INTRODUCTION: FD is a common gastrointestinal disorder with poorly understood pathophysiology. Patients with FD and SIBO frequently overlap symptomatically. The prevalence of SIBO in patients with FD is not well studied, particularly in relation to the predominant FD symptom profile. We aimed to evaluate the prevalence of SIBO diagnosed by glucose breath test (GBT) in patients with FD and compare the SIBO prevalence in FD subtypes - Postprandial Distress Syndrome (PDS), Epigastric Pain Syndrome (EPS) or both (PDS+EPS).

METHODS: Retrospective, tertiary center, study of patients fulfilling Rome criteria for FD who completed GBT (2018-2019). Demographics, history, medications, and GBT findings were reviewed. Patients with documented structural disease (eg. neoplasms) were excluded. GI symptoms (including mid upper abdominal pain or burning, early satiety and postprandial fullness) were prospectively collected from all patients at the time of their GBT. Based on these responses, patients were classified into: 1. PDS - EPS or both, 2. EPS, 3. PDS+EPS. A priori variables associated with SIBO were analyzed including: presence of diabetes, GERD, and gastroparesis; history of small bowel surgery or gastric bypass; use of opiates or proton pump inhibitors. Prior to GBT, patients had low carbohydrate diet (2 days), no antibiotics (30 days) and no tobacco (12 hrs). Positive GBT for SIBO was defined by ≥20 ppm H2 increase over basal within 90 min and/or ≥10 ppm CH4 increase at any time. Statistical methods included chi-square and t test.

RESULTS: 737 consecutive patients were studied (mean age 51±6.7 years; 70% female, 88% Caucasian, mean BMI 28±5.7). No differences in demographic or prior SIBO associated variables were found between the 3 subgroups of FD patients (P = NS). 31.4% of patients fulfilling Rome criteria for FD had a GBT positive for SIBO. Individual gas (H2/CH4, or both) excration responsible for a positive glucose HBT in each of the FD subgroups is shown on Table 1. There was no statistically significant difference in the prevalence of SIBO (by either H2, CH4 or both) between the three FD patient subtypes. There was borderline significant difference for slower H2 peak depicting a positive GBT in PD-PDS compared to PD-EPS and PD+EPS (83.8 vs. 70.7 vs. 65.7 minutes, P = 0.06).

CONCLUSION: SIBO diagnosed by GBT is common in patients with FD regardless of the predominant symptomatic pattern. The prevalence of SIBO was similar in the three PD subtypes.

Golden-Finger: Digital Rectal Exam Predicts Dyssynergic Defecation but Not Type of Dyssynergy Pattern on ARM

Giselle Malanos, MD, David Jarave, MD, Nina Desai, MD, Brooke Corning, MD, Andrew Copland, MD, Jennetta Fry, MD.
1University of Virginia Medical Center, Charlottesville, VA; 2University of Virginia, Charlottesville, VA; 3University of Virginia Health System, Charlottesville, VA; 4University of Virginia Digestive Health Center, Charlottesville, VA.

INTRODUCTION: Functional defecation disorders are a common cause of chronic constipation and the diagnosis include an abnormality in two or more of the following test: balloon expulsion test (BET), anorectal manometry (ARM) or uncoordinated defection on electromyography. Additionally, there have been four types of anorectal manometry dyssynergy patterns identified. Rao et al have shown that digital rectal examination (DRE) performed by a single expert gastroenterologist can accurately detect patients with dyssynergia. We conducted a study evaluating whether DRE performed by gastroenterology specialists could predict the presence and type of dyssynergia in patients with chronic constipation.

METHODS: Patients with chronic constipation as defined by Rome IV criteria were evaluated by GI specialty providers at a single tertiary care hospital. After performing a DRE, each provider documented a prediction regarding the type of dyssynergy pattern that would be identified on ARM as well as whether the patient would pass the balloon during BET. An abnormal BET was defined as failure to pass the balloon in less than 60 seconds. Patients subsequently underwent ARM and BET and results of predicted and measured values on ARM and BET were compared.

RESULTS: 21 patients were referred to undergo ARM and BET. 19 patients met the inclusion criteria. 16 displayed a dysynergia pattern on ARM. Of the 16 patients, 11 were also identified to have features of dysynergia on DRE with a detection rate of 69% (Table 1). One patient was noted to have features of dysynergia on DRE but had normal ARM. Two patients had normal DRE with normal ARM. 14 of the 16 patients with dysynergia on ARM had abnormal BET. Of the 11 patients with abnormal BET, 7 were predicted to have an abnormal BET based on DRE. The accuracy of DRE to predict the correct type of dyssynergia (type 1-4) was 51% of patients (Table 2).

CONCLUSION: Studies have shown that DRE can predict dysynergia when performed by a single expert gastroenterologist with a detection rate of 73%. Our analysis suggests that DRE can be used to predict dysynergia on ARM and outcomes of BET even when multiple providers perform the exam. However, DRE is not a good predictor of the type of dysynergia. Further studies are needed to evaluate the differences in detection rates between types of dysynergia classified by ARM, and to assess whether there is a difference in detection rates between trainees and attendings.

Caraway Oil Plus L-Menthol With Site-Specific Targeting (COLM-SST): A Novel Formulation for FD

Brian E. Lacy, MD, PhD, FACP,1 Michael S. Epstein, MD, FACP,2 Syed Shah, PhD,3 Patrick Corrino, PhD.1
1Mayo Clinic, Jacksonville, FL; 2Investigative Clinical Research, Amspechi, MD; 3IM HealthScience, Bozeman, MT.

INTRODUCTION: Functional Dyspnea (FD) is a common functional GI disorder in the upper abdomen (above the naval). The estimated prevalence is 15-30% worldwide. There are currently no FDA-approved medications for the treatment of FD. Proton pump inhibitors (PPIs) are commonly prescribed off-label. However, long-term use of these drugs has been associated with serious health concerns. Prokinetic agents are also often used off-label. However, many are associated with significant side effects (e.g. metoclopramide). A safe, effective, and readily available treatment option for FD is greatly needed. This study describes an important 24-month post-marketing point on an option for FD that has already demonstrated good efficacy and low side effects in RCTs. These RCTs have demonstrated that the combination of caraway oil and peppermint oil improves FD symptoms. Caraway oil plus L-menthol (the main component of peppermint oil) with site-specific targeting (COLM-SST) is a novel delivery system of triple-coated, solid-state microphosphes designed to target the duodenum, the main center of disturbance in FD. This study was conducted to report on the overall safety profile of COLM-SST and to determine if any unexpected pattern of side effects emerged.

METHODS: A call-in number for reporting adverse events (AEs) was provided on all boxes containing COLM-SST. An independent call center with pharmacovigilance-trained health care personnel, in accordance with the FDA and global regulatory guidelines on properly reporting AEs, also retained to receive and record customer AEs. The AEs for this study were collected and processed from July 8, 2016 to July 8, 2018.

RESULTS: An estimated 558,834 individual patients used COLM-SST during the surveillance. An analysis of the data showed that there were no serious AEs reported. Additionally, the self-reporting of non-serious AEs was low, with only 148 events received (from 127 patients), a 0.023% event rate for COLM-SST. The top reported, non-serious AEs were abdominal pain/discomfort/diarrhoea.
(18, 0.0032%), which were consistent with the pattern of commonly reported symptoms of FD, and headache (7, 0.003%).

CONCLUSION: 24 months of monitoring in-market, real-world use of caraway oil and L-menthol with site-specific targeting, for the treatment of FD demonstrates an extremely low rate of self-reported AEs. These data, combined with earlier RCT data, indicates that COLM-SST is a safe and effective therapy for FD, and is a viable alternative to PPDs and probiotics.

506

Impact of Colonoscopy Timing on Rifaximin in Patients With Irritable Bowel Syndrome With Diarrhea (IBS-D)

Brian E. Lacy, MD, PhD, FACG1, Anthony Lembo, MD2, Mark Pimental, MD, FACG3, Zeev Heimanson, PharmD4, Brooks D. Cash, MD, FACG5.

1Mayo Clinic, Jacksonville, FL; 2Beth Israel Deaconess Medical Center, Boston, MA; 3Cedars-Sinai Medical Center, Los Angeles, CA; 4Salix Pharmaceuticals, Bridgewater, NJ; 5University of Texas Health Science Center, Houston, TX.

INTRODUCTION: Bowel preps for colonoscopy can cause transient changes in gut microbiota. Rifaximin is indicated as IBS-D treatment in adults. This post hoc analysis evaluated effect of time since colonoscopy on rifaximin response for IBS-D.

METHODS: Two phase 3 studies (TARGET 1/2) comprised adults who had documented history of colonoscopy ≤2 y prior to enrollment for IBS evaluation; otherwise they had 1 within 30 d of signed consent. Patients (pts) were randomized to rifaximin 550 mg TID or placebo for 2 wks. Responders, grouped by time from colonoscopy to treatment start (≤60 d or >60 d), were analyzed using LOCF. Composite responders (FDA endpoint) were pts meeting weekly response criteria for abdominal pain ($0.16), and stool consistency (75.1% vs 65.5%; $0.13), or stool consistency (77.4% vs 69.7%; $0.08) decrease from baseline in mean weekly pain score [range, 0-6] (53.8% vs 39.2%; $0.002) responders. For colonoscopy ≤60 d prior to treatment, a greater percentage of pts responded (53.8% vs 39.2%; $0.002) responders. A greater percentage of pts treated with rifaximin (n = 109) vs placebo (n = 106) were composite (47.7% vs 34.0%; P = 0.04), abdominal pain (53.2% vs 40.6%; P = 0.06), or stool consistency (61.7% vs 58.3%; P = 0.03). In TARGET 2, a greater percentage of pts treated with rifaximin (n = 106) vs placebo (n = 97) in colonoscopy ≤60 d prior group were composite (45.3% vs 32.0%; P = 0.05), abdominal pain (50.0% vs 41.4%; P = 0.13), or stool consistency (77.4% vs 49.7%; P = 0.08) responders. A greater percentage of pts treated with rifaximin (n = 109) vs placebo (n = 223) in colonoscopy ≤60 d prior group were responders, although differences were smaller: composite (47.4% vs 38.1%; P = 0.05), abdominal pain (51.7% vs 44.8%; P = 0.16), and stool consistency (75.1% vs 65.5%; P = 0.03).

CONCLUSION: Larger differences in responder rates with rifaximin vs placebo were observed in pts in whom colonoscopy was ≥60 d from start of IBS-D therapy. This may be related in part to reestablishment of IBS-related gut microbiota dysbiosis further research is needed.

507

The Functional Gastrointestinal Disorders Population-Based Prevalence and Relationship to Dietary Factors in Latino Populations in the Resource Limited Setting of Rural Central America

Dalton A. Nernood Jr., MDY, Lucia Dominguez, MDZ, Andrea A. Paredes, Eliazar E. Montalvan, MDY, Michael K. Dougherty, MD, MSCRY, Ricardo L. Dominguez, MDY, Douglas Morgan, MD, MPHZ.

1Hospital Regional de Occidente, Santa Rosa de Copan, Copan, Honduras; 2Hospital de Occidente, Santa Rosa de Copan, Copan, Honduras; 3University of North Carolina School of Medicine, Chapel Hill, NC; 4University of Alabama at Birmingham, Birmingham, AL.

INTRODUCTION: The prevalence of the Functional Gastrointestinal Disorders (FGIDs) in Latino populations in resource-limited settings such as rural Central America is largely uninvestigated. The relationship of the FGIDs and dietary habits is unknown in this environment.

METHODS: With population-based sampling, we administered the Rome IV questionnaire and a validated dietary questionnaire to a cross-section of the general adult population of rural Western Honduras. We estimated the prevalence of specific FGIDs and used logistic regression with Bonferroni adjustment to evaluate the relationship of each FGID diagnosis with particular dietary habits.

RESULTS: We interviewed 815 subjects, of whom 151 fulfilled Rome IV criteria for an FGID (18.5% 95% CI 15.9-21.4%). The mean age was 40.6 ± 9.4 years, of whom 58.7% were female. Gastrointestinal FGIDs were noted in 10.1%, with epigastric pain syndrome (EPS) more common than post-prandial distress syndrome (PDS), 8.5% versus 1.6%. Among the bowel disorders, functional abdominal bloating (FAB) was most prevalent (62.2%, 95% CI 46.8-81.1), followed by irritable bowel syndrome (IBS, 3.5%, 95% CI 2.5-5.1; IBS-U 1.6%, IBS-C 1.2%, IBS-D 0.5%), functional diarrhea (FD, 3.4%) and functional constipation (FC, 1.1%). In multivariable logistic regression analysis, the diagnosis of any FGID was inversely associated with consumption of beans (OR 0.41, 95% CI 0.27-0.63, adjusted P = 0.009), driven by negative associations with IBS and FD. Overall vegetable consumption was associated with a lower prevalence of FD (OR 0.12, 95% CI 0.043-0.35, adjusted P = 0.048) and any diarrheal disorder (OR 0.11, 95% CI 0.42-0.31, adjusted P = 0.004). There was a trend toward association with all FGIDs for subjects who consumed greater than the mean daily intake of 4.6 corn tortillas per day, OR 1.74 (95% CI 1.22-2.30, adjusted P-value NS).

CONCLUSION: FGIDs are prevalent in the resource-limited setting of rural Central America, with an altered distribution of specific FGIDs (common FAB, versus less common PDS, IBS, FC) compared with other global populations and urban Latin America populations. In this setting, with locally grown foods and limited diet variability, local dietary influences such as vegetable, bean, and tortilla intake may be important factors in specific FGIDs.