Results: Of the initial 150 pts identified on lansoprazole, 50 filled out both questionnaires. The mean age of the pt group was 69 years. At the time the questionnaire was administered, the average time on the drug was 3.9 years for lansoprazole and 4.7 months for rabeprazole. Using the symptom distress scores during the week the pts were symptomatic on the two drugs, the Wilcoxon’s Signed Rank revealed no statistically significant differences in the symptom scores between the two drugs. (p = 0.97). Comparing the proportion of pts indicating presence of related symptoms, there were no statistically significant differences in the proportion of pts experiencing symptoms of heartburn, chest discomfort, nausea, hoarseness etc between the two drugs, except for a significantly higher proportion of pts with regurgitation on rabeprazole (p= 0.013).

Conclusions: In this study sample, the majority of the patient symptoms were well controlled with either PPI and there were no clinically relevant differences in patient symptoms when they were switched from one PPI to another during a national formulary change.

PRESENCE OF HIATAL HERNIA DOES NOT ADVERSELY AFFECT TREATMENT RESPONSE IN GERD

Purpose: To study the effect of hiatal Hernia on the symptomatology and treatment response in patients with GERD.

Background: It is conceivable that an anatomical abnormality i.e. hiatal hernia may aggravate reflux due to its effect on the lower esophageal sphincter, possibly creating resistance to treatment.

Methods: We did a prospective study of 96 consecutive patients with typical GERD symptoms, seen at the outpatient clinic of a University–affiliated teaching hospital.

We excluded patients with pregnancy, multiple comorbidity, h/o anti reflux surgery and gastric surgery. Data on severity, nocturnal vs diurnal pattern, frequency/duration of symptoms, medication, co-morbidity and extraesophageal manifestations were collected. The severity of heartburn was marked on a standardized analog scale of 0 to 10.

All patients underwent upper endoscopy and were prescribed standard dose of proton pump inhibitors (choice of the individual attending Gastroenterologist), and advised lifestyle modifications. A follow up was possible in 62 patients; symptoms were recorded in the same standard format as the first visit. Treatment response was defined as 1) The patient feeling subjectively better in terms of GERD symptoms and 2) At least 2 point decrease in the analog score of heartburn severity.

Results: Our patient population consisted of 72 men and 24 women, mean age 54± 15 yrs. Mean wt: 176 ± 4 lbs, BMI 29.6± 5.8. Only 23.5% had BMI < 25, while 30% were overweight (26–30) and 47% were obese (BMI >30). Mean reflux severity score was 6.4 on a scale of 0–10. Daily reflux was reported by 61%. Hiatal hernia was found in 32 patients. There was no age or gender difference between the patients with or without hernia. The two groups had similar severity, duration and pattern of symptoms. Symptom relief with proton pump inhibitors was documented in 90% of patients in whom follow-up was possible (n=62). Response to treatment did not vary between patients with or without hiatal hernia.

Using logistic regression analysis including variables such as age, gender, BMI, duration and severity of initial symptoms, brand of ppi used, presence of erosive esophagitis or hiatal hernia, we were unable to identify any discrete factor that affected treatment response in GERD.

Conclusions: 1.GERD patients with hiatal hernia had similar symptom profile as those without hernia. 2. Presence of hiatal hernia did not contribute to resistance to proton pump inhibitor therapy for GERD symptoms.

RADIOFREQUENCY ABLATION OF THE LOWER ESOPHAGEAL SPHINCTER FOR THE TREATMENT OF GERD: LONG-TERM FOLLOW-UP RESULTS WITH THE STRETTA PROCEDURE
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Purpose: In August 1999 we began enrolling patients into a multi-center trial investigating the treatment of GERD with the Stretta device. We observed a significant reduction in reflux related symptoms and use of acid inhibitory medications during the initial twelve month follow-up period. Eight of our original 13 patients were on no PPI or H2B therapy at 12 months. We present long-term follow-up data (mean 32.2 months) on this early cohort of patients who underwent radiofrequency ablation of the lower esophageal sphincter (LES) at our institution.

Methods: Our first thirteen patients who underwent the Stretta procedure (six male, seven female) had a mean body weight of 79.7 kg (range 48 to 102 kg). All had mild GERD and abnormal 24-hour esophageal pH studies (pH <4 more then 4% of the time). None had a hiatal hernia over 2cm. All patients had been on daily PPI to control their reflux symptoms. These 13 patients were recently re-contacted and were asked to fill out a questionnaire to assess current heartburn symptoms and medication use. Symptoms were compared to baseline using the Student paired t-test.

Results: Twelve patients returned the questionnaire (92.3% response rate). At a mean of 32.2 months follow-up (range 24 to 40 months), 4 of 12 patients (33.3%) were off all antisecretory medications. The other eight patients required treatment of their GERD. Seven patients were on daily PPI and one patient underwent a Nissen fundoplication 17 months after the Stretta procedure. The mean heartburn score at 32.2 months (12.9 ± 9.3) was significantly lower compared to baseline (17.4 ± 6.3).

Conclusions: The initial short-term (12 month) improvement in medication use following the Stretta procedure was not maintained for most patients at longer-term follow-up. However, the heartburn symptom score continued to be significantly lower. Only a third of patients in our small cohort are off acid inhibitory medications at a mean of 32 months following the radiofrequency intervention. Future studies may determine who would most benefit from this endoscopic therapy for GERD.

GERD WORSENS SLEEP RELATED QUALITY OF LIFE IN PATIENTS WITH OBSTRUCTIVE SLEEP APNEA
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Purpose: Patients with obstructive sleep apnea have significant reductions in the quality of their life due to the poor quality of sleep. We have shown previously that GERD may increase nocturnal arousal in some patients causing fragmentation of sleep. The aim of this study was to determine the effect of GERD on sleep related quality of life in patients with obstructive sleep apnea.

Methods: 98 consecutive patients undergoing polysomnography for excessive daytime sleepiness were studied. GERD severity was assessed using a validated symptom scale (GSRS). Sleep related quality of life was measured using a validated sleep quality of life questionnaire (SAQLI). Differences of 0.5 are clinically significant on this scale and differences of 1 are considered large. The sleep study was read by a polysomnographer blinded to the results of the GSRS or SAQLI. Multiple regression analysis was performed on key parameters to determine the factors affecting sleep related quality of life.

Results: There were 41 men and 57 women in the study. Moderate to severe symptoms of GERD were present in 16% and 10 of whom were receiving acid suppressive therapy (4 Histamine receptor antagonists and 6 standard dose PPI). All treated patients were still symptomatic for GERD.
Untreated GERD patients had more frequent arousals each hour (4.3/hr) compared to treated patients (1.4/hr). Sleep related quality of life was significantly poorer in patients with reflux and obstructive sleep apnea (2.5±0.89) compared to patients without reflux and without sleep apnea (3.7±1.2; p<0.05). Patients with sleep apnea and no reflux disease (3.3±0.9) had intermediate values. Multiple regression analysis demonstrated that sleep related quality of life was related to the patients age (coefficient 0.024; p=0.007), to the total number of spontaneous arousals (coefficient −0.084; p=0.04) and the presence of GERD symptoms (coefficient −0.25; p=0.002).

Conclusions: Untreated GERD in obstructive sleep apnea increases nocturnal arousals and worsens sleep related quality of life. We postulate that nocturnal heartburn causes partial wakening of the patient and fragments sleep resulting in poor QOL. GERD may not be adequately recognized in this population.

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ANALYSIS OF BARRETT’S ESOPHAGUS CAUSES AND RISK FACTORS FOR DYSPLASIA AND DRUG TREATMENT TO REVERSE DYSPLASIA IN BARRETT’S ESOPHAGUS

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Purpose: Analysis of a cohort of 208 consecutive Barrett’s patients from SE USA village of 30,000 9/92 and 9/97. A cohort of 208 consecutive Barrett’s and dysplasia and results of therapy program of PPI plus sucralfate plus folic acid in reversing Barrett’s and dysplasia. Risk factors for developing Barrett’s—sex, age greater than 51, age onset symptoms, gastric pH, were analyzed and show males equal females, 35 percent patients have no free gastric acid, 32 patients were status post gall bladder operation, 12 patients had positive family history of Barrett’s or esophageal cancer and 28 percent of patients diagnosed less than age 51.

Risk factors for developing dysplasia upon Barrett’s were pH >3.0, male equal female. Barrett’s > 5 cm most likely to occur in males, onset greater than age 41. 3 to 6 cm length Barrett’s more likely in females onset greater than age 41 with pH >3.0. Less than 3cm length Barrett’s more common in females all ages 20 to 80, with family history positive for Barrett’s or reflux in 15 percent. Therapy with PPI to block acid reflux plus sucralfate to inactivate bile and pepsin reflux plus folic acid to stabilize cells in epithelial regenerative phase, for > 9 months therapy for 144 patients, reversed the dysplasia in 7 of 8 moderate dysplasia and reversed mild dysplasia and indefinite dysplasia. Therapy reversed Barrett’s epithelium in 70 percent of patients after 9 months, but Barrett’s segments greater than 6cm took up to 3 years to reverse the abnormal intestinal metaplasia of Barrett’s epithelium. No new esophageal cancers occurred in the 144 patients in EGD to EGD observation period of 393.58 patients years and none occurred in EGD to clinical follow up for 501.75 patient therapy years.

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GENDER DIFFERENCES IN MEDICATION RESISTANT GERD PATIENTS AND RESPONSE TO ENDOSCOPIC THERAPY

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Purpose: This study was designed to evaluate the gender differences in symptoms of patients with medication refractory gastroesophageal reflux disease (GERD) and their response to endoluminal gastroplication (ELGP).

Methods: Patients with medication refractory GERD symptoms referred for evaluation of endoscopic treatment were included in this study. Reflux symptoms were followed using Heartburn Symptom Score (HSS) and Regurgitation Frequency Score (RFS). HSS = Heartburn Frequency X Heartburn Severity. Heartburn Severity was recorded by patient using a 32-point visual analog scale. RFS: 0=none, 1≤3 episodes per wk, 2=3–5 episodes per wk, 3=daily. Classic GERD symptoms, extra-esophageal symptoms including chest pain, cough, and wheezing, as well as medication usage were assessed pre-ELGP and at follow-up. Gender differences were analyzed.

Results: There were 30 males and 38 females with 94% follow up at 11 months post ELGP. There were no significant differences in the baseline patient profiles between female and male patients: age of 50 ± 14 vs 49 ± 12; body mass index (BMI) of 28 ± 6 vs. 28 ± 4. Typical reflux symptoms were similar in both female and male patients, HSS was 56 in female vs 53 in male, RFS was 1.7 vs 1.8. Proton pump inhibitor use was also comparable at 11 vs 10 doses/week. The main gender difference in symptom presentation was for extra-esophageal manifestations of GERD. Women had a nearly two fold increase in extra-esophageal symptoms: chest pain (24% females vs 13% males), cough (29% vs 20%), and hoarseness (34% vs 17%). Classic GERD symptoms responded similarly in both genders. Post-ELGP, HSS was 15 in women vs 11 in men, with RFS of 0.9 vs 0.6. Medication use was reduced to 5.2 doses/week in women and 4.9 doses/week in men respectively. The main difference between the genders was the response rate of extra-esophageal symptoms to endoscopic treatment. Women were more effectively treated with ELGP than men for relief of hoarseness (31% response vs. 0%) and wheezing (16% vs 0%) than men. However, male patients had a more favorable relief of chest pain (50% vs 33%). Cough was cured in half of both male and female patients post-ELGP.

Conclusions: There was no significant gender difference in patients with classic GERD symptoms in clinical presentation or the response rate to endoscopic therapy. However, female patients appear to have a higher incidence of extra-esophageal manifestations of GERD and these symptoms may be more effectively treated with endoscopic therapy.

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THE TEMPORAL RELATIONSHIP BETWEEN GASTROESOPHAGEAL REFLUX AND SLEEP EVENTS IN OBSTRUCTIVE SLEEP APNEA

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Purpose: Obstructive Sleep Apnea Syndrome (OSAS) is a prevalent and problematic disorder of sleep that is strongly associated with gastroesophageal reflux (GER). Over half of the patients with OSAS have substantial nocturnal and daytime GER, with few being symptomatic. Previous studies suggested that GER is not causal in the apneas and arousals in OSAS, but data using Multichannel Intraluminal Impedence (MII) in children have suggested this subject may need to be revisited in adults. This protocol uses a combination of standard pH monitoring and MII to evaluate the presence and temporal relationship of GER events to sleep events in the OSAS population.

Methods: All patients undergoing polysomnography for OSAS had either a traditional pH probe (with proximal and distal ports—5 cm proximal to LES) or an MII catheter placed during their sleep study. We recorded all GER events and related these temporally to apneas, hypopneas and arousals. Additionally, we recorded baseline GER symptoms and daytime somnolence as determined by questionnaires. Analysis included chi-squared statistics and intraclass correlation coefficients.

Results: Patients with OSAS have substantial nocturnal GER. Preliminary data does not show a statistically significant correlation between GER events and apneas or arousals, but a clear trend is emerging—especially with MII data. Contrary to previous studies, CPAP does not entirely abolish GER events.

Conclusions: This preliminary data suggests that there may be a causal relationship between GER events and sleep events in patients with OSAS. MII may allow us to better capture non-acid GER events that could play a role in the respiratory events that occur during polysomnography.