patients with colorectal cancer (CRC). Most have concentrated on the miss rate, and the reasons for the miss are generally unknown. This study was designed to analyze both the miss rates for C, BE, and FS and the reasons for the miss in order to discover ways to reduce the miss rate.

**Methods:** We created a database of 393 patients with CRC treated surgically at Scripps Green Hospital between January 2000 and December 2005. Patients with hereditary colon cancer syndromes and IBD were excluded. Records were reviewed for the result of C, BE, and FS in the three years prior to diagnosis. A missed examination was defined as a diagnostic test that was performed within three years of the diagnosis of CRC and was negative for cancer. Each missed examination was evaluated to determine the reason for the miss.

**Results:** 393 patients were treated for CRC; 14 patients were excluded. 379 patients, who had 459 diagnostic examinations, were analyzed. 65 patients had 81 (18%) screening examinations that missed the diagnosis. Of 286 Cs, 29 (10%) missed the cancer: 9 were considered normal; 8 were incomplete, none of which reached the site of the cancer; all of the incomplete exams were followed by a BE, 3 of which also missed the cancer (see below); 7 patients had sessile polyps that were difficult to remove; 4 were limited by poor prep; and 1 had difficulty with visualization at the hepatic flexure where cancer was diagnosed 18 months later. Of 79 BEs, 16 (20%) missed the cancer: 7 were interpreted as normal, 3 of which were performed after an incomplete colonoscopy; 6 were difficult to interpret, due to poor preparation or patient compliance; 3 were incomplete. Of 66 FSs, 36 (55%) missed the cancer: 29 (44%) missed cancers that were out of reach and 7 (11%) missed cancers that were within reach. Of the 7 FSs that missed cancers within reach, 6 were considered normal; 1 was limited by poor preparation. The differences in the miss rates were statistically significant.

**Conclusions:** Miss rates for C, BE, and FS were 10%, 20%, and 55%. Most common reasons for misses were: (1) inaccurate observation, (2) failure to examine the entire colon, (3) failure to follow advanced polyps closely, and (4) failure to follow-up sub-optimal exams.

### 1448

**Comparison of Colon Polyp Incidence in Males vs. Females under Age Fifty**

*James Conti, MD, Matthew Florczyk, PhD, Seth Richter, MD,*

**Internal Medicine/Gastroenterology, Albany Medical Center, Albany, NY.**

**Purpose:** Identify and compare the incidence, anatomic location and histologic features of colon polyps in male and female patients under the age of fifty.

**Methods:** At Albany Medical Center, a total of 4001 colonoscopies were performed on patients under fifty years of age between September 1, 2001 and August 31, 2005. We retrospectively reviewed the procedure and pathology reports of 1270 patients in which a colon polyp was identified on colonoscopy. Inclusion criteria included: age, gender, presence of colon polyps, polyp/lesion histology, and location. Exclusion criteria included: age greater than fifty at time of colonoscopy, absence of polyps, negative pathology (normal mucosa), undetermined location, absence of a pathology report, pathologic finding other than the four used for this study, and duplicate patient record. In the event that more than one tissue diagnosis was identified, only the highest grade lesion was included. Statistical analysis was performed using a two-tailed Fisher’s exact test.

**Results:** A total of 736 (18.4%) patients (415 male, 321 female) were selected for inclusion in this study, of which 185 right-sided (104 male, 81 female) and 551 left-sided (311 male, 240 female) polyps were identified, 534 patients were excluded. Male patients were more likely to have a right-sided adenomatous, TVA, or adenocarcinoma findings (p = 0.0065). Fourteen percent of males and 11 percent of females had right-sided polyps. However, there was no significant difference observed between male and female patients in the frequency of right versus left-sided colon polyps in which hyperplastic polyp type was considered in the analysis. Seventy percent of tubulovillous adenomas and seventy-seven percent of adenocarcinoma findings were male.

**Conclusions:** In our review colon polyps were fairly common in patients under fifty years of age. Male patients were significantly more likely to have a right-sided neoplastic polyp finding than female patients. Although not statistically significant, tubulovillous adenomas as well as adenocarcinomas were identified more frequently in male patients.

### Summary of Results

<table>
<thead>
<tr>
<th>Histologic Finding</th>
<th>Right Colon</th>
<th>Left Colon</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperplastic Polyp</td>
<td>21 (2.9)</td>
<td>156 (21.2)</td>
</tr>
<tr>
<td>Adenomatous Polyp</td>
<td>71 (9.6)</td>
<td>127 (17.3)</td>
</tr>
<tr>
<td>TVA Polyp</td>
<td>11 (1.5)</td>
<td>22 (3.0)</td>
</tr>
<tr>
<td>Adenocarcinoma</td>
<td>1 (0.1)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Total</td>
<td>104 (14.1)</td>
<td>311 (42.3)</td>
</tr>
</tbody>
</table>

Number of persons (percent of total number patients)

### 1449

**Five-Year Risk of Colorectal Neoplasia among Persons with No Neoplasia on Baseline Screening Colonoscopy: Final Results**

*Thomas F. Imperiale, MD, James D.rogge, MD, Elizabeth A. Glowinski, R.N., Ching L. Cooper, Gregory N. Larkin, MD, David F. Ransohoff, MD,*

**Department of Medicine, Indiana University School of Medicine; Indianapolis Gastroenterology Research Foundation; Eli Lilly and Co. Inc., Indianapolis, IN and Department of Medicine, University of North Carolina, Chapel Hill, NC.**
Purpose: Few data support the recommended re-screening interval for persons with no colorectal neoplasia. Our objective was to measure the risk of colorectal neoplasia in persons whose baseline screening colonoscopy (CY) showed no neoplasia.

Methods: From an 11-year old corporate-sponsored program of screening CY, we identified persons with no adenomas on 1st-time screening between 9/95 and 6/00, who returned for a recommended 5-year re-screening exam. For this analysis, the distal bowel was defined as the descending colon, sigmoid colon and rectum. Each bowel segment was categorized according to the most advanced lesion present, classified as no polyps; hyperplastic polyt(s) (HP); tubular adenoma < 1 cm; advanced adenoma(s) (AA), defined as a tubular adenoma ≥ 1 cm, or a polyp with villous histology or high-grade dysplasia; or cancer.

Results: 2436 persons had no adenomas at baseline; 1256 (51.6%) returned for re-screening CY a mean of 5.34 ± 1.34 years later. Re-screened persons were younger than the 1180 non-re-screened persons (54.7 vs. 58.3 years; p < 0.001), but were comparable in gender profile (57% vs. 53% men). No cancers were found on re-screening (95% CI, 0–0.24%); 201 persons (16%; CI, 14–18%) had ≥ 1 adenoma: 34% distal only, 40% proximal only, and 27% proximal and distal. Adenomas were more common in persons with HPs vs. no polyps at baseline (47 of 199 [23.6%] vs. 154 of 1057 [14.6%]; RR = 1.62 (CI, 1.21–2.15) despite comparable mean age (57.2 vs. 56.6 years; p = 0.34). Fifteen persons (1.2%; CI, 0.67–1.96%) had AAs, with similar risk between persons with baseline HPs (2%) vs. those with no polyps (1%) (p = 0.25). Men were more likely to have any adenoma (20.1% vs. 10.7%; RR = 1.88; CI, 1.42–2.51) and an AA (1.7% vs. 0.55%; RR = 3.07; CI, 0.94–10.12). Among 388 women < age 60 at baseline, 1 (0.26%; CI, 0.01% to 1.43%) had an AA. Among 634 persons < age 55 at baseline, 7 (1.1%; CI, 0.45% to 2.26%) had an AA.

Conclusions: Among previously screened persons with no colorectal neoplasia, the 5-year risk of colorectal cancer is extremely low. The risk of an AA is also low, though higher in men than in women. It is likely that re-screening may safely be performed beyond 5 years.

1450

PillCam™ Colon in Comparison with Standard Colonoscopy in the Detection of Polyps – Results from the First Prospective Multi-Center Study

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Purpose: Colorectal cancer (CRC) is the second most deadly malignancy in Western societies and screening recommendations are commonplace, with colonoscopy as one of the preferred tools for primary screening. However, compliance rates are low and capacity of screening colonoscopy is short.

Methods: We performed a prospective cohort study to evaluate the sensitivity and specificity of CRC with and without oral contrast compared to conventional colonoscopy in a colorectal cancer screening population from 2002 to 2003. We then retrospectively collected all clinic visits, imaging and laboratory studies, and medical procedures that were generated as a direct result of extra-colonic findings in this screening population and estimated the costs using Medicare 2006 reimbursement allowances in the state of North Carolina.

Results: A total of 143 subjects were enrolled and underwent CTC followed by conventional colonoscopy. Data were available for 136 subjects and 134 (98%) had at least one extra-colonic finding on CT. Evaluation of extra-colonic findings was performed in 32 subjects (24%). These subjects underwent 73 imaging studies (37 CT, 16 US, 6 MRI, 13 plain films, 1 IVP), 30 laboratory studies, 44 clinic visits, and 6 medical procedures (2 EGDs, 2 cystoscopies, 1 bronchoscopy, and 1 laparoscopy) over a mean of 38 months following the CTC. The most common findings leading to further evaluation were lung nodules and indeterminate kidney lesions. No extra-colonic malignancies were found in this study. A total of $3141 was spent in evaluating extra-colonic findings, which is $231 per patient enrolled.

Conclusions: The cost of evaluating extra-colonic findings following a virtual colonoscopy may be much higher in actual practice than is suggested by prior studies. This will impact the cost-effectiveness of using virtual colonoscopy for asymptomatic colorectal cancer screening and underscores the importance of standardizing the reporting of extra-colonic findings to encourage proper follow up.

1452

Colorectal Cancer Trends in the Era of Screening

Eugene J. Yoon, MD, Mazen M. Jamal, MD, M.E.H.,* Gastroenterology, Long Beach VA Medical Center, Long Beach, CA and Gastroenterology, University of California, Irvine Medical Center, Orange, CA.

Purpose: Colorectal cancer is largely a preventable malignancy and the implementation of colorectal cancer screening has impacted the incidence of colorectal cancer in the United States. The aim of this study was to observe national trends in the incidence of colorectal cancer from 1988–2002.

Methods: The Nationwide Inpatient Sample (NIS) database was utilized to determine the age-adjusted incidence of colon cancer for every three year
interval from 1988 to 2002. Trends were also observed from the Surveillance Epidemiology and End Results (SEER) database over the same time period. Age-adjusted colonoscopy rates were calculated from the State Ambulatory Surgery Database (SASD) from 1997–2003. ICD-9-CM codes and CPT codes were used to extract the data.

**Results:** The NIS database contained 651243 patients who had a diagnosis of colon or rectal cancer from 1988 to 2002. The mean age of the patients was 70.24 ± 12.75 years old and was composed of 49.6% male and 50.4% females. The age-adjusted incidence rate for colon cancer declined from 42.81 per 100000 patient discharges in 1988–90 to 41.74 in 1991–93 and declined again to 38.03 in 1994–96. The rate then increased slightly to 38.86 in 1997–99 then declined again to 38.59 during the 2000–02 period. There was a progressive incline in the percentage of proximal colon cancers from the 1988–90 time period to the 1997–99 time period (17.75% to 20.57%).

There was then a significant decline from 20.57% during the 1997–99 period to 19.36% during the 2000–02 period (p = 0.03).

The SEER database revealed a similar trend in colorectal cancer incidence. In 1988–90 the age-adjusted incidence of colorectal cancer was 61.27 per 100000 population which declined to 58.07 in 1991–93 and then declined again to 54.80 in 1994–96. Then, there was an increase in 1997–99 to 56.07 and a subsequent decline to 52.77 in 2000–02. The age-adjusted colonoscopy rates from the SASD database showed a continual increase for each successive year from 1997–2003. The age-adjusted colonoscopy rate nearly doubled from 1997 to the year 2003.

**Conclusions:** The incidence of colorectal cancer has been declining from 1988 to 2002. The decline has occurred during the implementation of the fecal occult blood test, the flexible sigmoidoscopy, and more recently, the sigmoidoscopy as screening modalities. The percentage of proximal cancers has been observed to increase over time. The SEER database revealed a similar trend in colorectal cancer incidence.

**Purpose:** According to the guidelines of American Gastroenterology Association (2003) and American Cancer Society (2001), “first degree relatives of persons with an adenomatous polyp at age <60yrs should be advised to have screening colonoscopy starting age 40yrs or 10yrs younger than the index case.” Aims: to assess physician compliance with these recommendations.

**Methods:** During DDW-Los Angeles, 2006, we randomly asked physicians to participate in an anonymous survey to assess how often they advise early screening colonoscopy in relatives of patients age 50yrs found to have adenomas on screening. We collected data on practice type (teaching hospitals, academic/teaching), years performing colonoscopy (<5yrs, 5–15yrs, and >15yrs), geographic location, and method of patient notification of pathology.

**Results:** 214 physicians were surveyed (102: <5yrs, 52: 5–15yrs, and 60: >15yrs). Only 29.4% of participants reported “always or mostly” to advise the proband in that setting. Responses regarding practice type and years of experience are shown in the tables. Subanalysis based on location and pathology notification were not significant.

**Conclusions:** (1) Less than one third of gastroenterologists surveyed are in compliance with the AGA/ACS guidelines for early screening of first degree relatives when an adenoma is found in a 50yrs old person. (2) Compliance was poor in both subgroups, but private practice physicians performed better than those in academic/teaching settings. (3) Compliance was lowest amongst trainees and physicians who recently completed fellowship. (4) The impact of colon screening should not stop at the proband, but gastroenterologists should be aware of the need to extend the effect of screening to relatives and know the details of the guidelines.

### Responses by type of practice

<table>
<thead>
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<th></th>
<th>Teaching/academia</th>
<th>Private practice</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Always or mostly</td>
<td>25 (20.7%)</td>
<td>38 (40.8%)</td>
<td>63 (29.4%)</td>
</tr>
<tr>
<td>Occasionally</td>
<td>32 (26.4%)</td>
<td>26 (28.0%)</td>
<td>58 (27.1%)</td>
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<tr>
<td>Never</td>
<td>64 (52.9)</td>
<td>29 (31.2%)</td>
<td>93 (43.5%)</td>
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</table>

**P value 0.001**

### Responses by years of experience

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<th>&lt;5yrs</th>
<th>5–15yrs</th>
<th>&gt;15yrs</th>
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<td>23 (22.5%)</td>
<td>15 (28.8%)</td>
<td>25 (41.7%)</td>
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<tr>
<td>Occasionally</td>
<td>27 (26.5%)</td>
<td>20 (38.5%)</td>
<td>11 (18.3%)</td>
</tr>
<tr>
<td>Never</td>
<td>52 (51.0%)</td>
<td>17 (32.7%)</td>
<td>24 (40.0%)</td>
</tr>
</tbody>
</table>

**P value 0.019**

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**Abstracts S553**

### 1453

**Physician’s Compliance with Guidelines for Screening of First Degree Relatives of Patients Age 50 with Adenomatous Polyps**

Saud F. Jazrawi, MD; Joseph Quaglia, MD; Safaa R. Amer, PhD; Sury Anand, MD; Nicholas M. Gualtieri, MD∗; James G. Robilotti, MD.

**Department of Medicine – Gastroenterology, NY Medical College – St. Vincent Catholic Medical Ctr – Manhattan, NY; NY, NY; Department of Medicine – Gastroenterology, Brooklyn Hospital Center, Brooklyn, NY and NORC, University of Chicago, Chicago, IL.**

**Purpose:** To assess the prevalence of subtotal colectomy and hysterectomy and examine attitudes toward prophylactic surgery among patients with HNPCC.

**Methods:** Two hundred and seventy individuals who met clinical criteria for HNPCC completed questionnaires about personal and family history, cancer risk perception, and cancer prevention practices. Subjects were asked whether any of their physicians had discussed prophylactic surgery and whether they would consider having surgery to prevent cancer.

**Results:** Overall, 68% of subjects would be willing to consider prophylactic colectomy as an alternative to colonoscopic surveillance; however fewer than 1 in 5 said their physician had discussed this as an option for reducing their cancer risk. Among subjects with prior CRC only 32 of 115 (28%) reported that their physician had presented the option of colectomy; of these 25 (78%) had either a subtotal or total colectomy.

Among women at risk for HNPCC-associated endometrial cancer, 84% said they would consider prophylactic hysterectomy to reduce their cancer risk, but only 1 in 3 said their physician had discussed it as an option for cancer prevention. Only 17 of 112 (15%) women at risk for HNPCC-associated endometrial cancer reported having undergone a hysterectomy for cancer prevention.

**Conclusions:** Although most individuals with HNPCC are willing to consider surgery to reduce their risk of cancer, many physicians do not discuss this as an option for cancer prevention. Given the high risk for metachronous tumors in HNPCC patients with striking personal or family cancer history may benefit from referral for genetic evaluation and discussion of risks and benefits of prophylactic surgery.
Employer-Based Stool DNA (sDNA) Colorectal Cancer (CRC) Screening Leads to Identification of Early-Stage Disease

David M. Spratt, D.O.* Medical Administration, Crown Cork & Seal, Inc (USA), Philadelphia, PA.

Purpose: CRC is the leading cause of U.S. cancer deaths among non-smokers with 57,000 estimated lives lost in 2006, affecting men and women equally. Non-invasive CRC screening using sDNA addresses common causes of patient non-compliance including safety, convenience, and access. We investigated the effectiveness of sDNA screening in an employer health fair setting.

Methods: Manufacturing plant employees and their spouses were invited to on-site health fairs via a three-letter direct mail campaign and on-site recruitment. sDNA screening was offered to individuals who refused colonoscopy.

Results: 396 employees (age range 27–73, mean 53.1, median 52.8, 60% male) who declined colonoscopy completed sDNA screening over a fifteen month period, September 15, 2004 through December 27, 2005. Most employees had not previously been screened for CRC. Of 364 employees with results available for review, 2 employees had clinically significant findings. One employee (age 50) was found to have a very early localized colon cancer (Stage I) and the other (age 52) was found to have multiple (110) hyperplastic polyps. This cancer rate of 3/1000 is roughly in line with expectations with reported incidence rates for a cohort with this age distribution.

Conclusions: Our experience with sDNA screening in an employer health fair setting suggests that sDNA CRC screening is both acceptable to employees and can identify colorectal cancer at an early stage.

Is Hearing Loss an Extracolonic Manifestation of FAP?

Thomas A. Lutz, MD, Rocio Lopez, Carol A. Burke, MD*, Patrick Lynch, MD, Ernie Hawk, MD, Donna Griebel, MD, Robin Phillips, MD, Andrew Latchford, MD, Hassan Hennie, R.N.. Cardiovascular Medicine, Quantitative Health Sciences, Gastroenterology and Hepatology, Cleveland Clinic, Cleveland, OH; MD Anderson, Houston, TX; National Cancer Institute, MD and St. Mark’s, London.

Purpose: FAP is due to a mutation in the APC gene. It is a recent discovery that APC protein dysfunction results in abnormal cytoskeletal organization of the cochlea of Min mice heterozygous for APC when compared to wild type litter mates (Mogensen M, J Cell Bio 2002). The hearing of FAP patients has never been studied. We performed audiograms in FAP patients to determine their hearing thresholds and report the characteristics of hearing impairment in FAP.

Methods: Patients who denied hearing loss and were being screened for eligibility in an international, multicenter, polyp chemoprevention study (Cleveland, London, Houston) underwent air-conduction, pure-tone audiogram after a normal otoscopic exam. We compared the audiometric results of the patients to gender and age-adjusted hearing threshold normative values. The normative values represent hearing in which at least 95% of the population have equal or better hearing (Morrell C, et al. J Acoust Soc Am 1996). Patients who didn’t meet audiometric norms were considered to have hearing loss. Characteristics of patients who failed audiometry including age, gender and the associated audiometric abnormalities (lateliness and frequency (ies)) of hearing loss were analyzed.

Results: 140 patients (65 women/75 men); mean age of 37.1 yrs (range 18–64) were tested. 41 patients (29.3%) failed the audiogram. Hearing loss was not associated with gender but was more common in younger patients. It was detected in 53.8% of patients between ages 18–25, 34.8% ages 26–35, 17.6% ages 36–45, 14.3% age 46–55 and 22% ages 56–65, p < 0.001. Hearing loss was more often bilateral vs unilateral (56.1 vs 43.9, p = 0.43). Hearing loss of multiple frequencies was more common than single frequency (65.9% vs 34.2%, p = 0.042). Higher frequency hearing loss was more common than lower frequency (p = 0.05) hearing loss. A greater percentage of patients failed their audiogram at the Cleveland site (50%) versus Texas 27.4% or London 22.5% (p = 0.038).

Conclusions: These data are the first report of hearing loss in humans with FAP and support the abnormal cell biology found in the cochlea of Min mice. Subclinical hearing loss occurs commonly in FAP but the clinical implications are unknown. Audiometric screening of FAP patients should be considered and genotype phenotype correlations should be explored.

Gender but Not Race or BMI Is Predictor for Finding Colorectal Adenomas on First Time Colonoscopy

Jason T. McNeese, MD, William D. Johnson, PhD, Anil Minocha, MD,* Medicine, University of Mississippi Medical Center, Jackson, MS and Preventive Medicine, University of Mississippi Medical Center, Jackson, MS.

Purpose: Data suggests that there are gender and race based differences in prevelance of colorectal polyps and cancer. However, most of the data is uncontrolled or derived from studies done in populations where African Americans (AA) are only a small minority of the population. There is a paucity of data about the direct race and gender comparisons where the AA and Caucasian Americans (CA) are in roughly equal numbers.

Methods: Adults undergoing first time colonoscopy performed at our institution from July 1, 2004 to June 30, 2005 formed the database. We excluded patients less than 18 years old. We recorded age, race, gender, height, body weight, family history of colon cancer, alcohol or tobacco use, colonoscopic and pathologic findings. We calculated body mass index (BMI). Statistical analysis was performed using Student’s t-test, Chi-square test, and logistical regression as appropriate.

Results: 1175 subjects underwent colonoscopy during this period. Of them, 930 met inclusion criteria. Of these, 59.5% were AA and 40.5% were CA. 64.5% were females. The mean age was 53.7(±12.0) years, while the mean BMI was 29.9(±7.7), 29.5% used tobacco, 20.5% used alcohol, and 15.6% had a family history of colon cancer. We found no difference between AA (19.9%) versus CA (21.2%) with respect to the incidence of adenomatous polyps. Logistical regression revealed that age >50 yrs (23.3% v 14.14%) and male sex (24.6% v 18.2%) were independent risk factors (p < 0.05). Neither race nor gender had effect on number of adenomas. In addition, there was no impact of obesity, smoking or alcohol abuse.

Conclusions: Males but not African Americans have a higher risk for adenomas. Body mass index, tobacco or alcohol use have no impact.

Results of logistic regression

<table>
<thead>
<tr>
<th>Effect</th>
<th>Comparison</th>
<th>Odds ratio</th>
<th>95% C.I.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Race</td>
<td>Caucasian vs African Americans</td>
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<td>0.8–1.5</td>
</tr>
<tr>
<td>Age</td>
<td>50+ vs 18–49</td>
<td>1.8</td>
<td>1.3–2.7</td>
</tr>
<tr>
<td>Gender</td>
<td>Male vs Female</td>
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<td>1.1–2.0</td>
</tr>
<tr>
<td>BMI</td>
<td>25–29 vs &lt;25</td>
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<td>30–34 vs &lt;25</td>
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<td>0.7–1.7</td>
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<td>35+ vs &lt;25</td>
<td>0.8</td>
<td>0.5–1.2</td>
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<tr>
<td>Family History</td>
<td>Positive vs Negative</td>
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<td>0.7–1.7</td>
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<td>Alcohol/Tobacco</td>
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<td>0.4–1.6</td>
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<tr>
<td></td>
<td>Tobacco alone vs Neither</td>
<td>1.1</td>
<td>0.7–17</td>
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<td></td>
<td>Alcohol+Tobacco vs Neither</td>
<td>1.4</td>
<td>0.9–2.2</td>
</tr>
</tbody>
</table>

Prospective Analysis of Cecal Intubation Rates at a Community Hospital

Allen Blosser, MD, M.A.C.G.* Myron Shoham, MD, Leonard Fischer, MD, Carla Rowe, P.A.-C., Rebecca Johnston, P.A.-C. GE, Fair Oaks Hospital, Fairfax, VA.

Purpose: To prospectively review the rate of cecal intubation amongst gastroenterologists performing colonoscopies at a community hospital.
Methods: Using the Olympus Evis Exera video capture system all colonoscopy reports at Fair Oaks hospital for the calendar year 2005 were collected. During the month of June 2005, all colonoscopy reports with pictures were submitted for review. The submitting gastroenterologists were blinded as to the nature of the data being collected. The reports were then reviewed by the assembled panel. The panel assessed the pictures as to the documentation of cecal landmarks. The following criteria were used: 1) identification of appendiceal orifice; 2) identification of cecal strap ligaments; 3) identification of ICV; 4) identification of terminal ileum or right ileocolonic anastomosis. Photodocumentation of at least two of the above criteria were considered evidence of cecal intubation. The data was then correlated with the operative report. The correlation between the two data bases were then assigned a number 1–4. #1 means both op report and photodocumentation confirmed cecal intubation, #2 means photodocumentation was deficient to confirm cecal intubation despite op report, #3 photodocumentation and op report both failed to document cecal intubation, #4 perforation or complication.

Results: 490 op reports were reviewed for the month. 5429 were reviewed for the year 2005. Photodocumentation using the above criteria revealed cecal intubation in 477/490 (97.7%) colonoscopies (#1–477, #2–5, #3–8, #4–0) for the study month (range 90–100%). Reported cecal intubation via review of op reports was 482/490 (98.2%) for the same month. Cecal intubation rates for the year as reported in the op notes was 5304/5429 (97.7%) (range 90–99%). Four of the colonoscopies that failed to meet photodocumentation guidelines were attributed to one physician. No complications occurred during the month in review. Two (2) perforations occurred during the year (0.0004% or 1 per 2700 cases).

Conclusions: 1) Photodocumentation of cecal intubation correlates closely with op reports. 2) Cecal intubation rates at our community hospital are higher than reported guidelines (98% v. 90–95%). 3) Current data collection systems for endoscopic procedures are readily available and should routinely be reviewed.
Methods: Patients were enrolled from an extant pool referred for lower GI endoscopy. Fiberoptic bundles were integrated between the jaws of specialized biopsy forceps. The fiberoptic bundles were attached to a light source and spectrometer controlled by a laptop computer using custom ESS software. The integrated device was used whenever endoscopic tissue sampling was indicated according to current standards of care. The integrated device measures the elastic scattering spectra from tissue exposed to pulsed broadband white light from a xenon lamp. This modified forceps device was then able to biopsy the exact tissue measured by ESS. The tissue was then submitted for standard histopathological diagnosis as well as for an independent secondary review to confirm histology. The optical biopsies were then correlated with the physical biopsies. The spectra obtained were classified with support vector machines (SVMs) using features extracted by performing principle component analysis (PCAs).

Results: Preliminary results are reported from the first 14 patients. A total of 21 biopsies of colonic polyps (13 adenoma and 8 hyperplastic) were analyzed. Signal processing thus far has yielded a sensitivity of 84.62% and specificity of 75% for adenomatous vs hyperplastic polyps.

Conclusions: The spectrascopically guided forceps are able to co-register optical and physical biopsies. Preliminary analysis is optimistic for the device’s ability to accurately and reliably differentiate dysplastic from non-dysplastic polyps of the colorectum. The study is ongoing and more data is required to fully evaluate the device. Use of the device could help endoscopists target biopsies thus increasing the yield of tissue biopsy. If applied to current colon cancer screening recommendations, the device and system could decrease risks and costs of biopsy as well as save procedure time.

1462

Favorable Comparison of Virtual Colonoscopy with Conventional Colonoscopy in a Community-Hospital Setting

David M. Miller, MD, Patrick Godet, MD, Lawrence A. Stein, MD, Mathangi Ramani, MD,* Diagnostic Radiology, McGill University Health Centre, Montreal, QC, Canada; Gastroenterology, Centre Hospitalier de LaSalle, LaSalle, QC, Canada and Diagnostic Radiology, Centre Hospitalier de LaSalle, LaSalle, QC, Canada.

Purpose: Studies of CT colonography (virtual colonoscopy) for colorectal neoplasia screening have thus far focused on university hospital settings. The purpose of this ongoing study is to evaluate the accuracy of virtual colonoscopy compared to conventional optical colonoscopy in screening for colorectal neoplasia in average-risk, asymptomatic patients at a Canadian community hospital.

Methods: 41 asymptomatic patients underwent same-day virtual colonoscopy followed by conventional colonoscopy at a 100-bed community hospital in LaSalle, Quebec, Canada. All virtual colonoscopies were performed on a 4-detector CT scanner and immediately interpreted by a single radiologist using both 2D and 3D interpretation for polyp detection. Patients were then transferred to the endoscopy suite for conventional colonoscopy. Colonoscopy was performed segmentally, with the gastroenterologist initially unaware of the virtual colonoscopy findings for the corresponding segment. At the completion of the endoscopic evaluation of a particular segment, the endoscopist was unblinded to the CT colonography result and, in cases of a discrepancy between the initial endoscopic interpretation and the virtual colonoscopy, repeat endoscopy of the colonic segment was performed. The final, unblinded optical colonoscopy data was then used as the reference standard.

Results: For polyps greater than or equal to 5mm (n = 7), virtual colonoscopy had a sensitivity of 86%, a specificity of 75% and a negative predictive value (NPV) of 98%. For polyps greater than or equal to 6mm (n = 4), the sensitivity was 100% with a specificity of 67% and NPV of 100%.

Conclusions: Preliminary data from this ongoing study suggests that CT colonoscopy compares favorably with conventional colonoscopy as an accurate screening method for clinically relevant colorectal lesions in a Canadian community hospital setting.

1463

Polyp Detection Rate during Colonoscopy Is Correlated with Quality of Bowel Preparation

Lawrence B. Cohen, MD,* David Kastenberg, MD, Sandra R. Lotte, PharmD, William P. Forbes, PharmD, Edwin Carter, B.S., Mt Sinai School of Med, NY, NY, Thomas Jefferson University, Phila, PA; Salix Pharmaceuticals, Morrisville, NC and Kentucky Clinical Research, Lexington, KY.

Purpose: The rate of polyp detection during colonoscopy may be impacted by the skill of the endoscopist, scope withdrawal time and adequacy of bowel preparation. To better understand these issues, we conducted an analysis of pts enrolled in a study designed to compare the efficacy and safety of 2 bowel preparations.

Methods: In a post-hoc analysis, we evaluated the No. of colon polyps detected during a randomized, investigator-blinded, multicenter study comparing a new 32-tablet sodium phosphate (NaP) prep (OSMOPREP) with 2L PEG + 4 bisacodyl (BIS) tabs (HALFYTELY). NaP tabs were taken as a split dose on the evening before (n = 20) and 3–5 hrs prior to (n = 12) colonoscopy. PEG+BIS was taken at noon on the day prior to colonoscopy (BIS tabs) and then ~6 hrs later (PEG). Overall colon cleansing (OCC) was assessed by the investigator using a 4-point scale (1 = excellent 2 = good 3 = fair 4 = inadequate). Endoscopic interventions were classified as biopsy, lesion catherization, polypectomy or polyp ablation. The total No. of polypctomies plus polyp ablations was used as a surrogate indicator for colon polyps. A Cochran-Mantel-Haenszel Row Mean Score Test with modified rridit scores was performed.

Results: 205 pts taking NaP tabs and 206 pts taking PEG+BIS underwent colonoscopy. No significant differences in pt demographics (age, gender, race, wt) were observed between groups. Mean OCC score was significantly better with NaP tabs vs 2L PEG+BIS (1.5 ± 0.74 vs 1.8 ± 0.76 p < 0.0001). 124 and 118 pts in the NaP tab and PEG+BIS groups had 281 and 248 interventions, respectively. Adjusting for grading of OCC, a significant correlation was observed between treatment and No. of polyps (p = 0.041). Additionally there was an association between quality of cleansing and frequency of intervention among pts using NaP tab prep (p = 0.035); a significantly higher proportion of pts taking NaP vs PEG+BIS had 1 or more intervention when colon cleansing was rated excellent (60% vs 36% p = 0.0002). NaP tabs were associated with a shorter adjusted procedure time (14.2 ± 5.77 vs 15.9 ± 6.16 min p = 0.0124).

Conclusions: The new NaP tablet prep was associated with an increased rate of polyp detection compared with 2L PEG+BIS. As anticipated, polyp detection increases as the grade of colon cleansing improves. These findings reinforce the clinical importance of achieving excellent colon cleansing results.

1464

Racial Disparity, Location and Stage at Diagnosis of Colorectal Cancer in Patients above and below 50 Years of Age

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Purpose: Incidence rates of Colorectal Cancer (CRC) are decreasing in the United States, possibly due to preventive screening. These programs target older populations and may not apply to younger patients. Our aim is to analyze racial disparity, stage at diagnosis, and location of CRC among patients below age 50 years compared to patients above age 50 years.

Methods: Patients with CRC were identified retrospectively from tumor registries at St Joseph’s Regional Medical Center, NJ and California Pacific Medical Center, CA., for the period of 1992 to 2004. Statistical analysis was done by Chi-square test.

Results: Overall number of patients diagnosed with CRC was 2723 [1963(72.1%) white, 287(10.5%) black, 473(17.4%) others]. We identified
279 (10.2%) less than 50 years of age. We found statistically significant increase in CRC prevalence in blacks compared to white below age 50 years (table 1). Blacks have approximately two (2.12) times greater odds of being diagnosed with CRC than whites below age 50 years (95% Confidence Interval (CI) 1.5–3.03). Regarding location of CRC, patients below 50 years have approximately two (1.75) times greater odds of having their lesion in the rectosigmoid than in the remaining colon (95% CI 1.35–2.27).(Table2) Regarding staging of CRC, patients below age 50 years have almost two times (1.85) greater odds of having advanced stage at the diagnosis as compared to above 50 (95% CI 1.43–1.85). (Table 2)

Conclusions: In this study there is a significant increase in the diagnoses of CRC in black patients below the age of 50 years. Our study reinforced the new CRC screening recommendation by ACG for blacks to begin screening at the age of 45 years rather than at age 50 years. Also, CRC in younger populations is diagnosed at later stages and is frequently in distal locations.

Racial disparity in the diagnosis of CRC in individuals < 50yrs

<table>
<thead>
<tr>
<th>Race</th>
<th>&lt;50</th>
<th>≥50</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>175</td>
<td>1788</td>
<td>1963</td>
</tr>
<tr>
<td>Black</td>
<td>49</td>
<td>238</td>
<td>287</td>
</tr>
<tr>
<td>Total</td>
<td>224</td>
<td>2026</td>
<td></td>
</tr>
</tbody>
</table>

two tailed p value <0.0001

Distal site distribution and Advanced stage at the diagnosis of CRC in individuals < 50yrs

<table>
<thead>
<tr>
<th>Location</th>
<th>&lt;50</th>
<th>≥50</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remaining Colon</td>
<td>121</td>
<td>1405</td>
<td>1526</td>
</tr>
<tr>
<td>Rectosigmoid</td>
<td>150</td>
<td>996</td>
<td>1146</td>
</tr>
<tr>
<td>Stage</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-1.2</td>
<td>116</td>
<td>1334</td>
<td>1450</td>
</tr>
<tr>
<td>3,4</td>
<td>123</td>
<td>746</td>
<td>869</td>
</tr>
<tr>
<td>Total</td>
<td>239</td>
<td>2080</td>
<td></td>
</tr>
</tbody>
</table>

two tailed p value <0.001

1466

Marked Racial and Ethnic Differences in Patient Satisfaction with and Preferences for CT Colonography and Optical Colonoscopy
Roshini C. Rajapaksa, MD, Michael Macari, MD, Edmund J. Bini, MD, M.P.H.,* Gastroenterology, NYU School of Medicine, New York, NY and Radiology, NYU School of Medicine, New York, NY.

Purpose: Previous studies have shown that there are racial/ethnic differences in the proportion of people that undergo colorectal cancer (CRC) screening, the types of screening tests utilized, and in the clinical presentation and long-term outcome of CRC. Although CT colonography (CTC) is being promoted as a less invasive and better-tolerated alternative to optical colonoscopy (OC), it is not known whether CTC will increase acceptance of CRC screening in minorities. Therefore, the aims of this study were to evaluate racial/ethnic differences in patient satisfaction with and preferences for CTC and OC.

Methods: Patients undergoing OC for clinically indicated reasons had CTC followed by same-day OC. After the sedation from the OC had worn off, a questionnaire was administered to assess patient satisfaction, pain, discomfort, bloating, embarrassment, and anxiety using a 10-point scale (1 = least and 10 = greatest), and patient preferences.

Results: A total of 272 patients (mean age 62.7 ± 9.4 years) were enrolled, including 134 whites, 71 blacks, 53 Hispanics, and 14 who self-identified their race as other. Although the proportion of subjects who preferred CTC over OC was not significantly different (52.9% vs. 47.1%, p = 0.36), we found that racial/ethnic minorities were significantly less likely than whites to prefer CTC over OC (whites: 65.7%, blacks: 45.1%, Hispanics: 35.8%, and other: 35.7%, p < 0.001). Racial/ethnic minorities were less satisfied and tolerated CTC less well than whites (see table). In addition, racial/ethnic minorities were significantly less willing to undergo CTC again in the future (whites: 95.5%, blacks: 80.3%, Hispanics: 84.9%, and other: 85.7%, p = 0.006).

Conclusions: Compared to white patients, OC is better tolerated and is preferred over CTC for evaluation of the colon among racial/ethnic minorities. Although CTC is less invasive than OC, our findings suggest that CTC is unlikely to overcome racial/ethnic disparities in CRC screening.

Satisfaction with CTC

<table>
<thead>
<tr>
<th>White</th>
<th>Black</th>
<th>Hispanic</th>
<th>Other</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Satisfaction</td>
<td>8.4 ± 1.7</td>
<td>7.9 ± 1.7</td>
<td>7.4 ± 1.8</td>
<td>7.5 ± 2.1</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>2.9 ± 2.1</td>
<td>3.4 ± 2.2</td>
<td>4.8 ± 2.6</td>
<td>3.4 ± 2.3</td>
</tr>
<tr>
<td>Discomfort</td>
<td>3.8 ± 2.2</td>
<td>4.1 ± 2.4</td>
<td>4.7 ± 2.7</td>
<td>4.8 ± 2.7</td>
</tr>
<tr>
<td>Bloating</td>
<td>5.3 ± 2.6</td>
<td>5.3 ± 2.8</td>
<td>6.0 ± 3.0</td>
<td>5.9 ± 2.9</td>
</tr>
<tr>
<td>Embarrassment</td>
<td>1.9 ± 1.4</td>
<td>2.6 ± 2.3</td>
<td>2.8 ± 2.3</td>
<td>1.8 ± 2.4</td>
</tr>
<tr>
<td>Anxiety</td>
<td>2.8 ± 2.2</td>
<td>3.9 ± 3.3</td>
<td>3.9 ± 3.2</td>
<td>4.3 ± 3.5</td>
</tr>
</tbody>
</table>
Diagnostic Yield of a Repeat Colonoscopy with Inadequate Colonic Cleansing on the Index Examination

Anu K. Mathew, MD, Sorin Petre, MD, Nooman Gilani, MD,* GI, Carl T. Hayden V AMC, Phoenix, AZ.

Purpose: The reported miss rate for small or advanced neoplasias ranges from 6–27%. There are no set guidelines for the timing of a repeat colonoscopy in the setting of an inadequate initial examination.

Aim: To evaluate the added yield of performing a good quality, repeat colonoscopy in finding the neoplasia within a year of suboptimal index colonoscopy.

Methods: Retrospective search in our endoscopy database between Jan, 04 and Nov, 05 identified 308 procedures who had a complete repeat test with a desired prep. Exam was complete if fecum was reached and incomplete otherwise. Prep results were: Poor (P) if large amount of feces present; Fair adequate (Fa) if enough residue to prevent a completely reliable exam; Fair compromised (Fc) if enough residue/feces to obscure a good view. Findings were: No change (NC), if no new neoplasia seen; Major change (MaC) if one adenoma of 10 mm or more, three or more adenomas < 10 mm, villous change, HGD or Ca seen and; Minor change (MiC), any adenomas except as above.

Results: The mean interval was 290 days. Major change found in 14.6%, Minor change in 23.05% and No change in 62.33% cases (p = 0.18, CI 95%, 10.9–19.1%).

Initial 183 exams were complete and 125 incomplete.

<table>
<thead>
<tr>
<th></th>
<th>Complete 183</th>
<th>Incomplete 125</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(59.41%)</td>
<td>(40.58%)</td>
<td></td>
</tr>
<tr>
<td>MaC</td>
<td>30/308 (9.74%)</td>
<td>15/308 (4.87%)</td>
<td>45/308 (14.61%)</td>
</tr>
<tr>
<td>MiC</td>
<td>36/308 (11.68%)</td>
<td>35/308 (11.36%)</td>
<td>71/308 (23.05%)</td>
</tr>
<tr>
<td>NC</td>
<td>117/308 (37.98%)</td>
<td>75/308 (24.35%)</td>
<td>192/308 (62.33%)</td>
</tr>
</tbody>
</table>

Of the complete gp, the findings are as below.

<table>
<thead>
<tr>
<th></th>
<th>Fa 70 (38.25%)</th>
<th>P 73 (39.89%)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>MaC</td>
<td>14 (7.65%)</td>
<td>6 (3.27%)</td>
<td>20 (10.56%)</td>
</tr>
<tr>
<td>MiC</td>
<td>16 (8.74%)</td>
<td>6 (3.27%)</td>
<td>22 (11.06%)</td>
</tr>
<tr>
<td>NC</td>
<td>40 (21.85%)</td>
<td>28 (15.30%)</td>
<td>68 (36.68%)</td>
</tr>
</tbody>
</table>

Although there was a trend towards more MiC in the incomplete gp with “P” prep, overall was not statistically sig in terms of the prep quality/rate of completion. 56 exams were for average risk screening (complete, 63.79%; incomp, 36.84%) MaC seen in 7.01%, MiC 22.80% and NC in 70.17%. All 5 cancers (2 rectal, 1 sig,1 trans,1 asc.) identified on the initial exam with a “P” prep.

Conclusions: In our study the likelihood of finding an advanced neoplasia within a year of suboptimal index exam is low. There seems to be a high probability of finding a cancer even with inadequate bowel cleansing. It is suggested, when possible, to complete the colonoscopy despite the suboptimal prep quality. In low risk groups, if prep is suboptimal, repeat colonoscopy beyond a year should be considered.

Colon Cancer Chemoprevention by Polyethylene Glycol Involves Epidermal Growth Factor Receptor (EGFR) Lysosomal Degradation

Mehal Pema, D.O., Ramesh Wali, PhD,* Hemant Roy, MD, Dhananjay Kunte, PhD, Jennifer Koetser, B.S. Department of Gastroenterology, Evanston Northwestern Healthcare, Evanston, IL.

Purpose: Colorectal Cancer (CRC) is one of the leading causes of cancer-related deaths in the USA, thus emphasizing the need for effective chemoprevention. Chemopreventive agents such as non-steroidal anti-inflammatory drugs (NSAIDS) have shown promise in clinical trials; however their cardiac and GI associated side-effects have prevented their population-wide use. This has put an onus on identifying novel agents that are safer and efficacious. Epidemiological and pre-clinical studies have validated the efficacy and safety profile of polyethylene glycol (PEG) in preventing CRC (Corpet & Pierre CEBP 2003). Our group has shown that PEG suppresses epithelial signaling (Cancer Letters, 2004) through inhibition of small/b-catenin (MCT, in press). Given the involvement of epidermal growth factor receptor (EGFR) on snail regulation and its importance in colon carcinogenesis (over expressed in > 80% of cancers) we took a candidate focus on EGFR. Furthermore, inhibition of EGFR has been shown to significantly reduce tumorigenesis (Nat Med 2000) and colonic hyperproliferation. We recently showed that PEG chemoprevention is possibly mediated by EGFR down regulation (AEG 2005). In this investigation we studied the mechanisms of PEG induced EGFR down regulation.

Methods: Fisher 344 rats (20) were treated with two weekly doses of azoxymethane (AOM) 15 mg/kg. Seven weeks post treatment (pre-malignant time-point), animals were randomized to receive daily doses of PEG-3530 (10%) or vehicle for one week and then sacrificed. Colonos were isolated and subjected to immunostaining (IHC) and epithelial EGFR expression was analyzed by western blot analysis. To study the mechanism of EGFR down regulation HT-29 colon cancer cells were treated with PEG-3530 and the lysosomal inhibitor bafilomycin.

Results: In both, AOM-treated rats and HT-29 cells treated with PEG for 24 hours, PEG decreased proliferation (45% and 52% p < 0.001, respectively) and caused reduction in EGFR expression (60% and 80% p < 0.001, respectively). Pre-treatment with bafilomycin blunted the down regulation of EGFR induced by PEG in HT-29 cells by 90%.

Conclusions: We demonstrate that short term treatment with PEG resulted in significant down regulation in EGFR by lysosomal degradation, thus suggesting that EGFR may be an important target in PEG mediated suppression of CRC. Future studies will be designed to identify PEG regimens that maximize its chemopreventive effect via EGFR down regulation.

An Analysis of the Prevalence of Diverticulosis in Association with Colon Adenocarcinoma

Amol S. Rangnekar, MD, Lawrence J. Brandt, MD, Aaron Z. Tokayer, MD.* Medicine, Division of Gastroenterology, Montefiore Medical Center, Bronx, NY.

Purpose: Diverticulosis and adenocarcinoma are both common colonial disorders. At colonoscopy, diverticulosis potentially may obscure small lesions which, if undetected, could develop into cancer. The aim of this study was to determine the prevalence of diverticulosis in colon segments affected by carcinoma, and to offer insight into considerations regarding screening colonoscopies in people with diverticulosis.

Methods: Patients with colon adenocarcinoma who underwent colon resection at our institution between 2004–2005 were identified. Pathology reports were evaluated for the presence of diverticulosis within the resected colon segment containing the neoplasm. For comparison, 600 consecutive colonoscopy reports from a single endoscopist at the same institution were reviewed to determine the prevalence and location of diverticulosis noted during routine colonoscopy. Cases in which masses were found or those with incomplete evaluations were excluded, leaving 589 colonoscopies for control comparisons.

Results: 88 resection specimens of colon adenocarcinoma (patient mean age: 64 yrs) were identified. 9 (10%) of which exhibited diverticulosis. Of these 88 resected cancers, 38 involved the rectosigmoid, 15 involved the left colon, and 35 involved the right colon. In a subset analysis, diverticulosis was identified in 13% (5/38) of the specimens with rectosigmoid cancer, 20% (3/15) of those with left colon cancer, and 3% (1/35) of cases with
right colon cancer. In comparison, diverticulosis was noted in 308 (52%) of 589 subjects (mean age: 61 yrs) who underwent routine colonoscopic examinations. Of these 589 routine colonoscopies, diverticulosis was located in the sigmoid in 252 patients (42%), left colon in 188 (31%), and right colon in 103 (17%). Thus, the prevalence of diverticulosis in association with colon cancer compared with diverticulosis noted on routine colonoscopies was 13% vs. 42% in the sigmoid colon (p = 0.001), 20% vs. 31% in the left colon (p = 1.000), and 3% vs. 17% in the right colon (p = 0.025).

**Conclusions:** The frequency of diverticulosis in areas of cancer in the sigmoid and right colon was significantly lower than expected when compared with the frequency of diverticulosis in these areas found on routine colonoscopy. A similar trend, which did not reach statistical significance, was observed for the left colon. The lower prevalence of diverticulosis in areas of adenocarcinoma suggests that diverticulosis does not obscure the colonoscopic identification of pre-cancerous lesions.

### 1470

**Capsule Colonoscopy—An Interim Report of a Pilot 3 Arm, Blinded Trial of Capsule Colonoscopy, Virtual Colonoscopy and Colonoscopy**

**Blair Lewis, MD,∗ Douglas Res, David Leiberman. Division of Gastroenterology, Mount Sinai School of Medicine, New York, NY; Division of Gastroenterology, Indiana University School of Medicine, Indianapolis, IN and Division of Gastroenterology, Oregon Health and Science University, Portland, OR.**

**Purpose:** Colon capsule endoscopy (CCE) is a new endoscopic capsule for visualization of the colon. The capsule is 31 × 11 mm. It has two imagers and obtains 4 frames per second. It is not a FDA approved device. A blinded trial is being performed to assess the efficacy of this technology in screening patients at risk for colon polyps and cancer.

**Methods:** At risk volunteers were recruited. Study entry required age over 50 and not having colonoscopy within 3 years or having a family history of colon cancer or the presence of symptoms suspicious for cancer. Volunteers were paid and signed IRB approved consent forms. Patients initially underwent CCE and within 3 weeks took a second preparation and underwent virtual (VC) and standard colonoscopy (SC) on the same day. The colonoscopist was blinded to the findings of the previous tests. At SC, results of the two previous tests were serially unblinded. Results were reviewed. Significant findings were defined as any polyp ≥6mm in size or 3 or more polyps of any size.

**Results:** 25 patients 14 M, 11 F, average 53 (40–64) have completed all three arms of the trial to date. All patients that entered completed all three phases. 22/25 capsules exited the rectum during the 10 hour acquisition time. The average time of expulsion was 4:00. The other three passed in less than 25 hours. The colon was without polyps in 6 CCE, 14 VC, 10 SC exams. 11/25 (44%) had significant findings confirmed at either blinded or unblinded SC. Of these, CCE identified 7/11, VC identified 6/11 and blinded SC identified 9 of the 11 significant findings.

**Conclusions:** Colon capsule endoscopy appears to be a promising new technology for screening the colon for polyps in patients at risk for colorectal cancer.

### 1471

**Colorectal Cancer Screening in Mexico: The First One Hundred Patients**

Aldo A. Garza, MD,∗ Cynthia A. Becerra, MD, José A. González-González, MD, Aline Ghaleb, MD, Wendy K. Ayala, MD, Héctor J Maldonado-Garza, MD, Juan P. Flores-Gutiérrez, MD Department of Medicine, Gastroenterology Division, School of Medicine/University Hospital. Universidad Autónoma de Nuevo León, Monterrey, Nuevo León, Mexico and Department of Pathology, School of Medicine/University Hospital. Universidad Autónoma de Nuevo León, Monterrey, Nuevo León, Mexico.

**Purpose:** Although colorectal cancer (CRC) screening guidelines are well established in the U.S, most Latin American countries including Mexico do not have such programs due to limited resources and lack of evidence supporting its cost-effectiveness. We report the initial results of screening colonoscopy in asymptomatic individuals at risk for CRC in Monterrey, Mexico.

**Methods:** One hundred asymptomatic patients over fifty years of age with or without family history of CRC were recruited for colonoscopy following current CRC screening guidelines in the U.S. Phospho-Soda bowel preparation and IV sedation were used for the procedure in all patients. Colonoscopy was performed by three hospital staff, AGC/ASGE member gastroenterologists.

**Results:** Colonoscopy was performed successfully in 98 patients. The mean age was 60.4 years (range 50–81), 34 men and 66 women. 70 patients were from Northern Mexico, 28 from Southern states, and 2 foreign who had lived in this country for over 20 years. 21% patients had a positive family history of CRC or colonic polyps. Two patients had carcinoma on colonoscopy: one cecal tumor and one arising from a large polyp and cured by polypectomy (Haggitt stage 1). 54 patients (55%) had polyps removed at colonoscopy. Of all patients in the study, 29 had at least one polyp containing adenomatous tissue, 3 had hyperplastic polyps only, 20 had polyps with non-neoplastic changes (focal inflammation or normal tissue), one had a small carcinoma tumor, and one more had an angiomatous lesion. Most of the polyps (83.3%) detected were <5 mm; 8 patients (14.8%) had polyps 6-15 mm and one had a polyp >2 cm which contained adenocarcinoma. 14 patients (25.9%) had a single adenoma. Only one non-malignant adenoma had high-grade dysplasia. In 17 of the 31 patients (54.8%) with neoplastic lesions, these were located proximal to the splenic flexure without distal polyps. There were no complications associated to colonoscopy.

**Conclusions:** The high incidence of lesions associated with CRC in asymptomatic individuals found at colonoscopy in the initial results of our program supports the need for further screening research studies in Mexico, and should encourage studies of this nature in other Latin American countries.

### 1472

**Adherence to Colonoscopy among Veterans**

Mubhkar Alsaadi, MD, Shaat Yasser, MD, M.P.H., Anne Le, MD,∗ Surgery, Baylor College of Medicine, Houston, TX; Gastroenterology, Baylor College of Medicine, Houston, TX and Health Services Research, Michael E. DeBakey Veterans Affairs Medical Center, Houston, TX.

**Purpose:** Non-adherence to colonoscopy contributes to ineffective resource utilization, increased cost, and delays in diagnosis. Reported rates of non-attendance for colonoscopy are 14%–22%. The objectives of this study were to determine the adherence rate and identify factors that are associated with colonoscopy attendance in a VA hospital.

**Methods:** A prospective study was conducted of patients scheduled for colonoscopy over a two month period. Hospital protocol requires that patients are given a pre-procedure clinic appointment prior to scheduling colonoscopy. Patients who attended both appointments were considered adherent. Charts were reviewed for referral source, colonoscopy indication, and receipt of a reminder call. A questionnaire surveying social and demographic characteristics, knowledge, beliefs, and attitudes was administered during the pre-procedure clinic appointment to adherent patients and by telephone to non-adherent patients. Comparisons and associations with adherence were examined with logistic regression.

**Results:** Of 154 patients referred, 45 (29%) failed to attend colonoscopy. Eleven (9%) patients who attended the pre-procedure clinic failed to attend colonoscopy. Of non-adherent patients, 53% successfully contacted by telephone completed the questionnaire. Non-adherent patients who did or did not complete the questionnaire were comparable. Non-adherent patients were younger than adherent patients (59 ± 1 vs. 64 ± 1, p < 0.01). Adherent patients were more likely to be retired (OR 4.5, CI 1.3–15.4, p < 0.05), to have received a reminder call (OR 1.85, CI 1.46–1.95, p < 0.001), to have reported information as inadequate (OR 1.7, CI 1.1–1.9, p < 0.05), to have concerns about the procedure, especially pain (OR 1.7, CI 1.2–1.9, p < 0.05), and to be influenced by family (1.7, CI 1.3–1.9, p < 0.05) and acquaintances (1.7, CI 1.2–1.9, p < 0.05). Reasons reported for failing to attend appointments were lack of time (21%), lack of transportation (16%), and lack of awareness (16%) or memory (8%).
Conclusions: Non-adherence to scheduled colonoscopy is higher among veterans than other patients. Younger patients who work have higher risk for and should be targeted for interventions. Interventions that serve to provide more information, involve patients’ family and friends, reduce transportation barriers, and effectively remind patients of appointments may increase adherence for colonoscopy among veteran patients.

1473
A Retrospective Study of Colorectal Cancer in a Hispanic Population
Theodore M. Perlman, MD, Kaleem M. Rizvon, MD, Omer K. Masood, MD, Steven S. Yang, MD, Paul J. Mustacchia, MD.* Gastroenterology, Nassau University Medical Center, East Meadow, NY.

Purpose: To determine if there are characteristics of colorectal cancer unique to the Hispanic population.

Methods: Data from our tumor board registry was retrospectively reviewed. From 1989 through 2004, 454 cases of colorectal cancer were identified. Of those 454 cases, 53 patients were of Hispanic origin (predominantly from South and Central America). The parameters that we studied included: age, sex, distribution of the tumor, and the cumulative survival rate.

Results: Out of the 454 cases of colorectal cancer, 53 were of Hispanic origin (11.4%). The mean age at diagnosis for non-Hispanics was 64 years, versus 55 years for Hispanics. There were no differences noted related to gender. Non-Hispanics had 241 male and 211 female cases with colorectal cancer. Hispanics also had an almost 1:1 gender distribution, with 26 males and 27 females diagnosed with colorectal cancer. No differences were noted in the distribution of the tumors when compared to the general population; left sided tumors represented approximately 60% of the cases and right sided tumors 40%. The cumulative survival rate for the Hispanic and non-Hispanic populations were similar at one and five years.

Conclusions: Our study suggests that Hispanics may be at risk for colorectal cancer at an age earlier than the general population. Despite this difference in natural history, the survival rate appears to be the same as the general population.

1474
The Prevalence of Advanced Colonic Neoplasia among Women Aged 50–59 yr Undergoing Average-Risk Screening Colonoscopy
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Purpose: Advanced neoplastic lesions in colon are considered more clinically relevant lesions as they have a higher likelihood of progressing to colorectal cancer compared to smaller or hyperplastic lesions. Among the persons who are above 50 years of age, women in 50–59 years age group are reported to have the lowest prevalence of advanced neoplasia. The aim of this study was to determine the prevalence of advanced neoplasia in asymptomatic, average-risk women in 50–59 year age group.

Methods: This is a retrospective cohort study of consecutive asymptomatic women aged 50–59 yr, who underwent average-risk screening colonoscopy. Women with evidence of gastrointestinal bleeding, anemia or previous history of adenomatous polyps and family history of colon cancer were excluded. Colonoscopy and pathology reports were reviewed to obtain data regarding the number, size and histology of the polyps. Advanced neoplastic lesions were defined as tubular adenoma measuring 1 cm or larger or any polyp with villous histologic characteristics, high-grade dysplasia, or cancer. The diameter of the polyp was determined based on both visual estimate per the endoscopy report and gross specimen size per pathology report. If there is discrepancy between these two reports regarding the size of a polyp, smaller size was chosen to avoid overestimation of the size. The prevalence of histopathological findings was determined by classification of patients according to their most advanced lesion.

Results: A total of 1116 persons underwent average-risk screening colonoscopy during the 13-month study period (May 2005 to May 2006). Among them, 498 (45%) were women, and 56% of them (280 of 498) were between 50 and 59 years of age. Overall prevalence of colorectal neoplasia was 25% (70 of 280 women) in the 50–59 age-group. Non-advanced adenomatous polyps were found in 56 women (20%) and advanced neoplasia was found in 14 women (5%).

Conclusions: 1) The point prevalence of advanced neoplasia among women aged 50–59 yr in our cohort is higher than previously reported and is similar to that of men in the same age group from other studies. 2) The overall prevalence of advanced neoplasia in women in 50–59yr age group is still comparatively low. 3) Risk stratification to identify this sub-group of persons at risk will lead to optimal colonoscopy resource utilization.

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Male Versus Female Gastroenterologist for Colonoscopy: The Mexican Preference
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Purpose: Gender issues in clinical medical practice are currently a growing topic in the field of gastroenterology. The preference for a male or female gastroenterologist by patients is a subject of particular interest, especially in populations undergoing colorectal cancer screening with colonoscopy. We describe our findings with regards to these issues in a population undergoing CRC screening with colonoscopy in a pilot study at our institution in Monterrey, Mexico.

Methods: One hundred patients 50 years or older undergoing colonoscopy for CRC screening were included in the study. Prior to the day of colonoscopy during a scheduled appointment all patients were individually interviewed by a female physician and a questionnaire was filled. Extensive information was obtained, including age, gender, medical and family history, among other data. A section of the questionnaire included patient’s preferences for a male versus a female gastroenterologist to perform his/her colonoscopy. Procedures were performed by either one of two male or one female staff gastroenterologists, all ACG/ASGE members, using IV conscious sedation. Information with regards to patient satisfaction after colonoscopy was obtained.

Results: Of the population included in the study, 66 were female and 34 male. Of the male patients, 85.3% had no preference for a male or a female gastroenterologist, but 14.7% did not want the procedure to be performed by a female physician. Of the 66 women in the study, 69.7% had no gender preference, 25.7% would prefer a female doctor if given the option, and 4.5% would only accept colonoscopy if performed by a female physician. All patients were granted their gender preference for a gastroenterologist to perform the procedure. Satisfaction with medical care, tolerance and outcome of colonoscopy was reported good to excellent by all patients.

Conclusions: Our results suggest that gender preferences when choosing a gastroenterologist to undergo colonoscopy by Mexican patients are present in a substantial percentage of our population, with a same-sex colonoscopy preference as the most frequent request. Women seem to have higher motivation to enter CRC screening programs. These observations may affect clinical practice when CRC screening programs are implemented in this country, emphasizing the potential need for more female gastroenterologists.

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Distribution of Large Colon Polyps and Cancer at First Colonoscopy. Is There Still a Place for Flexible Sigmoidoscopy?
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Purpose: Data has been previously collected on 2500 patients with colon polyps and cancer, but not from patients without polyps. There was a need to better define for the community the outcome of both screening colonoscopy and colonoscopy that was done for signs and symptoms.

Methods: Patient demographic, historical information and colonoscopic outcome information was collected on 1559 consecutive patients who
Conclusions: a significant increased incidence of large polyps at 14% and cancer at 7% with a history of either bleeding, occult blood positive stools or anemia had approximately 1.5 times that found in screening only patients. The 457 Patients a positive family history the frequency of polyps and cancer were approx- in 3.7% and cancer identified in 4 (0.44%). Of 207 patients screened for have an overall incidence of polyps of 20.9% with large polyps occurring in contrast to 233 patients 80 years and older in whom there were 13 cancers of which 8 were proximal in the colon, associated with a similar increased number of large polyps of which more than 50% were in the proximal colon. The data was further analyzed dividing patients into subgroups which included screening only patients, patients with symptoms but not bleeding, patients with positive family history, and patients with signs and symptoms of bleeding. Findings in screening patients only without a family history, and those with symptoms not related to bleeding were similar. These 901 patients have an overall incidence of polyps of 20.9% with large polyps occurring in 3.7% and cancer identified in 4 (0.44%). Of 207 patients screened for a positive family history the frequency of polyps and cancer were approxi- mately 1.5 times that found in screening only patients. The 457 Patients with a history of either bleeding, occult blood positive stools or anemia had a significant increased incidence of large polyps at14% and cancer at 7%.

Conclusions: This study demonstrate that there is an increased incidence of polyps and cancer with age associated with a proximal shift. History related to blood loss was the most important indicator of serious pathology. Although the number of patients under age 60 in this study are small, it does support the value of flexible sigmoidoscopy for screening and the evaluation of rectal bleeding in the younger patient.

Efficacy and Safety of a New Sodium Phosphate (NaP) Tablet Bowel Purgative vs a 2 L Polyethylene Glycol (PEG) Electrolyte Lavage Solution Plus Bisacodyl in the Elderly

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Purpose: A new NaP tablet formulation (OsmoPrep™; Salix Pharmaceuticals, Inc) was recently approved for colon cleansing prior to colonoscopy. Because colonoscopies are frequently performed in the elderly, a subanalysis of patients (pts) aged ≥65 y assessed the efficacy and safety of NaP tablets vs 2 L PEG plus bisacodyl tablets bowel prep kit (HalfLytely®; Braintree Laboratories, Inc) as a bowel purgative for screening colonoscopy.

Methods: Pts ≥18 y were randomized in a phase 3, investigator-blinded, multicenter study to receive 32 NaP tablets (48 g) or 2 L PEG + 4 bisacodyl tablets (20 mg). NaP tablets were taken 4 at a time with 8 oz clear liquid on the evening before (n = 20) and 3 to 5 h prior to (n = 12) colonoscopy. 2 L PEG + bisacodyl was taken as directed in US prescribing information. Overall colon cleansing was assessed by the investigator, using a 4-point scale based on colonic contents (1 = excellent, 2 = good, 3 = fair, 4 = inadequate). Adverse events were recorded from the first dose of study medication to 48 h (+2 days) postcolonoscopy. Vital signs and clinical lab evaluations were conducted at screening, the day of, and 48 h (+2 days) postcolonoscopy.

Results: 207 pts taking NaP tablets and 208 pts taking 2 L PEG + bisacodyl underwent colonoscopy, with 49 and 50 pts in each group (grp) aged ≥65 y, respectively. Within treatment grps, mean colon-cleansing scores were com- parable across age grps (1.5 ± 0.77 and 1.5 ± 0.68 for pts <65 y and ≥65 y with NaP tablets; 1.8 ± 0.77 and 1.9 ± 0.77 for pts <65 y and ≥65 y with 2 L PEG plus bisacodyl). However, between treatment grps, NaP tablets exhib- ited significantly better colon-cleansing scores vs 2 L PEG + bisacodyl in both age grps (P ≤ 0.028). In pts aged ≥65 y, abdominal distension and vom- iting occurred less frequently with NaP tablets vs 2 L PEG plus bisacodyl (P ≤ 0.0277). In general, for pts taking NaP tablets, both age grps exhibited transient shifts from mean screening levels in serum electrolytes measured. In addition, no differences between treatment grps were observed in serum creatinine or BUN levels in older pts.

Conclusions: NaP tablets were safe and efficacious as a bowel purgative in elderly pts, providing significantly better colon cleansing and tolerability profile vs a 2 L PEG plus bisacodyl.