FUNCTIONAL BOWEL DISEASE

S514 ACG Governors Award for Excellence in Clinical Research

Virtual Reality Improves Symptoms of Functional Dyspepsia: Results of a Randomized, Controlled, Double-Blind Pilot Study

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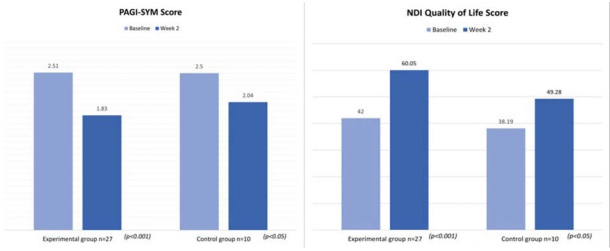
Introduction: Functional dyspepsia (FD) is a common functional GI disorder, characterized by symptoms of abdominal pain, nausea, and/or early satiety. Virtual reality (VR) is a promising intervention which has been shown to alleviate pain in various clinical settings. There are currently no studies assessing VR for the treatment of FD. The aim of this study was to investigate the effectiveness and safety of VR for the treatment of FD.
Methods: This is a prospective, single-center, randomized, controlled, double-blinded study of adult patients with FD (Rome IV criteria). Enrolled patients were randomized 2:1 (experimental to control). Experimental patients were given a VR headset with software consisting of immersive audiovisual programs. Control patients were given an identical headset with 2-D nature videos. Patients were asked to use their headset at least daily and completed Patient Assessment of Gastrointestinal Disorders-Symptom Severity Index (PAGI-SYM) and Nepean Dyspepsia Index (NDI) questionnaires at their initial visit, after 1 week of use, and at the conclusion of the 2-week study. Paired sample t-tests were used to compare questionnaire scores.
Results: Thirty-seven patients were enrolled in the study (27 experimental, 10 controls); demographic data are shown in Table (Table). Patients used the VR headset an average of 1.3 times/day for a mean of 23.2 minutes/day. Total PAGI-SYM scores significantly decreased for all patients [2.51 (baseline) to 0.62 (week 2); p=0.000]. Notably, patients in the experimental group had greater improvement in mean total PAGI-SYM scores [2.51 baseline) to 1.83 (week 2); mean difference -0.68; p=0.000], compared to the control group [2.50 (baseline) to 2.04 (week 2); mean difference -0.46; p=0.046]. Further, quality of life (QoL) significantly improved for all patients, as the total NDI QoL score increased from 40.97 (baseline) to 57.14 (week 2), p=0.000, though experimental patients saw greater improvement in QoL, compared to control patients (Figure). Seventeen patients (45.9%; 11 experimental, 6 controls) reported non-serious adverse effects (AE), with headache and dizziness being the most common; 1 experimental patient withdrew due to AEs (migraines).
Conclusion: In the first randomized, controlled, double-blind study to assess VR for the treatment of FD, VR was shown to be safe and result in statistically significant overall improvement in symptoms and QoL in FD patients. We propose VR as a novel treatment for FD worthy of further investigation.



[0514] **Figure 1.** Total PAGI-SYM and NDI Quality of Life Scores

Table 1. Study Population Demographic Data

Mean Age	**45 years (± 14)**
Mean BMI	24.56 (± 6.79)
Sex	
Female	30 (81.1%)
Male	7
FD subtype	
EPS	12 (32.4%)
PDS	20 (54.1%)
Mixed EPS/PDS	5 (13.5%)
Anxiety	17 (45.9%)
Depression	9 (24.3%)
PTSD	2 (5.4%)
Fibromyalgia	4 (10.8%)
Prior *H. pylori infection*	5 (13.5%)
Medications	
PPI	16 (43.2%)
Antidepressants	11 (29.7%)
Gabapentin	4 (10.8%)
Opioids	2 (5.4%)
NSAIDs	0
Alcohol Use	7 (18.9%)
Marijuana Use	4 (10.8%)

S515

App-Delivered Gut-Directed Hypnotherapy Program Nerva Improves Symptoms in Patients With Irritable Bowel Syndrome but How Can We Ensure Users Are Compliant?

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Introduction: App-delivered gut-directed hypnotherapy (GDH) is an efficacious treatment for irritable bowel syndrome (IBS), reducing overall and individual gastrointestinal symptoms at similar rates to face-to-face delivery.[1] However, program adherence is poor. This study aimed to retrospectively assess symptoms of patients with IBS undergoing the app-delivered GDH program *Nerva* and to assess whether healthcare provider (HCP) referral aids program adherence.

Methods: 15,552 patients with self-reported IBS downloaded a 42-session mobile app-delivered GDH program '*Nerva*'. The first 7 sessions were free. Overall and individual gastrointestinal symptoms were assessed at baseline and 6 weeks after starting the program, using a 100-mm visual analogue scale (VAS). Psychological outcomes were measured using the PHQ4, which is validated to categorise likelihood psychological distress into normal (0-2), mild (3-5), moderate (6-8) and severe (9-12). Data were parametric and presented per protocol.
Results: Out of 15,552 users, 3101 completed the program. Of those who completed the program, overall gastrointestinal symptoms improved by 28 mm, to a level that would be considered meaningful clinically (mean 67 mm to 39 mm; $p< 0.001$ t-test). In the those who did not complete the program, overall gastrointestinal symptoms still significantly improved, but to a smaller magnitude (68 mm to 58 mm). Similar results were seen with individual symptoms. Linear regression analysis indicated that users who completed the program were more likely to respond ($p< 0.001$). Total adherence rate was generally low, with only 20% of users completing the program. However, users who were referred to *Nerva* by a HCP were statistically more likely to complete the program (24%) compared with those self-referred (19%) (OR 1.3; $p< 0.001$ logistic regression). HCP referral did not alter gastrointestinal symptom response ($p=0.024$). Users who completed the program were more likely to improve psychologically (mean Δ3, shifting from moderate to mild distress, *vs* 1, $p< .001$).
Conclusion: App-delivered GDH improves overall and individual gastrointestinal symptoms. Users who complete the program report greater improvement in psychological outcomes. HCP referral is a positive predictor of program completion, but does not alter rates of efficacy.

S516 Presidential Poster Award

Virtual Visits for Initial Evaluation of Constipation Are Associated With Reduced Outpatient Order Compliance

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Introduction: In gastroenterology, telemedicine has emerged as a means for improving patient access to medical care while limiting viral transmission during the pandemic. The purpose of this study was to assess patient order compliance in the virtual vs. in-person setting during the COVID-19 pandemic for the initial evaluation of constipation.
Methods: Using natural language processing, we identified outpatient gastroenterology visits (virtual and in-person) for constipation from March 2020 through December 2021. We assessed the number of orders placed for patients during these encounters and determined compliance based on order completion. A generalized linear mixed effects model with fixed effects for visit type and random intercepts for intra-patient correlation was used. A multivariable model was built controlling for age, socioeconomic status, BMI, dementia, stroke, and congestive heart failure.
Results: Among 4,930 patients who presented for initial constipation evaluation since the start of the pandemic, 3,515 patients were evaluated in-person and 1,415 patients were evaluated virtually. Comparing order compliance in patients seen during the pandemic, patients seen virtually were 66% less likely to complete orders in comparison to patients seen in-person ($p < .001$). Patients seen in a pandemic virtual setting were 43% less likely to complete imaging orders ($p < 0.001$), 78% less likely to complete procedure orders ($p < 0.001$), and 90% less likely to complete lab orders ($p < 0.001$) (Table). Increased lab compliance was associated with the highest socioeconomic status ($75,000-$200,000) with patients eight times more likely to complete lab orders ($p=0.049$) and three times more likely to complete orders overall ($p=0.021$).
Conclusion: Compared with in-person visits, patients seen virtually for their first presentation of constipation were less likely to complete labs, imaging and procedure evaluation ordered. In-person visits were more successful in leading to patient order completion during the pandemic. These findings suggest that virtual visits for constipation, despite convenience, may compromise care delivery; such visits may thus require additional care coordination to achieve compliance with medical recommendations.

Table 1. Order Compliance Among Patients with Pandemic Virtual vs. In-person visits

Factors	Odds Ratio	95% CI	*P*-value
Total Orders	0.339	[0.263,0.436]	< **.001**
Imaging	0.103	[0.040,0.267]	< **.001**
Procedures	0.219	[0.131,0.365]	< **.001**
Labs	0.047	[0.024,0.092]	< **.001**

S517 Outstanding Research Award in the Functional Bowel Disease Category
Presidential Poster Award

Clinical Utility of Anorectal Manometry and Balloon Expulsion Testing to Predict Outcomes With Community-Based Pelvic Floor Physical Therapy: A Pragmatic Clinical Trial of Patients With Chronic Constipation

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Introduction: Chronic constipation is a common reason for referral to community and general gastroenterology practice. We aimed to assess the clinical utility of anorectal manometry (ARM) and balloon expulsion time (BET) to predict outcomes with up-front, community-based pelvic floor physical therapy as the next best step to manage chronic constipation among patients failing an empiric trial of soluble fiber supplementation or osmotic laxatives.
Methods: 60 treatment-naïve patients (mean age 46.4±17.6 years; 93.3% women) enrolled between January to June 2021 that were referred to general gastroenterology meeting Rome IV functional constipation criteria and failing two weeks of soluble fiber supplementation or osmotic laxatives. All patients underwent ARM and BET (following the London protocol) followed by pelvic floor physical therapy (following a simplified community-based ANMS/ESNM protocol standardized and monitored in a preceding feasibility study enrolling 39 patients). All patients maintained stable diet and osmotic laxatives during the study, with a rescue regimen of secretory laxatives no more than 2 days per week. We assessed outcomes at baseline and 12-weeks. The primary endpoint was clinical response defined on whether patients achieved the minimal clinically important difference at 12-weeks vs. baseline on a valid global endpoint appropriate to chronic constipation trials (Patient Assessment of Constipation Symptoms [PAC-SYM] score reduction >0.75).
Results: 53 patients completed pelvic floor physical therapy and symptom assessments. Balloon expulsion time and dyssynergic patterns (ARM) did not inform clinical outcomes (area-under-the-curve[AUC]< 0.6 on these parameters). BET poorly predicted outcomes as a single test (AUC=0.54 [95% confidence interval[CI] 0.38-0.69]). Maximum squeeze pressure (achieving >192.5mmHg on at least 1 of 3 squeeze attempts; sensitivity 47.6%; specificity 93.9%) and squeeze duration (maintaining 50% of squeeze pressure for >20 seconds; sensitivity 71.4%; specificity 58.1%) were the strongest predictors of clinical outcomes. Adding BET to squeeze profiles (abnormal BET classified as expulsion LESS THAN 6.5 seconds) resulted in greater predictive accuracy (AUC=0.75 (95% CI 0.59-0.90).
Conclusion: Squeeze profiles on ARM, rather than BET or dyssynergic manometric patterns, were the strongest predictors of clinical response with pelvic floor physical therapy delivered in the community as an up-front therapy to manage chronic constipation.

S518 Outstanding Research Award in the Functional Bowel Disease Category (Trainee)
Presidential Poster Award

Evaluation of Probiotic Use, SIBO, and Lactatemia in Patients With Brain Fogginess, Gas, and Bloating

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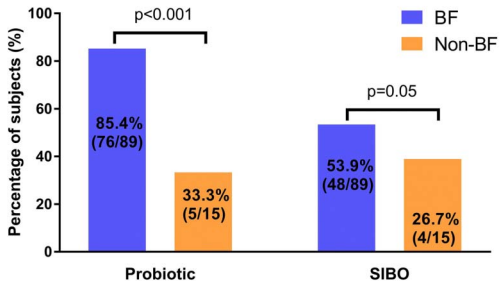
Introduction: Brain Fogginess (BF) may occur due to lactatemia (increased D/L-lactic acid) and may be associated with small intestinal bacterial overgrowth (SIBO). Aim: To examine the prevalence of probiotic use in patients with unexplained BF, gas, and bloating, and assess its association with SIBO and lactatemia.
Methods: Patients with chronic gas/bloating (>6 months) were assessed for BF using a structured questionnaire. Also, gas/bloating-related symptoms were recorded with validated questionnaire, along with the use of probiotic. BF symptoms included mental confusion, feeling sleepy, forgetfulness, and difficulty focusing. Subjects underwent glucose breath test (GBT) and/or small bowel aspiration/culture for SIBO as well as urine D-lactic acid and serum L-lactic acid during GBT. SIBO was diagnosed based on a positive GBT (≥ 20 ppm rise) and/or bacterial count ≥ 10^3 cfu/mL. Lactatemia was defined as ≥0.22 mmol/L (D-lactic acid) and/or ≥2.2 mmol/L (L-lactic acid). Data were compared between patients with and without BF.

Results: Of 104 patients (f/m = 77/27, mean age = 45 years), 89 (85.6%) reported BF (BF group) and 15 (14.4%) had no BF (non-BF GROUP). Prevalence of flatulence (90.8%) vs 83.3%), bloating (92.3% vs 100%), belching (83.1%) vs 83.3%), and abdominal pain (84.6%) vs 83.3%) were similar between the two groups. Difficulty thinking (90.4%), difficulty focusing (90.4%), feeling sleepy (90.4%), and forgetfulness (88.1%) were the most prevalent BF symptoms. There was significantly higher prevalence of probiotic use in the BF group compared to non-BF group (85.4% vs 33.3%; p = < 0.0001) (Fig. 1). Also, the prevalence of SIBO was higher in the BF group compared to the non-BF GROUP (53.9% vs 26.7%; p=0.05). Among BF patients who also took probiotics, 43/76 (56.6%) had SIBO and 45/76 (59.2%) had lactatemia. Most non-BF patients did not use probiotics (10/15, 66.7%) and 9/10 (90%) were negative for SIBO. In the non-BF group that took probiotics, 3/5 (60%) had SIBO, one with lactatemia.
Conclusion: BF is significantly associated with probiotic use and persistent gas/bloating and distention. These patients are significantly more likely to have SIBO as well as lactatemia compared to those without BF or history of probiotic use. In patients with unexplained gas/bloating, clinicians should, ask if they have BF and use probiotics, assess for lactatemia and SIBO, and recognize and manage this problem.

Figure 1. Comparative prevalence of probiotic use and SIBO in BF vs non-BF groups



[0518] **Figure 1.** Comparative prevalence of probiotic use and SIBO in BF VS non-BF

S519 Presidential Poster Award

Impact of COVID-19 on Motility Practices: New Onset Gastrointestinal and Autonomic Dysfunction After COVID-19 and the Effects of Vaccination in a Nationwide Cohort Study

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[1]Johns Hopkins University, Houthalen-Helchteren, Limburg, Belgium; [2]Johns Hopkins University, Baltimore, MD.

Introduction: COVID-19 has been linked to a higher risk of enteric and autonomic dysfunction, but studies have been limited by small sample sizes and follow-up.
Methods: We performed a retrospective cohort study using the TriNetX Research Network, including over 80M patients from 57 academic medical centers in the US. Using ICD-10 and CPT codes, patients diagnosed with COVID-19 between Jan 1 to Dec 31, 2020 were propensity score matched for risk factors to negative controls (NC), and patients diagnosed with either Influenza, Lyme's disease (LD), Infectious Mononucleosis (IM), Herpes Zoster (HZ), Varicella Zoster (VZ) and Cytomegalovirus (CMV). A Kaplan-Meier analysis was used to estimate the hazard ratio (HR) and cumulative incidence of new-onset outcomes within 3 months and 1 year after the diagnosis of the respective health event, including: GI symptoms or diagnoses, symptoms of autonomic (AN) sensory (SN), and motor (MN) neuropathy. We quantified the impact of prior vaccination for COVID-19 on these outcomes.
Results: A total of 1,355,657 COVID-19 patients were matched to 1,889,175 NCs, 698,253 Influenza, 61,826 IM, 129,246 LD, 457,984 HZ, 45,811 VZ, and 8,441 CMV patients. Both the risk of GI diagnoses and AN were increased (HR >1, p< 0.05) after COVID-19 compared to every other control population, except for GI diagnoses after CMV (HR 0.89, p:0.26). COVID-19 significantly (p< 0.05) increased the risk of vomiting (HR 1.78), diarrhea (HR 1.53) and irritable bowel syndrome (HR 1.07) compared to NCs, but it did not differ with that observed after Influenza (p >0.05). Although COVID-19 increased the risk of developing functional dyspepsia (HR 1.09), inflammatory bowel disease (HR 1.5) and abdominal pain (HR 1.38) compared to NCs, a diagnosis of Influenza yielded an even higher risk (p< 0.05); for all other GI diagnoses, the risk was consistently increased (p< 0.05) compared to both NCs and Influenza. Prior vaccination did not alter the risk of developing GI outcomes after COVID-19 (HR 0.95, p:0.32), but it did increase the risk of AN (HR 1.13, p:0.02) and MN (HR 1.6, p< 0.05). (Table)
Conclusion: This nationwide analysis reveals that COVID-19 increases the risk of new-onset ENS and ANS dysfunction compared to NCs and patients infected by neurotrophic and non-neurotrophic pathogens, but less pronounced compared to CMV. Given the magnitude of COVID-19 infections, a significant increase in patients with dysmotility and ANS dysfunction is expected, for which Gastroenterology as a specialty needs to prepare.

Table 1. **Kaplan Meier analysis comparing new-onset outcomes between patients diagnosed with COVID-19 and a matched Influenza and negative control cohort**

New-onset outcomes	COVID-19 vs Negative controls (n=1,889,175)				COVID-19 vs Influenza (n=698,253)			
	HR (95% CI)	Probability COVID	Probability NC	P-value	HR (95% CI)	Probability COVID	Probability Influenza	P-value
Gastrointestinal (GI) symptoms or diagnoses	1.37 (1.35 - 1.39)	11.43%	8.44%	< 0.001	1.04 (1.03 - 1.06)	11.41%	10.87%	< 0.001
Dysphagia	1.37 (1.33 - 1.41)	1.4%	1.03%	< 0.001	1.18 (1.14 - 1.23)	1.23%	1.03%	< 0.001
Gastro-esophageal reflux disease	1.30 (1.28 - 1.33)	4.21%	3.23%	< 0.001	1.13 (1.11 - 1.16)	3.97%	3.5%	< 0.001
Heartburn	1.15 (1.09 - 1.21)	0.42%	0.37%	< 0.001	1.20 (1.12 - 1.28)	0.44%	0.36%	< 0.001
Nausea	1.54 (1.50 - 1.58)	2.39%	1.56%	< 0.001	1.12 (1.09 - 1.15)	2.51%	2.24%	< 0.001
Vomiting	1.78 (1.71 - 1.85)	0.87%	0.49%	< 0.001	1.04 (0.99 - 1.08)	0.9%	0.87%	0.116
Early satiety	1.31 (1.20 - 1.43)	0.15%	0.12%	< 0.001	1.63 (1.44 - 1.85)	0.14%	0.09%	< 0.001
Abdominal and pelvic pain	1.38 (1.36 - 1.41)	6.38%	4.63%	< 0.001	0.97 (0.96 - 0.99)	6.62%	6.74%	0.01
Bloating	1.28 (1.24 - 1.33)	1.01%	0.78%	< 0.001	1.29 (1.24 - 1.35)	0.97%	0.75%	< 0.001
Gastroparesis	1.47 (1.35 - 1.60)	0.18%	0.12%	< 0.001	1.39 (1.25 - 1.55)	0.17%	0.12%	< 0.001
Functional dyspepsia	1.09 (1.02 - 1.17)	0.22%	0.2%	0.016	0.79 (0.73 - 0.86)	0.21%	0.27%	< 0.001
Constipation	1.35 (1.32 - 1.38)	2.61%	1.94%	< 0.001	1.17 (1.14 - 1.21)	2.4%	2.04%	< 0.001
Diarrhea	1.53 (1.49 - 1.57)	2.62%	1.71%	< 0.001	1.01 (0.98 - 1.03)	2.63%	2.61%	0.631
Irritable bowel syndrome	1.07 (1.02 - 1.12)	0.5%	0.47%	0.006	1.04 (0.98 - 1.10)	0.52%	0.5%	0.188
Inflammatory bowel disease	1.50 (1.45 - 1.56)	1.06%	0.71%	< 0.001	0.75 (0.72 - 0.78)	1.05%	1.4%	< 0.001
Autonomic neuropathy	1.32 (1.30 - 1.34)	8.69%	6.64%	< 0.001	1.15 (1.13 - 1.17)	8.22%	7.1%	< 0.001
Postural symptoms	1.43 (1.41 - 1.46)	5.89%	4.15%	< 0.001	1.15 (1.13 - 1.18)	5.64%	4.88%	< 0.001
Urinary dysfunction	1.22 (1.19 - 1.25)	2.76%	2.26%	< 0.001	1.12 (1.09 - 1.16)	2.53%	2.24%	< 0.001
Sexual dysfunction	0.99 (0.95 - 1.03)	0.66%	0.66%	0.751	1.04 (0.98 - 1.10)	0.59%	0.56%	0.168
Exocrine gland dysfunction	1.22 (1.18 - 1.26)	1.24%	1.02%	< 0.001	1.26 (1.21 - 1.31)	1.17%	0.93%	< 0.001

Table 1. (*continued*)

New-onset outcomes	COVID-19 vs Negative controls (n=1,889,175)				COVID-19 vs Influenza (n=698,253)			
	HR (95% CI)	Probability COVID	Probability NC	P-value	HR (95% CI)	Probability COVID	Probability Influenza	P-value
Sensory neuropathy	1.12 (1.09 - 1.15)	1.71%	1.53%	< 0.001	0.89 (0.86 - 0.92)	1.69%	1.89%	< 0.001
Motor neuropathy	1.22 (1.19 - 1.25)	1.52%	1.25%	< 0.001	0.98 (0.95 - 1.01)	1.47%	1.49%	0.247

Outcomes are presented as a HR, in which the numerator consists of the COVID-19 population. The cumulative incidence of the outcomes between 3 months and 1 year after the index is presented for each cohort. A P-value was calculated using a log-rank test.

S520 Presidential Poster Award

Development and Validation of Brain Fog Questionnaire in Patients and Healthy Volunteers

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[1]MD, Augusta, GA; [2]Deaconess Clinic, Newburgh, IN; [3]Medical College of Georgia, Augusta, GA; [4]Augusta University, Augusta, GA.

Introduction: Brain fogginess (BF) encompasses a constellation of neurocognitive symptoms that remain poorly characterized, in part due to its multidimensional symptoms. They are increasingly seen in gastroenterology patients, particularly those with gas, bloating and distension. We developed and psychometrically tested a 19-item questionnaire that described symptoms of importance to both patients and clinicians (Tetangco et al, ACG 2020). After due input from patients and clinicians, weightage analysis and item reduction, a 15-item new BF questionnaire (BFQ) was developed. Our aim here was to perform a preliminary comparative analysis of BFQ in patients with BF and healthy controls.
Methods: In this Phase II questionnaire study, patients with unexplained abdominal gas, bloating, distension, and symptoms of BF for ≥3 months completed the 15-item BFQ using a visual analogue scale, and a 10-item Gas and Bloating validated questionnaire at baseline and 2-weeks. The patients also completed Montreal Cognitive Assessment (MoCA) and Digital Symbol Substitution test (DSST). Healthy controls were invited to complete the aforementioned questionnaires. Data were compared for test-retest reliability, and between the two groups.
Results: Ten patients (8 females, mean age 44.4 years), and 12 healthy controls (5 females, mean age 42.8 years) participated. The most severe visual analogue scores for BF symptoms that were reported by patients included feeling sleepy (5.8±0.9), being easily distracted (5.8±1.0), and having difficulty focusing (5.5±0.9). The patients had a significantly higher BFQ total score compared to healthy controls (65.6±9.0 vs 9.8±4.1, p< 0.001), with all 15 BFQ items significantly higher than healthy controls on BFQ (Table). There was no significant difference in DSST scores (42.8±6.6 vs 61.5±17.6, p=0.065) or MoCA scores (25.6±0.9, vs 24.9±3.3, p=0.957) between the two groups. The BFQ had a good test-retest reliability (ICC=0.78, p=0.017) for 9/15 BFQ items.
Conclusion: The 15-item BFQ comprehensively captures key symptoms of BF and significantly differentiates healthy controls from BF patients. Also, the lack of difference in MoCA and DSST scores between BF patients and healthy controls suggests that these patients do not have cognitive impairment. The BFQ has good test-retest reliability, but therapeutic responsiveness requires further study.

Table 1. **Comparison of brain fog questionnaire responses in patients (baseline vs week 2), and healthy volunteers**

Brain Fog Questionnaire	Patients				HVs	p value (Pts vs HVs)
	Baseline questionnaire	2-week questionnaire	ICC	p value		
I am forgetful and/or experience short-term memory loss	4.5±0.9	4.4±0.7	0.500	0.160	1.0±0.5	**0.001**
I have difficulty thinking	4.4±0.6	4.8±0.7	0.835	**0.007**	0.7±0.4	**< 0.001**
I have difficulty focusing	5.5±0.9	5.2±0.7	0.817	**0.009**	1.1±0.7	**0.001**
I feel cloudy and/or spacey	5.4±1.0	5.3±0.9	0.878	**0.002**	0.6±0.4	**< 0.001**
I have difficulty finding the right word(s) to communicate	3.8±0.9	3.6±0.6	0.665	0.059	0.6±0.3	**0.003**
I have difficulty understanding what others say	2.8±0.6	3.0±0.7	0.364	0.255	0.2±0.1	**0.001**
I feel mentally fatigued and/or exhausted	5.3±1.0	5.0±1.0	0.764	**0.021**	0.9±0.3	**< 0.001**
I feel that I am slow	3.6±0.9	3.5±0.8	0.784	**0.016**	0.6±0.4	**0.009**
My mind goes blank	4.4±0.9	4.2±0.9	0.170	0.393	0.9±0.5	**0.003**
I am easily distracted	5.8±1.0	4.9±0.9	0.853	**0.004**	1.3±0.7	**0.002**
I have difficulty understanding words that I have read	3.5±0.9	2.6±0.7	0.872	**0.003**	0.2±0.1	**0.003**
I experience confusion	4.0±1.1	3.9±0.9	0.882	**0.002**	0.2±0.1	**0.001**
I feel sleepy	5.8±1.0	5.4±0.8	0.747	**0.027**	0.8±0.3	**< 0.001**
I feel that my thoughts are moving too quickly	3.3±0.9	3.6±1.0	0.463	0.184	0.2±0.2	**0.001**
I go somewhere to do something, but cannot remember why	3.8±0.9	4.4±1.0	0.272	0.321	0.7±0.3	**0.004**
BFQ total score	65.6±9.0	63.7±8.1	0.779	**0.017**	9.8±4.2	**< 0.001**

S521 Presidential Poster Award

IgG-based Elimination Diets for Patients with IBS: Results From a Prospective, Multi-Center, Double-Blind, Placebo-Controlled Trial

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Introduction: Studies indicate that diet modification can improve symptoms in patients with IBS. Food intolerances/sensitivities are common in patients with IBS but outcomes following self-directed elimination diets are poor. The role of IgG antibodies in identifying patients with food sensitivities is controversial. This study was designed to evaluate the utility of a novel, proprietary IgG-based elimination diet to improve symptoms in IBS patients.
Methods: Adults with IBS (Rome IV), all subtypes, were enrolled from 6 centers into a 2-week baseline period. Patients who tested positive ≥ 1 food in an IgG panel (InFoods®, Biomerica, Irvine, CA) and who reported an average daily IBS abdominal pain intensity(API) score (0-10) between ≥3 - ≤7.5 were randomized to either a treatment diet arm or a sham(placebo) diet arm for 8 weeks. Patients in the treatment diet arm were instructed to eliminate foods to which they tested positive. Patients in the sham diet arm were instructed to eliminate foods to which they tested negative. The sham diet arm was balanced to the active diet arm with respect to the number of foods eliminated and self-reported frequency of consuming a particular food. Daily assessments included bowel habits, bloating, and API, as well as weekly assessments for IBS Adequate Relief(AR), Subject Global Assessment of Relief(SGA), and Global Improvement Scale(GIS). Linear mixed and logistic regression modeling of endpoints in the intent-to-treat (ITT) population is presented for all IBS patients and for non-IBS-D patients. (Figure)
Results: 556 patients with IBS(all subtypes) entered the screening phase, 223 met eligibility criteria and entered the double-blind placebo-controlled diet treatment phase. IBS patients in the treatment diet arm showed a greater decrease in IBS-API and IBS-Bloating scores from baseline compared to patients in the sham diet arm (IBS-API p=0.0718; IBS-Bloating p=0.0827, these p-values did not reach the threshold of

p< 0.05). However, GIS and SGA did show significant improvement (GIS p=0.0302; SGA p=0.0093). Non-IBS-D patients (n=149) showed the greatest decrease from baseline (IBS-API p=0.0139; IBS-Bloating p=0.0214) as well as for global measures (GIS p=0.0020; SGA p=0.0010). No significant adverse events were noted during the study.
Conclusion: These results suggest that IgG-based elimination diets using a novel, proprietary diagnostic to guide therapy may offer benefit to patients with IBS. Results of this study should help guide other studies.

General Linear Mixed Models
Week 8 ITT p-value

Endpoint	IBS-ALL	IBS non-D
IBS-API (Change from baseline)	0.0718	0.0139
IBS-Bloating (Change from baseline)	0.0827	0.0214
GIS (Change from baseline)	0.0302	0.0020
SGA (Mean Score)	0.0093	0.0010

Logistic Responder Analyses
Week 8 ITT p-value

Endpoint	IBS-ALL	IBS non-D
SGA	0.0416	ND
GIS	0.0058	ND

[0521] **Figure 1.** Summary of GLMM and LMM analyses

S522

A Case Series of 25 Auto-Brewery Syndrome Patients: A Single Community Hospital Experience

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Introduction: Auto-brewery syndrome (ABS) is a rare condition where ingested carbohydrate is converted to alcohol by enteric fungi; a diagnosis often discounted by medical personnel. The goal of our study was to confirm or refute the diagnosis of ABS with a systematic investigative and treatment plan. Initial success caused patients from across the country to seek our center.
Methods: Criteria for evaluation were as follows: alcohol abstinence, positive breathalyzer without alcohol ingestion, concomitant elevated blood alcohol level, corroboration of abstinence from family member or close friend, and prior medical evaluation for an alternative cause of symptoms. If patient met criteria, they underwent endoscopic evaluation for collection of gastrointestinal secretions. Collected samples were sent for culture with sensitivities. After endoscopy, patient submitted to a Carbohydrate Challenge Test (CCT), which involved breathalyzer as well as initial serum glucose and ethanol levels. Then ingestion of 200g of glucose, followed by serial monitoring of breathalyzer, serum glucose and serum ethanol levels for 8 hours. Then patients started on antifungal therapy, carbohydrate free diet for 6 weeks and serial breathalyzer monitoring, followed by reintroduction of carbohydrates to diet. If breathalyzer turned positive, then antifungal regimen was adjusted based on cultures.
Results: The 25 patients included 20 males and 5 females, age range 20-63(41.8) years. All patients had antibiotic exposure prior to symptoms. 16(64%) had a positive CCT. 11(69%) patients had antifungal therapy prior to CCT. Cultures revealed a variety of fungi with multiple patients harboring multiple fungi. *Saccharomyces cerevisiae* was most common, present in 7(28%) patients. Also noteworthy was 1 patient with positive CCT had negative cultures. (Table) Significant associations were noted with esophagitis 12(48%) and Barrett's esophagus 7(28%). Lastly, all patients suffered from complications including: multiple hospitalizations for alcohol intoxication 8(32%), end stage liver disease 4(16%), arrest for driving under the influence 6(24%), pancreatitis 2(8%), and traumatic subdural hemorrhage 1(4%).
Conclusion: ABS represents a challenge in establishing diagnosis and administering effective treatment. These cases demonstrate ABS's varied presentation, shows our testing and treatment methodology, and highlights areas for further research both in diagnostic modalities and treatment protocols to more effectively manage this orphan disease.

Table 1. Bacteria* and Fungi Identified

Organism	Incidence
Aspergillus versicolor	1
Candida albicans	5
Candida dubliniensis	2
Candida glabrata	2
Candida guillienmondii	1
Candida intermedia	1
Candida lambica	1
Candida lusitaniae	1
Candida parapsilosis	4
Candida sojae	1
Cryptococcus albidus	1
Geotrichum klebahnii	1
*Klebsiella Species**	4
Penicillium	3
Pichia manschurica	1
Rhodotorula minuta	1
Rhodotorula mucilaginosa	4
Rhodotorula species	1
Saccharomyces cerevisiae	7
None	1

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A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy, Safety and Tolerability of ANJ908, a Novel DGAT1 Inhibitor, in Patients With Chronic Idiopathic Constipation

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Introduction: Current treatment for chronic idiopathic constipation (CIC) is limited by: 1. Low magnitude of drug effect (increase of only ~1-1.5 SBM per week) 2. Low overall response rate (typically < 20%) 3. Loss of efficacy within 3-6 months. Real-world experience where CIC patients often cycle through 2-4 pharmacotherapies shows the need for new medications with better efficacy. ANJ908 is a safe and well-tolerated diacylglycerol acyltransferase (DGAT) 1 inhibitor which increases bowel movement number and softens the stool in humans. We designed and conducted a phase 2 study of ANJ908 in CIC patients and present the data here for the first time.
Methods: ANJ908C2102 was a multicenter, randomized, placebo-controlled, double-blind study designed to assess the efficacy and safety of ANJ908 in CIC patients. Patients meeting ROME IV diagnostic criteria for functional constipation (a.k.a. CIC) and had < 3 SBMs/week for prior the two weeks were eligible. Enrolled patients underwent a 2 week run-in period where all previous constipation treatment was stopped. After run-in, patients were randomized (1:1:1) to 4 weeks of once daily treatment with placebo, ANJ908 at 20 or 40 mg. Bowel movement timing, stool details, and patient reported constipation symptoms were recorded in an eDiary. Patient safety labs and AEs were monitored throughout the study.
Results: A total of 191 patients were randomized. Patients were 77.9% female, with a mean (SD) age and BMI of 42.2 (14.4) years and 23.2 (4.36) kg/m^2, respectively. ANJ908 increased the mean (SE) placebo-subtracted number of SBM/week by +2.28 (0.75; p = 0.0027) and +3.10 (0.74; p < 0.0001) and CSBM/week by +1.53 (0.70; p = 0.03) and +1.81 (0.70; p = 0.01), respectively at week 4. ANJ908 improved stool consistency, provided constipation relief, decreased straining severity, and reduced rescue medication use. ANJ908 was safe and generally well tolerated. Mild diarrhea, nausea and vomiting were the most common AEs with a total of 7 (out of 64) patients in the ANJ908 20 mg group discontinuing treatment due to AEs.
Conclusion: ANJ908 demonstrated increases in weekly SBMs and CSBMs to a magnitude greater than previous treatments. Furthermore, ANJ908 improved patient reported stool consistency and relief of constipation symptoms. The benefit-risk profile of ANJ908 justifies advancement into phase 3 clinical development to confirm its efficacy and safety. If this profile is confirmed, ANJ908 may become a treatment better able to address the unmet need in CIC patients.

S524

Predictors of Placebo Response in Patients With Irritable Bowel Syndrome and Constipation: A Post-Hoc Analysis From Pooled Phase 2b/3 Studies Assessing the Safety and Efficacy of Linaclotide

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Introduction: In clinical studies of irritable bowel syndrome (IBS), the placebo response rate is variable, with a pooled placebo response rate of 34% for the US Food and Drug Administration (FDA) abdominal pain responder endpoint. Further understanding of the factors that drive the placebo response can improve clinical study design. We aim to identify potential factors associated with a high placebo response via a post-hoc analysis of clinical studies in IBS patients with constipation (IBS-C).
Methods: Patient data from placebo-controlled studies that assessed the efficacy and safety of linaclotide for IBS-C were pooled from 1 phase 2b (NCT02559206) and 3 phase 3 (NCT00948818, NCT00938717, NCT03573908) studies. Inclusion criteria were similar across studies, and all patients had a baseline abdominal pain severity score ≥3 (0–10 scale). The primary endpoint of interest was abdominal pain responder, defined as ≥30% improvement from a 2-week baseline in average daily worst abdominal pain score for ≥50% of the first 12 weeks on treatment. Predictors of placebo response were identified using backwards selection via a regression analysis from a list of demographics and baseline disease characteristics. Additionally, standardized coefficients were calculated to rank the magnitude of association of each selected predictor with the response.
Results: The 4 studies included 2073 patients (1027 placebo and 1046 linaclotide 290 μg). Two predictors of placebo response were identified as having the largest impact on the FDA abdominal pain responder endpoint. Higher baseline variation in abdominal pain was associated with higher placebo response (coefficient, standard error [SE]: 0.20, 0.068; P = .0032), and higher mean baseline abdominal pain was associated with lower placebo response (coefficient, SE: −0.15, 0.019; P < .0001) [**Table**]. Age, sex, baseline spontaneous bowel movement frequency, baseline Bristol Stool Form Scale score, anxiety, depression, and prior gastrointestinal drugs taken were not found to impact the placebo response for the abdominal pain responder endpoint.
Conclusion: In this pooled analysis of IBS-C clinical studies, higher baseline variation in abdominal pain was a positive predictor of placebo response, while higher mean baseline abdominal pain score was a negative predictor of placebo response. These findings may have implications towards future clinical study design.

Table 1. Factors that predict placebo response for abdominal pain improvement, pooled data from phase 2b/3 studies

Predictor	Placebo (n = 1046)		
	Estimated coefficient (SE)	*P* value	SC
SD of baseline abdominal pain	0.20 (0.068)	.0032	0.08
Mean baseline pain	−0.15 (0.019)	< .0001	−0.14

A responder was defined as ≥30% improvement in average daily worst abdominal pain score from baseline for 50% of weeks on treatment. Predictors assessed were age, sex, baseline spontaneous bowel movement, mean baseline abdominal pain score, SD of baseline abdominal pain score, pre-US Food and Drug Administration approval, baseline Bristol Stool Form Scale score, anxiety, depression, baseline pain conditions, prior gastrointestinal drug taken. SC, standardized coefficient; SD, standard deviation; SE, standard error.

REFERENCE

1. Bosman M, et al. Lancet Gastroenterol Hepatol. 2021;6(6):459–473.

S525

The Low FODMAP Diet Improves Abdominal and Overall Symptoms in Patients With All Subtypes of Irritable Bowel Syndrome

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Introduction: There is substantial evidence that a diet low in fermenTable oligo-, di-, monosaccharides, and polyols (FODMAPs) improves symptoms in patients with Irritable Bowel Syndrome and diarrhea (IBS-D). Though the low-FODMAP diet is increasingly used in patients with IBS and constipation (IBS-C) or mixed bowel habits (IBS-M), there is little data to support this practice. We aim to compare the real-world effectiveness of a low-FODMAP diet in patients with IBS-D, IBS-C, and IBS-M.
Methods: Utilizing a commercially available meal procurement service which prepares and delivers meals certified low in FODMAP content (Modify Health, Atlanta, GA), patients with suspected IBS met with a registered dietitian and completed the IBS symptom severity scale (IBS-SSS) questionnaire before starting the low-FODMAP diet and after the restriction phase of the diet plan. A decrease in IBS-SSS score of >100 was defined as a responder.
Results: 403 IBS patients filled out baseline and post-elimination IBS-SSS surveys. 26% of patients were referred by a GI specialist; the rest were self-referrals. 193 (48%) patients had severe IBS (IBS-SSS > 300) prior to the intervention. IBS-D patients had a 71% improvement in pain, 56% improvement in bloating, and 55% improvement in bowel movement satisfaction. 77% of IBS-D patients had improvement in total IBS-SSS >100. IBS-C patients had a 69% improvement in pain, 49% improvement in bloating, and 42% improvement in bowel movement satisfaction. 67% of IBS-C patients had improvements in IBS-SSS >100. IBS-M patients had 85% improvement in pain, 55% improvement in bloating, and 53% improvement in bowel movement satisfaction. 72% of IBS-M patients had improvement in total IBS-SSS >100. Those who used the commercial meals for "all" of the restriction phase had a mean IBS-SSS improvement of 174, and mean quality of life (QOL) improvement of 40%, while those who used the commercial meals for "some" of the elimination phase had mean IBS-SSS improvement of 153, and mean QOL improvement of 33% (p=0.059 and 0.03, respectively). (Table)
Conclusion: This data supports the effectiveness of a low-FODMAP diet for all IBS subtypes, including IBS-C and IBS-M. Patients who obtained prepared low-FODMAP meals during the entire restriction phase experienced greater benefits than those who only obtained meals for a portion of the restriction phase.

Table 1. Improvement in IBS-SSS Categories by IBS-Subtype

IBS Subtype	Total Number of Patients	IBS-SSS (Mean % Improvement)	Pain (Mean % Improvement)	Bloating (Mean % Improvement)	BM Satisfaction (Mean % Improvement)	% Improvement in IBS-SSS >100
IBS-D	87	59 (p< 0.001)	72	56	56	77
IBS-C	73	50 (p< 0.001)	70	49	42	67
IBS-M	91	56 (p< 0.001)	73	55	53	73

S526

Altered Fecal Microbiome in Patients With Irritable Bowel Syndrome With Diarrhea Is Related to Bile Acid Synthesis, Not to Rapid Colonic Transit

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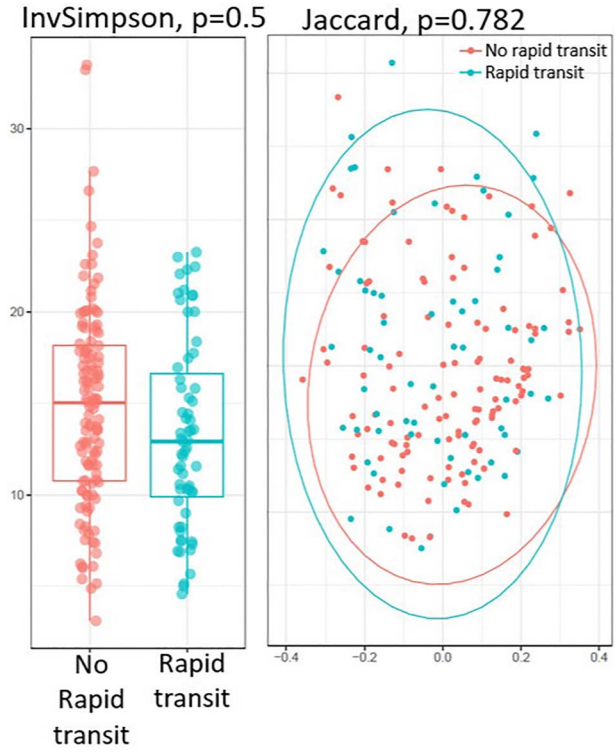
Introduction: Bile acid (BA) diarrhea (BAD) affects up to 30% of patients with irritable bowel syndrome with diarrhea (IBS-D). In a cohort of 194 patients with IBS-D, 43 had BAD (serum 7αC4 >52ng/mL) and, as a group, had faster colonic transit, lower microbial α diversity, and a different microbial compositional profile based on β diversity compared to IBS-D without altered BA metabolism (ABAM); 70 microbial species were differentially abundant between the two groups, with 61/70 decreased in BAD (PMID: 35580964). However, the effect of colonic transit on the relationship between BAs and the microbiome was not evaluated. Our **aim** was to compare the microbiome composition in the same cohort of patients with IBS-D (total 183) with and without rapid colonic transit as measured by the geometric center at 24 hours (GC24) before and after adjusting for ABAM (elevated serum 7αC4).
Methods: Participants with Rome III positive IBS-D provided a random single stool sample and measurements of fasting serum 7αC4 and colonic transit by scintigraphy as part of an institutional review board approved study. Patients with GC >3.45 (90th percentile of normal) were considered to have rapid transit. SHOGUN was used to perform taxonomic assignment of reads passing quality control. Microbiome analysis included α diversity, β diversity, and differential abundance.
Results: Patients with rapid colonic transit had borderline lower α diversity (InvSimpson, p=0.07) and a borderline different compositional profile based on β diversity (Jaccard, p=0.07) compared to patients without rapid transit. There were 6 genera and 14 species (**Table**) including *Clostridium polynesiense* and species belonging to the Ruminococcaciae and Lachnospiraceae families that were decreased in patients with rapid colonic transit. After adjustment of the analysis for age, sex, BMI, and serum 7αC4, there was no significant difference in α or β diversity (**Figure**) between the two groups. Moreover, these differences in differential abundance of microbiota at the genus and species levels were not maintained after adjustment, except for *Clostridium polynesiense* which was decreased with rapid colonic transit.
Conclusion: Altered fecal microbiome composition in patients with IBS-D and rapid colonic transit are significantly impacted by a biomarker of bile acid synthesis, serum 7αC4, rather than resulting from the rapid transit.



[0526] **Figure 1.** Microbial alpha (left) and beta (right) diversity in patients with IBS-D with and without rapid colonic transit after adjustment for age, sex, BMI, and serum 7αC4.

Table 1. Differentially abundant species in patients with IBS-D with or without rapid transit before and after adjustment for age, sex, BMI, and serum 7αC4

	Log 2-Fold Change ± Standard Error
	Before adjustment
Mobiluncus mulieris	-0.60 ± 0.17
Intestinimonas butyriciproducens	-1.12 ± 0.28
Intestinimonas massiliensis	-0.82 ± 0.21
Pseudoflavonifractor capillosus	-0.75 ± 0.20

Table 1. (*continued*)

	Log 2-Fold Change ± Standard Error
Anaerosalibacter massiliensis	-0.92 ± 0.27
Anaerofustis stercorihominis	-1.79 ± 0.48
Lachnospiraceae bacterium MC2017	-0.99 ± 0.28
Oscillibacter sp. KLE 1745	-1.13 ± 0.35
Anaerotruncus colihominis	-0.75 ± 0.20
Megasphaera genomosp. Type 1	-1.32 ± 0.38
Clostridium polynesiense	-1.62 ± 0.32
Clostridium cellulosi	-0.94 ± 0.29
Ruminococcaceae bacterium AE2021	-0.61 ± 0.17
Caloramator australicus	-0.35 ± 0.11
	After adjustment
Clostridium polynesiense	-1.34 ± 0.33

S527

Radiologic Identification of Visceroptosis in Patients With Hypermobile Ehlers-Danlos Syndrome (hEDS) With Functional Gastrointestinal (GI) Symptoms Compared to Healthy Subjects

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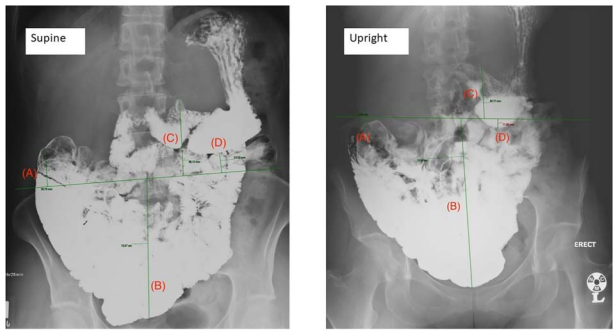
Introduction: hEDS is the most common form of EDS, characterized by joint hyperlaxity and a supporting clinical or family history. Visceroptosis, defined as a prolapse of abdominal organs below their natural position, has been proposed as a cause of functional gastrointestinal (GI) symptoms in hEDS. To date, no definitive testing for visceroptosis exists. We aim to develop normative radiologic measurements for visceroptosis from healthy subjects and subsequently assess the prevalence of visceroptosis in hEDS patients.
Methods: Healthy controls and subjects with hEDS fulfilling Rome IV criteria for functional GI symptoms were recruited. Patients with previous abdominal surgeries were excluded. Clinical history and Beighton scores were recorded. Following ingestion of 16 oz barium, the passage of contrast was followed through the small bowel until it reached the colon. At that point, supine and upright radiographs of the abdomen were obtained. Measurements were calculated on supine and fully upright positions with respect to a reference line drawn across the top of the iliac crests. Dynamic measurements included: the lowest point of stomach, bottom of small bowel column in the pelvis, inferior tip of the liver, and top of jejunal column. Correction for patients' height was made by normalizing data to the height of T12 vertebral body. hEDS subjects with visceroptosis were defined if any of their measurements exceeded two standard deviations above the mean established in the healthy control cohort. (Figure)
Results: Eleven healthy and nine subjects with hEDS were enrolled (91% vs 100% Female, mean age 34 ± 13 vs 30 ± 8 years, mean Beighton score 1.8 ± 2.2 vs 7.4 ± 1.3). All hEDS subjects had abdominal pain and bloating. Constipation and mixed pattern were present in 78% and 22%, respectively. Values for the lowest point of stomach and top of the jejunal column how altered distribution between healthy and EDS subjects. Three (33%) hEDS subjects meet the radiographic criteria for visceroptosis. Neither Beighton score, height, weight, or BMI correlated with radiographic evidence of visceroptosis. Lack of significant variability in symptoms and functional GI testing prevented further correlation analysis. (Table)
Conclusion: This is the first study to establish a normal range for the dynamic movement of the viscera during supine and upright radiographs of the abdomen. This will offer a simple and objective radiographic approach to define visceroptosis in hEDS patients.



[0527] **Figure 1.** Assessment for visceroptosis was performed by measuring the change in four defined landmarks in supine and upright position with respect to a line drawn across the iliac crest: (A) inferior tip of the liver, (B) bottom of small bowel column in the pelvis, (C) top of jejunal column, (D) lowest point of stomach.

Table 1. Normative values for radiographic measurements of visceroptosis in healthy controls along with values observed in hEDS subjects

Landmarks	Healthy controls		hEDS subjects with GI symptoms		
	Absolute change (cm mean ± std)	Change corrected for vertebral height (cm mean ± std)	Absolute change (cm mean ± std)	Change corrected for vertebral height (cm mean ± std)	Number of subjects with visceroptosis (>2 standard deviation)
Lowest point of stomach	8.99 (3.13)	2.92 (0.97)	9.89 (7.22)	3.25 (2.28)	3
Bottom of small bowel column	1.96 (1.89)	0.64 (0.59)	2.19 (1.70)	0.74 (0.58)	0
Inferior tip of the liver	4.28 (2.09)	1.47 (0.87)	3.60 (2.78)	1.19 (0.89)	0
Top of jejunal column	5.99 (2.02)	1.99 (0.73)	4.07 (2.91)	1.34 (0.90)	2

S528

Systematic Review and Meta-Analysis of the Effectiveness of the Lactinex Probiotic Against Diarrhea

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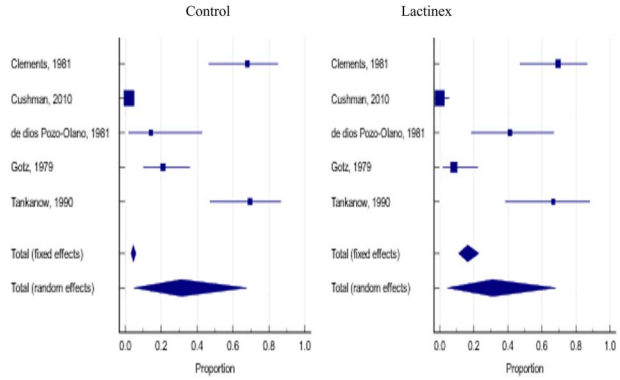
Introduction: Probiotics are widely used and prescribed to address a host of health issues. Despite evidence that different probiotic bacteria have differing therapeutic mechanisms of action, many probiotics are prescribed indiscriminately, with little research to support the use of specific formulations for a given ailment. Further investigation is required to assess the efficacy of one commonly prescribed probiotic formulation – Lactinex (*Lactobacillus acidophilus* and *Lactobacillus helveticus* (*bulgaricus*)) – for the treatment of diarrhea. This review seeks to assess whether administration of probiotics containing *Lactobacillus acidophilus* and *Lactobacillus helveticus* (*bulgaricus*) are more effective than placebo in reducing symptoms of diarrhea.
Methods: A systematic search of randomized placebo-controlled trials evaluating the effectiveness of combination *Lactobacillus acidophilus* and *Lactobacillus bulgaricus* in the treatment of diarrhea by any cause was conducted and captured all available studies (n = 2411). After application of exclusion criteria, four studies were identified as suitable for inclusion. Separate meta-analyses were conducted for the proportion of cases with diarrhea in the control group and the treatment group. To assess differences in proportions between the control and treatment groups, a generalized linear model assessment was performed.
Results: Analyses revealed the overall proportion of cases with diarrhea in the treatment group was only 3.5% lower than the overall proportion in the control group (P = 0.508), with our considering that the 3.5 lower percentage to be of little or no clinical importance.
Conclusion: Existing literature suggests little or no clinical benefit of Lactinex for the treatment of diarrhea, highlighting the need for more research or re-evaluation of its widespread use.



[0528] **Figure 1.** Shows the effectiveness of Lactinex vs Placebo at preventing all cause diarrhea. From the graphs, there is little to no statistical or clinical difference between the two at treating all-cause diarrhea.

S529

Do Social Determinants of Health Impact Which Patients Are Referred for the Low FODMAP Diet?

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Introduction: The aim of this study was to explore if differences in social determinants of health in irritable bowel syndrome (IBS) patients impact access to the low FODMAP diet (LFD).
Methods: A prospective cross-sectional survey of 486 adults was performed from May – June 2022. All respondents completed a 31-question survey via Survey Monkey. The survey link was distributed via social media platforms, low FODMAP dietician blog posts, and the IFFGD newsletter. Questions consisted of social determinants, such as the number of family members in their home, education attainment, employment status, healthcare insurance, access to healthcare, housing, utilities, transportation, childcare, and food access and insecurities. Statistical analyses included the Mann-Whitney *U* test and chi-square test. A *p*-value of ≤ 0.05 was considered statistically significant.
Results: 462/486 (95.1%) respondents reported a diagnosis of IBS. Patients without a diagnosis of IBS were removed from the analysis. IBS cohort demographics consisted of 93% female, 92.5% Caucasian, and 92.7% residing in the United States. The primary IBS complaint was equally distributed: IBS-Diarrhea (35.1%), IBS-Constipation (29.1%), and IBS-Mixed (35.1%). 83.6% (n = 400) of IBS respondents were recommended the low FODMAP diet for treatment of their GI symptoms by a medical provider. IBS respondents were divided into two groups: IBS-LFD+ (n = 400, those referred for low FODMAP diet education) and IBS-LFD- (n = 62, those not referred for low FODMAP diet education). Compared with their IBS-LFD+, IBS-LFD- respondents had a lower education level (14.8% with high school diploma or less vs. 5.8%, p =0.01), lower household income (46.7% with income ≤ $74,999 vs. 30.7%, p =0.03), and decreased access food when needed (8.1 vs. 2.8 %, p = 0.03). IBS-LFD- respondents were also less likely start a low FODMAP diet on their own compared to IBS-LFD+ counterparts (12.4% vs. 87.6%, p < 0.001).
Conclusion: IBS patients with a lower socioeconomic position were less likely to be recommended the low FODMAP diet as treatment compared to patients with higher socioeconomic positioning. This raises concern socioeconomic status negatively impacts referral for low FODMAP diet for IBS management and suggests implicit referral bias. Given the increasing evidence for dietary therapy for managing GI symptoms, further investigation is needed to identify how provider perceptions of patients influence dietary treatment recommendations.

Table 1. Comparison of social determinants between IBS patients recommended vs. NOT recommended the low FODMAP diet by their health provider

Social Determinant Variable	IBS patients recommended low FODMAP Diet [IBS-LFD+] (n = 400)	IBS patients NOT recommended low FODMAP Diet [IBS-LFD-] (n = 62)	P-Value	Cramer V Coefficient	Odds Ratio (OR)	95% Confidence Interval (CI)
Highest Level of Education Attainment						
High school diploma/ GED or less	5.8%	14.8%	0.01	0.12	2.31	1.26, 4.25
≥ High School Diploma/GED	94.2%	85.2%				
Household Income						
$0.00 - $74,999	30.7%	46.7%	0.03	0.11	1.81	1.05, 3.11
≥ $75,000	69.3%	53.3%				
Access to Food When Needed						
Unable to access food when needed	2.8%	8.1%	0.03	0.10	2.45	1.14, 5.26
Likely to start low FODMAP diet on their own						
Yes	87.6%	12.4%	< 0.001	0.19	0.28	0.16, 0.50
No	56.6%	44.4%				

Table 1. (*continued*)

Social Determinant Variable	IBS patients recommended low FODMAP Diet [IBS-LFD+] (n = 400)	IBS patients NOT recommended low FODMAP Diet [IBS-LFD-] (n = 62)	P-Value	Cramer V Coefficient	Odds Ratio (OR)	95% Confidence Interval (CI)
Visit a registered dietitian about the low FODMAP diet						
Yes	88.2%	11.8%	0.06	0.09	0.64	0.40, 1.03
No	81.6%	18.4%				

S530

Nutritional Aspects in Patients With Gastroparesis: Normal BMI Despite Abnormal Intake!

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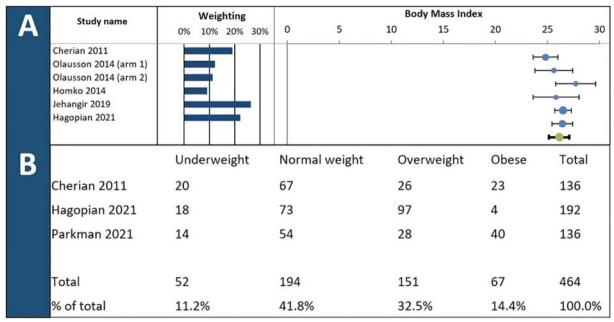
Introduction: Patients with gastroparesis have signs and symptoms including nausea, vomiting, and early satiety, thus leading to inadequate food intake and a high risk of malnutrition. The classic clinical picture of gastroparesis is a symptomatic patient losing weight. We performed a systematic review and a meta-analysis to identify average body mass index (BMI) in patients with gastroparesis.
Methods: Medline, Embase, Cochrane, CINAHL, and Scopus were searched for longitudinal studies reporting on nutrition in adult patients with gastroparesis. A search strategy was developed with core terms including "gastroparesis", "BMI", "calorie", and "nutrition". The main outcome was determined to be the average BMI in patients with gastroparesis. The secondary outcome was average calorie intake in these patients. Data was pooled and I^2 values were calculated to determine heterogeneity. No controls were identified for analysis.
Results: Initial database search resulted in 3999 studies (n=3999). 16 relevant studies were identified for full text review (n=16). 5 studies were identified eligible to be included in the average BMI meta-analysis after applying inclusion and exclusion criteria (n=5). The weighted average BMI in patients with gastroparesis was calculated at (26.1 kg/m^2). Heterogeneity (I^2 value) for these studies was noted to be moderate at 46.7% (Figure 1A). 3 of the initial 16 studies identified for full review reported on distribution of patients with gastroparesis among different BMI categories with details shown in (Figure 1B). Another 3 studies were identified eligible to be included in the average calorie intake meta-analysis (n=3). Weighted average calorie intake in patients with gastroparesis was calculated at (1161 kcal/day), forest plot is shown in (Figure 2).
Conclusion: Weighted average BMI in patients with gastroparesis laid in the overweight category, with most patients noted of normal weight per distribution of patient's prevalence per category of BMI (Figure 1B). These results contradict with what is commonly thought of these patients being likely underweight for their inability to meet dietary requirements. Average calorie intake in patients with gastroparesis is found to be less than the recommended daily intake for adult males and females in the US. Reasons why patients are mostly of normal weight to overweight despite less than recommended daily calorie intake are not well understood and more investigations of other factors affecting BMI in these patients is warranted.

Figure 1

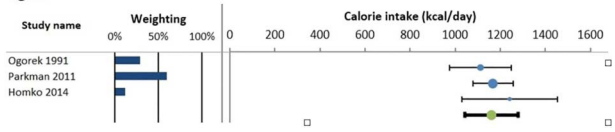


B

	Underweight	Normal weight	Overweight	Obese	Total
Cherian 2011	20	67	26	23	136
Hagopian 2021	18	73	97	4	192
Parkman 2021	14	54	28	40	136
Total	52	194	151	67	464
% of total	11.2%	41.8%	32.5%	14.4%	100.0%

[0530] **Figure 1.** A) Forest plot of average BMI in patients with gastroparesis meta-analysis, B) Distribution of gastroparesis patients' prevalence among BMI categories

Figure 2



[0530] **Figure 2.** Forest plot of average calorie intake in patients with gastroparesis meta-analysis.

S531

Safety and Tolerability of a Vibrating Capsule in Patients With Chronic Idiopathic Constipation

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Introduction: Chronic idiopathic constipation (CIC) is a common and bothersome condition. Up to 40% of patients with CIC fail to improve with medical therapies and many are interested in non-pharmacologic options. A recent phase III trial found an orally ingested vibrating capsule (VC) (Vibrant, Yokneam, Israel) significantly improved key constipation symptoms including stool frequency, straining, consistency and quality of life in patients with CIC. The aim of this study was to determine the safety, tolerability and ease of use of the VC in patients with CIC
Methods: This was secondary outcome analysis of a prospective, randomized, multi-center, double –blind, placebo-controlled study in patients with CIC. Patients received either VC (2 distinct stimulation modes) or placebo capsule, once daily, five days a week for 8 weeks. Patients in the VC and placebo arms were taught how to activate the VC which included connecting to wi-fi, using a mobile app, and activating the capsule using a base station. A questionnaire evaluated the ease of use and functionality of the VC system.
Results: A total of 79 adverse events (AEs) were considered possibly related to the study treatments (44 in VC Mode 1, 9 VC mode 2, and 26 with placebo). (Table) No serious AEs (SAE) or treatment related diarrhea were reported in the VC. Two AEs in the placebo arm were considered severe (one transient ischemic attack and one with abdominal pain) but neither were considered related to the study treatment by the investigator. A vibrating sensation was reported by 11% in VC arm, but no subject withdrew because of this. Regarding functionality, 94% of patients found `Connecting the base unit to Wi-Fi' – easy. 5% ranked it medium, 2% found it hard. Similarly, 97% of patients found `Setting up the base unit for use' - easy. Also,82% found `Activating capsules' - easy, 13% ranked it medium, 5% found it hard. Finally for the question, `Following the treatment for several months, once it is commercialized' - 85% reported that they would find it easy to use, 12% ranked it medium difficulty, and 3% ranked it hard.

Conclusion: In this large phase III trial of patients with CIC, a VC was found to be safe and well tolerated. In particular no SAEs or diarrhea were observed. In addition, 82-94% of study participants found the VC system easy to use and 85% were willing to try this treatment if available.

Table 1. Adverse Events

Adverse event	Vibrating Capsule, Mode 1 (n=163) No. of patients (%)	Vibrating Capsule, Mode 2 (n=37) No. of patients (%)	Placebo (n=149) No. of patients (%)
Adverse events during treatment (combined safety populations including interim analysis groups).*			
Any event	44 (27.0)	9 (24.3)	26 (17.4)
Sensation of vibration**	18 (11.0)	1 (2.7)	.
Headache	3 (1.8)	1 (2.7)	4 (2.7)
Urinary tract infection	3 (1.8)	1 (2.7)	2 (1.3)
Abdominal pain	2 (1.2)	.	6 (4.0) 1 SAE
Abdominal discomfort	2 (1.2)		2 (1.3)
Vomiting	2 (1.2)	2 (5.4)	1 (0.7)
Nausea	3 (1.8)	.	1 (0.7)
Abdominal distention	1 (0.6)	.	2 (1.3)
Anorectal problem	1 (0.6)	.	5 (3.4)
Diarrhea	2 (1.2)	.	.
Covid-19	1 (0.6)	.	2 (1.3)
Nasopharyngitis/Bronchitis	4 (2.5)	1 (2.7)	4 (2.7)
TIA	.	.	1 (0.7) SAE
Musculoskeletal	2 (1.2)	.	1 (0.7)

*Data shown for adverse events in at least 1% of the subjects
**Sensation of vibration means: ``I think I felt vibration``. In previous vibrant studies the reports were in both active and placebo arms

S532

Plecanatide Improves Severe Abdominal Pain and Severe Bloating in Individuals With Irritable Bowel Syndrome With Constipation (IBS-C): A Pooled Analysis of Two Phase 3 Trials

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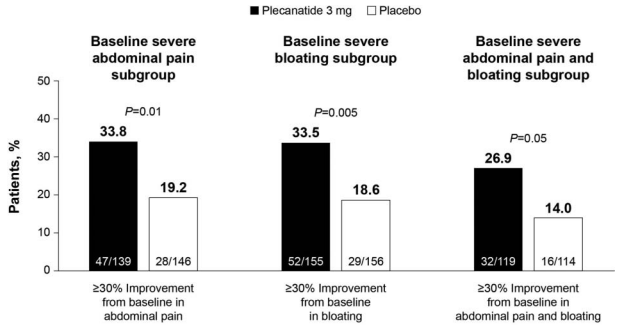
Introduction: IBS-C is a disorder of gut-brain interaction characterized by abdominal pain related to defecation and hard stool consistency. Bloating is also amongst the most common symptoms. Plecanatide is indicated in the United States for the treatment of IBS-C in adults. The aim of this study was to evaluate the efficacy of plecanatide for severe abdominal pain and/or severe bloating in patients with IBS-C.
Methods: Data were pooled and analyzed post hoc from two phase 3, randomized trials of adults with IBS-C treated with plecanatide 3 mg (FDA-approved dose) or placebo once daily for 12 weeks (NCT02387359; NCT02493452). Patients rated abdominal pain and bloating severity separately using an 11-point scale (0 [none] to 10 [worst possible]). A subgroup analysis was conducted in patients with severe pain, severe bloating, or both at baseline. Symptom scores ≥ 8 were defined as severe. Response was defined as a ≥ 30% improvement from baseline in symptom score(s) at Week 12. A correlation analysis measured the strength of associations between abdominal pain and bloating. A coefficient (r) value of > 0.90-1.00 was considered very strong positive correlation; > 0.70-0.90, strong positive correlation.
Results: At baseline, 285 (19.6%) of 1453 patients reported severe abdominal pain, 311 (21.4%) reported severe bloating, and 233 (16.0%) reported both symptoms as severe. A significantly greater percentage of plecanatide-treated patients with severe baseline abdominal pain were responders vs placebo at Week 12 (Δ=14.6%, P=0.01 [Figure]). In addition, a significantly greater percentage of plecanatide-treated patients with severe baseline bloating treated were responders vs placebo at Week 12 (Δ=14.9%; P=0.005 [Figure]). In patients with both symptoms rated severe at baseline, a numeric difference favored plecanatide vs placebo (Δ=12.9%; P=0.05 [Figure]). In the overall and severe pain/bloating patient subgroups, changes from baseline to Week 12 in abdominal pain and bloating were strongly correlated to each other (overall population: r=0.85-0.88; both severe subgroup, r=0.92-0.95; Table).
Conclusion: In patients with IBS-C and severe abdominal pain and/or severe bloating, plecanatide treatment reduced symptom severity vs placebo, with strong correlations in symptom responses. This suggests a parallel pathogenesis and associated generalized improvement in the visceral hypersensitivity underlying these symptoms



[0532] **Figure 1.** Percentage of Patients With ≥ 30% Improvement From Baseline in Severe Abdominal Pain, Bloating, or Both at Week 12, by Subgroup

Table 1. Correlation of Change From Baseline at Week 12 in Abdominal Pain and Bloating Symptoms in Overall Population and Those With Severe Baseline Abdominal Pain and Bloating

Population	Abdominal pain and bloating	
	Spearman correlation coefficient, r	Pearson correlation coefficient, r
Overall population	0.85*	0.88*
Severe abdominal pain and bloating population	0.92*	0.95*

*$P < 0.001$.

S533

Vibrating Capsule Is Efficacious in Patients With Severe Chronic Idiopathic Constipation (CIC)

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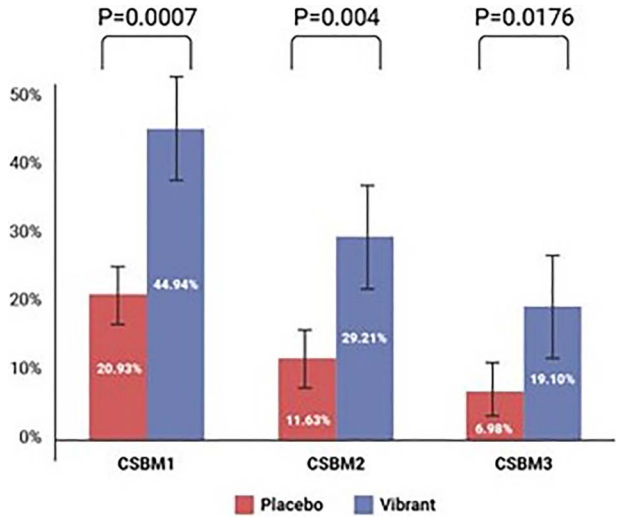
Introduction: Approximately 50 million Americans report constipation, of whom 28% have moderately severe illness (Am J Gastro 2020;115:895-905). The effectiveness of current therapies for severe chronic idiopathic constipation (CIC) is unknown. In a recent Phase III trial, a vibrating capsule (VC) proved superior to placebo in improving bowel and abdominal symptoms in patients with CIC. Aim: To determine the efficacy and safety of VC in patients with severe CIC.
Methods: We performed a post-hoc analysis of CIC patients (Rome III) who were enrolled in an 8-week phase 3, multicenter, double-blind trial, and randomly received one VC (Vibrant, Yokneam, Israel) or placebo orally for 5 days/week. Severe CIC was defined as patients who reported 0 complete spontaneous bowel movements (CSBM) during a 2-week baseline period on a daily electronic stool diary. Patients with history of dysphagia or bowel obstruction were excluded. Primary outcome measures were percentage of subjects with an increase of one ($CSBM_1$), two (CSBM2), or three (CSBM3) CSBM/week, during at least 6 of 8 treatment weeks compared to baseline. Secondary outcomes and safety were also assessed.
Results: 312 CIC patients were enrolled of whom 56% (VC n=89, placebo n=86) had severe CIC. There were significantly greater CSBM1 (p=0.0007), CSBM2 (p=0.0040), and CSBM3 (p=0.0176), responders in the VC group compared to placebo (Fig). The straining effort (p=0.0027) and stool consistency (p=< .0001) also improved significantly in the VC group compared to placebo. Also, QOL significantly improved in the VC group (p=< .0001) compared to placebo. The treatment was generally safe, without severe adverse events or diarrhea. The most common AEs in the group were a sensation of mild vibration (11.2%) and abdominal discomfort (2.25%), Table.
Conclusion: In individuals with severe CIC, VC significantly improved bowel and abdominal symptoms and QOL compared to placebo. The VC was safe and well tolerated. Vibrating Capsule is a first in class, novel, non-pharmacological treatment that is efficacious and safe in patients with severe chronic constipation.



[0533] **Figure 1.** Primary outcome measures showing proportion of CSBMs responders with severe constipation

Table 1. Adverse events in severe CIC population

Adverse event	Vibrating Capsule, Mode 1 (n=89) No. of patients (%)	Placebo (n=86) No. of patients (%)
Adverse events during treatment (combined safety populations including interim analysis groups).*		
Any event	23 (25.84)	15 (17.4)
Sensation of vibration**	10 (11.24)	
Headache	1 (1.12)	1 (1.16)
Urinary tract infection	1 (1.12)	1 (1.16)
Abdominal pain		2 (2.23)
Abdominal discomfort	2 (2.25)	
Vomiting	2 (2.25)	1 (1.16)
Nausea	3 (3.37)	1 (1.16)
Abdominal distention		2 (2.23)
Diarrhea	2 (2.25)	
Covid-19	1 (1.12)	1 (1.16)
Nasopharyngitis/Bronchitis	2 (2.25)	
Musculoskeletal		1 (1.16)

*Data shown for adverse events in at least 1% of the subjects
**Sensation of vibration means: "I think I felt vibration."

S534

Plecanatide Improves Symptoms of Chronic Idiopathic Constipation (CIC) and Irritable Bowel Syndrome With Constipation (IBS-C) Across Age Subgroups: An Analysis of Four Phase 3 Trials

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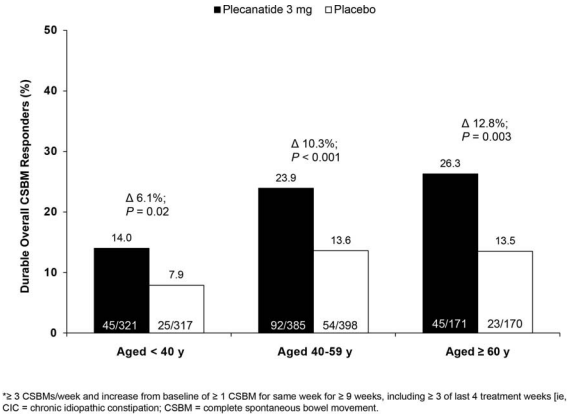
Introduction: CIC and IBS-C are common disorders of gut-brain interaction that may exist on a disease severity continuum. Plecanatide is a guanylate cyclase-C agonist approved in the US for treatment of adults with CIC or IBS-C. The aim of this analysis was to evaluate the potential impact of age on plecanatide efficacy in CIC and IBS-C.
Methods: Data were analyzed post hoc from two CIC (NCT01982240; NCT02122471) and two IBS-C (NCT02387359; NCT02493452) randomized, phase 3 trials of adults treated with plecanatide 3 mg (FDA-approved dose) or placebo once daily for 12 weeks. Data were pooled by indication and subgrouped by age (< 40 y, 40-59 y, and ≥ 60 y). The primary protocol-defined efficacy endpoint for CIC trials was the percentage of durable overall complete spontaneous bowel movement (CSBM) responders (≥ 3 CSBMs/week and increase from baseline of ≥ 1 CSBM for same week for ≥ 9 weeks, including ≥ 3 of last 4 treatment weeks [ie, durable]). For the IBS-C trials, the endpoint was the percentage of overall responders (≥ 30% reduction from baseline in worst abdominal pain and increase from baseline of ≥ 1 CSBM/week in the same week for ≥ 6 weeks). Treatment-emergent adverse events (AEs) also were evaluated by age group.
Results: Of the 1762 patients with CIC, 638 (36.2%) were < 40 y, 783 (44.4%) were 40-59 y, and 341 (19.4%) were ≥ 60 y. Of the 1453 patients with IBS-C, 582 (40.1%) were < 40 y; 659 (45.4%) were 40-59 y, and 212 (14. 6%) were ≥ 60 y. For CIC, significantly more plecanatide-treated patients were durable overall CSBM responders vs placebo in all 3 age subgroups (Figure). For IBS-C, significantly more plecanatide-treated patients were overall responders vs placebo in the < 40 y and 40-59 y subgroups, whereas a numeric difference favoring plecanatide was observed for the ≥ 60 y subgroup (Table). In the plecanatide group, the number of patients with ≥ 1 AE slightly increased with age for CIC (< 40 y, 29.2%; 40-59 y, 31.2%; ≥ 60 y, 35.1%) and IBS-C (< 40 y, 23.4%; 40-59 y, 23.4%; ≥ 60 y, 25.9%). Rates of diarrhea-related discontinuation in plecanatide-treated patients were low overall, occurring most often in the group aged 40-59 y for both CIC (< 40 y, 1.6%; 40-59 y, 2.6%; ≥ 60 y, 2.3%) and IBS-C (< 40 y, 0.3%; 40-59 y, 2.2%; ≥ 60 y, 0.9%).
Conclusion: Plecanatide 3 mg is an effective and well-tolerated treatment for patients with CIC or IBS-C across various age groups.



[0534] **Figure 1.** Durable Overall CSBM Responder Rate* in Population With CIC, Subgrouped by Age

Table 1. Overall Response Rate* in Population With IBS-C, Subgrouped by Age

Age Group	Patients, n/n (%)		Difference, %	*P* Value
	Plecanatide 3 mg	Placebo		
< 40 y	72/299 (24.1)	43/283 (15.2)	8.9	0.007
40-59 y	86/317 (27.1)	59/342 (17.3)	9.9	0.002
≥ 60 y	27/108 (25.0)	15/104 (14.4)	10.6	0.05

*≥ 30% reduction from baseline in worst abdominal pain and increase from baseline of ≥ 1 CSBM/week in the same week for ≥ 6 weeks. CSBM = complete spontaneous bowel movement; IBS-C = irritable bowel syndrome with constipation.

S535

Evaluating Irritable Bowel Syndrome Symptoms and Pelvic Floor Dysfunction in Patients With Deep Endometriosis of the Posterior Pelvis

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Introduction: The overlap of endometriosis and irritable bowel syndrome (IBS) diagnoses is well documented. Women with endometriosis have a 2.4-fold risk of fulfilling IBS criteria and there is a 3-fold risk of endometriosis diagnosis in women with IBS. Deep endometriosis (DE) can infiltrate organs in the posterior compartment including the rectosigmoid colon, potentially leading to bowel symptoms. We aim to evaluate prevalence of IBS and pelvic floor dysfunction (PFD) in patients with DE.
Methods: Identified women with endometriosis protocol MRI from 9/2015-7/2018. GI symptoms collected via validated survey at initial visit. MRI reports reviewed to identify posterior DE. IBS defined as reported change in bowel frequency and improvement/worsening of pain with defecation. PFD by MRI evaluated using rectal gas volume (RGV) with cutoff >900 m^2 (PPV 77%).
Results: 148 patients had baseline survey and endometriosis on MRI. Of these, 56(37.8%) patients met criteria for "baseline IBS". Prior IBS diagnosis was reported by 21(14%) patients, but only 11(52%) had "baseline IBS". A majority(80%, n=45) of "baseline IBS" patients did not have prior IBS diagnosis. These patients were not more likely to have experienced obstetric complications(21% vs.19%, OR 1.12, 95%CI 0.45-2.73, p=0.95). "Baseline IBS" was not associated with a higher likelihood of finding posterior DE (Figure). However, improvement of pain with defecation was significantly associated with posterior DE with OR 2.4 (95%CI 1.23-4.71, p= 0.011). Of the 153 patients with MRIs, 93 had endometriosis, 44 had DE. 13(30%) patients with DE had RGV >900 m^2, 1 underwent anorectal manometry(ARM). 10(20%,n=49) endometriosis patients without DE had RGV >900 m^2. 20(33%,n=60) patients without endometriosis had RGV >900 m^2, 16 underwent ARM. Of those with "baseline IBS"+DE, 37%(n=7/19) had RGV >900 m^2. Evaluation of 17 ARMs showed nonsignificant differences in patients with and without DE (Table) due to limited sample size.
Conclusion: Historic diagnosis of IBS does not predict GI symptoms at time of endometriosis diagnosis. Pain improvement with defecation was significantly associated with a higher likelihood of posterior DE. Similar percent of patients with DE and without endometriosis had PFD with RGV >900 m^2, with limited further evaluation suggesting underdiagnosis. On ARM, there is a small signal towards higher resting pressures and failed balloon expulsion test in women with DE, but statistically insignificant due to low power—further studies are needed.

Bowel or Posterior Compartment DE				
SURVEY QUESTION	Likely on MRI (N=60)	No/Neg MRI (N=88)	Odds Ratio (95% CI)	p-value
Do you have increased pain with bowel movements?				
No	15 (33.3%)	30 (66.7%)	Reference	
Yes	45 (46.4%)	52 (53.6%)	1.73 (0.83-3.62)	0.14
Does a change of frequency of bowel movements increase the pain?				
No	28 (35.0%)	52 (65.0%)	Reference	
Yes	27 (48.2%)	29 (51.8%)	1.73 (0.86-3.47)	0.12
Does your pain improve after completing a bowel movement?				
No	26 (33.3%)	52 (66.7%)	Reference	
Yes	31 (50.0%)	31 (50.0%)	2.00 (1.01-3.97)	**0.047**
What helps your pain? - Bowel movement				
No	36 (34.0%)	70 (66.0%)	Reference	
Yes	20 (69.0%)	9 (31.0%)	4.32 (1.79-10.45)	**0.001**
Does your pain improve after completing a bowel movement OR does bowel movement help your pain?				
No	26 (43.3%)	57 (64.8%)	Reference	
Yes	34 (56.7%)	31 (35.3%)	2.40 (1.23-4.71)	**0.011**
What makes your pain worse? - Bowel movement				
No	31 (35.2%)	57 (64.8%)	Reference	
Yes	21 (50.0%)	21 (50.0%)	1.84 (0.87-3.88)	0.11
Baseline IBS				
No	33 (35.9%)	59 (64.1%)	Reference	
Yes	27 (48.2%)	29 (51.8%	1.67 (0.85-3.27)	0.14

[0535] **Figure 1.** Irritable Bowel Syndrome symptoms and Deep Endometriosis

Table 1. Anorectal manometry with balloon expulsion test in patients with and without deep endometriosis

Balloon Expulsion Test	Deep Endometriosis (n=4)	Deep Endometriosis (n=4)	P – value
Failed Balloon Expulsion test	1 (25%)	4 (31%)	0.067
Anorectal Manometry Measure	**Deep Endometriosis (n=4)**	**No Deep Endometriosis (n=13)**	**P – value**
Mean sphincter pressure (Rest), mmHg (median, IQR)	99.25 (94.25; 108.5)	92.90 (84.3; 100.6)	0.3082
Max sphincter pressure (Squeeze), mmHg, (median, IQR)	195.3 (177.65; 228.35) 50.7 IQR	177.9 (146.3; 255.5) 109.2 IQR	0.5713
Rectoanal pressure differential, mmHg (median, IQR)	-55.75 (-81.45; -35.8) -45.65 IQR	-64.8 (-84.5; -48.7) -35.8 IQR	0.5713
First sensation, (median, IQR)	20 (20; 30) 10 IQR	20 (20; 40) 20 IQR	0.7767
Urge to defecate, (median, IQR)	40 (30; 65) 35 IQR	40 (40; 60) 20 IQR	0.6558
Discomfort (median, IQR)	75 (60; 120) 60 IQR	60 (60; 90) 30 IQR	0.4967

S536

Prevalence of Disaccharidase Deficiencies in Adults With Irritable Bowel Syndrome and Functional Diarrhea: Interim Analysis From a Multicenter, Prospective U.S. Trial

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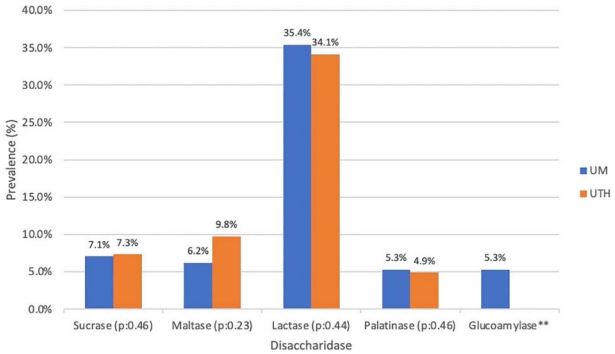
Introduction: Disaccharidases are brush border enzymes that digest disaccharides to monosaccharides for absorption across the intestinal epithelium. Patients with disaccharidase deficiencies (DD) may experience post-prandial abdominal pain, bloating, flatulence, & diarrhea that can mimic Irritable Bowel Syndrome and diarrhea (IBS-D) & functional diarrhea (FD). While well-characterized in children, the prevalence of DDs in symptomatic adults is poorly defined.
Methods: In this ongoing study, adult (>18 yrs) patients fulfilling Rome IV diagnostic criteria for IBS-D or FD were recruited at Michigan Medicine (UM) & the University of Texas Health Science Center at Houston (UTH). Exclusion criteria included pregnancy, lactation, severe GI or abdominal co-morbidities, & history of previous GI surgeries excluding cholecystectomy or appendectomy. Eligible patients completed upper endoscopy (EGD) with 2-4 small intestinal biopsies collected from the duodenum distal to the ampulla of Vater. Biopsy samples underwent disaccharidase assay to measure disaccharidase activity (normal sucrase: >28.0 μM/min/g, maltase: >120.8 μM/min/g, lactase: >15.4 μM/min/g, palatinase: >9.8 μM/min/g, glucoamylase: >13.1 μM/min/g) using validated protocols at experienced reference labs (Arnold Palmer Hospital Labs & Joli Diagnostics, Inc.).
Results: 154 patients (mean age = 45.6 yrs, 47% IBS-D, 53% FD, 74% female, 87% white) were enrolled & underwent EGD with biopsies collected to test for DD. More than a third of patients (56/154, 36.4%) had >1 DD. The most common DD was for lactase, found in 54 (35.1%) patients. Eleven patients (7.1%) tested positive for Sucrase-Isomaltase deficiency. Glucoamylase & palatinase deficiencies were each identified at 5%. Only lactase deficiency occurred in isolation. All patients with non-lactase deficiencies had other DDs, with at least 27% of these patients having pan-DDs (Table). The prevalence of the DDs were almost identical at both sites (Figure).
Conclusion: More than 36% of US adult patients with IBS-D or FD had >1 DD. Lactase deficiency was the most common DD & the most likely to occur in isolation. Sucrase & maltase deficiencies were identified in approximately 1 in 14 symptomatic patients, & typically associated with at least 1 other DD. Lactase & non-lactase DD may be important & overlooked causes for symptoms in US patients with IBS-D or FD.



[0536] **Figure 1.** Disaccharidase deficiency prevalence rates by study site. **Glucoamylase was not measured for patients recruited by and screened at UTH.

Table 1. Characterization of Disaccharidase Deficiencies (A, Top) Prevalence of single or multi-enzymatic deficiencies by disaccharidase (B, Bottom) Prevalence of enzymatic deficiency overlap by disaccharidase

A	Total	< 1 Def	1 Def	2 Def	3 Def	4 Def	5 Def
Total	154	63.64%	27.27%	2.60%	1.95%	2.60%	1.95%
Sucrase	11	0%	0%	9.09%	27.27%	36.36%	27.27%
Maltase	11	0%	0%	18.18%	27.27%	27.27%	27.27%
Lactase	54	0%	77.78%	5.56%	3.70%	7.41%	5.56%
Palatinase	8	0%	0%	12.50%	12.50%	37.50%	37.50%
Glucoamlyase	6	0%	0%	16.67%	0%	33.33%	50.00%
B	Sucrase	Maltase	Lactase	Palatinase	Glucoamylase		
Total	11	11	54	8	6		
Sucrase	X	90.91%	16.67%	87.50%	83.33%		
Maltase	90.91%	X	16.67%	75.00%	66.67%		
Lactase	81.82%	81.82%	X	87.50%	100.00%		
Palatinase	63.64%	54.55%	12.96%	X	66.67%		
Glucoamylase	62.50%	57.14%	15.00%	66.67%	X		

S537

Comparison of Disorders of Gut-Brain Interaction and Gastrointestinal Motility Between Patients With and Without IBD

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Introduction: Disordered brain-gut axis has been implicated in the pathogenesis of inflammatory bowel disease (IBD) and functional gastrointestinal disorders. It is increasingly recognized that patients can have overlapping IBD and irritable bowel syndrome (IBS). However, the prevalence of this phenomenon is not fully elucidated. The aim of the study was to determine the prevalence of coexisting gastrointestinal motility disorders and disorders of gut brain interaction (DGBI) in patients with Crohn's disease (CD) and ulcerative colitis (UC).
Methods: A population-based study was performed using IBM Explorys (1999-2022), a large pooled de-identified database with patient information from more than 300 hospitals across the US. CD and UC cohorts consisted of patients with a diagnosis of CD and UC, respectively. The control group consisted of patients without a diagnosis of IBD. We collected information about gastroparesis, IBS, functional dyspepsia (FD), gastroesophageal reflux disease (GERD), esophageal dysmotility and GI symptoms in all three cohorts. Categorial data was presented as number of subjects and percentages. Odds ratios (OR) with 95% confidence interval were used to compare between the cohorts.
Results: CD, UC and the non-IBD control cohorts consisted of 209,660, 251,570 and 79,390,670 patients respectively (Table). There was a higher prevalence of IBS and GERD in both CD and UC patients compared with non-IBD patients (IBS in CD, UC and control:13.2 vs 11.5 vs 1.24%; GERD in CD, UC and control: 33.2% vs 32.4 vs 8.8% respectively). Both CD and UC were more likely to have other co-existing DGBI and motility disorders compared with non-IBD patients, including gastroparesis (GP) and esophageal dysmotility (ED) (GP:CD vs control: OR [2.53-2.81], UC vs control: OR [2.28-2.57]; ED: CD vs control: OR [4.88-5.32], UC vs control: OR [5.39-5.90]). FD was more likely to occur in patients with CD than the control (OR 3.25-3.73), while UC has less risk of FD than the control (OR 0-0.04). Both patients with CD and UC were more likely to complain about various GI symptoms than the control, including nausea, vomiting, early satiety, epigastric pain, dysphagia, heartburn, diarrhea, and constipation ($p< 0.0001$).
Conclusion: IBD is associated with an increased prevalence of concomitant DGBI and motility disorders than non-IBD. IBD patients experience GI symptoms more often than non-IBD patients.

Table 1. Comparison of Disorders of Gut-Brain Interaction and Gastrointestinal Motility Between Patients with and without IBD

	CD (N=251,570)	UC (N=209,660)	Control (n=79,390,670)	CD vs control					UC vs control	
				OR	*P*				OR	*P*
IBS	33330	13.2%	24120	11.50%	984250	1.24%	12.02-12.31	< 0.0001	10.22-10.50	< 0.0001
GERD	83530	33.2%	67940	32.40%	7004850	8.82%	5.09-5.18	< 0.0001	4.91-5.00	< 0.0001
Gastroparesis	1410	0.6%	1070	0.51%	167720	0.21%	2.53-2.81	< 0.0001	2.28-2.57	< 0.0001
FD	790	0.3%	0	0.00%	71770	0.09%	3.25-3.73	< 0.0001	0.00-0.04	< 0.0001
Esophageal dysmotility	2050	0.8%	1890	0.90%	127820	0.16%	4.88-5.32	< 0.0001	5.39-5.90	< 0.0001

Table 1. (*continued*)

	CD (N=251,570)	UC (N=209,660)	Control (n=79,390,670)	CD vs control					UC vs control	
				OR	*P*				OR	*P*
Nausea	73350	29.2%	51380	24.51%	5036360	6.86%	6.02-6.13	< 0.0001	4.74-4.84	< 0.0001
Vomiting	59580	23.7%	42850	20.44%	4996190	6.81%	4.58-4.66	< 0.0001	3.78-3.87	< 0.0001
Early satiety	1500	0.6%	1180	0.56%	69760	0.10%	6.48-7.18	< 0.0001	6.07-6.82	< 0.0001
Epigastric pain	30350	12.1%	22810	10.88%	1894830	2.58%	5.54-5.68	< 0.0001	4.92-5.06	< 0.0001
Dysphagia	20120	8.0%	18390	8.77%	1664800	2.27%	4.00-4.12	< 0.0001	4.42-4.56	< 0.0001
Heartburn	7490	3.0%	6810	3.25%	506700	0.69%	4.67-4.89	< 0.0001	5.10-5.36	< 0.0001
Diarrhea	86060	34.2%	73500	35.06%	3731830	5.08%	10.45-10.63	< 0.0001	10.85-11.04	< 0.0001
Constipation	43000	17.1%	31800	15.17%	3585490	4.89%	4.31-4.40	< 0.0001	3.74-3.83	< 0.0001

S538

Gastrointestinal-Isolated Distress Is Common in Alpha-Gal Allergic Patients on Oral Challenge

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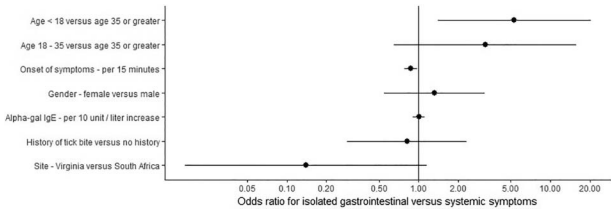
Introduction: Alpha-gal allergy causes a delayed reaction to mammalian meats and has been reported worldwide. Patients with the allergy may present with isolated gastrointestinal (GI) symptoms, but this phenotype is poorly understood.
Methods: We pooled and analyzed symptoms and demographics of patients from two prospective cohorts of patients with diagnosis of alpha-gal allergy who reacted after eating mammalian meat under observation. We compared characteristics of patients who demonstrated GI-isolated symptoms on challenge with those who exhibited symptoms outside the GI tract (skin, respiratory, circulatory).
Results: Among the 91 children and adult alpha-gal allergic patients who exhibited symptoms after oral challenge with mammalian meat, 72.5% experienced GI distress with one or more GI symptoms, which was the most frequent class of symptoms, compared to skin changes in 57.1% and respiratory distress in 5.5%. The most common GI symptoms were abdominal pain (71.0%) and vomiting (22.0%). GI-isolated symptoms occurred in 37 patients (40.7%) who reacted. These patients reacted more quickly than patients who exhibited systemic symptoms (median onset of symptoms in GI-isolated group 90 minutes vs. 120 minutes), were more likely to be children than adults (RR=1.94, 95% CI 1.04-3.63), and had a higher median alpha-gal IgE. The distribution of sex and self-reported history of tick bites was similar in the GI-isolated group versus those with systemic symptoms. (Figure)
Conclusion Isolated GI distress occurred in 4 in 10 alpha-gal allergic individuals who developed symptoms on oral food challenge with mammalian meat. GI isolated symptoms may be a result of differences in GI mast cell numbers, high-affinity IgE receptor expression levels, or variations in the numbers of gut microbes responsible for stimulating the endogenous anti-alpha-gal IgA, IgM and IgG responses. Further prospective studies are necessary to better understand the epidemiology, pathophysiology, and manifestations of GI-isolated alpha-gal allergy. Alpha-gal allergic patients, particularly children, may exhibit GI distress alone, and adult and pediatric gastroenterologists should be aware of the diagnosis and management of the allergy. (Table)



[0538] **Figure 1.** Characteristics that predicted a GI-Isolated reaction to mammalian meat challenge, by univariate analysis.

Table 1. **Characteristics of patients with GI-isolated symptoms and those with systemic symptoms on oral food challenge**

Characteristic	GI-Isolated Symptoms (n=37)	Systemic Symptoms (n=54)	P Value
Gender, n (%)			
Female	25 (67.6%)	33 (61.1%)	0.66*
Male	12 (32.4%)	21 (38.9%)	
Age, Median range; IQR	11 (5-57; 8-13)	17 (4-65; 9-38)	0.03**
Age< 18 (%)	28 (75.7%)	28 (51.8%)	0.03*
Onset of symptoms in minutes, median (range; IQR)	90 (45-330; 75-120)	120 (45-375; 100-185)	< 0.003**
Alpha-gal IgE U/L, median (range; IQR)	18.7 (0.7-74.7; 4-35)	10.45 (0.9-344.5; 4.5-25)	0.23**
History of Tick Bite	7 (18.9%)	12 (22.2%)	0.8*

IQR, Interquartile ratio; U/L Units per litre P-values calculated with * Fisher's exact and ** Mann-Whitney ranksum.

S539

Systematic Review and Meta-Analysis of the Prevalence of Constipation and Nausea Among Adults Using Calcitonin Gene-Related Peptide (CGRP) Inhibitors for Preventative Treatment of Cluster Headache or Migraine

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Introduction: Constipation and nausea are frequently encountered medication-associated side effects. Calcitonin gene-related peptide (CGRP) inhibitor use may be potential cause of constipation and nausea, but the magnitude of this impact in patients with cluster headaches or migraines has not been well characterized.
Methods: We conducted a systematic review using PUBMED and ClinicalTrials.Gov to identify randomized, placebo-controlled clinical trials using anti-CGRP antibodies or CGRP receptor antagonists for the prevention of cluster headaches or chronic migraine. We extracted data including CGRP inhibitor dose, dose frequency, and the reported proportions of patients in these trials with constipation and nausea. We compared the prevalence of these symptoms in those on medication to those on placebo, using two-tailed paired t-tests. The risk of a specific adverse event was assessed using odds ratios with 95% confidence intervals.
Results: We identified an initial pool of 449 studies to which we applied a priori criteria to yield 27 studies for nausea and 15 studies for constipation analyses. In the anti-CGRP antibody-treated group, the pooled prevalence of constipation was 2.69% (N=3,574) and nausea was 2.03% (N=9,231), compared with 1.39% (N=4,520, p=0.004) and 2.47% (N=11,680, p=0.0095) in placebo-treated groups, respectively. In the CGRP receptor antagonist-treated group, the prevalence of constipation was 5.20% (N=1,847) and nausea was 6.04% (N=1,689), compared to 1.46% (N=1,852, p=0.002) and 3.05% (N=1,967, p=0.0001) in placebo-treated groups, respectively. CGRP receptor antagonist use demonstrated greater risks of constipation (OR=3.71 [2.41, 5.71], p< 0.0001) and nausea (OR=2.04 [1.48, 2.83], p< 0.0001) than anot-CGRP antibody use (constipation: OR=1.96 [1.41, 2.72], p=0.0001; nausea: OR=0.82, [0.68, 0.99], p = 0.0343). Anti-CGRP antibody use did not appear to be associated with an increased risk of nausea.
Conclusion: Constipation and nausea are associated with CGRP inhibitor use in those with cluster headache or migraine. With the increased prevalence of CGRP inhibitor use, CGRP inhibitor-associated constipation and nausea cases could grow substantially. Gastroenterologists should consider CGRP inhibitor use as a medication-induced cause of nausea and constipation. CGRP receptor antagonist use is associated with higher rates of these gastrointestinal side effects than the use of anti-CGRP antibodies.

S540

Change in Severity of Abdominal Pain and Flatulence During Lactulose Breath Testing Associated With Positive Small Intestinal Bacterial Overgrowth Diagnosis

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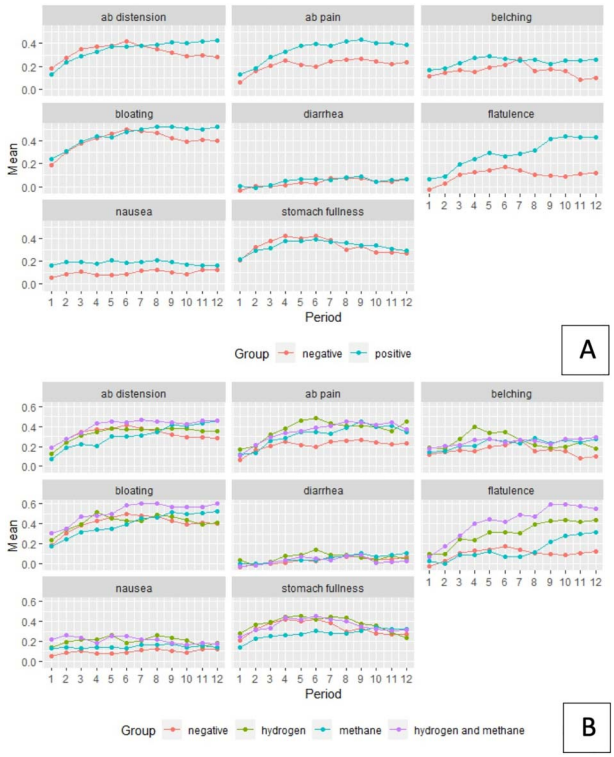
Introduction: Small intestinal bacterial overgrowth (SIBO) can be indirectly diagnosed by assessing expired hydrogen and methane gas peaks during lactulose breath testing (LBT). Ingestion of lactulose for the test can induce gastrointestinal symptoms, some of which mimic the patient's baseline SIBO symptoms. We seek to evaluate whether these symptoms reported during the LBT predict the ultimate test result.
Methods: Patients that underwent LBT between 11/2018 to 3/2020 were included. LBT was performed using the BreathTracker Analyzer (QuinTron Instruments). SIBO by hydrogen (H-SIBO) was defined as a rise of 20 ppm within the first 90 minutes. SIBO by methane (M-SIBO) was defined as a peak value of >10ppm. Patients answered pretest questionnaires of baseline demographics, Patient Assessment of Gastrointestinal Disorders- Symptom Severity Index (PAGI-SYM), and their symptom severity of eight SIBO symptoms (abdominal distension, abdominal pain, belching, bloating, diarrhea, flatulence, nausea, and stomach fullness). During LBT, patients then re-scored their 8 symptoms at 15-minute increments for the 3-hour test duration. Longitudinal symptom severity over this duration was analyzed with a series of two-level mixed effects regressions estimated for each symptom separately.
Results: 608 patients underwent LBT yielding 103 H-SIBO, 144 M-SIBO, and 141 positives by hydrogen and methane (HM-SIBO). Baseline PAGI-SYM analysis revealed increased symptom severity in the SIBO negative group in nausea (p=0.009), upper abdominal pain (p=0.02), upper abdominal discomfort (p=0.01), and lower abdominal discomfort (p=0.02). Parameter estimates of the mixed models demonstrated significant difference in the SIBO positive and SIBO negative groups in abdominal pain (+0.131, p< 0.05) and flatulence (+0.190, p< 0.01) out of 8 symptoms assessed, presenting early into the testing period. Subgroup analysis revealed H-SIBO and HM-SIBO groups had increases in flatulence severity compared to the negative group by 0.213 (p< 0.01) and 0.323 (p< 0.01), respectively. (Figure)
Conclusion: Despite initially reporting lower baseline PAGI-SYM symptom severity, over the course of LBT, patients with SIBO reported a greater increase in abdominal pain compared to their SIBO negative counterparts. H-SIBO and HM-SIBO was also associated with greater development of flatulence during testing. These results indicate change in symptoms severity during LBT may have diagnostic value for SIBO.



[0540] **Figure 1.** (A) Mean Change in Reported Symptom Severity over Twelve 15-minute Increments in Lactulose Breath Testing Corrected for Baseline Severity (B) Mean Change in Reported Symptom Severity over Twelve 15-minute Increments in Lactulose Breath Testing Corrected for Baseline Severity with Positive Group Stratified by Respiratory Gas

S541

Symptomatic Response to Antibiotics in Patients With Small Intestine Bacterial Overgrowth: A Systematic Review and Meta-Analysis

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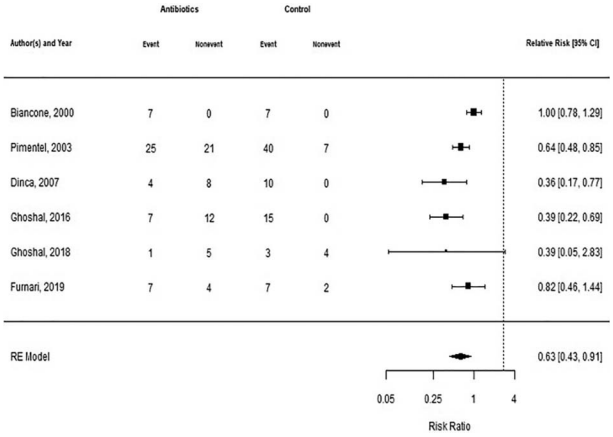
Introduction: Small intestinal bacterial overgrowth (SIBO) is characterized by an increase in proteobacteria in the small intestine and is associated with gastrointestinal symptoms. Antibiotics are used to treat this condition and previous meta-analyses have shown that antibiotics can successfully eradicate SIBO. Currently, there have been no high-quality, multicenter trials evaluating the efficacy of antibiotics in improving symptoms. Here, we performed a systematic review and meta-analysis to assess the efficacy of antibiotics to relive symptoms in patients with SIBO.
Methods: Following the PRISMA protocol a systematic review and meta-analysis was conducted. From inception to March 2021, MEDLINE, EMBASE, Web of Science, and Cochrane database were searched. Randomized controlled trials and prospective studies were included. Studies were included if SIBO was diagnosed based on breath test or small bowel aspirate. The rate of no improvement in symptoms were compared between antibiotics and no antibiotics. To assess study bias, the Cochrane Risk of Bias Tool was used. Studies with all categories with low risk of bias were deemed good quality. If 1 category had high or unclear risk of bias, they were deemed fair, the rest were deemed as poor quality.
Results: Of 694 citations, 647 were excluded based on the title or abstract. After a full manuscript review, 6 studies met inclusion criteria and were included (Table). There was a total of 196 patients, out of which 101 received antibiotics and 95 received placebo or no antibiotics. Two studies compared rifaximin to placebo, 1 compared rifaximin with bran to placebo with bran, 1 compared norfloxacin to placebo, 1 compared neomycin to placebo, and another compared rifaximin to no antibiotics. Overall, the RR (95% CI) of no improvement was 0.63 (0.43-0.91) with antibiotics compared to no antibiotics or placebo (Figure). The NNT for antibiotics in relieving symptoms was 2.8. There was significant heterogeneity with $I^2 = 69.3\%$. There was no publication bias based on Egger's test ($t = -1.5936$, $df = 4$, $p = 0.1863$). Four studies were deemed to be of poor quality and 2 studies were deemed to be of fair quality.
Conclusion: This is the first systemic review and meta-analysis to evaluate the efficacy of antibiotics in relieving symptoms in patients with SIBO. Our data suggests that antibiotics provide symptomatic relief for patients with SIBO. A large multicenter randomized control trial is needed to validate these findings.



[0541] **Figure 1.** Pooled analysis of the studies comparing the efficacy of antibiotics as compared to placebo or no antibiotics in SIBO. The RR of no improvement on antibiotics is 0.63.

Table 1. Study characteristics of studies evaluating symptomatic response for antibiotics in patients with SIBO

Study	Country	Sample size (% female)	Disease	Method to diagnose SIBO	Criteria for symptomatic improvement	Antibiotic used	Duration of therapy	Duration of follow-up	Rate of no improvement on antibiotics	Rate of no improvement on placebo
Biancone 2000	Italy	14 (50%)	Crohn's disease	Glucose breath test	Change in CDAI	Rifaximin 400 mg BID	7 days	7 days	7/7 (100%)	7/7 (100%)
Pimentel 2003	US	93 (62%)	Rome I IBS	Lactulose breath test	≥ 50% reduction in composite score of abdominal pain, diarrhea, and constipation	Neomycin 500 mg BID	10 days	7 days	25/46 (54.3%)	40/47 (85.1%)
D'inca 2007	Italy	22	Diverticular disease	Lactulose breath test	Global symptomatic improvement	Rifaximin 600 mg BID	14 days	End of treatment	4/12 (33.3%)	10/10 (100%)
Ghoshal 2016	India	34 (19%)	Rome III IBS	Duodenal aspirate 10^3 CFU	No longer meeting Rome III Criteria for IBS	Norfloxacin 400 mg BID	10 days	30 days	7/19 (36.8%)	15/15 (100%)
Ghoshal 2018	India	13 (54%)	Rome III IBS-C or FC	Lactulose breath test (methane)	BSS ≥ 3	Rifaximin 400 mg BID	14 days	7 days	1/6 (16.7%)	3/7 (42.9%)
Furnari 2019	Italy	20 (48%)	Cystic Fibrosis	Glucose breath test	≥ 50% reduction in composite GI score	Rifaximin 10 mg/kg TID (up to 400 mg TID)	14 days	21 days	7/11 (63.6%)	7/9 (77.8%)

S542

Different Duodenal pH Profiles Relating to Individual Dyspeptic Symptoms Measured by Wireless Motility Capsules in Suspected Gastroparesis: Evidence for Delayed Neutralization in Patients With Greater Epigastric Pain

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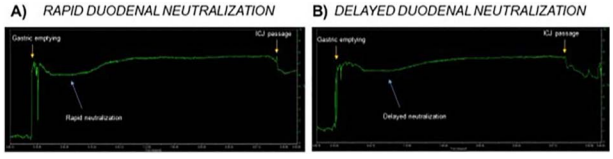
Introduction: Increased duodenal acid exposure is proposed as a mechanism of symptoms in functional dyspepsia but is rarely measured. Wireless motility capsules (WMC) measure transit in suspected dysmotility but also quantify small bowel (SB) pH. WMC SB pH has not been related to dyspepsia severity. We compared SB pH to severity of epigastric pain and nausea/vomiting (NV) in patients with suspected gastroparesis and devised an estimate of delayed duodenal neutralization as a marker of possible increased duodenal acid exposure.
Methods: 91 patients with symptoms suspicious for gastroparesis from a parent study of concurrent WMC and gastric scintigraphy had interpretable WMC SB pH tracings from gastric emptying (GE) to ileocecal junction (ICJ) passage. Nausea/vomiting (NV) scores from GCSI surveys and epigastric pain scores from PAGI-SYM surveys (0=no symptoms, 5=very severe) were related to SB pH. Delayed duodenal neutralization was defined when mean SB pH over the first 30 minutes after GE remained below pH values in the first 15 minutes after GE.
Results: GE was detected by WMC pH increases >2 units. Most tracings showed initial rapid duodenal pH decreases followed by increases progressing to ICJ passage (Fig 1A). Others showed delayed pH decreases then slower increases, perhaps reflecting delayed duodenal neutralization (Fig 1B). Duodenal pH profiles were similar in patients with epigastric pain scores above and below median severity (Table). However patients with NV scores above median severity showed higher duodenal pH than with NV scores below median. 18/30 patients (60%) with pain scores above median showed delayed duodenal neutralization (lower pH in the 30 vs. 15 minutes after GE) compared to 20/61 (33%) with pain scores below median (P=0.02). Conversely, 16/36 (44%) with NV scores above median and 22/55 (40%) with NV below median showed delayed neutralization (P=0.83).
Conclusion: Duodenal pH profiles in suspected gastroparesis relate to symptom severity and vary depending on the symptom measured. Compared to milder symptoms, severe nausea/vomiting is associated with increased duodenal pH and little delay in duodenal neutralization while increased overall duodenal pH is not seen with severe epigastric pain. Rather, a subset of patients with severe pain exhibits delayed initial duodenal pH decreases followed by slow neutralization. These findings support possible increased duodenal acid exposure relating to dyspeptic pain severity in some patients.



[0542] **Figure 1.** pH tracing on left (A) shows rapid pH decrease after gastric emptying followed by prompt neutralization. pH tracing on right (B) shows delayed pH decrease followed by more gradual neutralization.

Table 1. WMC Duodenal pH Profiles in Relation to Symptom Severity in Suspected Gastroparesis

		0 to 15 Minutes After Gastric Emptying		0 to 30 Minutes After Gastric Emptying		0 to 60 Minutes After Gastric Emptying	
Symptom	Symptom Score Severity	pH	P Value	pH	P Value	pH	P Value
Epigastric pain	Above median (4.2+0.5) Below median (1.9+1.0)	6.3+0.4 6.3+0.6	0.43	6.3+0.5 6.3+0.4	0.63	6.4+0.4 6.4+0.4	0.74
Nausea/vomiting	Above median (2.9+0.9) Below median (0.7+0.5)	6.4+0.4 6.2+0.5	0.04	6.4+0.4 6.2+0.5	0.04	6.5+0.4 6.3+0.4	0.03

S543

Efficacy of Tenapanor in Improving IBS-C Abdominal Symptoms: A Post Hoc Analysis of Multi-Item Abdominal Score From the 26-Week Phase 3 T3MPO-2 Study

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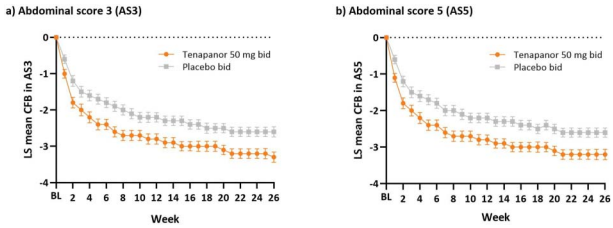
Introduction: Tenapanor is a minimally absorbed, small-molecule inhibitor of intestinal sodium/hydrogen exchanger 3 (NHE3), approved for the treatment of irritable bowel syndrome with constipation (IBS-C). Preclinical studies demonstrated that tenapanor reduced intestinal permeability, inhibited TRPV1 signaling, and was associated with reduced visceral hypersensitivity and abdominal pain. Here we investigate the effects of tenapanor on multi-item abdominal score using data from T3MPO-2 (NCT02686138), a long-term phase 3 study of tenapanor.
Methods: Patients with IBS-C with < 3 weekly complete spontaneous bowel movements and weekly abdominal pain score ≥3 (0-10 scale) during a 2-week screening period were randomized to tenapanor 50 mg or placebo twice a day in a 26-week randomized treatment period (RTP). Patients rated 5 abdominal symptoms on an 11-point scale (0=no symptom to 10=worst possible symptom) using an eDiary. The abdominal score 3 (AS3) is the mean of weekly scores for abdominal pain, discomfort, and bloating. The abdominal score 5 (AS5) is the mean of weekly scores for abdominal pain, discomfort, bloating, fullness, and cramping. The overall change from baseline (CFB) in the 26-week RTP and week 26 CFB in AS3 and AS5 were compared between arms using mixed-effects models with repeated measures. The cumulative distribution of CFB in AS3 or AS5 at week 26 was compared along with the Wilcoxon rank sum test. The 13/26-week AS3 or AS5 response, defined as achieving a reduction of ≥2 points in AS3 or AS5 for ≥13 weeks of the 26-week RTP, was compared using the Pearson's chi-square test.
Results: T3MPO-2 randomized 620 patients. In the intent-to-treat analysis set (tenapanor, n=293; placebo, n=300), the tenapanor arm had greater mean reduction in AS3 than placebo over the 26-week RTP (**Figure a;** −2.74 vs −2.15, P=0.0001) and in week 26 (−3.27 vs −2.60, P=0.0007). At week 26, cumulative distribution of CFB significantly favored tenapanor over placebo (P=0.0094). The tenapanor arm also had a higher 13/26-week AS3 response rate than placebo (46.4% vs 35.7%, P=0.0078). For AS5, mean CFB (**Figure b;** P=0.0001), distribution of CFB at week 26 (P=0.0121), and 13/26-week response rate (P=0.0015) were similarly improved with tenapanor.
Conclusion: Few treatments for IBS-C improve abdominal pain, discomfort, or bloating. This post hoc analysis demonstrates that tenapanor significantly improves IBS-C–associated abdominal symptoms with an early onset of action that is sustained throughout the treatment period.



[0543] **Figure 1.** Treatment with tenapanor resulted in a greater and sustained reduction from baseline in combined abdominal symptom scores over the 26-week treatment period vs placebo. Error bars represent standard error. AS3, abdominal score 3; AS5, abdominal score 5; bid, twice a day; BL, baseline; CFB, change from baseline; LS, least squares.

S544

Rifaximin Improves Both Fecal Urgency and Stool Consistency in Adults With Irritable Bowel Syndrome With Diarrhea (IBS-D): A Composite Endpoint Analysis of Two Randomized, Phase 3 Trials

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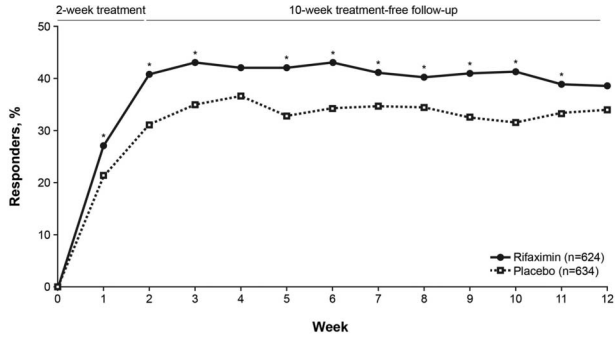
Introduction: For patients with IBS-D, in addition to loose stool consistency, fecal urgency is a common, bothersome symptom. The aim was to evaluate rifaximin for simultaneously improving symptoms of fecal urgency in addition to loose/watery stool consistency as a unique composite bowel symptom endpoint.
Methods: A post hoc analysis was conducted with data from 2 identically designed, phase 3, randomized, double-blind trials. Adults with IBS-D, with screening daily mean stool consistency score of ≥3.5 (range, 1 "very hard"; 5 "watery"), took rifaximin 550 mg TID or placebo for 2 weeks, followed by a 4-week treatment-free phase to assess response. Fecal urgency was based on patient response to the daily question, "Have you felt or experienced a sense of urgency today?" Composite bowel symptom responders were defined as patients who simultaneously achieved a ≥30% decrease from baseline in the percentage of days with fecal urgency and had a mean weekly stool consistency score of < 4 for ≥2 of the first 4 post-treatment weeks. Data were analyzed using last observation carried forward; P values were calculated using the Cochran-Mantel-Haenszel method, adjusting for analysis center.
Results: A total of 1258 adults (rifaximin [n=624], placebo [n=634]) were included (mean ± SD age, 45.9 ± 14.5 years; 72.3% female). Similar values at baseline were observed for rifaximin and placebo groups for the percentage of days with fecal urgency (82%), mean daily stool consistency score (3.9), and mean ± SD number of daily bowel movements (3.0 ± 1.5). A significantly greater percentage of patients treated with rifaximin were bowel symptom composite responders vs placebo for ≥2 of the first 4 weeks post-treatment (47.9% vs 39.3%, respectively; P=0.002). A higher percentage of responders with rifaximin was observed vs placebo when analyzed by week (Figure). A significantly higher percentage of patients who were bowel symptom composite responders during ≥2 of the first 4 weeks post-treatment maintained response during ≥3 of the additional 6 weeks of treatment-free follow up (Week 12) in rifaximin vs placebo groups (44.7% vs 36.1%; P=0.002). For the individual components of response, a significantly greater percentage of patients in rifaximin group were fecal urgency responders vs placebo (52.9% vs 43.1%; P< 0.001) or stool consistency responders (82.7% vs 77.8%; P=0.03).
Conclusion: A 2-week course of rifaximin significantly and simultaneously improved fecal urgency and stool consistency vs placebo in adults with IBS-D.



[0544] **Figure 1.** Percentage of patients with ≥30% decrease from baseline in percentage of days with fecal urgency and mean weekly stool consistency score of < 4, by week *P< 0.05 vs placebo.

S545

Impact of Abdominal Symptoms in Patients With Chronic Idiopathic Constipation (CIC) in the United States

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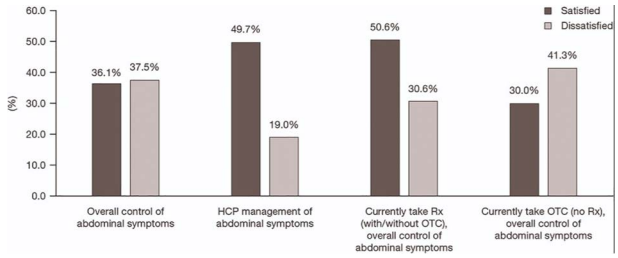
Introduction: Patients with CIC report a variety of abdominal symptoms beyond reduced stool frequency or straining. However, our understanding of these additional symptoms is limited. This study examined the impact of abdominal symptoms on patients with CIC.
Methods: A cross-sectional, on-line health survey collected data from 8/2020-12/2021 on US adults. CIC patients were defined using Rome IV criteria. Endpoints assessed were care, symptom burden and satisfaction with control, health care provider (HCP) management and treatment of abdominal symptoms. Categorical data were described by percentage; continuous data were described by means and standard deviation.
Results: Of 29,359 total participants, 9.2% (n=2,696) met criteria for CIC. CIC patients were primarily female (68.4%), White (80.9%), with a mean age of 45.1 years. Of CIC patients who sought care in the past year (58.9%), 33.1% sought care due to not getting adequate relief of and/or worsening abdominal symptoms. Of CIC patients who had an ER visit or hospitalization in the past year (15.7%) (Table), abdominal pain (84.1%), abdominal discomfort (51.2%) and abdominal bloating (42.2%) were the most common reported reasons. 91.1% of CIC patients took a medication in the past year due to abdominal pain (63.4%), abdominal discomfort (62.2%) or abdominal bloating (45.2%). Abdominal discomfort was the symptom most experienced (58.4%), while abdominal pain was the most bothersome symptom (26.5%) and the predominant symptom limiting ability to work or conduct household chores (33.6%). CIC patients were slightly more dissatisfied than satisfied with overall control of their abdominal symptoms (37.5% vs 36.1%), and more satisfied than dissatisfied with HCP management of their abdominal symptoms (49.7% vs 19.0%). Those currently taking an Rx with or without an OTC were more satisfied with the control of their abdominal symptoms than those currently taking an OTC only (50.6% vs 30.0%) (Figure).
Conclusion: CIC patients suffer with abdominal symptoms typically associated with IBS-C patients highlighting the overlap of these two common disorders of gut-brain interaction. Symptom impact is high as one-third of CIC patients sought care due to abdominal symptoms, and abdominal symptoms were the most-reported reasons for ER visits or hospitalizations.



[0545] **Figure 1.** Satisfaction with Control, HCP Management and Treatment of Abdominal Symptoms

Table 1. Characteristics of Patients with CIC

	Rome IV CIC Cohort (N=2,696)	
	%	N
Female	68.4%	1,843
Age, mean (SD)	45.1	(16.8)
Black or African American	10.6%	286
White	80.9%	2,180
Other	8.5%	230
Proportion of Hispanic, Latino or Spanish origin	10.0%	269
Northeast	18.7%	504
Midwest	22.5%	607
South	38.2%	1,031
West	20.5%	554
Charlson Comorbidity Index (CCI) score, mean (SD)	0.8	(1.6)
Body Mass Index (BMI) (lbs/in^2), mean (SD)	27.8	(7.3)
Median household income (Census derived from zip code), mean (SD)	64,556	(26,352)
Proportion educated more than high school	75.5%	2,036

Table 1. (*continued*)

	Rome IV CIC Cohort (N=2,696)	
	%	N
Proportion employed per Work Productivity and Impairment (WPAI) (1)	54.3%	1,111
Sought care for bowel and/or abdominal symptoms in the past 12 months	58.9%	1,589
ER visit or hospitalization for bowel and/or abdominal symptoms, past 12 months	15.7%	422
(1) Question fielded 12/20-12/21; n=2047		

S546

Age and Gender Differences in the Attitudes Towards Complementary and Alternative Medicine in Gastroenterology

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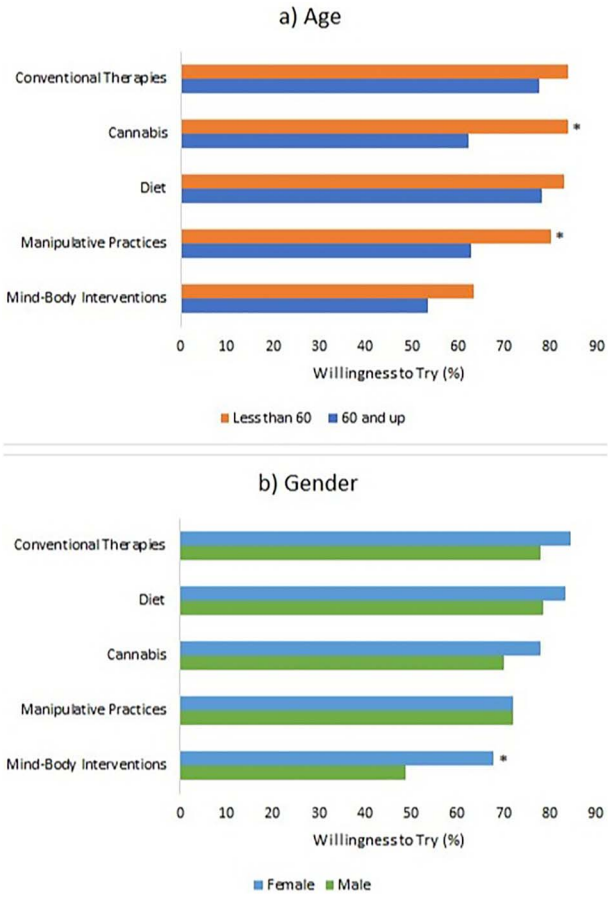
Introduction: While there is growing evidence to support Complementary and Alternative Medicine (CAM) such as diet and mind-body interventions in Gastroenterology (GI), little is known about the current state of CAM use and acceptance. Prior studies have reported more CAM use and positive attitudes among females, but they are not representative of current, U.S. patients. The aim of our study is to identify age and gender differences associated with the attitudes towards CAM therapies among GI patients in a tertiary care setting.
Methods: A total of 218 patients consecutively seen in general GI clinic voluntarily completed a survey evaluating their prior experience with and attitudes towards 1) "Conventional Therapies" such surgery and medications, 2) "Manipulative Practices" such as chiropractic and massages, 3) "Mind-Body Interventions" such as psychotherapy, yoga and hypnotherapy, 4) "Diet" such as diet modifications, supplements and probiotics, and 5) "Cannabis" such as CBD and THC. The survey also gathered data on background such as age and gender.
Results: Acceptance of CAM was generally higher among female patients and those aged less than 60 years. (Figure) Younger patients were more willing to try cannabis (p=0.004) and manipulative practices (p=0.017) than patients aged 60 and up. Female patients were more willing to try mind-body interventions (p=0.01) than their male counterparts. Mind-body interventions received the least acceptance overall. Among those who have previously used CAM, there was no significant differences in the perceived benefit when stratified by age and gender. However, female and younger patients generally reported less satisfaction with their prior experience of conventional therapies. (Table)
Conclusion: Female and younger patients display more openness towards CAM that is comparable to standard therapy. In fact, they report less satisfaction with their prior use of conventional therapies, which makes them a good target for introducing evidence-guided CAM to augment disease management. More studies are warranted to investigate the origin of age and gender differences in the perception of CAM, specifically in the categories of cannabis, mind-body interventions and manipulative practices, with the goal of expanding the knowledge of CAM among patients and clinicians in Gastroenterology.



[0546] **Figure 1.** Acceptance of therapy by age and gender. Statistically significant difference is indicated with an asterisk (*).

Table 1. Satisfaction of conventional therapies by age and gender

	Age			Gender		
	Less than 60 (N=108)	60 and up (N=110)	p value	Female (N=123)	Male (N=92)	p value
Major Surgery						
Did not work	5 (15.6%)	3 (7.7%)	0.577	4 (11.4%)	4 (11.8%)	0.049
Worked somewhat	4 (12.5%)	5 (12.8%)		8 (22.9%)	1 (2.9%)	
Worked well	23 (71.9%)	31 (79.5%)		23 (65.7%)	29 (85.3%)	
Prescription Medications						
Did not work	17 (20.7%)	4 (6.0%)	0.014	13 (16.2%)	8 (11.9%)	0.424
Worked somewhat	36 (43.9%)	27 (40.3%)		36 (45.0%)	26 (38.8%)	
Worked well	29 (35.4%)	36 (53.7%)		31 (38.8%)	33 (49.3%)	
Over-the-counter Medications						
Did not work	30 (38.0%)	5 (8.5%)	< 0.001	21 (25.9%)	13 (23.6%)	0.452
Worked somewhat	34 (43.0%)	36 (61.0%)		44 (54.3%)	26 (47.3%)	
Worked well	15 (19.0 %)	18 (30.5%)		16 (19.8%)	16 (29.1%)	

S547

Rising Inpatient Utilization and Costs of Cannabis Hyperemesis Syndrome Hospitalizations in Massachusetts Following Cannabis Legalization

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Introduction: As cannabis legalization has become widespread, we sought to describe the demographics, inpatient utilization, and cost of services among patients hospitalized for cannabinoid hyperemesis syndrome (CHS) predating and postdating cannabis legalization in Massachusetts.
Methods: We performed a retrospective cohort study of patients admitted to Tufts Medical Center in Boston, Massachusetts (MA) with CHS pre- and post-Dec 15, 2016, the date of cannabis legalization in MA. We examined the demographic and clinical characteristics of admitted patients as well as utilization of hospital services including length of stay, laboratory services, antiemetic drugs, intravenous fluids, endoscopies, imaging, gastroenterology consulting services and intensive care requirements both pre- and post- legalization. We also estimated inpatient cost pre- and post- legalization.
Results: We identified 63 patients admitted between 2012-2020 with CHS across 72 hospitalizations, with more admissions post-legalization (n=57) than pre-legalization (n=15). Patient demographics were similar pre- and post- cannabis legalization, with a mean age of 33, 52% identifying as female, and the majority smoking cannabis as the primary route of administration. Utilization of hospital resources increased post-legalization for CHS, with increased length of stay (3 days vs 1 day, p< .005) and increased anti-emetic use (3 days vs 1 day, p< 0.05) compared to pre-legalization, with multivariate linear regression confirming that post-legalization admissions were independently associated with increased length of stay (B=5.35, p< 0.05). The mean cost of hospitalization per patient post-legalization was significantly higher than for pre-legalization ($18,714 vs $7,460, p< .0005), with intravenous fluid administration and endoscopy costs significantly increased post-legalization (p< 0.05). On multivariate linear regression, hospitalization for CHS during post-legalization significantly predicted increased costs (B=10,131.25, p< 0.05). (Table)
Conclusion: In the post-legalization era of cannabis in Massachusetts, we found increased hospitalizations due to CHS, with a concomitant increase length of hospital stay and total cost per patient. As cannabis use increases, the recognition, measurement, and cost of the deleterious effects are necessary to incorporate into future practice strategies and public health policy development.

Table 1.

Demographics	Pre-legalization (n=12 patients)	Post-legalization(n=51patients)	*p*-value
Number of hospital admissions	15	57	NA
Female gender n, (frequency)	4 (33.3)	29 (50.9)	0.25
Age mean, (st dev)	35.5 (11.5)	32.9 (13.5)	0.32
Cannabis type used n, (frequency)			
Smoking	6 (50.0)	31 (60.8)	0.53
Vaping	0	2 (3.9)	-
Edibles	0	2 (3.9)	-
More than one type	0	1 (2.0)	-
Not reported	6 (50.0)	15 (29.4)	-
Cannabis use frequency n, (frequency)			
Less than daily	0	9 (17.6)	0.19
At least daily	3 (25.0)	24 (47.1)	0.21
Multiple times daily	3 (25.0)	8 (15.7)	0.42
Unknown	6 (50.0)	10 (19.6)	-
Utilization of Services	**Pre-legalization (n=15 hospitalizations)**	**Post-legalization (n=57 hospitalizations)**	**p-val**
Length of inpatient stay, days median, (IQR)	1.0 (1.0-2.0)	3.0 (1.0-4.0)	**< 0.005**
Cannabis urine screen positivity n, (frequency)	10 (66.7)	37 (64.9)	1.0
Cannabis urine screen not performed n, (frequency)	4 (26.7)	16 (28.1)	1.0
Basic metabolic panel, days median, (IQR)	2 (1.0-2.8)	2.0 (0.25-3.0)	0.79
Antiemetics, days median, (IQR)	1.0 (1.0-2.5)	3.0 (2.0-4.0)	**< 0.05**
Intravenous fluids, days median, (IQR)	1.0 (1.0-2.0)	1.0 (1.0-2.0)	0.32
Endoscopies performed n, (frequency)	3.0 (20.0)	14.0 (24.5)	1.00
Imaging studies performed n, (frequency)	12.0 (80.0)	43.0 (75.4)	1.00
GI consults n, (frequency)	5.0 (33.3)	26.0 (45.6)	0.57
ICU-level care needed days median, (IQR)	0.0	9.0 (15.8)	0.19

Table 1. (*continued*)

Demographics	Pre-legalization (n=12 patients)	Post-legalization(n=51patients)	*p*-value
Cost of Services	**Pre-legalization (n=15 hospitalizations)**	**Post-legalization (n=57 hospitalizations)**	***p*-value**
Mean inpatient charge	$7460	$18,714	< **0.0005**
IVF charges, mean	$551	$745	< **0.05**
Endoscopy charges, mean	$1512	$2360	< **0.05**

S548

Point of Care Bowel Sound Analysis Shows a 3-Way Correlation Between IBS Symptom Severity and Lactulose Breath Testing

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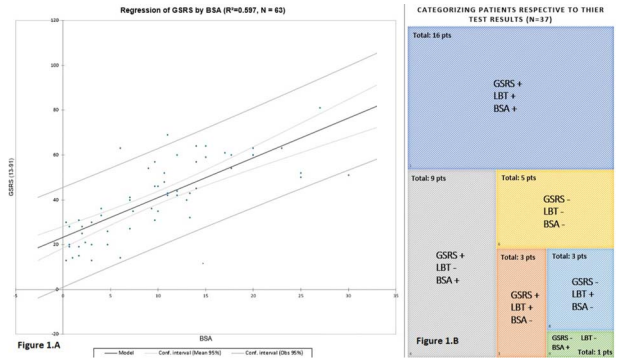
Introduction: Given the subjective nature of Irritable Bowel Syndrome (IBS), excess testing is often ordered. Prior studies have postulated IBS is due to overgrowth of intestinal bacteria and subsequent alteration in intestinal gas composition. Our pilot investigation with Bowel Sound Analysis (BSA) reveals correlation between bowel sound activity and IBS symptom severity. This study further explores BSA and its proposed correlation with Lactulose Breath Test (LBT) and IBS symptom severity. Point of Care analysis of bowel sounds is a potential diagnostic tool that is non-invasive and may provide objective data for evaluating the severity of IBS.
Methods: This is a case-control study including IBS patients who met Rome IV criteria. Gastrointestinal Symptom Rating Scale IBS (GSRS-IBS) was used to quantify severity of symptoms. A score of >35 was considered an IBS flare-up. Bowel sounds were collected for 45 seconds from 3 points around the umbilicus with an electronic stethoscope. Audio files were analyzed based on proprietary computer software modeled after previous IBS patients. The model uses scores < 5 as normal, 5-10 as mildly abnormal, and >10 as abnormal. Patients were given a TrioSmart LBT provided by Gemelli Biotech to complete post-appointment. (Figure)
Results: A total of 63 patients completed the GSRS and BSA. A scatterplot of GSRS vs BSA scores demonstrated an R^2 of 0.591 with ANOVA calculated p-value < 0.0001. A total of 37 patients completed the LBT. Using the established thresholds of symptom severity, a chi-square test between 3 variables yielded a p-value < 0.005 with the tree map exhibiting the categories each patient fell into. We note, as seen in the proximity matrix Table, that the BSA had a greater overlap with symptom severity when compared to the LBT. This suggests the BSA captures audio data pertinent to the severity of IBS symptoms beyond bacterial dysbiosis. (Table)
Conclusion: Point of Care BSA may serve as a promising objective assessment for IBS. The time-efficient and point-of-care application of BSA may allow it to serve as a screening procedure to help evaluate and treat patients with IBS. A large sample cohort study of the BSA between pre and post-treatment patients would need to be done to establish a better understanding. If validated, the BSA could provide clinicians with an objective marker to ascertain IBS presentation, response to therapy, as well as couple with the LBT to assess specific abnormal intestinal gas levels that may subsequently guide treatment plans.



[0548] **Figure 1.** A. Scatterplot of IBS symptom Score over the Bowel Sound Score: The above graph details a best of fit model to predict IBS symptom severity over the score received on the BSA. The data fits the model to an R^2 of 0.591 with an ANOVA of regression showing a p-value <0.0001 B. Proportional chart represents 3-way correlation between 3 given tests: The Treemap bins each patient into a category depending on the results of all 3 tests. The probabilities of each positive test within the 37 patient sample were used to create an expected value Table which was then used to perform a chi-square test of independence. The test of association showed a p-value of <0.005.

Table 1. **Proximity Matrix (Percent agreement) between Gastrointestinal Symptom Rating Scale IBS (GSRS), Lactulose Breath Test (LBT), and Bowel Sound Analysis (BSA)**

	GSRS	LBT	BSA
GSRS	1	0.708	0.784
LBT	0.708	1	0.708
BSA	0.784	0.708	1

S549

The Individualized Gut Microbiome Response to 2'-Fucosyllactose (2'-FL) Captured Using An App-Connected Breath Tester

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FoodMarble, Dublin, Dublin, Ireland.

Introduction: The gut microbiota strongly influences our health. Prebiotic supplementation has the potential to positively alter this microenvironment. 2'-Fucosyllactose (2'-FL) is the most abundant oligosaccharide found in human breast milk. Studies have shown that 2'-FL can boost host immunity and stimulate the growth of Bifidobacteria in the gut. However, the metabolism and associated benefits of any prebiotic are heavily dependent on the host's microbiome. Daily breath testing may provide real-time feedback on whether a particular prebiotic is being metabolized by the host's microbiome.
Methods: 9 IBS and 11 healthy subjects were provided with an app-connected breath tester (AIRE 2®, FoodMarble) which measures breath hydrogen (H_2) and methane (CH_4). All subjects followed standard preparation and fasted for 12 hours prior to the test. Subjects recorded a baseline breath test before ingesting a 2'-FL (Aequival® 2'-FL, FrieslandCampina, The Netherlands) sample (10g healthy, 5g IBS). Breath was measured every 15 min for a total of 3 hr. A positive response was defined as a rise in ≥ 20ppm and/or ≥ 10ppm from baseline for H_2 and CH_4 respectively.
Results: Overall, 75% of subjects had a positive CH_4 response (4 healthy, 5 IBS) or positive H_2 response (7 healthy, 2 IBS). However, only 15% (2 healthy, 1 IBS) were positive for both gases. Interestingly, 25% (2 healthy, 3 IBS) did not reach the positive criteria for either gas.30% (2 healthy, 4 IBS) were positive for CH_4 only and 30% (5 healthy, 1 IBS) were positive for H_2 only. The IBS group had significantly higher (p =

0.009) H_2 baseline (14.1 ± 7.1 ppm (mean ± SD)) than controls (6.8 ± 3.9 ppm). The IBS group baseline CH_4 (12.1 + 11.5 ppm) was 36% higher than the healthy controls (7.8 ± 7.8 ppm) but didn't reach statistical significance (p = 0.3) (Table)

Conclusion: Given the connection between diverse gut microflora and health, finding mechanisms to influence this environment is favorable. Prebiotic fibers, like 2'-FL, have the potential to enrich this microenvironment through microbial fermentation. However, in order to gain such a health benefit, the prebiotic must be metabolized by the host's gut microflora. Our data demonstrate the individualized nature of host-microbiome fermentation response across subjects and support the use of a more personalized approach. Daily breath analysis has the potential to identify microbial responders, as well as being used to help optimize dosing and tolerance over time.

Table 1. Breath hydrogen and methane response of healthy (10g 2'FL) and IBS (5g 2'FL) subjects in response to prebiotic supplementation after a 12-hour fast

	H_2 or CH_4 responder	H_i responder	CH_4 responder	H_2 and CH_4 responder	Non responder
All (n=20)	75% (15)	30% (6)	30% (6)	15% (3)	25% (5)
IBS (n=9)	66% (6)	11% (1)	44% (4)	11% (1)	15% (3)
Healthy (n=1)	81% (9)	45% (5)	18% (2)	18% (2)	10% (2)

A hydrogen responder is defined as a ≥20 ppm rise in breath hydrogen above baseline and a methane responder is defined as a ≥10 ppm rise in breath methane above baseline.

S550

Naloxegol and Naldemedine in the Treatment of Persistent Opioid-Induced Constipation (OIC) in Patients With Cancer Pain: A Systematic Review

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Introduction: Opioid-induced Constipation (OIC) has been a major cause of distress in patients treated with opioids for cancer pain. Numerous drugs have been studied so far to manage refractory OIC. Naloxegol (NKTR-118), a pegylated form of naloxone, and Naldemedine, a peripherally acting μ-opioid receptor antagonist (PAMORA), have shown to alleviate OIC without affecting central analgesia. We study here the efficacy and safety of Naloxegol and Naldemedine in the treatment of OIC - both in clinical trials and in real-world clinical practice.

Methods: We searched and screened a total of 397 articles from databases such as PubMed, Cochrane, Embase, and Web of Science. A total of 9 studies assessing the use of Naloxegol and Naldemedine in patients with cancer pain were included in our review. We extracted data related to response rate and adverse events. Patient assessment of constipation symptoms (PAC-SYM) and assessment of constipation quality of life (PAC-QOL) scales were also analyzed. STATA version 3.2 was used for data analysis.

Results: Of the 397 studies that were identified by our database search, 9 studies were found to be relevant and met the inclusion criteria. Five studies (three RCT and 2 observational), and four observational studies were included for the assessment of Naldemedine and Naloxegol efficacy respectively. A total of 953 OIC cancer patients were treated with Naldemedine, and the response rate for Spontaneous Bowel Movements (SBM) is 72 % (95 % CI, p = 0.004). A significant improvement in Quality-of-life scales such as PAC-SYM and PAC-QOL was also reported. A total of 570 patients from four observational studies treated with Naloxegol were included in our review. In all these studies there was a significant improvement in Bowel Function and Quality of Life after adding Naloxegol despite the poor performance status of the participant. The most common adverse events leading to drug discontinuation were diarrhea, and abdominal pain, dysesthesia. (Table)

Conclusion: Our results suggest that Naloxegol and Naldemedine are safe and effective in the treatment of refractory OIC in cancer patients. This review is significant in terms of that it includes data from both clinical trials and observational studies. The lack of a control group and a placebo arm in Naloxegol studies warrants more research. However, the randomized control trials employing Naldemedine had an efficacious and safer profile than placebo which is promising in the treatment of OIC with cancer pain.

Table 1.

Author & Year	Type of Study	Participants assessed for efficacy (n)	Male n (%)	Follow up period	Spontaneous bowel movements responder RATES (%)	Any Adverse effects N (%)
Naldemedine						
Katakami, 2017	Phase IIb RCT	225, Nal- 169, P- 56	Nal- 100 (69%), P- 34 (60%)	2 weeks	Nal- 122 (72%), P- 21 (37.5%)	Nal- 120 (71%), P- 29 (52%)
Katakami, 2017	Phase III RCT	193, Nal- 97, P- 96	Nal- 59 (61%), P- 60 (62.5%)	2 weeks	Nal- 69 (71%), P- 33 (34%)	Nal- 43 (44%), P- 25 (26%)
Katakami 2017	Open-label extension study	Nal- 131	Nal- 74 (56.5%)	12 weeks	NA	Nal- 105 (80%)
Hiruta, 2021	Multi-center Retrospective study	255	Nal- 179 (60.5%)	NA	Nal- 235 (79%)	204 (69%)
Nishiba, 2022	Multi-center Retrospective study	149	Nal- 89 (60%)	NA	Nal- 98 (66%)	116 (78%)
Naloxegol						
Cobo Dols, 2021	Prospective study	126	74(59%)	12 m	98/126 (77.8%	19 (15%)
Lemaire, 2021	Non interventional follow-up study	124	117 (63.2%)	1 m	79 (73.4%)	43 (32.8%)
Ostan, 2021	Observational study	150	77(51.3%)	1 m	NA	51 (33%)
Davies, 2022	Observational study	170, assessed for efficacy- 143, assessed for safety- 170 Group I- 76, Group II- 98	65 (45%)	1 m	Group I 55(72%), Group II 74(75.5%)	89/170 (52.4%)

N= number, Nal= Naldemedine, P= Placebo, NA= Not Applicable.

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Loss of Bifidobacteria in Lyme Disease: Cause or Effect

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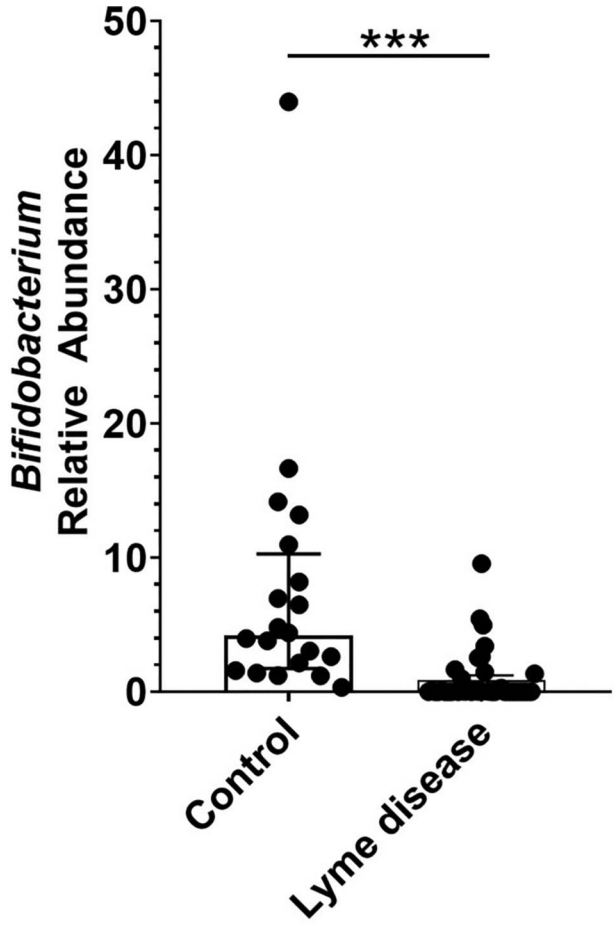
Introduction: Lyme disease is a poorly understood condition which starts with a rash but may continue with chronic fatigue and neurological symptoms. Approximately 1 in 5 early Lyme disease patients have GI symptoms, such as nausea, anorexia, abdominal pain, or diarrhea. Lyme disease is thought to be cased by microbes in the spirochetes phylum transmitted by black legged ticks. Lyme-related healthcare costs in America exceed 1.3 billion dollars annually. *Bifidobacteria* are known for their beneficial probiotic actions within the human gut microbiome. Their numbers are reduced in severe COVID-19, *Clostridioides difficile* infection and Inflammatory Bowel Disease. To our knowledge *Bifidobacteria* levels have not been studied in Lyme disease patients. Given the importance of Bifidobacterium abundance in other diseases, we focused on relative abundance of Bifidobacterium in fecal samples of patients with Lyme disease compared to controls.

Methods: Fecal samples were assessed for relative abundance of Bifidobacterium in Healthy Control subjects without Lyme disease (n=20) compared to patients with Lyme disease (n=39). The average symptom duration in patients with Lyme disease was 5 years and none were on antibiotics 2 weeks prior to sample collection (range of symptoms from 1 month to 20 years, all treated initially with antibiotics).Metagenomics Next Generation sequencing was performed on fecal samples, where DNA samples were extracted and normalized for library downstream analysis using Shotgun Methodology. Mann-Whitney Statistical test was used for comparison. This study was IRB approved.
Results: Relative Abundance of *bifidobacteria* was significantly decreased ($p < 0.0001$) in patients with Lyme disease. Median and interquartile range (IQR) were: Control (Median:4.175%; IQR:1.72-10.27%) and Lyme disease (Median:0.0014%; IQR:0.00%-0.96%)(Figure). 30/39 Lyme disease patients (77%) were found to possess < 1% relative abundance of Bifidobacterium in their stool sample. Of interest only 1/39 samples showed presence of Spirochetes in stool samples.
Conclusion: This is the first study that demonstrates low levels of *Bifidobacteria* in patients with chronic Lyme disease. These results raise three questions; whether the disease was caused by 1. the original microbe creating loss of Bifidobacterium 2. baseline low *Bifidobacteria* due likely to either diet or medications or 3. excessive treatment. Given Lyme disease comprises a gut dysbiosis issue, therapies should also aim at restoration of depleted *Bifidobacteria*.



[0551] **Figure 1.** Lyme disease subjects have significantly ($p<0.001$) reduced relative abundance of genus bifidobacterium.

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Low-Grade Duodenal Eosinophilia Is Associated With cag-A in *Helicobacter pylori*-Related Dyspepsia

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Introduction: Functional dyspepsia (FD) is a multifactorial disorder. *Helicobacter pylori* (*H. pylori*) related dyspepsia (HpD) may be considered a separate entity. Duodenal eosinophilia is a potential pathogenic mechanism in FD. However, the impact of duodenal eosinophilia and H. pylori virulence genes in HpD was not explored. Thus, our aim was to evaluate the association of H. pylori virulence genes and low-grade duodenal eosinophilia in HpD.
Methods: A multi-center cross-sectional study was conducted. A total of 301 patients who meet Rome-III criteria were selected before upper endoscopy and 95 patients were included after normal endoscopy and positive *H. pylori* in gastric biopsies were assessed. Clinical parameters, *H. pylori* virulence genes (*cagA*, *oipA* and *vacA*) and duodenal histology were evaluated.
Results: 69 (72%) patients had epigastric pain syndrome (EPS), 17 (18%) post-prandial distress syndrome (PDS) and 9 (10%) EPS/PDS overlap. FD syndromes were not associated with *cagA* or *oipA* strains. A significantly trend of *vacA s1/m1*(78%) and s1/m2 (80%) positive strains in EPS was observed. Histological duodenal grading of chronic inflammation, low-grade duodenal eosinophilia and intra-epithelial lymphocytes showed no difference in *oipA* and *vacA* strains. Low-grade duodenal eosinophilia was significant in *cagA* positive strain (Table), the OR for low-grade duodenal eosinophilia with *H. pylori cagA* positive strain was 4.2 (95% CI, 1.77-9.93). Adjusting for age, gender, smoking, PPI and *vacA s1/m1* the OR was 4.7 (95% CI, 1.66-13.3).
Conclusion: Our findings suggest that low-grade duodenal eosinophilia is significantly associated with *cagA* strain in HpD.

Table 1. Low-grade duodenal eosinophilia, H. pylori virulence genotypes and clinical variables

Variable	Low-grade duodenal eosinophilia	
	Positive (44)	Negative (51)
Age (SD)	44 (11.6)	51 (13)
Gender (Fem %)	22 (50%)	22 (43%)
PDS (%)	9 (20%)	8 (17%)
EPS (%)	32 (73%)	37 (72%)
EPS/PDS overlap (%)	3 (7%)	6 (11%)
BMI (SD)	26.6 (3.9)	27.6 (5.2)
cagA positive (%)	28 (64%) *	15 (29%)
oipA positive (%)	31 (70%)	34 (67%)
vacA s1 m1 positive (%)	21 (48%)	20 (39%)
PPI (%)	14 (32%)	20 (39%)
NSAID (%)	17(39%)	19 (37%)
Diabetes (%)	9 (20%)	18 (35%)
Hypertension (%)	14 (32%)	13 (25%)
Smoking (%)	13 (29%)	20 (39%)

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Artificial Intelligence and Anorectal Manometry: Automatic Detection and Differentiation of Anorectal Motility Patterns - A Proof of Concept Study

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Introduction: Anorectal manometry (ARM) has gained increasing relevance in the evaluation and diagnosis of defecation disorders and anal incontinence, both prevalent in the general population. Despite its usefulness, ARM accessibility is difficulted by the insufficient availability of this exam. Indeed, the complexity of data analysis and the time required for its completion and analysis are significant drawbacks to its clinical availability. This study aimed to develop and validate a deep learning, artificial intelligence (AI) model to automatically differentiate motility patterns of fecal incontinence (FI) from obstructed defecation (OD), using raw data from ARM.
Methods: Pressure signals were collected from a total of 2469 ARM studies (including 837 patients with anal incontinence and 1189 with obstructed defecation). Both identification and labeling were performed by 2 expert interpreters in ARM and included, besides the reference group, patients with FI and OD. Before training, all signals were resampled by interpolation or by removal of redundant points. The dataset was then split into train and test sets in a patient-based manner, for training and validation respectively. We normalized the training data to avoid data leakage. We then trained and evaluated a deep learning model comprised of a series of 1D Convolutional Neural Networks (1DCNN) followed by a series of Dense layers.
Results: The trained CNN automatically detected and differentiated FI from OD motility patterns with a sensitivity of 84.1%, a specificity of 80.2%, and a precision of 78.1% in a patient-split analysis. Furthermore, The overall accuracy was 85.7%. Patient-split analyses are an important step toward the real-life implementation of deep learning models, mitigating potential biases of its applicability to a clinical setting.
Conclusion: Our group developed a pionner AI algorithm for automatic detection and differentiation of relevant anorectal motility patterns. Subsequent development of the CNN as well as more data are required to further develop the model's diagnostic performance and to incorporate additional manometric diagnoses according to the London classification of anorectal disorders. Nevertheless, this proof of concept study highlights the feasibility of AI analysis in the interpretation and classification of ARM studies. The further development of these tools may optimize the access to ARM studies, which may have a significant impact on the management of patients with anorectal functional diseases.

S554

COVID-19 Is Associated with Increased Risks for Development of Esophagogastrointestinal Motility Disorders

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Introduction: Patients with COVID-19 infection can present with various gastrointestinal symptoms. There is growing evidence that COVID-19 can affect smooth muscle, peripheral and central nervous system, which may lead to brain-gut dysfunction, a major pathophysiologic mechanism for esophagogastrointestinal motility disorders (EGMD). It is unclear if COVID-19 will increase the risk for patients to develop EGMD. The goal of the study was to determine the incidence of common EGMD in patients after testing positive for COVID-19, and to compare the incidence of EGMD in non-COVID patients.
Methods: A retrospective cohort analysis was performed using IBM Explorys, which contained deidentified healthcare information from over 64 million patients across the US. COVID-19 cohort is consisted of patients with a positive COVID test or a diagnosis of coronavirus infection from 2020-2022. The control group consists of patients who did not have a positive COVID test or documented coronavirus infection from 2020-2022. We collected diagnosis of gastroparesis (GP), irritable bowel syndrome (IBS), esophageal dysmotility, functional dyspepsia (FD) and common gastrointestinal symptoms that happen after COVID-19 was diagnosed; Same information was collected in the non-COVID group. Incidence rate per 100000 person-year was calculated. Odds ratios (OR) with 95% confidence interval were used to compare the cohorts.
Results: There was a total of 287,950 patients in the COVID-19 positive cohort and 18,346,510 patients in the COVID negative cohort (Table). The incidence of EGMD was higher in COVID-19 positive group compared with the COVID negative group, including GP (OR 1.90-2.17), IBS (OR 1.47-1.58), esophageal dysmotility (OR 1.38-1.68) and FD (OR 1.09-1.42). COVID positive cohort had a higher incidence of new onset gastrointestinal symptoms, including nausea (OR 1.75-1.80), vomiting (OR 1.31-1.35), early satiety (OR 1.75-2.10), epigastric pain (OR 1.42-1.50), heartburn (OR 1.79-1.97), diarrhea (OR 1.94-2.00), constipation (OR 1.44-1.49) and bloating (OR 5.34-6.77).
Conclusion: COVID-19 positive patients are associated with a higher incidence of newly diagnosed EGMD and various gastrointestinal symptoms compared to the non-COVID patients. Further research is warranted to determine the pathophysiological connection between COVID and the development of EGMD.

Table 1. Esophagogastrointestinal Motility Disorders in COVID-19 positive patients and non-COVID patients

		COVID positive (N=287950)		COVID Negative (N=18346510)		OR	P
		N	Incidence/100000 person year	N	Incidence/100000 person year		
FGIMD	Gastroparesis	870	101	27380	50	1.9-2.17	< 0.0001
	IBS	2910	337	122010	222	1.47-1.58	< 0.0001
	Esophageal dysmotility	400	46	16790	31	1.38-1.68	< 0.0001
	FD	220	25	11270	20	1.09-1.42	0.0013

Table 1. (*continued*)

		COVID positive (N=287950)		COVID Negative (N=18346510)		OR	P
		N	Incidence/100000 person year	N	Incidence/100000 person year		
Symptoms	Nausea	18960	2195	701870	1275	1.75-1.8	< 0.0001
	Vomiting	13390	1550	649310	1180	1.31-1.35	< 0.0001
	Early satiety	500	58	16630	30	1.75-2.10	< 0.0001
	Epigastric pain	5580	646	245200	445	1.42-1.50	< 0.0001
	Heartburn	1680	194	57190	104	1.79-1.97	< 0.0001
	Diarrhea	14990	1735	497340	904	1.94-2.00	< 0.0001
	Constipation	11970	1386	527460	958	1.44-1.49	< 0.0001
	Bloating	300	35	3180	6	5.34-6.77	< 0.0001

S555

Impact of Constipation on Resource Utilization in Patients with Parkinson's Disease: A Nationwide Analysis

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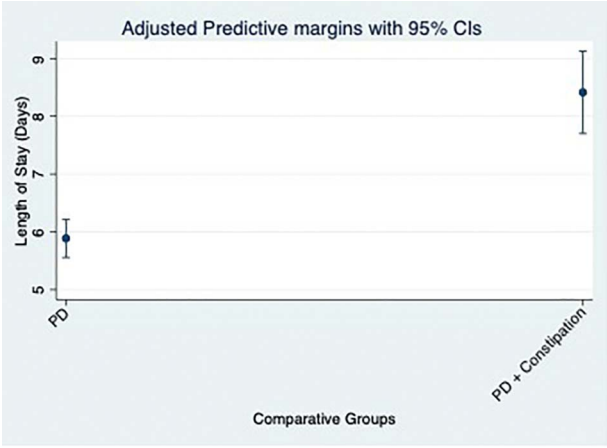
Introduction: Parkinson's disease (PD) is a grave neurodegenerative disorder characterized by motor and non-motor symptoms. Constipation is a major disabling non-motor symptom that enormously affects the quality of life. It is one of the most common functional gastrointestinal disorders in patients with PD. Our study aimed to evaluate the prevalence of Constipation and its impact on resource utilization in hospitalized patients with PD in the US.
Methods: National Inpatient Sample (NIS) for 2019 was queried using ICD-10-CM Codes to identify a cohort of inpatient admissions with a primary discharge diagnosis of PD with and without a secondary diagnosis of Constipation. A weighted sample was used to get baseline characteristics and resource utilization during the inpatient admissions. Multivariate linear regression analysis followed by predictive margins was used to obtain adjusted estimates of the length of stay and total hospital charges. (Figure)
Results: Among 21125 patients admitted with PD, 2860 (13.5%) patients had a concurrent diagnosis of Constipation. Mean age was similar in PD patients with or without Constipation (74 years vs. 75.1 years). In adjusted analysis, Constipation was associated with a significantly longer length of hospital stay in PD patients with Constipation compared to without, 8.56 days vs. 5.89 days, respectively (p-value < 0.01). A lesser number of PD patients with Constipation were discharged home than those without Constipation (18.7% vs. 32.7%, p-value < 0.01). A higher percentage of Constipated PD patients were discharged to skilled nursing facilities compared to non-constipated PD patients (51.2% vs. 43.1%). There was no statistically significant difference in hospital charges between the two groups. (Table)
Conclusion: Our study showed a high prevalence of Constipation among hospitalized patients with PD. The presence of Constipation leads to an increased length of stay. In addition, these patients are more likely to be discharged to skilled nursing facilities, which can increase overall healthcare costs. Careful assessment and prompt intervention to address Constipation is required for these hospitalized patients. It will help mitigate adverse outcomes in these patients, improve quality of life and decrease the economic burden on the health system.



[0555] **Figure 1.** PD: Parkinson's Disease; PD+constipation: Parkinson's Disease with Constipation

Table 1. **Adjusted for Age, Charlson Comorbidity Index, Hospital (Location, Teaching status), Insurance status, Malnutrition**

Variables	Parkinson's without Constipation (18265)	Parkinson's with Constipation (2860)	*p*-value
	a) Baseline Patient and Hospital Characteristics		
Age (SD)	74.0 (9.8)	75.1 (8.7)	0.01
Female (%)	6175 (33.8)	950 (33.2)	0.78
Race (%)			0.38
White	14210 (79.7)	2145 (77.2)	
Charlson Comorbidity Index (SD)	1.6 (1.7)	1.8 (1.7)	0.02
Hospital Type (%)			
Urban	16810 (92.0)	2660 (93.0)	0.41
Teaching	13985 (76.6)	2305 (80.6)	0.05
Hospital Bed Size (Large)	9935 (54.4)	1520 (53.2)	0.34
Payer Information (%)			< 0.01
Medicare	15020 (84.1)	2545 (90.1)	

Table 1. (*continued*)

Variables	Parkinson's without Constipation (18265)	Parkinson's with Constipation (2860)	*p*-value
Private Insurance	2275 (12.7)	180 (6.4)	
Disposition (%)			< 0.01
Home SNF Died	5970 (32.7) 7860 (43.1) 200 (1.1)	535 (18.7) 1465 (51.2) 10 (0.4)	
Malnutrition	1660 (9.1)	365 (12.8)	0.01
b) Resource Utilization			
LOS (Unadjusted)	5.83 (95% CI 5.47-6.18)	8.56 (95% CI 7.84-9.28)	< 0.01
LOS (Adjusted)	5.89 (95% CI 5.56-6.22)	8.41 (95% CI 7.70-9.13)	< 0.01
TOTAL CHARGES (Unadjusted)	59555 (95% CI 56066-63043)	56882 (95% CI 52109-61656)	0.31
TOTAL CHARGES (Adjusted)	59419 (95% CI 56292-62547)	57770 (95% CI 52983-62557)	0.51

SD: Standard Deviation ; SNF: Skilled Nursing Facility; LOS: Length of Stay.

S556

Potential of Tenapanor as a Treatment for Chronic Idiopathic Constipation (CIC): A Post Hoc Analysis From the T3MPO-1 and T3MPO-2 Phase 3 Studies for Irritable Bowel Syndrome With Constipation (IBS-C) in Adults

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Introduction: Tenapanor is a first-in-class, minimally absorbed, small-molecule inhibitor of the intestinal sodium/hydrogen exchanger isoform 3 (NHE3), approved for the treatment of IBS-C in adults. Most recently ROME IV diagnostic criteria recognize that rather than being distinct entities functional constipation (FC) and IBS-C represent a continuum of symptoms. Wong, et al (AJG 2010) demonstrated that 89.5 % of patients meeting ROME III criteria for IBS-C also met the criteria for FC. Recognizing this overlap we performed a post hoc analysis, evaluating the efficacy of tenapanor for FC by utilizing the primary endpoint for chronic idiopathic constipation (CIC) in patients with IBS-C from the T3MPO-1 (NCT02621892) and T3MPO-2 (NCT02686138) phase 3 studies. Am J Gastroenterol 2010; 105:2228–2234 Wong RK et al.
Methods: Adult patients with IBS-C (ROME III) with < 3 weekly complete spontaneous bowel movements (CSBM), ≤5 weekly spontaneous bowel movements (SBM) and weekly worst abdominal pain score ≥3 (0-10 numerical rating scale) during a 2-week screening period were randomized to tenapanor 50 mg or placebo twice a day. Data from the first 12 weeks of both trials was used to calculate the durable responder rate, which is the regulatory endpoint for CIC. A durable responder is a patient with a weekly increase of ≥1 CSBM from baseline and ≥3 CSBM per week for 9 of 12 weeks and 3 of the last 4 weeks of study.
Results: In the T3MPO-1 ITT population (tenapanor, n=307; placebo, n=299; mean age 45 years; 81% female), the responder rate vs placebo in durable responder rate was 11.28% (adjusted relative risk 3.35; $p < 0.001$). In the T3MPO-2 ITT population (tenapanor, n=293; placebo, n=300; mean age 45 years; 82% female), the responder rate vs placebo in durable responder rate was 15.49% (adjusted relative risk 3.75; $p < 0.001$). Tenapanor was generally well tolerated. Diarrhea was the most common adverse event; severe diarrhea was reported in 2.5% of tenapanor-treated patients.
Conclusion: Based on results from this post hoc analysis of the T3MPO-1 and T3MPO-2 Phase 3 studies for IBS-C in adults, tenapanor, with its novel mechanism of action, shows promise as a potential therapeutic option for CIC. Further clinical trials are needed to evaluate tenapanor for the CIC population to confirm these results.

S557

Comparison of Surgical Interventions in Patients With Gastroparesis and Functional Dyspepsia

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Introduction: Gastroparesis (GP) and functional dyspepsia (FD) present with overlapping symptoms differentiated by delayed gastric emptying in GP. Postsurgical GP is the third leading etiology for GP. Surgical history is not commonly considered to be a risk factor for FD. A lot of patients received cholecystectomy for abdominal pain without clear indications. The goal of the study was to compare if there was any difference of surgical interventions in patients with GP and FD.
Methods: We performed a retrospective analysis using IBM Explorys (1999-2022). Patient populations were identified using SNOMED. We selected patients who have completed a gastric emptying study and divided them into GP and FD cohort. GP cohort included patients with gastroparesis with the exclusion criteria of cyclical vomiting syndrome, psychoactive substance abuse, eating disorder, factitious disorder, malignant tumor of esophagus and stomach, neoplasm of abdomen, gastric or intestinal obstruction, IBD, adhesion of intestine, carcinomatosis, perforation of intestine, Roux-en-Y gastrojejunostomy, and gastrectomy. FD cohort was similarly constructed with additional exclusion criteria: gastroparesis, gastrointestinal ulcer, brain neoplasm and pancreatitis. Surgical history and its timeline were collected, including fundoplication, cholecystectomy, and para-esophageal hernia repair. To select the patients who did not have a clear indication for cholecystectomy, we excluded cholangitis, cholecystitis, gallbladder polyp and neoplasm, obstruction of biliary tree, and injury of gallbladder. Number of patient and percentage were obtained. Odds Ratios (OR) with 95% confidence interval were calculated.
Results: We identified a total of 17570 patients with GP and 60230 patients with FD. A significant percentage of patients with GP received cholecystectomy, which was higher than that of FD (26.9 vs 17.9%, $p< 0.001$). There were a higher percentage of fundoplication and paraoesophageal hernia repair in GP than FD (1.99 vs 1.69%, p=0.0082; 0.80 vs 0.53%, p=0.0001). A total of 3720 (79%) of patients with GP and 8360 (77%) of patients with FD received cholecystectomy without a clear indication. Interestingly, for patients with GP who underwent cholecystectomy, the diagnosis of GP was made after cholecystectomy in 30.2% of the cases. (Table)
Conclusion: Patients with GP are more likely to receive surgical intervention than FD, especially cholecystectomy. Over three quarters of patients with GP and FD receive cholecystectomy without a clear indication.

Table 1. **Comparison of Surgical Interventions in Gastroparesis and Functional Dyspepsia**

	GP (N=17570)	%	FD (N=60230)	%	OR	*P*
Fundoplication	350	2.0%	1020	1.7%	1.04-1.33	0.0082
Cholecystectomy	4730	26.9%	10790	17.9%	1.62-1.76	< 0.0001
Paraesophageal hernia repair	140	0.8%	320	0.5%	1.23-1.84	0.0001

S558

Association of Chronic Opioid Use With Dyssynergic Defecation: Dose and Exposure Effects

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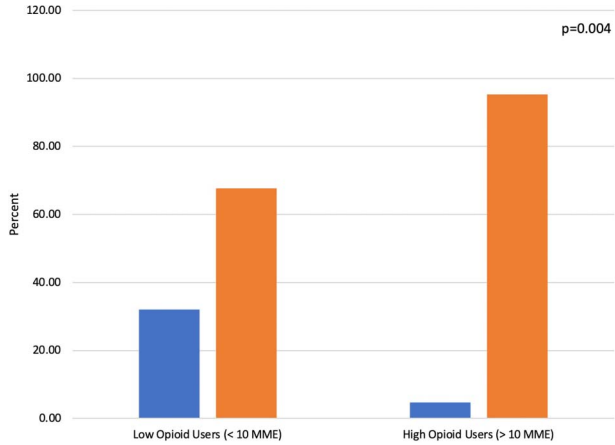
Introduction: While opioids can be effective management for analgesia, GI side effects can limit tolerability. Chronic opioid use (OU) is associated with opioid-induced constipation (OIC) through slowing of GI transit. Studies have noted possible associations between OU and dyssynergic defecation (DD). The aim of this study was to identify chronic OU amongst patients who underwent anorectal manometry (ARM) testing to determine dose or exposure related effects on anorectal function.
Methods: We conducted a retrospective study of patients who had ARM from January 2015 to October 2021. OU was determined by pre-procedure questionnaire and medical record review. OU was considered at least one month of use at time of ARM and was standardized based on morphine milliequivalents (MMEs).
Results: Demographics are summarized in Table. Of 773 patients undergoing ARM, 12.7% had chronic OU. OU was associated with having DD; Type 1 DD being most common ($p< 0.001$). Chronic OU patients were older than patients without OU ($p< 0.001$). ARM in chronic OU patients was performed more often for constipation, constipation and fecal incontinence, and constipation and diarrhea when compared to patients without OU ($p=0.04$). Chronic OU patients were more likely to have abnormal balloon expulsion time (BET) defined as > 60 seconds ($p< 0.001$). Within OU, patients were divided into low and high dose of opiates for likelihood of DD findings on ARM (Figure). The lowest group dosing that reached significance defined low OU as 0-10 MME and high OU as ≥10 MME ($p=0.005$). Of the 34 low dose patients, 67.6% had DD; of the 64 high dose patients, 95.3% had DD ($p=0.004$). High dose OU was associated with fewer normal ARM tests and more Type I-III DD ($p=0.005$). Of the chronic OU, high dose patients were more likely to have abnormal defecation index (DI) defined as < 1.4 compared to low dose patients ($p=0.006$).
Conclusion: Our data suggests a correlation between OU and ARM indications as well as OU and DD. We also found that 10 MME was the opioid dose threshold above which there is a greater association with anorectal dysfunction. Chronic OU patients suffered from constipation, were older, and had greater abnormal BET than those without OU, suggesting exposure-dependent association with OU. DI was abnormal at high dose OU compared to low dose OU, suggesting dose-dependent association with OU. Our study suggests that OIC can be associated with DD in addition to the known delayed colonic transit.



[0558] **Figure 1.** Presence of Dyssynergic Defecation in Low Dose Opioid Use and High Dose Opioid Use Groups (Blue: Normal ARM, Orange: Dyssynergic Defecation on ARM) [p=0.004]

Table 1. Distributions and Variables for Non-Opioid Users and Opioid Users in Patients undergoing Anorectal Manometry

		Non-Opioid (n=675)	All Opioid (n=98)	p-Value	Low Dose (0-10 MME) Opioid (n= 34)	High Dose (> 10 MME) Opioid (n=64)	*p*-Value
Gender	Male	142 (20%)	24 (24%)	0.43	7 (20.6%)	17 (26.6%)	0.62
	Female	533 (80%)	74 (66%)		27 (79.4%)	47 (73.4%)	
Age (mean) y		48.7 + 16.0	56.0 + 16.9	< 0.001	55.9 + 17.0	56.0 + 17.0	0.98
ARM Indication	Constipation	511 (75.6%)	78 (79.6%)	0.04	24 (70.6%)	54 (84.4%)	0.14
	Fecal Incontinence	120 (17.8%)	13 (13.3%)		8 (23.6%)	5 (7.8%)	
	Constipation and Fecal incontinence	23 (3.5%)	5 (5.1%)		1 (2.9%)	4 (6.2%)	
	Fecal Urgency	8 (1.2%)	0		-	-	
	Incomplete Defecation	2 (0.3%)	0		-	-	
	Diarrhea	10 (1.5%)	0		-	-	
	Constipation and Diarrhea	1 (0.1%)	2 (2%)		1 (2.9%)	1 (1.6%)	
ARM Result	Normal	281 (41.6%)	14 (14.3%)	< 0.001	11 (32.4%)	3 (4.7%)	0.005
	Type I DD	174 (25.8%)	43 (34.9%)		10 (29.4%)	33 (51.6%)	
	Type II DD	33 (4.9%)	9 (9.2%)		2 (5.9%)	7 (10.9%)	
	Type III DD	116 (17.2%)	18 (18.4%)		6 (17.6%)	12 (18.8%)	
	Type IV DD	71 (10.5%)	14 (14.3%)		5 (14.7%)	9 (14.1%)	
Defecation Index	Abnormal (< 1.4)	502 (74.3%)	80 (81.6%)	0.13	21 (61.8%)	59 (92.2%)	0.006
	Normal (>1.4)	174 (25.7%)	18 (18.4%)		13 (38.2%)	5 (7.8%)	
Balloon Expulsion Time	Abnormal (>60sec)	238 (35.3%)	64 (65.3%)	< 0.001	21 (61.8%)	43 (67.2%)	0.65
	Normal (< 60 sec)	436 (64.7%)	34 (34.7%)		13 (38.2%)	21 (32.8%)	
Sensory Threshold	Low	155 (22.9%)	26 (26.5%)	0.50	11 (32.4%)	15 (23.4%)	0.33
	Normal	339 (50.1%)	43 (43.9%)		16 (47.1%)	27 (42.2%)	
	High	182 (26.9%)	29 (29.6%)		7 (20.6%)	22 (34.4%)	
Mean sphincter pressure (resting) mmHg		64.60 + 23.6	63.50 + 25.3	0.66	58.6 + 25.3	66.1 + 25.2	0.16
Max sphincter pressure (squeeze) mmHg		157.5 + 68.0	147.0 + 62.9	0.15	138.6 + 64.9	151.5 + 61.8	0.33

S559

The Contribution of Psychiatric Comorbidity and Cannabis Usage to Cyclic Vomiting Syndrome Severity

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Introduction: Cyclic vomiting syndrome (CVS) is a disorder characterized by sporadic, repeated episodes of intense nausea vomiting. Psychiatric comorbidities (up to 84% for anxiety and 78% for depression) and cannabis use (up to 53%) are common among patients with CVS. However, the relationship between cannabis usage and psychological symptom severity using validated surveys is unknown. Among adults with CVS, we aimed to identify: (a) the frequency of comorbid psychiatric disorders and current cannabis use, (b) the severity of anxiety and depression symptoms and relationship to cannabis use.
Methods: Adults diagnosed by a gastroenterologist with CVS at a tertiary gastrointestinal (GI) clinic were sequentially enrolled in an observational registry. Self-report of psychiatric disease diagnosis and current cannabis use were captured in addition to validated measures including anxiety/depression (Hospital Anxiety and Depression Scale; HADS); general quality of life (Short Form-36); and upper GI symptom severity (Patient Assessment of Gastrointestinal Disorders-Symptoms Severity Index; PAGI-SYM) and related quality of life (Patient Assessment of Upper Gastrointestinal Disorders-Quality of Life; PAGI-QOL).
Results: Enrolled CVS patients (N=48; ages 19-64 years; 61% female) had frequent psychiatric comorbidity, with anxiety disorders (n=32; 97%) and depression (n=22; 46%) most common (Table). Current cannabis use was present in 28 (58%) and significantly associated with higher HADS-depression scores (p=0.02) and lower SF-36 Mental Component Summary (MCS) scores (p=0.02), but not HADS-anxiety, SF-36 Physical Component Summary, PAGI-SYM, PAGI-QOL scores. Using age-adjusted logistic regression, higher HADS-depression scores were independently associated with an increased likelihood of current cannabis use (OR=1.4, 95% CI 1.1–1.8, p=0.01). Similarly, a separate age-adjusted logistic regression showed that better SF-36 MCS scores were associated with a decreased likelihood of current cannabis use (OR=0.95, 95% CI 0.9-1.0, p=0.02).
Conclusion: Despite high prevalence of cannabis use in a CVS registry, it was not cross-sectionally associated with worse gastrointestinal symptom severity or related quality of life. Instead, both depression and poor mental health-related quality of life were associated with cannabis use, suggesting that cannabis use may be a marker of comorbid psychiatric disease and mental health distress in a CVS population.

Table 1. Demographics and clinical characteristics of adults with cyclic vomiting syndrome

	Overall Study Cohort (N=48)	Current Cannabis Use (n=28)	No Current Cannabis Use (n=20)	P-value[i]
Age, M(SD)	34 (12.6)	33 (11.1)	36 (14.6)	0.65
Sex-Female, n (%)	29 (61%)	16 (57%)	13 (65%)	0.80
Race, n (%)[ii]				
American Indian or Alaskan Native	0 (0%)	0 (0%)	0 (0%)	–
Asian	0 (0%)	0 (0%)	0 (0%)	–
Black or African American	1 (2%)	1 (4%)	0 (0%)	–
White	48 (100%)	28 (100%)	20 (100%)	–
Other	0 (0%)	0 (0%)	0 (0%)	–
Ethnicity, n (%)				
Hispanic/Latino	1 (2%)	1 (4%)	0 (0%)	–
Not Hispanic/Latino	46 (96%)	26 (93%)	20 (100%)	–
Unknown	1 (2%)	1 (4%)	0 (100%)	–
Comorbid Psychiatric Disorders, n (%)[iii]				
Any Psychiatric Disorder	32 (67%)	20 (71%)	14 (70%)	1.00
Anxiety Disorder[iv]	32 (67%)	18 (64%)	14 (70%)	0.92
Depression	22 (46%)	15 (54%)	7 (35%)	0.33
Obsessive Compulsive Disorder (OCD)	3 (7%)	1 (4%)	2 (10%)	0.76
Schizophrenia	0 (0%)	0 (0%)	0 (0%)	0.25
Bipolar Disorder	3 (7%)	1 (4%)	2 (10%)	0.76
Substance Abuse	2 (5%)	1 (4%)	1 (5%)	1.00
Post-Traumatic Stress Disorder (PTSD)	5 (90%)	5 (18%)	0 (0%)	0.13
Attention Deficient Hyperactive Disorder (ADHD)	1 (3%)	0 (0%)	1 (5%)	0.86
Patient Assessment of Gastrointestinal Disorders-Symptoms Severity Index (PAGI-SYM), M(SD)				
Total	1.3 (0.91)	1.5 (0.93)	1.2 (0.88)	0.30
Heartburn/Regurgitation	1.4 (1.1)	1.5 (1.2)	1.1 (0.90)	0.32
Fullness/Satiety	1.6 (1.3)	**1.9 (1.3)**	**1.2 (1.2)**	**0.04**
Nausea/Vomiting	1.5 (0.95)	1.5 (0.90)	1.6 (1.1)	1.00
Bloating/Distension	1.3 (1.2)	1.4 (1.2)	1.2 (1.1)	0.40
Upper Abdominal Pain	1.1 (1.0)	1.2 (1.1)	0.88 (0.97)	0.40
Lower Abdominal Pain	0.78 (0.99)	0.89 (1.1)	0.63 (0.78)	0.48
Patient Assessment of Upper Gastrointestinal Disorders-Quality of Life (PAGI-QOL), M(SD)				
Total	1.7 (1.2)	2.0 (1.3)	1.3 (0.8)	0.07
Daily Activities	1.9 (1.3)	2.2 (1.4)	1.6 (1.2)	0.12
Clothing	1.1 (1.5)	1.4 (1.7)	0.75 (1.3)	0.19
Diet and Food Habits	2.1 (1.6)	2.3 (1.5)	1.8 (1.6)	0.21

Table 1. (*continued*)

	Overall Study Cohort (N=48)	Current Cannabis Use (n=28)	No Current Cannabis Use (n=20)	P-value[i]
Relationship	1.1 (1.5)	1.5 (1.7)	0.62 (0.7)	0.16
Psychological Well-Being/Distress	1.9 (1.5)	**2.4 (1.6)**	**1.3 (1.0)**	**0.03**
Short Form-36 (SF-36), M(SD)				
Physical Component Summary (PCS)	44 (11)	45 (10)	42 (13)	0.93
Mental Component Summary (MCS)	40 (15)	**36 (14)**	**46 (14)**	**0.01**
Hospital Anxiety and Depression Score (HADS), M(SD)				
Anxiety	11 (2.2)	11 (2.5)	11 (1.8)	0.36
Depression	6.3 (3.1)	**7.3 (3.3)**	**5.0 (2.0)**	**0.02**

i. Continuous variables analyzed with Kruskal Wallis H-Tests for non-normally distributed data. Categorical variables analyzed with Pearson's Chi-squared Tests for descriptive purposes. ii. Subjects could select more than one race category. iii. Subjects could select more than one psychiatric disorder. iv. Anxiety disorders included generalized anxiety disorder and panic disorder.

S560

The Strong Association Between Bloating, Abdominal Pain, and Global Irritable Bowel Syndrome (IBS) Symptom Scores in IBS With Diarrhea (IBS-D): A Phase 3 Trial Pooled Correlation Analysis of Individual Symptoms

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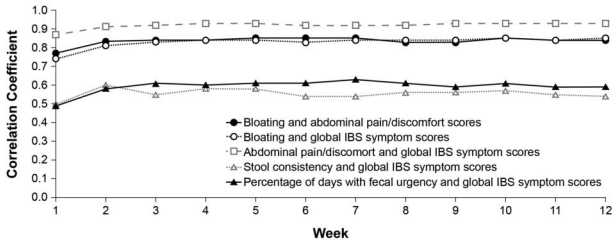
Introduction: Although recurrent abdominal pain and altered stool consistency/frequency are diagnostic criteria for IBS, other symptoms (eg, bloating) are common and bothersome. Given the need to address multiple symptoms concurrently, the aim was to assess potential relationships between improvement in abdominal pain, bloating, and global IBS symptoms in patients with IBS-D.
Methods: Data were analyzed post hoc from 2 identically designed, phase 3, randomized trials. Adults with IBS-D with both mean daily abdominal pain/discomfort and bloating scores, rated separately, of 2 to 4.5 on a 7-point Likert Scale (range, 0 ["not at all"] to 6 ["a very great deal"]) and a daily mean stool consistency score of ≥ 3.5 (range, 1 "very hard" to 5 "watery") received rifaximin 550 mg TID or placebo for 2 weeks, with 10 weeks of treatment-free follow-up. In addition to symptoms above, fecal urgency was assessed daily, based on patients' yes/no responses to "Have you felt or experienced a sense of urgency today?" Global IBS symptoms were also assessed daily ("In regards to all your symptoms of IBS; on scale of 0-6, how bothersome were your symptoms of IBS today?"). Pearson correlation analyses compared change from baseline in abdominal pain/discomfort, bloating, stool consistency, or fecal urgency and global IBS symptoms (overall [12 weeks] or by week). A coefficient (r) value of > 0.70-1.00 was considered a strong positive correlation (> 0.50-0.70 [moderate] and ≤ 0.50 [weak-to-negligible]).
Results: A strong positive correlation was observed between changes from baseline in both weekly average and daily symptom scores over time for bloating and abdominal pain/discomfort scores, bloating and global IBS symptom scores, and abdominal pain/discomfort and global IBS symptom scores (r ≥ 0.78; **Table**). The correlation between global IBS symptoms scores was moderate with stool consistency score assessed either weekly or daily and percentage of days with stool urgency assessed weekly (r ≤ 0.60; **Table**). When assessed by week, correlations for average weekly symptoms were consistent for Weeks 2 through 12 (**Figure**).
Conclusion: Abdominal bloating and pain/discomfort are key symptoms in patients with IBS-D. These symptoms strongly correlate with each other and with global IBS symptom scores. Bloating and pain/discomfort may have a greater effect on patient perception of global IBS symptoms than altered stool consistency/fecal urgency. Therefore, effective therapies for IBS-D should target bloating as well as pain and diarrhea.



[0560] **Figure 1.** Correlation Coefficients for Weekly Average Symptom Score Comparisons, By Week IBS = irritable bowel syndrome.

Table 1. **Overall Correlations Between Change From Baseline in IBS Symptom Scores**

	Pearson Correlation Coefficient, r	
Symptom Comparison	**Average Symptom Scores Assessed Weekly**	**Symptom Scores Assessed Daily**
Bloating and abdominal pain/discomfort scores	0.84	0.78
Bloating and global IBS symptom scores	0.84	0.79
Abdominal pain and global IBS symptom scores	0.92	0.88
Stool consistency and global IBS symptom scores	0.56	0.53
Percentage of days with fecal urgency and global IBS symptom scores	0.60	—*

*Due to definition, not assessed daily.
IBS = irritable bowel syndrome.

S561

The Gas and Bloating Diary APP: A Prospective Comparison With Daily Paper Diary

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Introduction: Physicians rely on subject's recall of gas-related symptoms to facilitate diagnosis and treatment, but patient's recall may be unreliable or biased. Aim: To develop and prospectively test the reliability of a novel Gas and Bloating digital Diary APP and compare with a validated paper diary in healthy subjects.

Methods: In a randomized, prospective, cross over study, healthy subjects recorded daily symptoms on either a paper diary or digital phone APP for 2 weeks each. Symptoms include bloating, gas, nausea, belching, abdominal distension, abdominal pain, constipation, indigestion, vomiting, and diarrhea. Symptoms frequency (0=none, 1=1/day, 2=2-3/day and 3=more than 3/day), duration (0=none,1=1-10 minutes, 2=10-30 mins, and 3= ≥ 30 mins), and severity (VAS (0 (none) to 10 (several)) were assessed. An overall index score was calculated for each symptoms, range from 9 (none) to 60 (severe). Correlational analysis were performed to determine the test-retest reliability, subject's preference, and validity of APP.
Results: Thirty subjects (F/M=16/14; 18-75 yrs) participated. The APP symptom scores significantly correlated (ICC > 0.915, p< 0.001) between week 1 and 2, except diarrhea (ICC+0.099, p=0.390) (Table). There were significant correlations for 14-day APP diary and paper diary for bloating, gas, belching, abdominal pain, constipation, and indigestion (ICC >0.585, p< 0.010). However, mean indices for nausea, distension, diarrrhea, and vomiting were low in both diaries suggesting infrequent occurrence of these symptoms in health, and lack of significant association (icc< 0.102, P >0.602). Significantly more subjects preferred the APP to paper diary (63.3% vs 33.3%, p=0.018).
Conclusion: Gas and Bloating Diary APP is a reliable and reproducible digital tool for assessing gas-related symptoms and highly correlates with paper diary. APP was significantly preferred over paper diary. The detailed daily log and summary report together with normative data allows for improved understanding and management of patients with gas and bloating but requires validation in patients. The research module provides accurate analysis of symptoms and saves time for research use.

Table 1. Test-retest/Reliability, and Validity of Gas and Bloating APP versus Paper Form Diary in Healthy Subjects

	APP Test-retest/Reliability (n=30)				Validity (n=30), APP vs Paper			
	First week	Second week	ICC	*P*	APP	Paper	ICC	*P*
Bloating index	0.91 ± 0.40	0.67 ± 0.30	0.926	<0.001	0.75 ± 0.34	0.32 ± 0.13	0.585	0.010
Gas index	2.37 ± 0.58	1.92 ± 0.50	0.915	<0.001	2.04 ± 0.53	1.90 ± 0.72	0.889	<0.001
Nausea index	0.29 ± 0.27	0.23 ± 0.21	0.984	<0.001	0.26 ± 0.25	0.05 ± 0.02	0.210	0.265
Belching index	0.62 ± 0.32	0.82 ± 0.43	0.936	<0.001	0.67 ± 0.36	0.92 ± 0.45	0.873	<0.001
Distention index	0.27 ± 0.19	0.31 ± 0.21	0.969	<0.001	0.27 ± 0.20	0.09 ± 0.45	0.226	0.248
Abdominal pain index	0.19 ± 0.12	0.17 ± 0.14	0.964	<0.001	0.16 ± 0.13	0.09 ± 0.04	0.680	0.002
Constipation index	2.87 ± 0.71	2.94 ± 0.68	0.962	<0.001	2.84 ± 0.68	0.93 ± 0.72	0.925	<0.001
Indigestion index	0.25 ± 0.21	0.31 ± 0.25	0.988	<0.001	0.28 ± 0.23	0.33 ± 0.21	0.969	<0.001
Vomiting index	0.00 ± 0.00	0.00 ± 0.00			0.00 ± 0.00	0.00 ± 0.00	0.000	0.500
Diarrhea index	0.03 ± 0.01	0.03 ± 0.01	0.099	0.390	0.02 ± 0.01	0.04 ± 0.03	-0.065	0.566

S562

Patient Compliance With Vibrating Capsule Predicts Outcome in Chronic Idiopathic Constipation (CIC)

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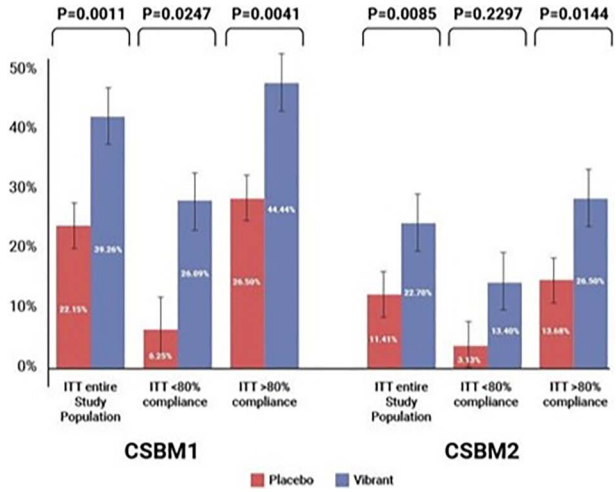
Introduction: Many patients with chronic idiopathic constipation (CIC) are dissatisfied with available medications, suggesting a need for new therapies. A recent phase III trial showed that an orally ingested vibrating capsule (VC) improved stool frequency, bowel and abdominal symptoms and quality of life in patients with CIC. Our aim was to evaluate the impact of compliance/adherence on efficacy of the VC in a post-hoc analysis of a Phase III trial.
Methods: Many patients with chronic idiopathic constipation (CIC) are dissatisfied with available medications, suggesting a need for new therapies. A recent phase III trial showed that an orally ingested vibrating capsule (VC) improved stool frequency, bowel and abdominal symptoms and quality of life in patients with CIC. In this 8-week randomized double-blind placebo-controlled Phase III trial, activation of the vibrating capsule (Vibrant®, Yokne'am Illit, Israel) was automatically and remotely recorded, permitting accurate assessment of compliance. Two outcomes were analyzed: CSBM $_1$, an increase of ≥ 1 CSBM/week and CSBM$_2$, an increase of ≥ 2 CSBMs/week, averaged over the study period and compared to baseline.
Results: Patients whose adherence to the recommended number of capsules was >32 capsules ingested over the 8 weeks of treatment (n=117), (out of the recommended 5 capsules per week X 8 weeks = 40 capsules), had higher response rates for both CSBM $_1$ and CSBM$_2$, compared to either the entire study population or those who ingested < 32 capsules per week (n=42) (Figure and Table).
Conclusion: Patients with CIC with >80% adherence to capsule dosing frequency had a superior response, supporting the appropriateness of the proposed dosing schedule. By virtue of its design, this first in class system enables accurate monitoring of compliance when assessing clinical response.



[0562] **Figure 1.** Primary outcome measures showing proportion of complete spontaneous bowel movement 1 and 2 (CSBM1 and CSBM2) responders according to compliance rate and in comparison to the entire study population (intention-to-treat analysis)

Table 1. Impact of compliance on relative efficacy of vibrating capsule (VC) and placebo

		VC (Vibrant□) Mean change from baseline ITT [95% CI]	Placebo Mean change from baseline ITT [95% CI]	P-value (χ^2 test)
Entire Study Population (ITT population from Phase III study) VC n=163 Placebo n=149	$CSBM_1$	39.26% [32.10%;46.93%]	22.15% [16.23%;29.47%]	0.0011
	$CSBM_2$	22.70% [16.94%;29.72%]	11.41% [7.25%;17.51%]	0.0085
ITT < 80% compliance VC n=117 Placebo n=117	$CSBM_1$	26.09% [15.601%;40.26%]	6.25% [1.73%;20.15%]	0.0247
	$CSBM_2$	13.40% [6.12%;25.67%]	3.13% [0.55%;15.74%]	0.229)
ITT >=80% compliance VC n=46 Placebo n=32	$CSBM_1$	44.44% [35.76%;53.48%]	26.50% [19.34%;35.15%]	0.0041
	$CSBM_2$	26.50% [19.34%;35.15%]	13.68% [8.60%;21.06%]	0.0144

S563

Post-Colon Ischemia Irritable Bowel Syndrome: A Multi-Center Prospective Study

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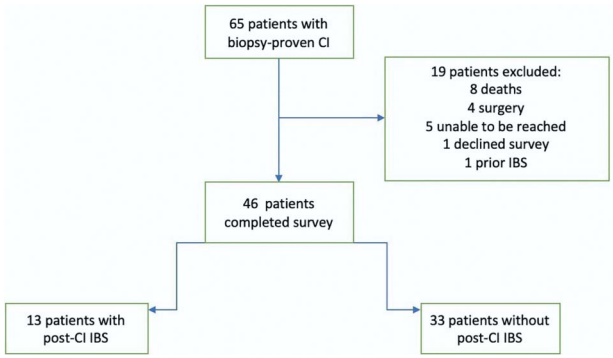
Introduction: Colon ischemia (CI) is the most common form of intestinal ischemic injury and is a common cause of acute lower gastrointestinal bleeding. Post-infection irritable bowel syndrome (IBS) is a well-described entity that occurs in up to 20% of patients after an episode of infectious colitis and IBS is almost 5 times more common in patients after a bout of diverticulitis than in controls. To date there are no data as to whether IBS occurs following an episode of CI.
Methods: We reviewed the charts of all patients who underwent colonoscopy at Montefiore Medical Center from 1/2021 and 3/2022 and Yale New Haven Medical Center from 5/2021 and 3/2022. Inclusion determinants were (1) clinical presentation consistent with CI; (2) colonoscopic findings suggestive of CI; and (3) colonic pathology consistent with CI. Patients without all 3 inclusion determinants were excluded. Patients with intestinal surgery after CI, death prior to survey, previously diagnosed IBS, or an underlying GI disorder to explain symptoms also were excluded. All patients were contacted within 3-6 months of their index diagnosis of CI to answer a 4-question survey based on the Rome IV Criteria for IBS. The primary outcome of our study was the frequency of IBS after an episode of CI. Secondary outcomes were whether antibiotic usage, gender, or affected segment of colon correlated with the development of post-CI IBS. (Figure)
Results: 65 patients with biopsy-proven CI were identified. 12 patients were excluded because they died or required surgery, 5 were unable to be reached, 1 declined to complete the survey, and 1 had IBS prior to CI. 46 patients were evaluated and completed the survey, of whom 13 (28.3%) developed post-CI IBS. Patients who received antibiotics were significantly more likely to develop post-CI IBS (p=0.02): 84.6% of patients with post-CI IBS received antibiotics, compared with 45.5% of patients who did not develop post-CI IBS. The segment of affected colon did not correlate with development of post-CI IBS (p=0.66). There was a trend for woman to develop post-CI IBS more frequently than men (84.6% vs 60.6%; p=0.16). (Table)
Conclusion: Based on our study, post-CI IBS is likely a real entity, which has not been previously described. Our study indicates that antibiotics may play a role in its development and that consideration should be taken prior to initiating antibiotics in patients with mild-to-moderate CI. Larger studies are needed to validate our findings.



[0563] **Figure 1.** Post-CI IBS Flow Diagram

Table 1. Predictors of Post-CI IBS

	Post-CI IBS	No Post-CI IBS	*p* value
Post-CI IBS vs. No Post-CI IBS n (%)	13 (28.3%)	33 (71.7%)	-
Age (yrs)	63.3	67.0	0.41
Gender, n (%) Female Male	 11 (84.6) 13 (15.4)	 20 (60.6) 13 (39.4)	0.16
Antibiotics, n (%) Yes No	 11 (84.6) 13 (15.4)	 15 (45.5) 18 (54.5)	**0.02**

Table 1. (*continued*)

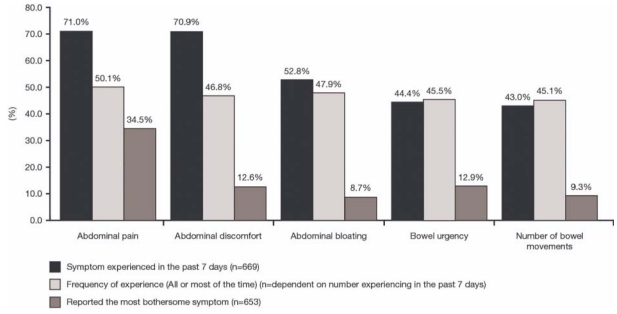
	Post-CI IBS	No Post-CI IBS	*p* value
Location of Disease, n (%)			0.66
IRCI	1 (7.6)	5 (15.2)	
Left-sided or pancolitis	12 (92.4)	28 (84.8)	

S564

Burden of Disease in U.S. Patients With Irritable Bowel Syndrome With Diarrhea (IBS-D)

Brian E. Lacy, MD, PhD, FACG[1], Yanqing Xu, MS, PhD[2], Douglas C. Taylor, MBA[3], Katherine J. Kosch, RPh[2], Rachel Dobrescu, BA[2], Amy Morlock, MA[2], Robert Morlock, PhD[5], Ceciel Rooker, BS[6]. [1]Mayo Clinic, Jacksonville, FL; [2]AbbVie, Inc., North Chicago, IL; [3]Ironwood Pharmaceuticals, Inc., Cambridge, IL; [4]Acumen Health Research Institute, Ann Arbor, MI; [5]YourCareChoice, Ann Arbor, MI; [6]International Foundation for Functional Gastrointestinal Disorders, Milwaukee, WI.

Introduction: Symptoms of irritable bowel syndrome with diarrhea (IBS-D) impose a significant burden to patients. Our study examined disease burden and care-seeking behavior of patients with IBS-D.
Methods: A cross-sectional, on-line health survey collected data during 8/2020-12/2021 from US adults. IBS-D patients were defined using Rome IV criteria. Health outcomes comparing IBS-D patients to controls included anxiety and depression screeners, health-related quality of life (HRQoL) and productivity measures. Care, treatment and symptom burden were assessed for IBS-D patients. Differences in anxiety, depression, HRQoL, and productivity between IBS-D patients and the general population were assessed with a 1:1 matched sample by sex, age, race, region and Charlson Comorbidity Index score. Categorical data were described by percentage and continuous data by mean and standard deviation. Means were compared with ANOVA and proportions with chi-square tests.
Results: Data was collected from 29,359 participants. Matching IBS-D participants resulted in 669 patients and 669 controls. Most patients were female (74.6%), White (84.0%), with a mean age of 41.9 years. IBS-D patients had significantly higher proportions of moderate to severe anxiety and depression ($p < .001$) and significantly lower HRQoL vs controls ($p < .001$). Health impact on work productivity and daily activity was significantly higher among IBS-D patients vs controls (Table). Of IBS-D patients, 91.5% sought care for their symptoms, 59.3% within the past year. Of those having an ER visit/hospitalization in the past year (17.3%), abdominal pain was the most reported reason (87.1%). 65.9% of IBS-D patients reported currently taking an Rx and/or an OTC for their symptoms (13.2% Rx alone, 13.9% Rx and OTC, and 38.9% OTC alone). Abdominal pain and abdominal discomfort were the symptoms most experienced (71.0% and 70.9%, respectively). Abdominal pain was reported to be the most bothersome (34.5%) (Figure). IBS-D patients currently taking an Rx with/without an OTC were more satisfied with the control of bowel (39.2% vs 21.5%) and abdominal (40.3% vs 22.7%) symptoms than those currently taking an OTC alone.
Conclusion: This large survey study demonstrates that the health impact of IBS-D is high. Nearly 1 in 5 patients sought care at an ER for their symptoms. Abdominal pain and discomfort are common bothersome symptoms with patients reporting better control with Rx medications compared to OTC agents.



[0564] **Figure 1.** Symptom Experience, Frequency and Bothersomeness

Table 1. Characteristics of the Rome IV IBS-D Cohort vs Controls (1) WPAI fielded 12/20-12/21: Rome IV IBS-D cohort n=463; control n=397. (2) GAD-7: Generalized Anxiety Disorder, 7-item; range: 0-21. (3) PHQ-9: Patient Health Questionnaire, 9-item; range: 0-29. (4) Veterans RAND 12-item Health Survey (VR12). (5) Question fielded 12/20-12/21: Rome IV IBS-D cohort n=251; control n=233

	Rome IV IBS-D Cohort (N=669)	Control (N=669)	Sig.
Female	74.6%	74.6%	1.000
Age, mean (SD)	41.9 (15.0)	41.9 (15.0)	0.990
Black or African American White Other	7.8% 84.0% 8.2%	7.8% 84.0% 8.2%	1.000
Proportion of Hispanic, Latino or Spanish origin	7.8%	8.5%	0.617
Northeast Midwest South West	17.2% 22.6% 42.8% 17.5%	17.2% 22.6% 42.8% 17.5%	1.000
Charlson Comorbidity Index (CCI) score, mean (SD)	0.6 (1.1)	0.6 (1.1)	1.000
Body Mass Index (BMI) (lbs/in^2), mean (SD)	30.2 (9.0)	27.9 (7.4)	< 0.001
Proportion employed per Work Productivity and Impairment (WPAI) (1)	54.2%	58.7%	0.187
Median household income (Census derived from zip code), mean (SD)	65,468 (28,360)	65,459 (26,647)	0.996
Anxiety (GAD-7 [2]) score, mean (SD)	9.9 (6.1)	6.8 (5.8)	< 0.001
Depression (PHQ-9 [3]) score, mean (SD)	11.4 (7.3)	7.9 (7.1)	< 0.001
Chronic pain	61.4%	38.6%	< 0.001
Migraine	64.2%	35.8%	< 0.001

Table 1. (*continued*)

	Rome IV IBS-D Cohort (N=669)	Control (N=669)	Sig.
Insomnia	67.7%	32.3%	< 0.001
GERD	75.9%	24.1%	< 0.001
VR-12 Mental Component Summary (MCS [4]), mean (SD)	36.7 (12.5)	43.9 (11.8)	< 0.001
VR-12 Physical Component Summary (PCS [4]), mean (SD)	40.3 (11.2)	44.4 (10.6)	< 0.001
VR-12 Health utility (VR-6D [4]), mean (SD)	0.60 (0.11)	0.67 (.12)	< 0.001
Health problems affected work productivity rating (0-10 scale), mean, SD (5)	3.1 (2.9)	2.1 (2.8)	< 0.001
Health problems affected daily activities rating (0-10 scale), mean, SD (1)	4.3 (3.2)	2.6 (3.1)	< 0.001

S565

Home Care In-Use Evaluation of Intermittent Colonic Exoperistalsis (ICE) Device to Treat Chronic Functional Constipation in the General Population

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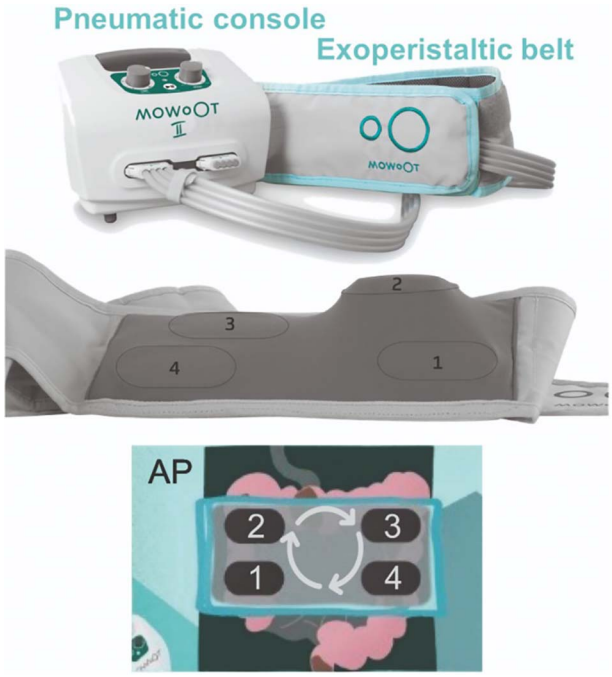
Introduction: Up to 24% of the general population is diagnosticated of chronic constipation, leading to negative clinical and social consequences for patients and additional costs for the health care systems. Intermittent colonic exoperistalsis (ICE) treatment administered with the MOWOOT medical device, is a non-invasive, non-drug solution for the treatment of chronic constipation. It has been developed to facilitate natural bowel movements and reduce the side effects of laxatives, enemas, or other invasive approaches. The ICE medical device has been proven in a multicentric clinical trial to be safe and effective in constipation from either neurogenic or idiopathic etiology (McClurg et al., CTG 2020).
Methods: Patients with chronic functional constipation, with or without previous diagnosis of slow bowel transit were recruited in 4 hospitals in Germany. The treatment consisted in using the ICE device for 15 to 30min daily, at home. In-use-evaluation was performed through anonymous, structured feedbacks collected at baseline (F1) and after some time under ICE treatment (F2). Satisfaction, tolerability, and usability were valued by patients from 1 (very high) to 6 (very low). (Figure)
Results: Data resulted from n=18 patients (17 female, 1 male), from 18 to 75 yr (average age 49,06 (18,52) yr). Most of patients (66.67%) have a previous diagnosis of slow bowel transit. The mean time of ICE treatment at F2-feedback collection was 6,33(5,18) months (min 0,5; max 16). No one reported any serious adverse event. Six patients described occasional low to moderate abdominal pain, which did not affect the treatment compliance. There was a significant improvement in bowel function (Table) toghether with a reduction in laxative use (6 patients stopped and 5 reduced oral laxatives, 61.1%, Chi ^{2} P= 0.0018). The satisfaction with bowel function and management increased in average by 40.6% after the ICE treatment. Tolerability and usability of the ICE device were rated as high or very high by 87.5% and 88.2% of patients, respectively.
Conclusion: The high number of satisfied patients relates with the clinically significant amelioration in their bowel function. Especially concerning the reduction by ~1h in time spent per evacuation. This structured feedback in the out-patient sector demonstrates the medical benefit of ICE in constipated patients with or without slow bowel transit. Therefore, the ICE device has the potential to substitute more conservative approaches in bowel management strategies of the general population.



[0565] **Figure 1.** The ICE device is composed of an exoperistaltic belt connected to a pneumatic desktop device, which contains the source of energy and the panel control. The belt is placed on the patient´s abdominal area to administer the ICE treatment on the ascendant and descendent colon, emulating natural peristaltic contractions and colon massage techniques.

Table 1. **Results are shown as mean (SD)**

		PRE (F1)	TREAT (F2)	DIFFERENCE (F2 - F1)	*P*
#Bowel mov. / week	slowT	2.67 (1.91)	5.32 (3.23)	2.65	0.0037
	All	2.61 (1.81)	5.62 (2.93)	3.01	< 0.0001

Table 1. (*continued*)

		PRE (F1)	TREAT (F2)	DIFFERENCE (F2 - F1)	*P*
Time spent/evacuation (min)	slowT	148.3 (164.7)	72.1 (79.5)	-76.00	0.0447
	All	105.9 (146.4)	50.9 (71.1)	-55.00	0.0308
Average Fecal consistency (Bristol 1 - 7)	slowT	2.00 (1.13)	3.75 (1.91)	1.75	0.0084
	All	2.84 (1.81)	3.94 (1.85)	1.10	0.0099
Satisfaction w/ bowel function & management (1-6)	slowT	5.75 (0.45)	3.42 (2.23)	-2.33	0.0206
	All	5.50 (0.98)	3.06 (2.01)	-2.44	0.0034

The quantitative variables # Bowel mov/week and Time spent/evacuation were analyzed with Student's t-Test for paired measures. The semi-quantitative variables Fecal consistency and Satisfaction with bowel funct.&manag. were analyzed with the non-parametric Wilcoxon test for paired measures. P<0.0500 were considered statistically significant.

S566

Evaluation of Secondary Bile Acids in Stool as Predictors of Chronic Bile Acid (BA) Diarrhea

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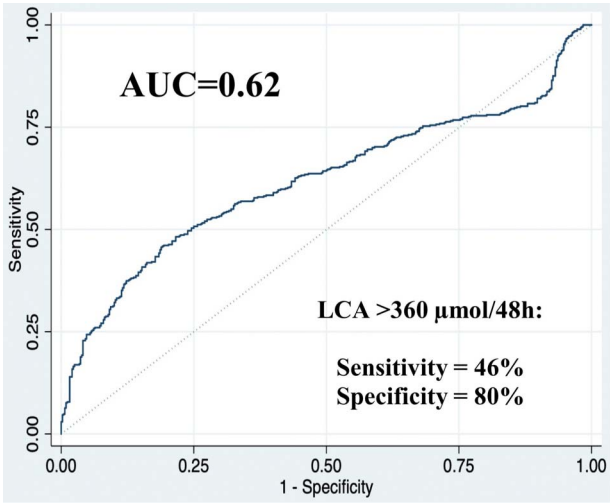
Mayo Clinic, Rochester, MN.

Introduction: Bile acid diarrhea (BAD) accounts for ~25% of chronic "functional diarrhea" (FD). Diagnosis of BAD is currently based on serum 7αC4 >52ng/mL, total fecal BA (TBA) >2,337 μmol/48h, or fecal primary BAs [cholic acid (CA) and chenodeoxycholic acid (CDCA)] >10%. Secondary BAs [deoxycholic acid (DCA) and lithocholic acid (LCA)] are produced by 7α dehydroxylation of CA and CDCA, respectively. DCA promotes colonic secretion, serotonin release, and peristalsis. LCA is a potent stimulus of the Takeda G-protein coupled BA receptor (TGR5, or GPBAR1) which is a mechanism accelerating colonic transit. However, the utility of fecal secondary BAs (DCA and LCA) as markers of both diarrhea [increased fecal weight (FW)] and BAD is unclear.
Methods: We conducted a retrospective study of fecal BA 48h data of 913 patients with FD and no prior intestinal surgery or active inflammatory disease. Patients consumed a 100g fat diet for four days with stool collection in the final 48h. Objective diarrhea was defined as FW >400 g/48h. Associations between TBA, main BA components, observed FW, or objective diarrhea (FW >400g/48h) were assessed using linear or logistic regression as appropriate. Multivariate analyses, adjusting for age, sex, and other fecal BAs, were conducted to appraise the role of each BA component.
Results: Mean age was 51.5y (range: 11-90y), and 67.6% were female. Mean 48h FW was 546.1g (10-90%ile: 158-1056g). Mean TBA was 1921 μmol/48h (10-90%ile: 256-4328 μmol/48h). In the adjusted analyses, a 2-fold increase in CA and LCA was associated with 12.2% (95% CI: 7.4%-17.2%, $p < 0.05$) and 15.3% (7.9%-23.1%, $p < 0.05$) increases in FW, respectively. In contrast, a 2-fold increase in DCA was associated with a 6.8% (1.4%-11.9%, $p < 0.05$) decrease in FW. **Table** presents risk of FW >400g [OR (95% CI)] for a 2-fold increase in each BA (adjusted for age and sex) in all patients, and in 2 groups without or with BAD based on TBA >2,337 μmol/48h. The 48h total LCA conferred the greatest risk. In all patients, 48h fecal LCA of 360 μmol/48h had 46% sensitivity and 80% specificity for FW >400g (AUC=0.62, **Figure**). Adding total LCA to the prediction from total primary BAs increased the AUC from 0.75 to 0.78.
Conclusion: Among patients presenting with FD, 48h fecal total LCA is associated with FW >400g with comparable risk estimates to total primary BAs and with CA alone. Therefore, fecal LCA also has potential utility in the diagnosis of BAD.



[0566] **Figure 1.** Receiver operating characteristic (ROC) curve for LCA as a predictor of objective diarrhea

Table 1. **Estimated risk of diarrhea (fecal weight >400 g/48 hours) for 2-fold increase in bile acid component**

Bile Acid	All patients (N=913)	TBA < 2,337 μmol/48h (N=676)	TBA > 2,337 μmol/48h (N=237)
CA	1.34 (1.16-1.55)***	1.22 (1.03-1.46)*	1.66 (1.11-2.49)*
CDCA^	0.98 (0.84-1.14)	0.95 (0.79-1.15)	0.73 (0.49-1.10)
DCA^	0.80 (0.67-0.95)*	0.82 (0.67-1.01)	0.51 (0.34-0.76)**
LCA	1.47 (1.20-1.80)***	1.34 (1.06-1.69)*	2.12 (1.41-3.19)***
UDCA	1.07 (0.99-1.15)	1.11 (1.02-1.22)*	0.91 (0.75-1.11)

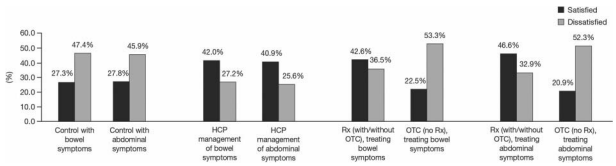
TBA=total fecal bile acid; UDCA=ursodeoxycholic acid.
^secretory BA.
*p<0.05.
**p<0.01.
***p<0.0005.

S567

Disease Burden and Care-Seeking Behavior of Patients With Irritable Bowel Syndrome With Constipation (IBS-C) in the United States

Brian E. Lacy, MD, PhD, FACG[1], Douglas C. Taylor, MBA[2], Yanqing Xu, MS, PhD[3], Katherine J. Kosch, RPh[3], Rachel Dobrescu, BA[4], Amy Morlock, MA[4], Robert Morlock, PhD[5], Ceciel Rooker, BS[6].
[1]Mayo Clinic, Jacksonville, FL; [2]Ironwood Pharmaceuticals, Inc., Cambridge, MA; [3]AbbVie, Inc., North Chicago, IL; [4]Acumen Health Research Institute, Ann Arbor, MI; [5]YourCareChoice, Ann Arbor, MI; [6]International Foundation for Functional Gastrointestinal Disorders, Milwaukee, WI.

Introduction: Symptoms of IBS-C impose a significant negative burden to patients and the healthcare system. Our study examined disease burden and care-seeking behavior of patients with IBS-C.
Methods: A cross-sectional, on-line health survey collected data on US adults from 8/2020-12/2021. IBS-C patients were defined using Rome IV criteria and matched 1:1 by sex, age, race, region and Charlson Comorbidity Index score to the general population. Outcomes comparing IBS-C patients to controls included an anxiety/depression screener, health-related quality of life (HRQoL) and productivity. Means were compared with ANOVA; proportions with chi-square tests. Endpoints assessed descriptively for IBS-C patients were care, treatment, symptom burden and satisfaction with control, health care provider management, and treatment.
Results: Of 29,359 participants, 3.3% (956) met Rome IV criteria for IBS-C. Matching resulted in 910 patients and 910 controls. Most patients were female (76.9%), White (82.2%), with a mean age of 41.2 years. IBS-C patients had significantly higher proportions of moderate to severe anxiety and depression ($p < .001$) and significantly lower HRQoL vs controls ($p < .001$). Health impact on work productivity and daily activity was significantly worse among IBS-C patients vs controls (Table). Of IBS-C patients, 92.4% sought medical care for symptoms; 59.6% within the past year. 97.3% of IBS-C patients experienced ≥1 symptoms in the past 7 days. Abdominal discomfort was the symptom most experienced (71.0%); abdominal pain was the most bothersome (34.0%). Of the IBS-C patients that visited an ER or were hospitalized in the past 12-months due to bowel movement or abdominal symptoms, abdominal pain was the most common reason (90%). 74.2% reported currently taking an Rx and/or an OTC for their symptoms (12.6% Rx alone, 14.7% Rx and OTC, and 46.8% OTC alone). IBS-C patients were more dissatisfied than satisfied with control of bowel (47.4% vs 27.3%) and abdominal (45.9% vs 27.8%) symptoms. Those currently taking an Rx with or without an OTC were more satisfied with the control of bowel (42.6% vs 22.5%) and abdominal (46.6% vs 20.9%) symptoms than those taking only an OTC (Figure).
Conclusion: New data from a large survey study demonstrates that there remains a considerable disease burden and unmet need for IBS-C patients, many of whom commonly experience pain and discomfort and are dissatisfied with their symptom control. This highlights the need to better address the multiple symptoms of IBS-C.



[0567] **Figure 1.** Satisfaction with Control, HCP Management and Treatment

Table 1. Rome IV IBS-C Cohort vs Control Comparisons (1) Question fielded 12/20-12/21; cohort n=687 and control n=556. (2) GAD-7: Generalized Anxiety Disorder, 7-item; range: 0-21. (3) PHQ-9: Patient Health Questionnaire, 9-item; range 0-29. (4) Question fielded 12/20-12/21; cohort n=387 and control n=340

	Rome IV IBS-C Cohort (N=910)	Control (N=910)	Sig.
Female	76.9%	76.9%	1.000
Age, mean (SD)	41.2 (14.9)	41.2 (14.9)	0.995
Black or African American White Other	9.3% 82.2% 8.5%	9.3% 82.2% 8.5%	1.000
Proportion of Hispanic, Latino or Spanish origin	8.6%	10.2%	0.296
Northeast Midwest South West	16.5% 24.7% 39.7% 19.1%	16.5% 24.7% 39.7% 19.1%	1.000
Charlson Comorbidity Index (CCI) score, mean (SD)	0.5 (1.0)	0.5 (1.0)	1.000
Body Mass Index (BMI) (lbs/in^2), mean (SD)	27.2 (7.3)	28.0 (7.3)	0.033
Proportion employed per Work Productivity and Impairment (WPAI) (1)	56.3%	61.2%	0.086
Proportion educated more than high school	75.5%	72.2%	0.110
Mean household income (Census derived from zip code), mean (SD)	64,553 (26,853)	64,629 (25,910)	0.951
Anxiety (GAD-7)[2]) score, mean (SD)	9.1 (6.1)	6.6 (6.0)	< 0.001
Depression (PHQ-9 [3]) score, mean (SD)	10.9 (7.3)	7.9 (7.4)	< 0.001
Chronic Pain	60.4%	39.6%	< 0.001
Migraine	60.2%	39.8%	< 0.001
Insomnia	67.1%	32.9%	< 0.001
GERD	74.6%	25.4%	< 0.001
VR-12 Mental Component Summary (MCS), mean (SD)	38.0 (12.5)	44.5 (12.2)	< 0.001
VR-12 Physical Component Summary (PCS), mean (SD)	41.2 (10.7)	45.6 (10.3)	< 0.001
VR-12 Health utility (VR-6D), mean (SD)	0.61 (0.11)	0.68 (0.12)	< 0.001
Health problems affected work productivity rating (0-10 scale), mean, SD (4)	2.8 (2.7)	1.8 (2.8)	< 0.001
Health problems affected daily activities rating (0-10 scale), mean, SD (1)	3.8 (3.1)	2.4 (3.1)	< 0.001

S568

Public Interest in Irritable Bowel Syndrome Increased in Subsequent Waves of the COVID-19 Pandemic

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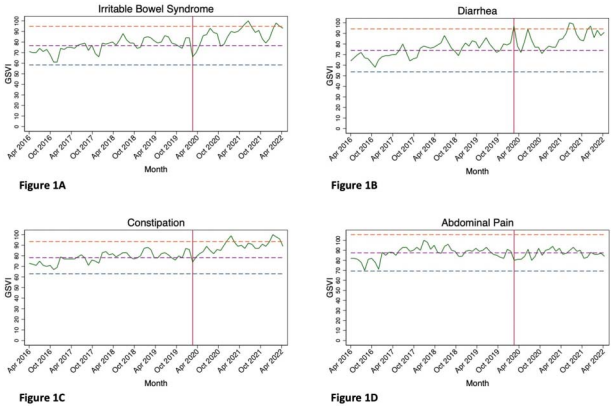
[1]Sidney Kimmel Medical College at Thomas Jefferson University, Philadelphia, PA; [2]Thomas Jefferson University Hospital, Philadelphia, PA.

Introduction: The COVID-19 pandemic has placed tremendous stress on patients' physical and mental health nationwide. The purpose of this study was to examine public interest in irritable bowel syndrome (IBS) and its related symptoms during various waves of the COVID-19 pandemic.
Methods: We used the Google Trends Platform and the Google Search Value Index (GSVI) to quantify public interest in IBS topics between Apr 2016-May 2022. We searched the following four main search terms to examine public interest in IBS topics: "Irritable Bowel Syndrome," "Abdominal Pain," "Diarrhea," and "Constipation." We also compared public interest in IBS topics between states with vaccine mandates versus no vaccine mandates using ANOVA tests. Finally, we examined potential differences in public interest in IBS between men and women using the terms "IBS Women" and "IBS Men."
Results: Public interest in IBS, constipation, and abdominal pain initially decreased following the onset of the pandemic (Figure). In March 2020, search interest in IBS, abdominal pain, and constipation decreased by 13.7%, 8.5%, and 5.4%, respectively. Search interest in diarrhea increased by 31% in March 2020. However, public interest in IBS, constipation, and diarrhea increased in the latter waves of the pandemic (delta: Jun 2021-Nov 2021, and omicron: Dec 2021-Mar 2022), leading to an overall significant increase in search popularity post-pandemic compared to pre-pandemic (Table, P< 0.001). During all waves of the pandemic, there was no significant difference in public interest in IBS among states with varying COVID-19 vaccine mandates. Sub-analysis on gender revealed public interest in "IBS Women" and "IBS Men" increased during the COVID-19 pandemic, but the increase was statistically greater in "IBS women" (P=0.047).
Conclusion: Following the initial decline in public interest in most IBS related topics at the onset of the pandemic, there was a significant overall increase in public interest in IBS, diarrhea, and constipation post-pandemic compared to pre-pandemic. These results suggest that during the first wave of the pandemic, heightened focus on COVID-19 led to decreased interest in most IBS topics. The subsequent increase in public interest in IBS in latter waves of the pandemic suggest that IBS patients faced a greater disease burden during the pandemic. Our sub-analysis on gender revealed that the pandemic may have disproportionally affected women with IBS compared to men with IBS.



[0568] **Figure A-D.** Public interest in IBS (1A), Diarrhea (1B), Constipation (1C), and Abdominal Pain (1D). Green line represents google search value index (GSVI), dashed orange, blue, and purple lines represent upper control limit, lower control limit, and pre-pandemic mean GSVI, respectively. Vertical red line indicates March 2020, the beginning of the COVID-19 pandemic. Upper limit= Pre-Pandemic Mean+3*(SD), Lower limit=Pre-Pandemic Mean-3*(SD).

Table 1. Google Search Value Index (GSVI) for IBS and its related symptoms during various waves of the COVID-19 pandemic

	Before COVID-19	First Wave (Mar-May 2020)	Delta Wave (June 2021-Nov 2021)	Omicron Wave (Dec 2021-Mar 2022)	*P*-Value
Irritable Bowel Syndrome	77.3 (6.9)	71.0 (5.6)	92.3 (6.1)	88.0 (8.6)	<0.001
Diarrhea	74.6 (7.3)	82.3 (13.1)	90.8 (7.3)	92.2 (4.6)	<0.001
Constipation	78.8 (5.8)	78.3 (4.0)	89.2 (2.4)	95.0 (5.0)	<0.001
Abdominal Pain	87.4 (6.0)	80.7 (0.6)	88.5 (3.7)	85.8 (2.1)	0.20

Data represented as mean (SD). Values 0-100, with 100 representing peak popularity.

S569

Comparing the Use and Acceptance of Complementary and Alternative Medicine in Gastroenterology and Gynecology

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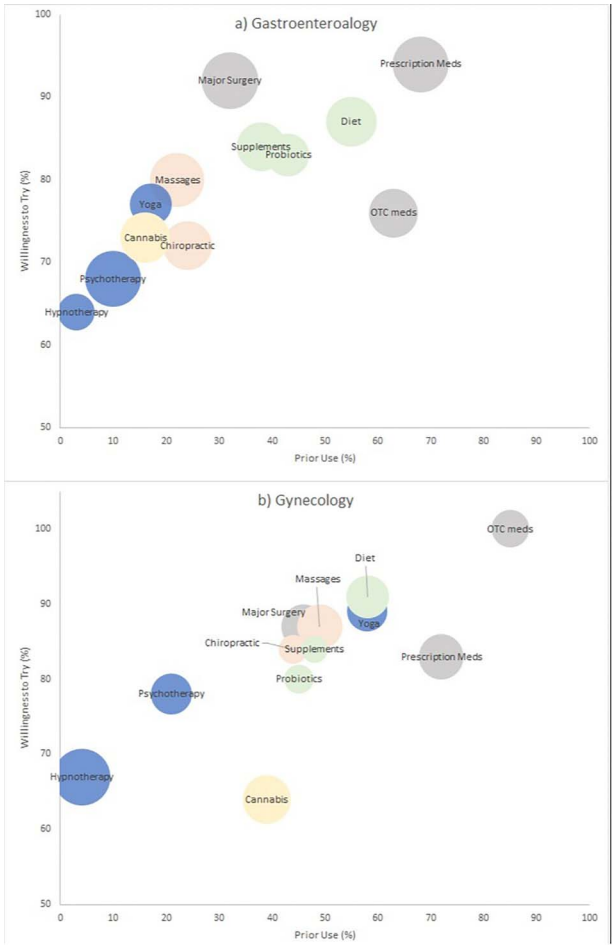
Introduction: Complementary and Alternative Medicine (CAM) is gaining popularity across medical specialties including Gastroenterology (GI) as a means to augment conventional therapies in managing complex, chronic conditions such as cancer and disorders of gut-brain interaction. The implementation and compliance of such therapy relies heavily on baseline patient acceptance and prior experience. We sought to assess the current opinion of CAM in Gastroenterology compared to Gynecology in a tertiary care setting to identify any gaps in the use and acceptance of CAM.
Methods: 218 general GI patients and 85 gynecology patients enrolled consecutively prior to clinic visits participated in a survey evaluating their prior experience with and attitudes towards 1) standard therapies such surgery and medications, 2) manipulative practices such as chiropractic and massages, 3) mind-body interventions such as psychotherapy, yoga and hypnotherapy, 4) diet such as diet modifications, supplements and probiotics, and 5) cannabis. The questionnaires were printed in hard copies and voluntarily completed. The deidentified responses were manually entered into an online database for analysis. (Figure)
Results: Gynecology patients were more likely to have used CAM compared to GI patients especially in the categories of manipulative practices (p=< 0.001), cannabis (p=< 0.001), and mind-body interventions such as yoga (p=< 0.001) and psychotherapy (p=0.01). There was no significant difference between the two specialties in willingness to try an intervention in any treatment categories including the conventional therapies. Patient demographics varied widely based on age, gender and presence of comorbidities such as anxiety, depression, migraine, and endometriosis (Table). Interestingly, the prevalence of irritable bowel syndrome was not significantly different between the two specialties.
Conclusion: GI patients, compared to gynecology, were similarly willing to try, but much less likely to have used CAM. The underuse of CAM in GI could be related to underlying socioeconomic and medical conditions that vary by specialty. For example, gynecology patients in our study were younger and had more comorbidities than our GI counterparts. More studies and educational interventions are recommended to help narrow the gap between the acceptance and use of CAM in Gastroenterology.



[0569] **Figure 1.** Prior use (x-axis) and acceptance (y-axis) of various treatment modalities in a) gastroenterology and b) gynecology. Each treatment modality is color coded into the following categories of therapy: gray = conventional therapies, red = manipulative practices, blue = mind-body interventions, green = diet, yellow = cannabis. Size of the bubbles indicate the perceived benefit from prior use (i.e., higher satisfaction corresponds to bigger width of bubbles).

Table 1. Demographics

	Gastroenterology (N=218)	Gynecology (N=85)	Significance
Age			
Mean (SD) Median (Q1, Q3)	58.0 (15.3) 60.5 (45.0, 70.0)	47.0 (25.5) 47.0 (26.0, 69.0)	2-tail < 0.001
Gender			
Female Male	123 (57.2%) 92 (42.8%)	84 (100.0%) 0 (0.0%)	< 0.001
Comorbidities			
Anxiety	71 (32.6%)	53 (62.4%)	< 0.001
Depression	58 (26.6%)	52 (61.2%)	< 0.001
Irritable Bowel Syndrome	50 (22.9%)	25 (29.4%)	0.241
Migraine	36 (16.5%)	29 (34.1%)	< 0.001
Endometriosis	21 (9.6%)	61 (71.8%)	< 0.001
Restless Leg Syndrome	16 (7.3%)	8 (9.4%)	0.548
Fibromyalgia	15 (6.9%)	8 (9.4%)	0.455
Chronic Fatigue Syndrome	11 (5.0%)	5 (5.9%)	0.770
Interstitial Cystitis	4 (1.8%)	2 (2.4%)	0.771
Vulvodynia	1 (0.5%)	2 (2.4%)	0.135
Total Comorbidities			
Mean (SD) Median (Q1, Q3)	2.29 (1.58) 2.0 (1.0, 3.0)	2.88 (1.48) 3.0 (2.0, 4.0	2-tail < 0.001

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Comparison of Quality of Life Between Patients With Diarrhea- and Constipation-Predominant Irritable Bowel Syndrome

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Introduction: Irritable bowel syndrome (IBS) is characterized by recurrent abdominal pain and change in the form and consistency of stool. Two subtypes of IBS are diarrhea-predominant IBS (IBS-D) and constipation-predominant IBS (IBS-C). While IBS symptoms have been shown to decrease quality of life (QOL), the effects of IBS subtypes on QOL are still unclear. The aim of this study was to compare QOL parameters in patients with IBS-D and IBS-C.
Methods: Data were obtained as part of an institutional review board-approved study where participants with ROME III positive criteria for IBS-D and IBS-C completed the following validated questionnaires: Bowel Disease Questionnaire, IBS-QOL, Hospital Anxiety and Depression Scale (HADS), Symptom Checklist 90 (SCL-90). We used two sample t-test, Wilcoxon rank sum test, and Pearson chi squared to compare the results between the two groups.
Results: The study included 219 patients with IBS-D and 33 with IBS-C. The participants' demographics are reported in the Table. Most patients with IBS-C (70%) had 2-4 bowel movements (BM) per week, while 48% of patients with IBS-D had 13-26 BM per week and 13% had more than 26 BM per week. Patients with IBS-D had higher anxiety, depression, and total anxiety-depression scores on the HADS compared to patients with IBS-C (Table). Patients with IBS-D had higher scores (reflecting worse symptoms) on the somatization, obsessive compulsive, depression, anxiety, and psychoticism dimensions as measured by the SCL-90. Moreover, patients with IBS-D had higher (reflecting worse) IBS-QOL total and subscale scores on 7 out of the 8 subscales (Table). Notably, 42% of patients with IBS-D felt like they were slightly or moderately losing control of their lives because of their bowel problems, whereas 92% of patients with IBS-C reported not feeling loss of control at all. While 96% of patients with IBS-C did not feel that their life revolved around their bowel movements, 20% of patients with IBS-D reported life revolved around their bowel movements quite a bit or a great deal, specifically due to needing to be in proximity to a toilet and inability to take long trips.
Conclusion: Our study shows that patients with IBS-D seem to have a worse general and IBS-specific quality of life compared to patients with IBS-C. These data reinforce the importance of considering QOL impact of IBS and opportunities for shared decision-making when discussing individual management plans for patients with IBS-D.

Table 1. Comparison of demographic factors, Hospital Anxiety and Depression Scale, and IBS-Quality of Life subscale results in 219 patients with IBS-D and 33 patients with IBS-C

	IBS-D	IBS-C	*P*-value
		Demographics	
Age (years), mean (SD)	**41 (14)**	**51 (12)**	**0.001**
% females	79	100	0.004
BMI (kg/m^2), mean (SD)	30 (7)	28 (6)	0.1878
		Hospital Anxiety and Depression Scale (HADS) score, mean (SD)	
HADS total score	8.5 (5.2)	3.4 (2.6)	< 0.0001
HADS anxiety score	6 (3.6)	2.5 (1.9)	< 0.0001
HADS depression score	2.5 (2.3)	0.97 (1.1)	0.0006
		IBS-Quality of Life total score, mean (95% CI)	
Total score	30.1 (27.6, 32.5)	9.1 (6.7, 11.5)	< 0.0001
		IBS-Quality of Life subscales, mean (95% CI)	
Dysphoria	28.1 (24.8, 31.5)	4.2 (1.9, 6.4)	< 0.0001
Interference with activity	37.2 (34.2, 40.2)	7.1 (4.3, 10.0)	< 0.0001
Proximity to toilet important: grades (1-5)	*6/27/24/20/22%*	*59/37/4/0/0%*	*< 0.0001*
Long trips difficult: grades (1-5)	*14/32/20/19/16%*	*78/19/4/0/0%*	*< 0.0001*
Body image	26.9 (24.2, 29.6)	18.3 (13.6, 23.0)	0.0249
Food avoidance	52.7 (48.5, 56.9)	13.0 (8.0, 17.9)	< 0.0001
Social reaction	27.5 (24.5, 30.5)	8.1 (4.0, 12.2)	< 0.0001
Sexual	17.2 (14.1, 20.2)	8.3 (2.8, 13.8)	0.0425
Relationship	20.1 (17.5, 22.8)	3.7 (1.4, 6.0)	< 0.0001

SD=standard deviation; CI=confidence interval. Italicized factors reflect participants' answers on a 1-5 scale for the interference with activity subscale, with 1 being "not at all" and 5 being "extremely"; higher scores reflect worse QOL.

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Knowledge and Utilization of Laxatives in the Inpatient Setting: A Resident Survey

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Introduction: Constipation has become a major problem with increasing prevalence, especially in the current era of opioid use. It is often under-recognized in the hospital setting due to lack of universally accepted diagnostic criteria. The aim of this study is to understand the practice of prescribing laxatives among internal medicine residents at our hospital.
Methods: A 12-question survey was developed on laxative use in hospitalized patients. The survey was emailed to all internal medicine residents at a university hospital center in Washington, DC. After a two-week duration, responses and results were analyzed.
Results: A total of 81 internal medicine residents were emailed the survey, of which 55 responded. Among the risk factors, polypharmacy (36%) was considered as the highest risk for constipation compared to having chronic medical conditions, immobility, dehydration and aging. Although 93% of respondents were aware of the common risk factors of constipation, only 63% were cognizant of prophylactic laxative therapy. Surface active agents (docusate) was the preferred laxative (53%) while the least ordered was an osmotic agent (7%). More than half of the residents (55%) ordered laxatives as needed than as a scheduled medication. In hospitalized patients on opioid medications, 85% of respondents had a low threshold to start prophylactic laxatives, and the majority considered stimulants over osmotic laxatives (44% vs. 5.8% respectively). Based on sub-analysis, third years were more aware of contraindications to prescribing laxatives compared to interns and second years (83% vs. 76% & 64% respectively). Overall, 67% of residents were confident in prescribing laxatives in hospitalized patients.
Conclusion: Based on our study, residents were aware of risk factors of constipation but still two-thirds of them were not confident in prescribing laxatives. Osmotic agents were least preferred among residents though there are evolving expert opinions favoring its use. Overall, we encourage future research on developing a systematic approach for managing constipation and broadening the knowledge on laxative use in the hospital setting.

S572

A Pilot Study for Precision Nutrition in Irritable Bowel Syndrome: In-Vitro Stimulation of Pro-and Anti-inflammatory Cytokine Release

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Introduction: Inflammation plays a role in the pathogenesis of irritable bowel syndrome (IBS). Foods can trigger and exacerbate IBS flare-ups and symptoms. Diet-induced inflammation is characterized by the release of cytokines as a common feature. The lack of evidence regarding which diet is ideal for IBS underlined the need for personalized and more precise dietary treatment options. The objective of this study was to determine in-vitro the degree of blood inflammatory cytokines release in response to food antigens exposure in subjects with IBS.
Methods: Blood samples were collected at Oxford Biomedical Technologies, Inc. from 12 subjects diagnosed with IBS. Whole blood was diluted with buffered physiologic saline, and then an aliquot was pipetted into eight reaction wells, each containing a single food extract. Following a predetermined incubation period at 37°C, all specimens were stored at -20°C until cytokine analysis were performed. Cytokines [interleukin-8 (IL) and IL-10)] reactivity to food antigens challenge was evaluated using Bio-Plex 200 System (Bio-Rad, CA). The IBS-Severity Scoring System (IBS-SSS) was used to measure the severity and intensity of symptoms. The questionnaire scores range from 0 to 500, with cutoffs rated as mild (75-175), moderate (175-300), and severe (>300). The study received approval from an independent Institutional Review Board (IRB), and all statistical analyses were performed using SPSS version 27.0 (IBM Corp., NY).
Results: Mean age was 52.2±17.5 years, 10 (83%) were female and had a BMI of 26.2±5.7 kg/m^2. According to IBS-SSS scores, 8 (67%) of the subjects had moderate symptoms, whereas 4 (33%) had severe symptoms. We found statistically significant differences in IL-8 and IL-10 concentrations (pg/mL) release pre- vs. post-antigen exposure to broccoli [(2.17±0.75, P=0.016)]; corn [(1.25±0.44, P=0.018) and (-0.21±0.09, P=0.041)]; milk [(1.40±0.48, P=0.017); egg [(1.17±0.48, P=0.034)]; navy bean [(0.83±0.30, P=0.019) and (-0.14±0.01, P=.004)]; orange [(2.19±1.04, P=0.063)]; tomato [(2.77±1.15, P=0.038) and (-0.26±0.13; P=0.073)]; and wheat [(0.90±0.36, P=0.033) and (-0.27±0.08, P=0.011)] respectively.
Conclusion: The findings from this study generate much-needed data to aid the understanding of non-physiological inflammatory responses to foods which can optimize targeted dietary therapy for IBS. Further work is needed to develop a diagnostic assay that could be used to create a precise and personalized diet for clinical practice.

S573

Efficacy of Rifaximin in Patients With Abdominal Bloating or Distension: A Systematic Review and Meta-Analysis

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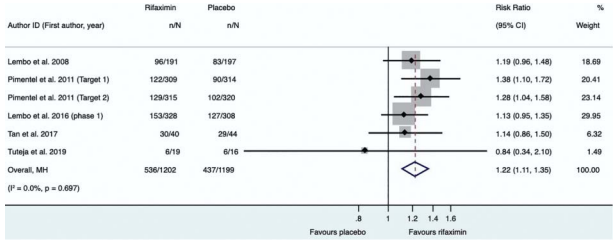
Introduction: Abdominal bloating is a common complaint in patients with functional and organic bowel disease. Rifaximin, a non-absorbable antibiotic, has been tried for the treatment of this disease. We performed a systematic review and meta-analyses to study the efficacy of rifaximin in abdominal bloating and distension in patients with functional gastro-intestinal disorders (FGID).
Methods: We accessed four database (MEDLINE, Embase, SCOPUS, and Web of Science) to identify randomized placebo-controlled trials that utilized rifaximin in FGID. We excluded observational studies, studies including patients with organic bowel disorders such as inflammatory bowel disease, or when rifaximin was given for another indication such as HE. The protocol was registered on PROSPERO.
Results: 1426 articles were available of which 813 articles were screened after removing duplicates, and 34 articles were selected for full-text review. Finally, ten trials (3326 patients) were included. Rifaximin was administered in doses ranging from 400 to 1650 mg per day for one to two weeks. Rifaximin therapy led to higher likelihood of improvement in symptoms of bloating (44.6% vs 34.6%, RR 1.22, 95% CI 1.11, 1.35; n=2401 patients) without significant heterogeneity [Figure]. However, daily doses less than 1200 mg/day were similar to placebo (p=0.09). Bloating was quantified subjectively in 7 studies, and rifaximin led to greater reduction in bloating scores compared to placebo (standardized mean difference-0.3, 95% CI -0.51, -0.1, p=0.04) but carried significant heterogeneity (I2 =61.6%, p= 0.01). There is paucity of data on the role of repeat treatment with rifaximin among patients who developed recurrence of symptoms following a successful therapeutic trial. The trials included in the meta-anlaysis suffered from low risk of bias.
Conclusion: Rifaximin therapy at doses of 1650 mg/day for 2 weeks led to an increased likelihood of improvement in bloating and distension as well as reducing subjective severity of these symptoms in patients with FGID.



[0573] **Figure 1.** Forest plot depicting the proportion of patients demonstrating improvement in abdominal bloating or distension in each study. The pooled risk ratio (1.22, 95% CI 1.11, 1.35) favors intervention (rifaximin).

S574

TikTok and Irritable Bowel Syndrome (IBS): A Cross-Sectional Study of Social Media Content Quality

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Introduction: Social media has increasingly become the main platform individuals and medical professionals use to share their lived experience with medical conditions along with health advice. User-generated content about irritable bowel syndrome (IBS) is among the most popular health topics on the video-sharing social media platform TikTok. We sought to investigate the quality of Tiktok content to characterize the educational content and accuracy of information related to IBS being distributed.
Methods: The first 100 videos meeting inclusion criteria under the hashtag #IBS were thematically analyzed by two independent reviewers for source, number of views, intent and content. The source or entity posting the video was categorized as an influencer, lay individual or medical professional. The intent was classified as educational, factual and content categories included comedy, lifestyle and acceptability, marketing, and medical advice. The overall quality, understandability and actionability of the video was assessed using The Patient Education Materials Assessment Tool for Audiovisual Materials (PEMAT-A/V) and Journal of American Medical Association (JAMA) benchmark criteria, understandability, and actionability of the videos.
Results: Across all videos meeting inclusion criteria, 42% (n = 42) of videos were posted by social media influencers compared to 10% (n = 10) posted by medical professionals. Of the 30% (n = 30) of videos rated as educational, 47% (n = 14) were determined to be factual. A vast majority (97%) of the non-educational videos (n = 68) were posted by non-medical professionals. Content posted by influencers had a higher average number of shares (16,382, SD 25,673) compared to content by medical professionals (10,869, SD 19,488). In contrast, the average number of views was higher among medical professionals (3,661,000, SD 3,807,115) compared to videos posted by influencers (2,926,476, SD 2,874,250). The most common themes discussed in IBS videos included lifestyle/acceptability (43%, n = 43) and health advice (40%, n = 40).
Conclusion: Almost half of the TikTok videos about IBS are posted by influencers and have poor educational content. Content posted by influencers was more likely to be shared while medical professionals garnered more average views. These findings support the partnership of healthcare organizations and professionals with influencers to increase health information sharing and dissemination of factual educational content.

S575

Rate and Reasons for Non-Elective 30-Day Readmissions for Functional Dyspepsia in the U.S.

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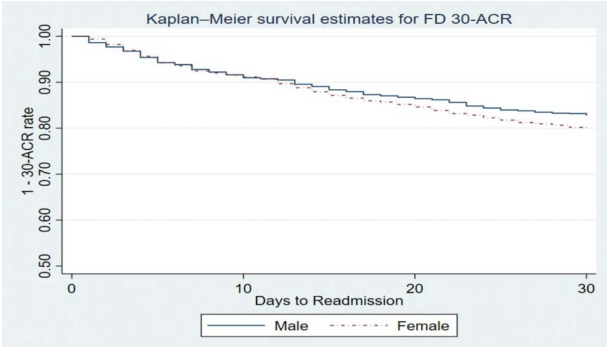
Introduction: Functional dyspepsia (FD), a diagnosis of exclusion, has a 10–20% prevalence(1,2). The pathophysiology is unclear, often multifactorial, and involves treatment with a detailed education about its benign nature. Tricyclic antidepressants and psychotherapy are warranted if functional dyspepsia (FD) is refractory or severe (1). Functional dyspepsia (FD) can present with postprandial distress (70% of FD cases) or epigastric pain syndrome (30% of FD cases) (3). FD can decrease quality of life and place a significant cost burden on healthcare services. Our study sought to determine the rate and reasons for 30-day all-cause readmissions for FD to help identify potentially modifiable factors and decrease the burden of readmissions.
Methods: From the NRD, we identified all adults discharged with a principal diagnosis of FD after hospitalization from 2016 to 2019. Then, we identified any readmission of the same patient within 30-days for FD, excluding elective and traumatic encounters. Outcomes assessed included 30-day all-cause readmissions, top principal diagnosis for the readmitted patients, comparison of mortality, length of stay (LOS), and total hospital charges (THC) following readmission.
Results: 4 917 patients with FD during index admissions were identified. The 30-day all-cause readmission rate was 19.3%. The Kaplan-Meier curve for 30-day all-cause readmissions was split by sex (Figure). There was no significant difference in age and sex distribution between patients with initial hospitalizations and those with readmissions. The most common reasons for readmissions in patients with FD were gastroparesis (5.9%), FD (5.8%), sepsis unspecified (5.2%), unspecified nausea and vomiting (3.1%), unspecified abdominal pain (2.1%), and acute renal failure (2.0%). Readmission was associated with higher odds of mortality (2.8% vs. < 0.01%, p< 0.001), longer LOS (6.0 vs. 5.0 days, p< 0.001), and higher THC. Over the period, readmissions for FD accounted for a cumulative 5.694 days of hospitalization, costing over $14 million.
Conclusion: 1 in 4 patients was readmitted with FD within 30 days. Gastroparesis contributed more to readmissions than a primary diagnosis of FD. Higher rates of poorer outcomes were found with 30-days readmissions. Cohort studies are needed to validate these results.



[0575] **Figure 1.** Survival estimates for 30-day all-cause readmissions in male and Female patients with functional dyspepsia

S576

High Resolution Anorectal Manometry Findings in Men and Women With Parkinson's Disease, Using London Classification

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Introduction: Gastrointestinal dysfunction, particularly constipation, is among the most common non-motor manifestation in Parkinson's Disease (PD). We aimed to identify high-resolution anorectal manometry (HR-ARM) abnormalities in patients with PD using the London Classification.
Methods: We conducted a retrospective case series of all PD patients at our institution who underwent HR-ARM for evaluation of constipation between 2015-2021. Using age- and sex-specific normal values, HR-ARM recordings were re-analyzed and abnormalities were reported using the London Classification. A combination of Wilcoxon rank sum test and Fisher's exact test were used to compare men and women.
Results: Of 71 PD patients who underwent ARM, 36 with 2D HR-ARM were included. Median age at time of evaluation was 71 (69-74). Median BMI in men was 25.4; in women was 23.7, but 50% of women were overweight. Common comorbidities included depression/anxiety (61%), IBS (36%), and GERD (56%). Using the London classification, 7 (19%) of all patients had anal hypotension, 17 (47%) had anal hypocontractility, and only 3 women had combined disorders. Anal hypocontractility was significantly more common in females compared to males (Table). Recto-anal coordination with abnormal expulsion and dyssynergia were noted in 22 (61%) of patients (12 of whom (70%) were males vs 12 (52%) females, p=0.32) and were significantly higher than abnormal expulsion with poor propulsion in 2 (5%) or combined 2 (5%). Major rectal sensation abnormalities with rectal hyposensitivity and hypersensitivity were reported in 12 (33%) and 3 (8%) respectively and were similar in both males and females (Table). Max squeeze pressures were significantly higher in males. Residual anal pressures and paradoxical anal contraction during simulated defecation were also significantly higher in males, resulting in significantly more negative recto-anal pressure gradients. Balloon expulsion was similar in both groups.
Conclusion: Our data affirms the high prevalence of functional anorectal disorders in PD. Using the London classification, disorders of rectoanal coordination with abnormal expulsion and dyssynergia, followed by abnormal anal hypocontractility were the most common minor and major abnormal findings in both men and women. Whether the higher prevalence of anal hypocontractility in females is directly related to PD or other confounding factors will require further research.

Table 1. **London Classification of Manometric Parameters for Major and Minor Findings of Anorectal Disorders**

Variable	All (n=36)	Female (n=19)	Male (n=17)	p-value
Disorders of anal tone and contractility (Major findings)				
Combined Hypotension and Hypocontractility	3 (8)	3 (16)	0 (0)	0.23
Anal Hypotension	7 (19)	4 (21)	3 (17)	1
Anal Hypocontractility	17 (47)	13 (68)	4 (23)	**0.01**
Disorders of rectoanal coordination (Minor findings)				
Abnormal Expulsion with poor propulsion	2 (5)	1 (5)	1(6)	1
Abnormal Expulsion with Dyssynergia	22 (61)	10 (52)	12 (70)	0.32
Abnormal Expulsion with Poor Propulsion with Dyssynergia	2 (5)	1 (5)	1(6)	1

Table 1. (*continued*)

Variable	All (n=36)	Female (n=19)	Male (n=17)	p-value
Disorders of rectal sensation (Minor findings)				
Rectal Hyposensitivity	12 (33)	7 (37)	5 (29)	0.73
Rectal Hypersensitivity	3 (8)	2 (10)	1 (6)	1

S577

Comparison of Gastrointestinal Symptoms and Gastric Emptying Scintigraphy Between Postural Orthostatic Tachycardia Patients With and Without Small Fiber Neuropathy

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Introduction: Autonomic dysfunction is common in patients with postural orthostatic tachycardia syndrome (POTS) and affects multiple systems, including the gastrointestinal (GI) tract. Various subtypes of POTS exist: autoimmune, hyperadrenergic, and neuropathic. While these subtypes share features of common autonomic symptoms; it remains unclear how symptom presentation amongst other affected systems, such as the GI tract, differ across subtypes. We aimed to compare gastrointestinal symptom presentation and gastric emptying scintigraphy (GES) between POTS patients with and without small fiber neuropathy (SFN).
Methods: We conducted a retrospective case series of all POTS patients at our institution who underwent autonomic testing between 2013-2021. Patients were divided into those with SFN (abnormal QSART test) and those without SFN (normal QSART). Demographics, comorbidities, and reported GI symptoms were extracted. GES results were also extracted with percentage emptying at 60-minute intervals (4-hour study). Chi2 and glmnet testing were used to compare the groups.
Results: 97 POTS patients (14 men), who underwent autonomic testing for SFN were included. Median age was 36 (21-67). Common comorbidities included hypermobile Ehlers Danlos Syndrome (44%), and chronic fatigue syndrome (22%). POTS patients with SFN were more likely to have nausea (75% vs 55%, p=0.03), poor oral intake (32% vs 9%, p=0.01), parenteral nutrition dependence (9% vs 0%, p=0.01), and early satiety (36% vs 18%, p=0.05) (Table). Most demographics and GI symptoms did not show significance as predictors for SFN. Of the 97 patients, a total of 33 underwent GES for evaluation of reported GI symptoms. The percentage of patients with delayed GES was numerically higher but not statistically significant in POTS patients with SFN (45% vs 23%, p=0.21). There were no significant differences in mean gastric emptying between groups (Table).
Conclusion: Our data affirms the high prevalence of GI symptoms in patients with POTS independent of SFN. Patient with SFN were more likely to have upper GI symptoms of nausea, poor oral intake and early satiety despite similarities in GES. This suggests that symptoms may be due to sensory rather than motor dysfunction. While some GI symptoms were more common in those with SFN, there was a lack of predictability of symptoms and demographics for SFN. This suggests the need to have a high clinical suspicion for diagnosing SFN in patients with POTS whose GI symptoms do not respond to conventional therapy.

Table 1. **Baseline Demographics and Gastrointestinal Symptom Presentation across POTS patients with and without SFN and Gastric Emptying Results**

Variable	All (n=97)	POTS with SFN (n=53)	POTS w/o SFN (n=44)	p-value
Basic Demographics				
Age: Median (IQR)	36 (30-46)	37 (32-48)	35 (27-40)	0.12
Sex, n (%)				0.59
Female	83 (86)	45 (85)	39 (89)	
Male	14 (14)	8 (15)	5 (11)	
Race, n (%)				0.17
White	83 (86)	43 (81)	40 (91)	
Other	14 (14)	10 (19)	4 (9)	
Co-morbidities				
Hypermobile EDS	43 (44)	23 (43)	20 (45)	0.84
CSF Leak	19 (20)	13 (25)	6 (14)	0.18
Chronic Fatigue Syndrome	21 (22)	14 (26)	7 (16)	0.21
Fibromyalgia	15 (15)	9 (17)	6 (14)	0.27
Diabetes	2 (2)	1 (2)	1 (2)	0.89
Hypothyroidism	14 (14)	5 (9)	9 (20)	0.12
Chronic Narcotic Use	7 (7)	1 (2)	6 (14)	**0.03**
Gastrointestinal Symptoms				
Abdominal pain, n (%)	63 (65)	37 (70)	26 (59)	0.27
Bloating, n (%)	44 (45)	26 (49)	18 (41)	0.42
Nausea, n (%)	64 (66)	40 (75)	24 (55)	**0.03**
Vomiting, n (%)	28 (29)	19 (36)	9 (20)	0.10
Dyspepsia, n (%)	9 (9)	7 (13)	2 (5)	0.09
Constipation, n (%)	57 (59)	35 (66)	22 (50)	0.11
Diarrhea, n (%)	34 (35)	23 (43)	11 (25)	0.06
Early Satiety, n (%)	27 (28)	19 (36)	8 (18)	**0.05**
Dysphagia, n (%)	11 (11)	6 (11)	5 (11)	0.99
Weight Loss, n (%)	26 (27)	16 (30)	10 (23)	0.41
Poor oral intake, n (%)	21 (22)	17 (32)	4 (9)	**0.01**
Enteral nutrition dependence, n (%)	4 (4)	3 (6)	1 (2)	0.40
Parenteral nutrition dependence, n (%)	5 (5)	5 (9)	0 (0)	**0.04**
Gastric Emptying				
Delayed Gastric Emptying, n (%)	12 (36)	9 (45)	3 (23)	0.21

Table 1. (*continued*)

Variable	All (n=97)	POTS with SFN (n=53)	POTS w/o SFN (n=44)	p-value
Percentage Emptying at Various Durations				
60 minutes: Mean (SD)	32.1 (22.3)	28.9 (24.6)	37.0 (18.2)	0.35
120 minutes: Mean (SD)	57.3 (27.3)	53.3 (29.4)	62.5 (24.6)	0.37
180 minutes: Mean (SD)	74.3 (24.9)	68.7 (26.8)	83.3 (19.2)	0.15
240 minutes: Mean (SD)	85.8 (17.4)	84.1 (18.4)	88.2 (16.6)	0.55

S578

IBS Patients Report a Lack of Symptom Control, HCP-Prescribed Options

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Introduction: Irritable bowel syndrome (IBS) is often under-recognized by patients and healthcare providers (HCPs). Many patients do not consult an HCP and are not formally diagnosed. Even with a formal diagnosis and treatment, IBS is hard to control. We aim to understand how IBS patients who report a lack of symptom control perceive their quality of care and HCP relationships.
Methods: We surveyed 1,930 IBS patients online from June to August 2020. The survey measured treatment experiences, quality of life, and HCP engagement. Responses were evaluated using descriptive statistics and comparison tests.
Results: Of all patients surveyed, only 4% consider their IBS mild, while 55% describe their IBS as moderate and 40% as severe. Despite the availability of various drugs to treat IBS, only 12% of patients felt their current treatment plan keeps their IBS under control. Most patients report seeing a PCP (n=403) or gastroenterologist (n=1,047). Compared to patients with uncontrolled IBS, those with controlled IBS are more likely to report they are satisfied with the care received from their HCP (68% vs 48%, $p< 0.0005$) and that their HCP clearly explains treatment options (70% vs. 49%, $p< 0.0005$). Overall, 51% of patients who see an HCP for their IBS are satisfied with their care. Of those who see an HCP, patients who report themselves as satisfied with their care are more likely to report they feel comfortable discussing all aspects of IBS with an HCP (92% vs 59% of those not satisfied, $p< 0.0005$) and that their HCP agrees with them on the severity of their IBS (80% vs 26%, $p< 0.0005$), clearly explains treatment options (84% vs 18%, $p< 0.0005$), and regularly discusses quality of life (74% vs 17%, $p< 0.0005$). Of the 739 patients who characterized their IBS as severe, 51% see an HCP and are not satisfied with their care. This differs from those who see an HCP and are satisfied with their care (38%) and those who do not see an HCP (37%, $p< 0.0005$).
Conclusion: Despite IBS treatment availability, few report their IBS is controlled by their treatment plan. Patients who experience greater IBS control report more positive HCP relationships. Those who characterize their IBS as severe report less satisfaction with their care. Cultivating positive HCP relationships is instrumental in improving the quality of life for IBS patients. Future research should examine factors that facilitate patient-provider relationships and close the gap in treatment dissatisfaction.

S579

Effects of an Herbal Supplement on Intestinal Methanogenic Overgrowth

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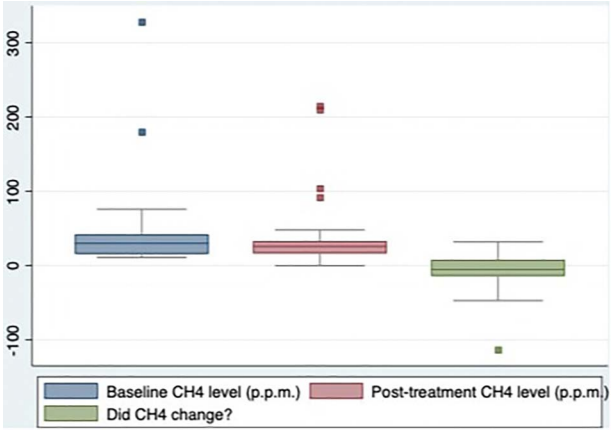
Introduction: Intestinal methanogenic overgrowth (IMO) refers to overproduction of methane (CH_4) in the GI tract. To date, there is no consensus on treatment for IMO and it is unclear if reducing CH_4 improves symptoms. The aims of this pilot study were to: (1) describe symptoms in individuals with IMO; (2) investigate the effects of a quebracho/horse chestnut/peppermint oil neutraceutical (Atrantil®) on CH_4 levels and symptoms.
Methods: Successive patients with positive breath tests ($CH_4 \geq 10^3$ ppm) were recruited from a single academic center. Subjects were provided the manufacturer-recommended dose for 4 weeks and completed weekly PROMIS GI symptom questionnaires and daily Likert scales for pain, discomfort, bloating, and distention. Post-treatment breath tests and assessments of adequate relief were performed at trial completion. PROMIS GI t-scores were analyzed using fixed effect regression models (RStudio: Boston, MA). A change in t-score ≥5 was considered a positive minimal clinically important difference.
Results: 46 subjects were recruited, and 39 subjects (76.9% female, mean age 44.8 years) completed the study. The most common baseline symptoms were bloating (85%), constipation (46.3%), and pain/discomfort (39%). 12.2% of subjects had IBS; 17.7% had been diagnosed with dyssynergia. Treatment was associated with significant improvements in weekly measures of belly pain (-5.75, 95% CI -8.46 to -3.05) and gas/bloating (-5.27, 95% CI -7.41 to -3.12) (Table). There were no significant changes in daily symptoms. Median baseline CH_4 levels decreased from 30 at baseline to 26 post-treatment. The median change in CH_4 was -5 (Figure). Despite 86.11% of breath tests remaining positive for IMO after treatment, 56% of subjects reported adequate relief. No correlations between overall symptom improvement and reductions in CH_4 ($p=0.387$) or normalization of CH_4 levels were identified ($p=0.181$). There were no treatment-related adverse events.
Conclusion: Atrantil® was associated with clinically and statistically significant improvement in key abdominal symptoms (pain and bloating) at 4 weeks. Symptom improvement and adequate relief did not appear to be related to changes in CH_4 levels. Results from this pilot study will be used to guide a forthcoming placebo-controlled, randomized trial.



[0579] **Figure 1.** Median methane levels at baseline, after treatment, and median change in methane level. The median baseline methane level was 30 p.p.m., 26 p.p.m. after treatment, and the median change was 5 p.p.m.

Table 1.

Scale	t-score	Change at 4 weeks
Belly pain	59.07 (56.40-61.74)	-5.75 (-8.46 to -3.05)
Gas/bloating	62.81 (61.02-64.60)	-5.27 (-7.41 to -3.12)
Constipation	53.34 (51.04-55.65)	-3.66 (-5.47 to -1.85)
Reflux	46.67 (44.37-48.96)	-1.62 (-3.59-0.35)
Nausea/vomiting	49.48 (47.01-51.96)	-2.60 (-4.23 to -0.97)

S580

Effect of Probiotics on Serum Cytokines in Irritable Bowel Syndrome With Gulf War Illness

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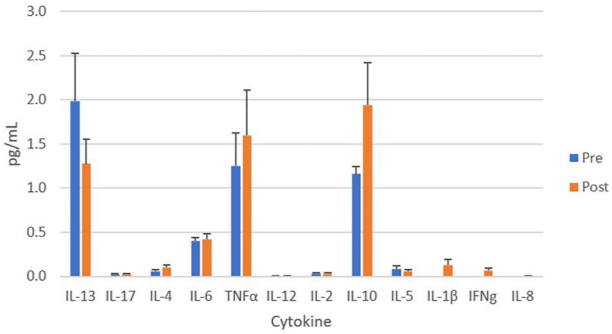
Introduction: Gulf war illness (GWI) is a multisystem disorder of unknown etiology. There is high prevalence of IBS among Veterans with GWI. There is inconsistent evidence that low grade chronic gastrointestinal (GI) inflammation may play a part in the pathogenesis of IBS and GWI. We examined the blood cytokines profile of Veterans with IBS and GW illness before and after treatment with probiotics.
Methods: In a randomized double-blind placebo controlled trial we enrolled Veterans with IBS (Rome III criteria) and two or more symptoms of GWI. Veterans were randomized to receive probiotic (De Simone Formulation; formally known as VSL#3) or identical placebo. Blood was collected at enrollment and after 8-week treatment with probiotics. A multiplexed immunoassay was used to assess the serum concentration of 13 cytokines/inflammatory markers: interferon (IFN)-γ; interleukins (ILs)-1β, 2, 4, 5, 6, 8, 10, 12, 13, and 17; tumor necrosis factor (TNF-α, IL-2 receptor. The cytokine levels were compared to reference intervals established on 120 healthy controls.
Results: Data was analyzed from 42 Veterans who provided baseline and 11 Veterans who provided both pre and post treatment blood samples for cytokine analysis. The serum pro- and anti-inflammatory cytokines levels were no different between IBS with GWI and healthy controls. There was no change in pro- or anti-inflammatory cytokines after treatment with probiotics (Figure).
Conclusion: The level of pro- and anti-inflammatory cytokines were no different in Veterans with IBS and GWI compared with healthy controls and the levels do not alter after treatment with probiotics. The role of cytokines in pathophysiology, and as a biomarker of treatment of IBS and GWI is likely complex and remains unknown.



[0580] **Figure 1.** Comparison of Pre and Post treatment with probiotics cytokines (mean±SE)

S581

Is Rectal Sensitivity a Marker of Irritable Bowel Syndrome in Chronic Constipation?

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Introduction: Sensory testing is a standard component of anorectal manometry (ARM), but controversy exists about its clinical value. Patients with irritable bowel syndrome (IBS) are traditionally thought to be hypersensitive to rectal balloon inflation. We sought to determine whether rectal hypersensitivity was a marker of IBS in a large cohort using multiple different technologies.
Methods: We analyzed data from consecutive patients undergoing ARM for chronic constipation between July 2017 and April 2022. We collected demographics; disease characteristics including Rome IV IBS diagnosis and symptom severity (via Patient Assessment of Constipation Symptoms (PAC-SYM)); and psychological features including anxiety/depression (Hospital Anxiety and Depression Scale (HADS)) and GI-specific anxiety (Visceral Sensitivity Index (VSI)). We correlated this data with ARM sensitivity measurements, which were collected with both high-resolution (HR) and 3D ARM catheters. Volume measurements >75th percentile of first sensation, urge sensation and maximum tolerable volume were defined as hypersensitivity in order to homogenize differences in HR and 3D ARM measurements. We used logistic regression to examine associations with rectal hypersensitivity.
Results: We recruited a total of 456 patients (mean age 49.5+/-17.5 years, 90.0% female), who predominantly met Rome IV criteria for functional constipation (FC)((n=405, 88.8%) vs n=51 (11.2%) with IBS-C)). Patients with IBS-C tended to have more severe constipation symptom severity (driven by abdominal symptoms subscale) and increased GI-specific anxiety relative to patients with FC (Table). There were no differences in proportion of hypersensitive patients for any threshold between the groups (Table). Age-adjusted logistic regression demonstrated that IBS-C was not associated with rectal hypersensitivity at first sensation volume, (OR=0.61, 95% CI 0.30-1.15, p=0.14), urge sensation volume (OR=0.75, 95% CI 0.38-1.43, p=0.40), or discomfort volume (OR=0.78, 95% CI 0.38-1.50, p=0.47).
Conclusion: In this large cohort of patients undergoing ARM for chronic constipation using two different types of ARM catheter technology, we found no evidence to support increased rectal sensitivity to volumtetric inflation in IBS patients relative to those with functional constipation. These findings indicate that rectal sensation may not be reflective of the visceral hypersensitivity thought to drive underlying disease pathophysiology in IBS.

Table 1. Demographic Characteristics, Disease Severity, Psychological Traits and Anorectal Manometry Measures among those with Functional Constipation vs. Irritable Bowel Syndrome with Constipation (IBS-C)

	Functional (N=405)	IBS-C (N=51)	p-values
Age Mean (SD)	49.3 (17.7)	51.2 (16.0)	0.44
Sex Male Female	64 (15.8%) 341 (84.2%)	12(23.5%) 38 (74.5%)	0.21
ARM Type 3D HR	212 (52.3%) 193 (47.4%)	29 (56.9%) 22 (43.1%)	0.65
PACSYM score Total Abdominal Rectal Stool	2.75 (0.778) 2.76 (1.05) 2.40 (0.865) 2.94 (0.935)	3.04 (0.600) 3.42 (0.754) 2.61 (0.770) 3.03 (0.884)	0.02 < 0.0001 0.10 0.55
HADS score Anxiety Depression	7.98 (4.81) 4.67 (4.18)	8.74 (4.37) 5.29 (3.85)	0.26 0.20
VSI	35.0 (20.7)	48.7 (16.7)	< 0.0001
First Sensation Levels Below 75th percentile Above 75th percentile	255 (63.0%) 143 (35.3%)	38 (74.5%) 13 (25.5%)	0.19
Urge Sensation Levels Below 75th percentile Above 75th percentile	274 (67.7%) 124 (30.6%)	38 (74.5%) 13 (25.5%)	0.51
Discomfort Sensation Levels Below 75th percentile Above 75th percentile	287 (70.9%) 113 (27.9%)	39 (76.5%) 12 (23.5%)	0.59

S582

Gastroparesis Is Associated With More Concurrent Gastrointestinal Symptoms and Motility Disorders Than Functional Dyspepsia

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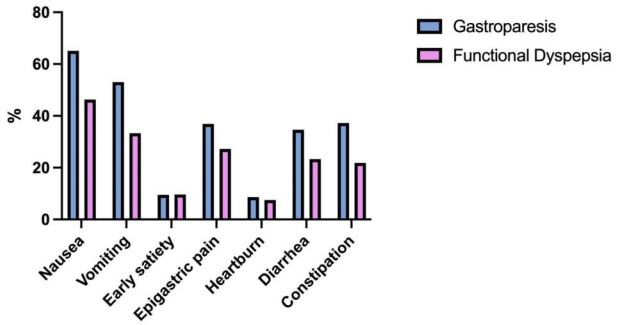
Introduction: Gastroparesis (GP) and functional dyspepsia (FD) present with overlapping upper gastrointestinal (GI) symptoms, such as: nausea, vomiting, early satiety, postprandial fullness, epigastric pain, and bloating. Other gastrointestinal motility disorders may be concurrent in patients with GP. The goal of study was to compare the presence of GI symptoms and other motility disorders in patients with GP and FD.
Methods: A retrospective cohort study was performed on IBM Explorys (1999-2022), which contains de-identified healthcare information from more than 64 million patients across the United States. Adult patients who have completed gastric emptying study were selected, and subsequently divided into GP and FD cohorts. GP cohort consists of patients with a diagnosis of gastroparesis, with exclusion criteria: cyclical vomiting syndrome, psychoactive substance abuse, eating disorder, factitious disorder, malignant tumor of esophagus and stomach, neoplasm of abdomen, gastric or intestinal obstruction, IBD, adhesion of intestine, carcinomatosis, perforation of intestine, Roux-en-Y gastrojejunostomy, and gastrectomy. FD cohort was similarly constructed with additional exclusion criteria: gastroparesis, gastrointestinal ulcer, brain neoplasm and pancreatitis. The presence of GERD, IBS, GI symptoms and common GI medications were collected. Odds ratios (ORs) with 95% confidence interval were used to compare the cohorts.
Results: GP and FD cohort consisted of 17,570 and 60,230 patients respectively (Table). There was a higher prevalence of concurrent motility disorders in patients with GP than FD, including GERD and IBS (65.1 vs 50.9%, 18.6 vs 13.3%). Patients with GP tend to present with more upper and lower GI symptoms than FD, including nausea (65.1 vs 46.3%), vomiting (53.0 vs 33.3%), epigastric pain (36.9 vs 27.2%), heartburn (8.6 vs 7.5%), diarrhea (34.6 vs 23.3%) and constipation (37.2 vs 21.8%) (P< 0.0001) (Figure). However, there was no difference in terms of early satiety and bloating when comparing the two groups. Acid reducing medications, anti-nausea medications and prokinetic agents were more commonly prescribed for patients with GP than FD, including proton pump inhibitors (PPIs), H2 receptor antagonists (H2RA), Metoclopramides and Ondansetron (p< 0.0001).
Conclusion: GP is associated with more concurrent GI symptoms and motility disorders compared with FD. Acid reducing medications, anti-nausea and prokinetic medications are more commonly prescribed for patients with GP.



[0582] **Figure 1.** Comparison of GI symptoms between gastroparesis and functional dyspepsia

Table 1. Comparison of GI motility disorders, symptoms and medications between gastroparesis and functional dyspepsia

			GP (N=17570)	%	FD (N=60230)	%	OR	*P*
	GI diseases	GERD	11430	65.1%	30650	50.9%	1.74-1.86	< 0.0001
		IBS	3260	18.6%	8030	13.3%	1.42-1.55	< 0.0001
Symptoms	Upper GI symptoms	Nausea	11430	65.1%	27910	46.3%	2.08-2.23	< 0.0001
		Vomiting	9310	53.0%	20060	33.3%	2.18-2.34	< 0.0001
		Early satiety	1660	9.5%	5780	9.6%	0.93-1.04	0.5556
		Epigastric pain	6490	36.9%	16380	27.2%	1.51-1.62	< 0.0001
		Heartburn	1510	8.6%	4500	7.5%	1.10-1.24	< 0.0001
	Lower GI symptoms	Diarrhea	6070	34.6%	14050	23.3%	1.67-1.80	< 0.0001
		Constipation	6540	37.2%	13110	21.8%	2.06-2.21	< 0.0001
		Bloating	60	0.3%	170	0.3%	0.90-1.63	0.2039
	Medications	PPI	13680	77.9%	35430	58.8%	2.37-2.56	< 0.0001
		H2RA	7710	43.9%	18310	30.4%	1.73-1.85	< 0.0001
		Metoclopramide	8630	49.1%	12490	20.7%	3.56-3.82	< 0.0001
		Ondansetron	12570	71.5%	31330	52.0%	2.24-2.41	< 0.0001

S583

Comparison of Demographics, Colonic Transit, and Quality of Life in Patients With Bile Acid Diarrhea With and Without a History of Cholecystectomy

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Introduction: Bile acid diarrhea (BAD) accounts for roughly 30% of patients diagnosed with functional diarrhea or diarrhea-predominant irritable bowel syndrome (IBS-D). Patients with BAD have unique biochemical, microbial, and mucosal findings as well as more rapid colonic transit when compared to IBS-D (PMID: 35580964). One cause of BAD in the absence of ileal resection or disease is cholecystectomy. Our **aim** was to compare demographics, colonic transit, and quality of life (QOL) in patients with BAD with and without a history of cholecystectomy.
Methods: We conducted a retrospective analysis of prospectively obtained data from a prior study (IRB #16-001445). Patients with intestinal resection or underlying gastrointestinal diseases were excluded. As part of the study, patients with biochemically confirmed BAD underwent measurement of colonic transit testing by validated scintigraphic method that utilizes ^{111}In-activated charcoal in a methacrylate-coated delayed release capsule. Patients also completed the IBS-QOL and Hospital Anxiety and Depression Scale (HADS) questionnaires. Baseline demographics and those measurements of patients with post-cholecystectomy BAD and idiopathic BAD were compared using median and interquartile range (IQR). Statistical testing between both groups utilized Chi-square, Fisher's exact, or the Wilcoxon Rank Sum test as appropriate.
Results: Among 44 patients with BAD, 36 (83.7%) were female with a median age of 46 years (IQR 35.5, 57.5) and body mass index (BMI) of 33.7 (IQR 29.9, 38.3). Fifteen (34.9%) patients had undergone cholecystectomy; these patients were older (p=0.024) with numerically higher BMI (p=0.09) compared to those without cholecystectomy. Similarly, those patients with BAD with and without cholecystectomy had similar colonic transit at 24 hours (p=0.696), and ascending colon emptying $T_{1/2}$ (p=0.261). Cholecystectomy did not appear to be associated with different levels of anxiety and depression based on the HADS (p=0.594) or reduced QOL based on the IBS-QOL (p=0.994). Patients with BAD and history of cholecystectomy were more likely to respond with worry about losing control of bowel function (Question 31 of IBS-QOL) (p=0.0296), but this did not meet statistical significance after adjustment for multiple comparisons.
Conclusion: Clinical features, QOL, and colonic transit times appear to be similar in BAD secondary to cholecystectomy or idiopathic BAD.

Table 1. Comparison of patients with bile acid diarrhea (BAD) with and without history of cholecystectomy

Characteristics [median (IQR) or N (%)]	BAD (N = 44)		p-value
	Prior cholecystectomy (N = 16)	No cholecystectomy (N = 28)	
Number, % female	16 (100%)	28 (75%)	0.029
Age, years	56.5 (41.5, 65.0)	39.5 (33.5, 53.5)	0.024
Body mass index, kg/m^2	34.5 (32.4, 39.4)	31.8 (28.4, 36.4)	0.09
Serum FGF-19, pg/mL	59.8 (25.1, 91.7)	59.1 (31.1, 110.6)	0.868
Serum 7αC4, ng/mL	74.3 (61.7, 104.0)	73.2 (60.0, 87.4)	0.508
Total fecal bile acids, μmol/g stool	4.9 (2.9, 6.7)	3.7 (2.4, 4.5)	0.097
Fecal primary bile acids (CDCA + CA), %	6.5 (1.0, 31.8)	20.0 (1.8, 53.8)	0.281
Colonic geometric center at 8 hours	1.4 (1.0, 2.9)	1.2 (0.6, 1.6)	0.238
Colonic geometric center at 24 hours	3.6 (2.2, 4.4)	3.4 (2.6, 3.8)	0.696
Ascending colon emptying $T_{1/2}$, hours	11.0 (4.4, 16.8)	13.9 (7.6, 18.1)	0.261
HADS score, % > 7	1 (6.3%)	3 (10.7%)	0.537
IBS-QOL, composite score*	32.0 (16.5, 44.9)	29.8 (17.6, 44.1)	0.930

*Calculation: [(participant score – minimum score) / (maximum score – minimum score)] x 100, where higher scores equate to worse quality of life.
BAD, bile acid diarrhea; CA, cholic acid; CDCA, chenodeoxycholic acid; FGF, fibroblast growth factor; HADS, Hospital Anxiety and Depression Scale; IBS-QOL, Irritable Bowel Syndrome – Quality of Life; IQR, interquartile range.

S584

The Clinical Impact of Brain-Gut Psychotherapy on Psychological Symptoms for Patients With Complex Gastrointestinal Disorders: Outcomes in a Real World Practice Setting

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Introduction: Evidence-based brain-gut psychotherapies, such as cognitive behavioral therapy (CBT), are increasingly recognized as important aspects of gastroenterology (GI) care. However, there are few studies conducted in real-world GI community practices. ***Aim***: To describe clinical characteristics and outcomes of patients who underwent brain-gut psychotherapy in an ambulatory GI clinic.
Methods: We retrospectively examined demographic and patient-related characteristics for a subset of patients who completed treatment in a psychology clinic embedded into an outpatient GI clinic in a large, metropolitan community practice. Depressive (Patient Health Questionnaire-9), anxiety (Generalized Anxiety Disorder-7) and somatization (Patient Health Questionnaire-15) symptoms were assessed.
Results: Patients (n=14) were primarily female (88%), with a diverse age-range (19-89 years). Patients were referred for complex gastrointestinal conditions; most had functional and/or motility and disorders and syndromes (i.e., IBS, functional dyspepsia, globus sensation, dyssenergic defection), and two patients had inflammatory bowel diseases. A GI-focused CBT approach was utilized for all patients. For most patients, therapy was short-term (e.g., 4-7 sessions), but therapy timeframes varied. At baseline, nine patients presented with depressive symptoms that ranged from mild (n=5) to moderate (n=3) to severe (n=1). At follow-up, depressive symptoms improved or remained the same; slightly half presented with mild symptoms (n=6), and one patient continued to have severe symptoms. At baseline, 11 patients

presented with anxiety symptoms that ranged from mild ($n=6$) to moderate ($n=3$) to severe ($n=2$). At follow-up, anxiety symptoms improved or remained the same; only two patients presented with mild symptoms, and one patient continued to have severe symptoms. Two patients worsened, from minimal depressive symptoms at baseline to mild at follow-up. Somatization was the most elevated at baseline, with symptoms that ranged from mild ($n=2$), to moderate ($n=5$) to severe ($n=7$). At follow-up, all patients' somatization symptoms improved or remained the same: three patients had mild symptoms, five were in the moderate range, and two remained severe.
Conclusion: Brain-gut psychotherapy, particularly CBT, improved anxiety, depressive, and somatization symptoms in real-world practice. More effectiveness studies are warranted to confirm these findings.

S585

A Social Media Analysis of Constipation-Related Videos on TikTok

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Introduction: The transmission of healthcare information on social media platforms has become increasingly prevalent. The guidance provided in videos can greatly influence patients' understanding and decisions. Thus, scrutinizing the content consumed by patients on popular platforms, such as TikTok, is imperative. TikTok is one of the fastest growing social media platforms in the world, with over 1 billion active monthly users. The goal of this study is to analyze constipation related videos on TikTok and characterize the sources posting them.
Methods: The TikTok hashtag related to constipation with the greatest number of views was identified. The top 100 videos based on *a priori* exclusion criteria (no connection to the medical condition of constipation, non-English speaking, or repeated video) were collected. The videos were dichotomously categorized into educational or non-educational. Furthermore, the specific content topics, such as diet, medication, and hydration, present in the video were specifically noted. The source for each video was categorized based on involvement in healthcare, gender, and race. A healthcare provider was defined as an individual with a professional medical degree, including MD, PA, RN, PharmD etc.
Results: #constipation was the most popular relevant TikTok hashtag with 729.2 million total views. The top 100 included videos had a combined total of 349,303,900 plays, 31,895,000 likes, 1554,409 shares, and 339,261 comments. Out of the 100, 60% of videos were educational, while 40% were non-educational. The most common topics presented in the videos were diet (26%) medical treatment (18%), and increased movement (14%); proper hydration was only highlighted in 4% of videos. Other topics presented are quantified in Table. The video sources for 23% of videos were healthcare based, while the remaining 77% were laypersons. The specialty breakdown of healthcare professionals was 9 physical therapy, 6 surgery, 3 alternative medicine, 2 other, 1 gastroenterology, 1 obstetrics/gynecology, and 1 general medical center. The racial designations of the subjects in videos consisted of 53% White, 35% Asian, 3% Black, and 12% unknown/non-applicable (no human subject); the gender designations present in the video were 75% female, 18% male, 2% male and female, and 5% unknown/non-applicable (no human subject).
Conclusion: The majority of constipation based TikTok videos was not posted by qualified healthcare professionals, with only one gastroenterologist presented video in the top 100.

Table 1. Specific Components of TikTok Videos Analyzed (n=100)

Components*	%
Diet	26
Medical Treatment/Supplement	18
Increase Movement	14
Reflexology/Acupuncture	12
How to Sit on Toilet	9
Newborn/Infant	9
Hydration	4

*Content categories are not mutually exclusive.

S586

Prevalence and Significance of Restrictive Eating Habits Among Patients Presenting to a Tertiary Care Gastroenterology Clinic

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Introduction: Complaints of gastrointestinal (GI) symptoms, such as postprandial fullness, abdominal distention, abdominal pain, gastric distention, early satiety, constipation, vomiting, flatulence, decreased appetite, borborygmi, and nausea, are frequent among patient with eating disorders, including anorexia nervosa and bulimia nervosa. In addition, there is a significant correlation between GI symptoms and hypochondriasis. Despite potential overlap of eating disorders and gastrointestinal disorders, it is unknown how many of these patients have restrictive eating habits and hence may benefit from further therapy including counseling by a specialist in eating disorders. The purpose of this study is to investigate the prevalence of restrictive eating habits in the patients seen an Ohio State University Gastroenterology clinic by conducting a retrospective review of the electronic medical records of patients in clinic.
Methods: This is an observational and retrospective IRB approved chart review study. Patients seen in Ohio State University Gastroenterology clinic between August 1, 2021 and March 31, 2022 were screened for eligibility. Those who have completed the SCOFF questionnaire, are 18 years an older, speak English, and attended an appointment during the study time frame were included. Chart review included demographic information, past medical history, current medication use, eating habits, digestive symptoms, stress, and quality of life. Data was entered in RedCap and analyzed using t-tests.
Results: A preliminary analysis of 20 patients found 20% screened positive for eating disorder using the SCOFF questionnaire, despite none having a prior established eating disorder diagnosis. Those with positive SCOFF screening had a diagnosis of anxiety more commonly than those with a negative SCOFF ($p=0.02$). All patients with a positive SCOFF had gastroesophageal reflux, type 2 diabetes mellitus, and prescription for a non-SSRI antidepressant. No significant difference in quality of life, perceived stress, dysphagia, or swallowing was identified in this group.
Conclusion: The prevalence of positive eating disorder screen in patients with gastrointestinal disease is more than double the prevalence of eating disorders in the United States. Screening for eating disorders in gastrointestinal patients may be an important, previously unrecognized aspect of care for these patients.

FUNCTIONAL BOWEL DISEASE

S2459

Bad News Gummy Bears: A Case of Gastrointestinal-Isolated Alpha-Gal Allergy

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Introduction: Galactose-α-1,3-galactose (alpha-gal) allergy is an IgE-mediated reaction to mammalian meat and dairy, with symptoms typically developing 3 to 6 hours after ingestion. Alpha-gal allergy with isolated gastrointestinal (GI) symptoms (abdominal pain, diarrhea, vomiting) without urticaria or anaphylaxis has been described.
Case Description/Methods: A 49-year-old male presented to GI clinic with years of episodic cramping abdominal pain and 4-6 diarrheal stools daily. Colonoscopy, EGD, CT abdomen, and hydrogen breath testing were unrevealing. We diagnosed irritable bowel syndrome. Rifaximin briefly relieved symptoms. He did not tolerate tricyclic antidepressants. Serum alpha-gal IgE level was found to be elevated at 0.27 kU/L (reference range, < 0.1 kU/L) after the patient reported past tick bites. The patient stopped eating mammalian meat and symptoms improved but continued. He further excluded gelatin in the form of gummy bears, dairy, and carrageenan, which led to near resolution of symptoms. At a visit 2 years following allergy diagnosis, he reported one formed stool daily and no chronic abdominal pain. Self-challenging with foods that have small amounts of alpha gal, like a handful of gummy bears, had resulted in severe abdominal cramping.
Discussion: The diagnosis of GI alpha-gal syndrome can be challenging because of delayed onset of symptoms after eating mammalian products, nonspecific GI complaints on presentation, and overlap with preexisting GI diseases. While sensitization is believed to be caused by a bite from the Lone Star tick, not all patients report a history of tick bites. Further studies are needed to better characterize GI alpha gal, but 2 cohort studies found that ~75% of patients improved on a diet free of mammalian products. These diets are somewhat ill-defined in how strict they are, particularly whether they are just free of mammalian meat or all products containing alpha-gal. A stepwise approach is recommended, starting with mammalian meat, then dairy, and then gelatin, gelatin capsules, and mammalian food additives if symptoms persist. Our patient experienced improvement in symptoms with elimination of mammalian meat from his diet, but no resolution until he eliminated all alpha-gal, particularly gelatin and carrageenan. This case highlights the importance of a thorough history, increased awareness of foods containing alpha-gal, and the need for future prospective studies for improving early recognition and treatment of GI alpha gal (**Figure**).

[2459] **Figure 1.** Recommended order of alpha-gal elimination from the diet: (i) mammalian meat with or without dairy; (ii) dairy; and (iii) gelatin, gelatin capsules, and mammalian food additives. Figure used with permission from McGill SK, Richards RD Jr, Commins SP. Suddenly Steakless: A Gastroenterologist's Guide to Managing Alpha-Gal Allergy. Am J Gastroenterol. 2022;117(6):822-826.

S2460

Autoimmune Enteropathy (AIE) in a Patient Diagnosed with Thymoma: A Case Report

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Introduction: Autoimmune enteropathy (AIE) is a very rare immune disorder that mainly attacks the gastrointestinal tract by T-cell. The full pathology mechanism is not clear. Typically, characterized by intractable diarrhea and nutritional malabsorption with extra-intestinal manifestations. The proposed diagnostic criteria include small bowel villous atrophy not responding to diet restriction, circulating gut epithelial cell autoantibodies (GECA), and lack of immunodeficiency. We describe a case of AIE with extensive GI involvement, presenting in a 60-year-old patient diagnosed with Type AB thymoma.
Case Description/Methods: Our gentleman with a history of Covid-19 complicated with pulmonary embolism and an incidental finding of malignant thymoma. A CT-guided biopsy was consistent with undifferentiated malignant thymoma supported by immunohistochemistry staining. Subsequently, complicated severe diarrhea erupted with significant weight loss. Conservative management, antibiotics, and diet restriction were ineffective. Diagnostic work-up was unremarkable except for anti-enterocytes antibodies (AEA) and anti-goblet cells antibodies (AGA). Bowel biopsy revealed villous blunting, loss of Paneth cells, and minimal intraepithelial lymphocytosis with no evidence of crypt abscesses. Corticosteroid and Octreotide have helped the patient's diarrhea. Thoracoscopy thymectomy performed with radiation therapy due to local and lymphovascular invasion.
Discussion: AIE characterized by severe villous blunting with the absence of goblet cells and Paneth cells, intraepithelial lymphocytosis, and increased crypt apoptosis. In comparison, graft vs host disease lack crypt abscesses, celiac disease shows increase in the intraepithelial lymphocytosis with intact goblet and Paneth cells, whereas inflammatory bowel disease has intact goblet and Paneth cells, and CVID characterized by absence of plasma cell in the lamina propria. The presences of the GECA are nonspecific but it may help in confirming the diagnosis or may predict the prognosis and recurrence. Only AGA has been reported in IBD. Neither has been observed in celiac disease. The low incidence of AIE and the limited existing literature available on the optimal guidance in management. Oral nutritional supplementation as well as total parenteral nutrition is helpful. The target is to control diarrhea and optimize the nutritional status before surgery. The main treatment is thymectomy.

S2461

Chronic Diarrhea: A Rare Presentation of Eosinophilic Granulomatosis With Polyangiitis

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Introduction: Diarrhea is a common occurrence with a significant healthcare burden, responsible for nearly 1 million emergency department (ED) visits per year. Chronic diarrhea affects up to 5% of adults and is defined by greater than 4 weeks of symptoms. In resource-abundant countries, the most common etiologies include irritable bowel syndrome, inflammatory bowel disease, malabsorption syndromes, chronic infections, and drug-induced. We describe a case of chronic diarrhea with an unusual etiology, eosinophilic granulomatosis with polyangiitis (EGPA).
Case Description/Methods: A 60-year-old man with a history of asthma and nasal polyps presented to the ED with nonbloody diarrhea starting 5 weeks prior. Associated symptoms included a dry cough. Of note, the patient was prescribed montelukast for asthma roughly one year prior to admission. Vital signs on presentation were normal and physical exam was unremarkable. A complete infectious workup was negative including autoimmune testing for antineutrophil cytoplasmic antibody (ANCA) panel. However, the patient had profound eosinophilia. A computed tomography scan of the chest and abdomen revealed scattered ground-glass opacities in bilateral lungs and a moderate amount of fluid throughout the colon. Upper and lower endoscopy with biopsy demonstrated chronic inflammation with marked eosinophilia in lamina propria of the gastroesophageal junction, gastric antrum, and duodenum. Nasal polyp biopsy results were obtained and consistent with vasculitis. The patient was diagnosed with chronic diarrhea secondary to montelukast induced EGPA. Montelukast was discontinued and his symptoms resolved with corticosteroids.
Discussion: EGPA is the rarest ANCA-associated vasculitis and affects small to medium-size vessels. It is characterized by eosinophilic granulomatous inflammation and an association with asthma and eosinophilia. Typical organs involved include peripheral nerves, paranasal sinuses, and lungs. Gastrointestinal manifestations are rare, and some studies have shown increased mortality in these patients. Numerous case reports have shown an association with montelukast and the development of EGPA. Glucocorticoid therapy leads to remission in a majority of patients, however, a relapsing disease course is common. Immunosuppressant maintenance therapy is controversial, and some studies have shown rituximab and mepolizumab to be effective in treating ANCA-positive and ANCA-negative EGPA, respectively.

S2462

Hereditary Alpha Tryptasemia Syndrome (HαTS): An Autobiographical Case Report and Literature Review of an Under-Recognized Clinical Entity Emulating Irritable Bowel Syndrome (IBS) and Inflammatory Bowel Disease (IBD)

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Introduction: HαTS is an autosomal dominant disease first characterized in 2014 by Lyons JJ. et al. and present in ~5% of the White population. HαTS is responsible for ~90% of patients in the western world with elevated basal serum tryptase (eBST). It modifies clonal and nonclonal mast cell (MC) disorders with increased prevalence and/or severity of anaphylaxis and MC mediator-related symptoms. We aim to present an autobiographical case report and peer literature review of HαTS.
Case Description/Methods: We conducted a review of peer literature selected using search terms: HαTS, Tryptase, IBS, IBD. Case: A 26-year-old male with a cc of change in bowel habits for 3 years, going from 1-2 formed stools to up to 6 loose bowel movements (BMs) per day. These are associated with excessive flatulence and crampy abdominal pain relieved by passage of BMs. GERD, nausea, and generalized pruritus worse at night which frequently awakens him from sleep. He also has chest and facial flushing with alcohol intake. No symptom relief from low-FODMAP or low-histamine diets, with relief of symptoms on a very low carbohydrate diet. Negative work up included allergy testing, celiac serology and HLA testing, brush border disaccharidases, CBC and CMP, thyroid panel, fecal elastase. VIP slightly elevated at 65 pg/mL (nl < 58.8 pg/mL). Endoscopy revealed small esophageal ulcer that resolved. Duodenal biopsies showed increased MC density at 24 per hpf (nl < 15 per hpf) and increased intraepithelial lymphocytosis. Colonoscopy with biopsies nl. Initial serum tryptase was 5.6 ng/mL, repeated 2 years was elevated to 11.4 ng/ml (nl < 6.5 ng/mL). Diagnosis: genetic PCR testing of buccal swab revealed extra-allelic copy of alpha tryptase gene on TPSAB1 gene locus, consistent with HαTS. Literature Review: HαTS presents with variable multisystemic symptoms with 1/3rd of patients asymptomatic, 1/3rd have mild disease, and 1/3rd have severe disease. Flushing, pruritis, dysautonomia, and symptoms emulating IBS and IBD with diarrhea present in 30-50%. Other symptoms may include food intolerances, IgE-mediated food allergies, neuropsychiatric symptoms, and joint hypermobility (**Table**).
Discussion: HαTS should be considered in the differential for symptoms of IBS and IBD—especially when flushing, pruritis, or dysautonomia are present. This will prevent delay of diagnosis and reduce total costs. Duodenal biopsies showing increased density of MCs and elevated serum tryptase (>6.5 ng/mL) are suspicious for HαTS. Genetic testing is confirmatory.

Table 1. Clinical features of HαTS, IBS, and IBD patients

Clinical Feature	HαTS	IBS	IBD
Age of Onset	Unknown	20-30 y/o	Major peak 15-25 y/o, minor peak 50-70
Male:Female	Male = Female	Female > Male	Male = Female
Western Prevalence	~5% of Whites	10-20%	1.3%
Common Symptoms and Signs	Diarrhea predominant, crampy abdominal, pain, GERD, flushing, and pruritus	Diarrhea and/or constipation, crampy abdominal pain, GERD	Diarrhea, crampy abdominal pain, bloody stools, bowel fistulas, intestinal strictures/fibrosis, weight loss, anemia
Serum Lab Values	Elevated Basal Serum Tryptase (Suspicion Mild-Moderate 6.2-7.9 ng/mL; Suspicion High >8.0 ng/mL)	No significant findings	Elevated C-reactive protein, erythrocyte sedimentation rate, fecal calprotectin, and Iron deficiency
Genetic Characterization	Extra allelic copy of alpha tryptase encoding gene on TPSAB1 gene locus[2]	Normal	+/- Positive
Small Bowel Histology	Increased density of Mast Cells forming 2-15 cell clusters	No significant findings	Granulomas, Inflammation, crypt abscesses
Current Treatments	H1 and H2 antihistamines, Oral Cromolyn, Carbohydrate Restriction*, Compounded Oral Ketotifen**, Sub Q Omalizumab**, Other Biologics**	See 2019 ACG Clinical Guidelines for IBS	Immunomodulation Therapies

*Treatment used successfully by patient in case study, but not described in literature.
**Treatments reported in literature with variable responses and not used by patient in case study).

S2463

Immunosuppression in Chronic Total Parenteral Nutrition Patient Causing Invasive Pulmonary Candidiasis

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Introduction: The complications of total parenteral nutrition (TPN) are well established in the literature, including a higher risk of fungal infections via immune system dysregulation, translocation, seeding, etc. We present a 42-year-old female requiring chronic TPN who was found to have cavitary pulmonary candidiasis.
Case Description/Methods: A 42-year-old female with ileocolonic Crohn's disease complicated by multiple bowel resections and Roux-en-Y bypass was evaluated inpatient for a 2-week history of daily fevers and nonproductive cough. The patient had a significant history of nutritional replacement therapy with failed percutaneous endoscopic gastrostomy requiring Mediport catheter placement for TPN feedings. Due to short gut syndrome, she was dependent on TPN. She had no history of malignancy or cardiac conditions, including valve abnormalities. CT scan revealed a 2x2 cm cavitary consolidation in the lingula and a 1.9x1.7 cm cavitating lesion in the left upper lung lobe. Voriconazole was initiated, but the patient continued to spike high fevers without improvement. The Mediport catheter was removed and sent for cultures. Bronchoscopy was also done. Mediport and bronchial wash cultures both grew Torulopsis glabrata. Fungal blood cultures were negative. After 4 weeks of appropriate antifungal therapy, the patient's fevers resolved and she was discharged home in stable condition.
Discussion: TPN predisposes to fungal infections by varied mechanisms. In our patient, given the anatomical path of the catheter, septic fungal emboli from the Mediport is the most plausible mechanism of invasive candidiasis. However, the vulnerability of our patients to fungal infections is likely because of gut disruption in the setting of short gut syndrome and long-term TPN dependence. The risk of infection with TPN occurs at both tissue and cellular levels. Loss of gut barrier function due to epithelial disruption and decreased IgA production is seen in chronic TPN users. Studies also show that TPN causes shifts in the gut microbiome resulting in decreased regulatory T-cells and dysregulation of toll-like receptors. Furthermore, some fungi, such as Candida species, can multiply in parenteral nutrition solutions in which even bacteria cannot grow. Some care centers prophylactically start antifungals in critically ill patients who require TPN, but data on the efficacy of prophylactic antifungal therapy for those requiring long-term TPN is needed.

S2464

Misnomer Leading to Delayed Diagnosis of an Autoinflammatory Syndrome in a Latino Male

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Introduction: Familial Mediterranean Fever (FMF) is a rare auto-inflammatory disease ordinarily found in patients of Mediterranean and Middle Eastern descent, however it can affect any ethnic group. Symptoms of FMF are non-specific and can mimic many common diseases, resulting in unnecessary workup, surgeries, and delayed diagnosis. The following case report demonstrates the ease of overlooking a classic presentation due to implicit bias, racial disparities, and a disease misnomer.
Case Description/Methods: We present a case of a 30-year-old Latino male who was evaluated for a 15 year history of episodic peritoneal type abdominal pain associated with constipation. The patient reported that his first attacks began at age 9, during which he had severe abdominal pain associated with bloating, constipation, chills and night sweats. The pain was so severe that he was unable to get out of bed or walk without hunching over. These attacks occurred twice a year, lasted 3-4 days, and severity was significantly exacerbated by stress. The patient had no relief from laxatives and prune juice taken for constipation. He stated that many family members in Mexico were diagnosed with irritable bowel syndrome (IBS) or "colitis nerviosa." He was also told that he had IBS-C, even though his constipation and pain resolved between attacks. He reported a normal colonoscopy at age 10, in addition to an appendectomy. During one attack, his inflammatory markers were found to be markedly elevated. The patient denied any associated chest pain, joint pain, or rashes. His parents were originally from Jalisco, Mexico, an area that was colonized heavily by the Spanish. His lab work and physical exam in between attacks were unremarkable. As the patient did not meet Rome criteria for IBS, and due to the suspicion of recurrent peritonitis, MEFV mutation testing was ordered. Genetic testing revealed that the patient was heterozygous for the M694I mutation. Due to classic presentation and supportive genetic testing, he was prescribed 1.2 mg of Colchicine daily. At 6 months follow up, he has had no further attacks.
Discussion: This case illustrates the implications of a misnomer as well as how racial disparities and implicit bias delayed diagnosis in a patient with classic presentation of FMF. The patient was untreated for over 2 decades and may have undergone an unnecessary appendectomy. It is important to remember that despite the name, FMF can affect any ethnic group and awareness should be raised about this treatable disease.

S2465

Neurogastroenterology & Motility Manifestations After COVID-19 Infection: A Case Series

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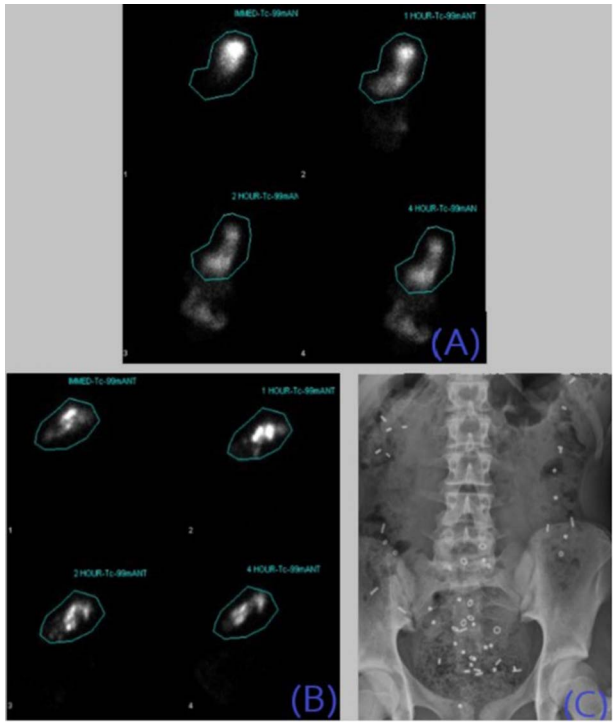
Introduction: In a subset of Covid19-convalescent patients, a multitude of long-term sequelae are increasingly being reported. We report 4 cases with varying neuro-GI and motility manifestations after recent COVID-19 infection.
Case Description/Methods: Case 1: A 23-year-old man contracted COVID-19 and had a protracted course of respiratory illness. Despite resolution of respiratory symptoms and dysgeusia, he continued to experience early satiety, postprandial nausea, vomiting and unintentional weight loss. Gastric Emptying Scan (GES) revealed gastroparesis (**Figure** A). Dietary modification and metoclopramide led to symptomatic improvement. Case 2: A 39-year-old woman with migraines, suffered from Covid-19 infection where anosmia and respiratory symptoms lasted for 2 weeks. Despite resolution of initial symptoms, she started experiencing nausea and vomiting, and reported stereotypical symptoms with complete absence of vomiting between episodes. Endoscopic examination, CT head and GES were normal. Urine tox screen was negative for cannabinoids. She responded favorably to amitriptyline and ondansetron. Case 3: A 47-year-old man started experiencing severe constipation associated with abdominal pain and bloating soon after being diagnosed with COVID-19. Three months after resolution of respiratory symptoms, in addition to constipation, he began reporting postprandial fullness, early satiation and epigastric pain. GES showed gastroparesis (**figure** B) and a Sitzmarks® Study revealed delayed colonic transit (**Figure** C). Prucalopride was started, leading to improvement in symptoms. Case 4: A 74-year-old woman with obesity and diabetes, was hospitalized and intubated for severe respiratory distress due to COVID-19. After discharge, she had persistent symptoms of brain fog, fatigue, dyspnea as well as diarrhea and abdominal cramping, persisting despite loperamide and dicyclomine. *C. difficile* toxin, random colonic biopsies and H_2 breath test were unremarkable. Her symptoms eventually improved with rifaximin.
Discussion: We report 4 cases with post-COVID gastroparesis, cyclical vomiting syndrome, pan-gut dysmotility, and post-infectious IBS phenotypes.The pathophysiology of post-infectious-gut–brain disorders is still obscure. The current conceptual framework implicates acquired neuropathy, altered motility, intestinal barrier disruption and persistent intestinal inflammation. Similar pathophysiology may be involved in COVID-19 infection leading to sustained neurogastroenterological dysfunction and gut dysmotility.



[2465] **Figure 1.** Image (A) showing delayed gastric emptying with 64% retention at 4 hours. Images (B) and (C) both from Case-3 showing markedly delayed gastric emptying with 86% retention at 4 hours and abnormal colonic transit study with X-ray showing large amount of stool and retention of markers throughout the entire colon, in the same patient.

S2466

Pelvic Floor Dysfunction as a Cause of Chronic Intestinal Pseudo Obstruction

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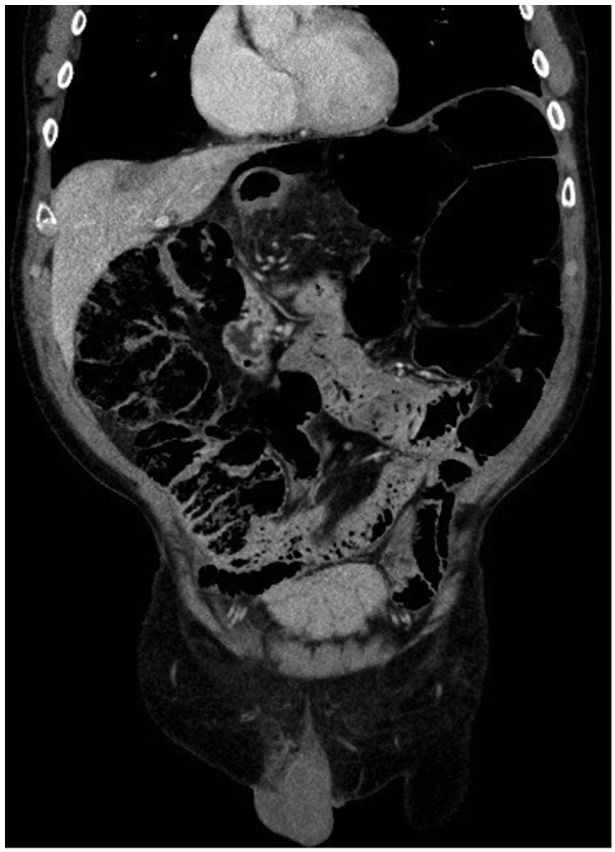
Introduction: Chronic intestinal pseudo-obstruction (CIPO) is a rare motility disorder with a variety of secondary causes, including genetics, metabolic disease, paraneoplastic syndromes, inflammatory disorders, and neurologic disorders. We present a case of CIPO secondary to pelvic floor dyssynergia.

Case Description/Methods: A 64 year-old male with a past medical history of hypertension, atrial tachycardia, and heavy alcohol use was referred for further GI workup by his primary care physician following a 5 month history of worsening constipation after a viral infection. Prior to the infection, he had a bowel movement 2-3 times per week. However, he now describes one Bristol 4 or 7 bowel movement with straining per month. Symptoms were refractory to Dulcolax and Colace. Initial workup included a normal extended electrolyte panel, normal TSH, and negative Celiac disease serologies. A CT abdomen and pelvis revealed extensive dilation of proximal colon, compression of descending and sigmoid colon, and small bowel fecalization. A representative coronal image is shown in **Figure** 1. Subsequent colonoscopy did not reveal any evidence of obstruction. Anorectal manometry (ARM) findings included elevated resting pressure (74.94 mmHg), decreased sensation, paradoxical contraction with Valsalva, and inability to pass the balloon catheter after 2.5 minutes. Normal rectal capacity (280 mL) and excellent squeeze pressure but paradoxical contraction with Valsalva is consistent with pelvic floor dyssynergia. Biofeedback therapy was recommended.
Discussion: Evaluating for secondary causes of CIPO (i.e., obstruction, metabolic disturbances, autoimmune disorders, neurologic disorders, and musculoskeletal disorders) is an important diagnostic step. Key tests include imaging, colonoscopy, electrolytes and autoimmune panels, and anorectal manometry. This case highlights long-standing pelvic floor dyssynergia as an underlying cause of CIPO.



[2466] **Figure 1.** CT abdomen and pelvis with extensive dilation of proximal colon and small bowel fecalization.

S2467

Sclerosing Mesenteritis: A Case Report in a Young Female

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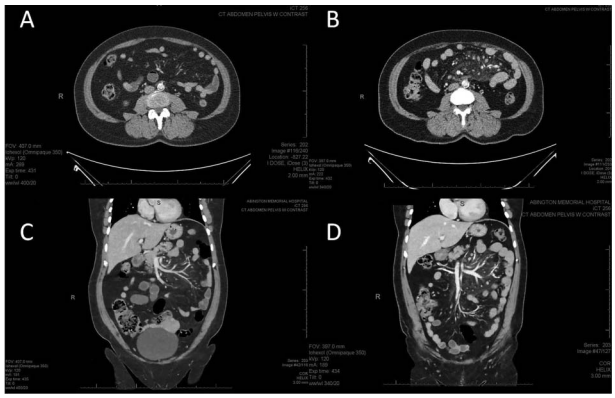
Introduction: Sclerosing Mesenteritis (SM) is a rare fibrotic inflammatory condition of mesenteric adipose tissue. It is of clinical significance since it appears to carry a 5 times higher risk of malignancy. In this case report we present a female with both clinical symptoms and radiographic findings suggestive of SM.
Case Description/Methods: A 58-year-old female presented to the resident clinic with the complaint of epigastric pain. On exam she had abdominal distention and tenderness over the epigastrium. Shortly after evaluation in the clinic the patient presented to the ED twice in 2 weeks with worsening abdominal pain where she got a CT scan both times demonstrating generalized haziness and interval enlargement of mesenteric lymphadenopathy. Colonoscopy and EGD for her ongoing abdominal pain which were both unremarkable. Duodenal and stomach biopsies were normal. AST, ALT, CRP, ESR, and CBC were all unremarkable. MRI of the pelvis as well as MR enterography was performed and this showed unchanged haziness of the mesentery but found the lymph nodes were not enlarged. The patient was seen by oncology who agreed that her lymphadenopathy had largely resolved, and it was unlikely she had an underlying malignancy. Surgery was consulted to evaluate for biopsy but felt given the clinical picture of SM was clear it was not warranted. The patient was seen in the clinic again and started on a regiment of colchicine. She currently has follow-up scheduled.
Discussion: Risk factors for SM are abnormal post-surgical healing, autoimmune mediated, and malignancy. Our patient did have prior abdominal surgery but no other risk factor. Studies have shown a connection with a variety of malignancies, but no statistically significant correlation. The interval enlargement in lymph nodes noted on our patient was concerning but this had resolved on MRI. SM is frequently found incidentally on CT scan. Findings suggestive of SM on CT are a "fat ring sign" or "pseudo-capsule" formation. More rarely "misty mesentery" can be seen which is the generalized haziness seen in our patient (**Figure**). Confirmation of SM is by biopsy. In our patient it was felt that the imaging was consistent enough to not warrant a biopsy. Treatment includes prednisone or colchicine. We will continue to follow our patient and see if she has a response to the colchicine with the possibility of starting prednisone in the future if there is no response.



[2467] **Figure 1.** A: Axial cut from Aug. B: Axial cut from Sep. C: Coronal cut from Aug. D: Coronal cut from Sep.

S2468

Stop, Drop, and Roll: One Woman's Pelvic Floor Disease Journey

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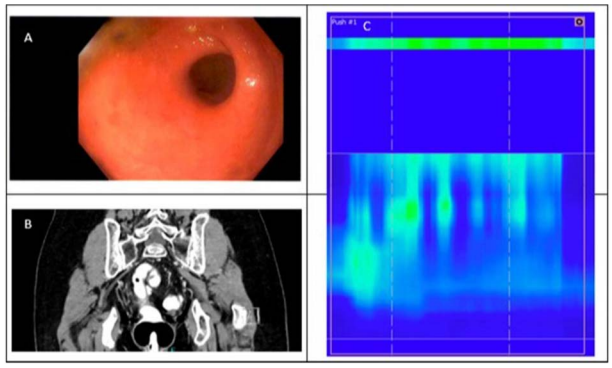
Introduction: Pelvic floor disease includes symptoms of the anterior (urinary, vaginal) and posterior (anorectal) pelvic floor. This case describes a woman who developed dyssynergic defecation after surgical management of urinary incontinence. The diagnostic route taken to reveal the unusual cause of her symptoms is a lesson in how to evaluate ambiguous gastrointestinal(GI)/genitourinary symptoms.
Case Description/Methods: A 69-year-old woman presents with bloating and difficulty defecating for 2 years. She senses incomplete evacuation, passing 1-2 thin stools per day despite an extensive bowel regimen (e.g. posturing, straining). Two years ago, she underwent sacrocolpopexy and mesh placement to treat pelvic organ prolapse. Her urinary incontinence improved but constipation worsened. She was thus evaluated by GI- many CTs showed nonspecific sigmoid (SC) thickening. A colonoscopy noted SC narrowing; mucosa pathology was normal. She came to our clinic to investigate further. Digital rectal exam had a normal tone with widening of the vault with strain. Anorectal manometry (ARM) showed dyssynergic defecation and unsuccessful balloon expulsion, consistent with mechanical obstruction. A flexible sigmoidoscopy showed benign-appearing extrinsic compression at the rectosigmoid junction. The SC also had a large stool burden despite 2 pre-procedure enemas. Given a concern for mass effect of the mesh into the colon, an exploratory laparoscopy was performed, showing a redundant SC with scarred, edematous mesentery. A partial sigmoidectomy was performed and adhesions at the anterior rectal wall (near the sacrocolpopexy mesh) were lysed. In just 3 months, the patient's symptoms resolved. Repeat ARM had a normal defecation pattern and balloon expulsion (**Figure**).
Discussion: Postoperative adhesions are present after 63-97% of open abdominal surgeries. The most common complication of such adhesions is bowel obstruction, occurring in 15% of patients within 1 month of surgery. Our patient had an even more unique complication- constipation and dyssynergic defecation. Literature on post-op adhesions and defecation dysfunction mainly describes surgery of the rectal sphincter. In contrast, the sacrocolpopexy did not involve the rectum or surrounding peritoneum, but caused adhesions with a mass effect on the rectum. Given the morbidity associated with lower abdominal adhesions, suspicion must remain high in populations with a history of complicated abdominal surgery- especially for treatment of anterior pelvic floor disease.



[2468] **Figure 1.** A. Flexible sigmoidoscopy: Very narrowed lumen in the sigmoid colon. B. CT abdomen and pelvis: Coronal view showing sharp angulation in the sigmoid colon (due to the mass effect of the mesh and adhesions) C.Anorectal manometry: The Y-axis notes length (cm) from anal sphincter (0cm) into sigmoid. The X-axis shows time (in seconds). The color of the data points denotes pressure exerted. Here, the top horizontal line in green shows rectal pressure. The same amount of pressure is shows in the bottom "green" areas, indicating that anal tone faily to appropriately relax. This increase in anal pressure with a good push, indicating dyssynergic defecation pattern.

S2469

The Big Stretch: A Report of Three Cases of Gastroparesis as an Uncommon Complication of Hypermobile Ehlers-Danlos Syndrome

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Introduction: Ehlers-Danlos syndrome (EDS) is a rare autosomal dominant connective tissue disorder that affects the gastrointestinal system, skin, joints, and vasculature. Hypermobile EDS (hEDS) is a subset of EDS with a prevalence of 1 in 5000 people. Major GI features of hEDS include abdominal pain, nausea, constipation, heartburn, and irritable bowel syndrome-like symptoms. Gastroparesis is a debilitating disorder defined as delayed gastric emptying in the absence of a mechanical obstruction. However, hEDS as a cause of gastroparesis is not well established in the literature. Here we report 3 cases of gastroparesis in patients with hEDS to demonstrate its uncommon and varying presentations.
Case Description/Methods: Our first patient is a 20-year-old woman who was diagnosed with hEDS at a young age and then developed severe epigastric postprandial abdominal pain with bloating, intractable nausea, early satiety, and unintentional weight loss. She had multiple ER admissions over the past few years for similar symptoms. Physical examination revealed hyperflexible joints, normal bowel sounds with nontender abdomen. Lab values were within normal limits. Esophagogastroduodenoscopy (EGD) and gastric emptying studies both confirmed Grade III gastroparesis. She was initially started on Metoclopramide and Ondansetron without improvement. Patient ultimately achieved symptom control with Azithromycin, Ondansetron, Promethazine as needed and diet modifications. The second patient is a 24-year-old man who was also diagnosed with hEDS at an early age and presented with recurrent postprandial abdominal pain with bloating and heartburn, but no weight loss. He underwent EGD and was found to have gastritis, hiatal hernia and reflux esophagitis. Subsequent gastric emptying scintigraphy later confirmed Grade II gastroparesis and his symptoms improved with diet modifications as well as

Metoclopramide. Lastly, our third patient is a 26-year-old woman also with known history of hEDS who presented with mild intermittent postprandial abdominal pain and abdominal bloating. Prior work-up with EGD and gastric emptying scans confirmed the diagnosis of Grade I gastroparesis. Fortunately, her symptoms clinically resolved with regular cannabis use.
Discussion: Gastroparesis should be considered in patients with hEDS complaining of severe postprandial abdominal pain. Due to its uncommon presentation and multi-system organ involvement, EDS should be considered in patients with idiopathic gastric dysmotility and joint hypermobility.

S2470

Unusual Suspect: Diarrhea and Shock Secondary to Pheochromocytoma and VIPoma

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Introduction: Pheochromocytoma is a catecholamine secreting tumor that is found at a rate of 0.0008% annually in the general population. Vasoactive intestinal peptide, also known as vasoactive intestinal polypeptide or VIP, is a peptide hormone that enhances cardiac contractility, produces vasodilation, increases glycogenolysis, reduces arterial blood pressure, and relaxes the smooth muscle of the trachea, stomach, and gallbladder. Moreover, VIP may lead to the secretion of water and electrolytes, hypokalemia, and flushing. This case presentation involved a patient with an atypical pheochromocytoma, suspected of producing VIP.
Case Description/Methods: A 51-year-old male presented with palpitations, diaphoresis, nausea, and intermittent substernal chest pain that exacerbated when he lied on his right side. Hypertension and left adrenal mass are among his medical history. He developed emesis, stomach pain, distention, and profuse secretory diarrhea. On day 4 of his hospital stay, this resulted in hypovolemic shock due to a 5L/day output. He further developed metabolic acidosis, hypokalemia, and his EKG revealed intermittent ventricular tachycardia and T wave inversion. Plasma metanephrines were 5679 pg/mL, VIP was 239 pg/mL, and gastrin was 313 pg/mL, according to an endocrine examination. CT scan revealed a 5 cm adrenal mass in the gastro-entero-pancreatic area; pheochromocytoma was then confirmed with the positive metanephrines. Patient finally underwent adrenalectomy.
Discussion: Pheochromocytoma is a rarely identified and diagnosed tumor in the majority of patients. The classical presentation of pheochromocytoma is typically an episodic headache, diaphoresis, headache, and tachycardia. On rare occasions, these tumors may also secrete Vasoactive intestinal peptide (VIP). VIP can result in the relaxation of smooth muscles of the GI tract along with peripheral vasodilation and hypovolemia. This patient presented with atypical pheochromocytoma, suspected of secreting VIP. Due to the VIP secretion, the patient developed copious secretory diarrhea, leading to hypovolemia and in turn leading to hypokalemia. The hypokalemia resulted in the development of Ventricular tachycardia. This presentation leads to the conclusion that it is imperative to test metanephrines and image catecholamine-secreting-tumors if suspected in a patient. Pancreatic VIPomas must also be ruled out as elevated VIP levels may be due to pheochromocytomas and be detrimental to the patient's health.

S2471

Using Prokinetic Agents in Chronic Intestinal Pseudo-Obstruction (CIPO)

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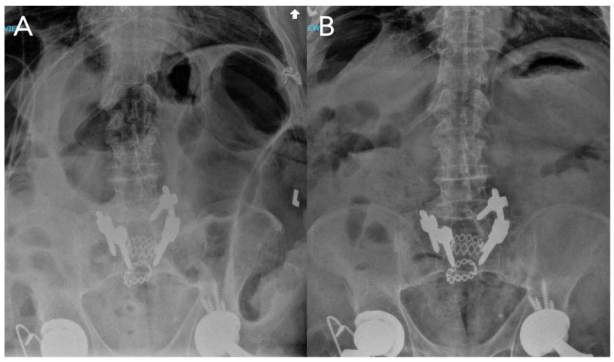
Introduction: Chronic intestinal pseudo-obstruction (CIPO) is a rare disease. Dilatation may involve the colon or small bowel and is usually due to an underlying neuropathic disorder. Clinical manifestations of CIPO include abdominal distention, bloating, and pain, which can be acute, chronic, or recurrent. Diagnosis of CIPO should be suspected in patients with these symptoms for at least 3 months in the absence of a mechanical cause. Diagnosis requires exclusion of mechanical obstruction and other causes of dysmotility (**Table**).
Case Description/Methods: This is a case of a 62-year-old male presenting with 3 weeks of worsening abdominal pain and distention. History includes colon cancer with sigmoid resection/colostomy reversal, alcohol use disorder, and L5-S1 fusion on chronic opioids. He had 2 recent hospitalizations for similar symptoms thought to be due to non-obstructive ileus. At that time, colonoscopy showed significant colonic dilation with no masses or strictures. He was endoscopically decompressed and started on methylnaltrexone with relative improvement during a prior hospitalization. On this presentation, he had a massively distended abdomen with minimal tenderness. He was initially managed conservatively with bowel rest, rectal tube, and avoidance of opioids. However, serial abdominal X-rays showed no improvement in dilation (**Figure**). He was started on pyridostigmine with significant improvement in dilation and had normal bowel movements prior to discharge.
Discussion: This patient had recurrent CIPO with multiple admissions without complete resolution of previously suspected non-obstructive ileus despite conservative management and methylnaltrexone. Imaging was consistent with severe colonic dilation. As the patient had no improvement with conservative management, he was started on a trial of pyridostigmine after which he had significant improvement of bowel dilation on X-ray with normal bowel movements, illustrating the role of prokinetics in treating suspected CIPO. Knowledge of CIPO is important to prevent delays in diagnosis. Intervention focuses on diet and treatment of the underlying disease. For patients with symptoms despite dietary modifications, prokinetics such as prucalopride or pyridostigmine can be used for symptomatic relief. Pyridostigmine has demonstrated efficacy in the chronic phase of CIPO in small observational studies and is more commonly used in pediatric CIPO. Through this case, prokinetic agents show promise for broader use in adult CIPO cases.



[2471] **Figure 1.** Abdominal X-Rays of patient before (A) and after (B) use of pyridostigmine showing improvement of colonic pseudo-obstruction.

Table 1. Acute Intestinal Pseudo-Obstruction vs Chronic Intestinal Pseudo-Obstruction (CIPO)

	Acute Intestinal Pseudo-Obstruction	Chronic Intestinal Pseudo-Obstruction
Prevalence	100 per 100,000*	0.80-1.00 per 100,000
Course	Acute	Chronic
Presentation	Abdominal distention Cramping pain Nausea/vomiting	Abdominal distention Abdominal pain Bloating
Anatomic involvement	Colonic dilatation, usually cecum, right colon	Colonic or small bowel dilatation
Pathophysiology	Multifactorial Autonomic dysfunction strongly implicated	Neuropathic disorder of enteric or extrinsic nervous system Myopathic disorder of smooth muscle Malfunction of interstitial cells of Cajal
Management	Fluid resuscitation, correction of electrolyte abnormalities, avoidance of opioids/ anticholinergics Ambulation, bowel rest Decompression with nasogastric or rectal tubes Pharmacologic treatment with neostigmine Operative intervention in cases of colonic perforation or ischemia	Dietary modification, treatment of underlying disease Prokinetics, such as Prucalopride, for symptomatic relief (Grade 2C) Pyridostigmine in chronic phase of CIPO

*Inpatient admissions.

S2472

A Case of Functional Bowel Disease Misdiagnosed as Carcinoid Syndrome

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Introduction: Carcinoid tumor is a well-differentiated neuroendocrine tumor (NET) that arises from enterochromaffin cells. NETs produce serotonin which is metabolized to the inactive 5-hydroxyindoleacetic acid (5-HIAA) by the liver and the lungs. Carcinoid syndrome results from the secretion of serotonin into the systemic circulation by a metastatic NET that originates from the midgut. The primary screening method for carcinoid syndrome is 24-hour urinary 5-HIAA (U-5HIAA) which has a 90 percent sensitivity and specificity in diagnosing carcinoid syndrome. This case illustrates a unique scenario of a markedly elevated U-5HIAA not due to NET.
Case Description/Methods: A 29-year-old female presented to our clinic with abdominal pain, bloating, diarrhea, and weight loss associated with postprandial facial flushing. Medications included Dextroamphetamine and Fremanezumab. Based on her symptoms, U-5HIAA was ordered and was elevated at 148 mg (normal < 6). Carcinoid Syndrome was suspected based on symptoms and markedly elevated U-5HIAA. Imaging studies were ordered to identify primary or metastatic NET. These included negative CT abdomen/pelvis and a negative Ga68 Dotatate NETSPOT PET scan. Upper endoscopy and Colonoscopy were also negative. The patient expressed difficulty in stopping dextroamphetamine for the urine collection but due to the negative evaluation for NET she finally agreed to hold it for 3 days. Repeat U-5HIAA decreased down to 10.4 mg. Her symptoms were then believed to be secondary to functional bowel disease. The patient's symptoms improved with mirtazapine and dicyclomine, and she regained the weight.
Discussion: This is a unique case with a misleading U-5HIAA. While mildly elevated levels of U-5HIAA can be seen with tryptophan rich foods and certain drugs, including amphetamines, marked elevation, like in our case is more specific and usually seen with the carcinoid syndrome. Our patient had symptoms suspicious of carcinoid syndrome and a U-5HIAA of 148 mg, which is 25 times the upper normal. However, there was no evidence for NET on extensive work up, and the levels rapidly decreased with stopping dextroamphetamine. To our knowledge, this is the highest falsely positive U-5HIAA reported. This case shows the importance of a complete drug history, including over-the-counter medications. When the 5-HIAA is elevated, the test needs to be repeated after discontinuing all potentially interfering medications.

S2473

A Case of Familial Mediterranean Fever Diagnosed by Abdominal CT Scan in a Patient Previously Diagnosed With Functional Abdominal Pain

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Introduction: Familial Mediterranean fever (FMF) is a hereditary autoimmune disease in which patients present with periodic, self-limited episodes of fever and serositis. It is prevalent in individuals of Middle Eastern origin. Since no definitive diagnostic test is available, FMF is suspected based on clinical symptoms; there are major and minor criteria to aid in making the diagnosis. Imaging modalities are not included in these criteria. We present a patient whose only symptom was recurrent abdominal with no family history of FMF. At the time he was diagnosed with Functional Abdominal Pain. FMF was suspected based on unexplained focal peritonitis on computerized tomography (CT).
Case Description/Methods: A 45-year-old male of Middle Eastern descent was seen in clinic complaining of episodic right upper quadrant (RUQ) abdominal pain since he was 17 years old. The pain occurred once or twice per month. Over the years he had multiple visits to the emergency department and extensive work up including endoscopic evaluation and imaging studies. He underwent cholecystectomy, and bilateral inguinal hernia repair without benefit. He was diagnosed with Functional Abdominal Pain then. When evaluated in our clinic, lab work showed mild iron deficiency anemia; otherwise, unremarkable. Upper endoscopy, colonoscopy, small bowel series and capsule endoscopy were normal. 3 months later he presented to our ER with an acute episode of severe RUQ pain. He was afebrile; abdominal exam was remarkable for localized tenderness in the RUQ. Lab work was remarkable for an elevated erythrocyte sedimentation rate of 31. Abdominal CT was only remarkable for fat stranding around the hepatic flexure and the proximal half of the transverse colon. Colonoscopy was normal with no evidence for segmental colitis to explain the inflammatory changes. Given the history of recurrent abdominal pain, ethnicity, and focal unexplained peritonitis on CT scan, FMF was suspected, and treatment with colchicine was initiated without recurrence of symptoms for now several years since the diagnosis, meeting diagnostic criteria for FMF.
Discussion: If not considered, FMF can remain misdiagnosed for many years leading to unnecessary procedures and surgeries. This was an unusual presentation with afebrile episodes of intermittent RUQ pain with the diagnosis ultimately suspected by CT imaging and confirmed by response to colchicine. Clinicians should consider FMF in patients of high-risk ethnic origin presenting with unexplained focal peritonitis on CT scan.

S2474

Ankylosing Spondylitis Improved Following Faecal Microbiota Transplantation: Two Case Reports

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Introduction: Ankylosing spondylitis (AS) is an autoimmune disease which causes inflammatory arthritis in the spine and sacroiliac joints. Symptoms of AS include back pain, stiffness and reduced mobility in the spine. Patients with AS are known to have subclinical gut wall inflammation and dysbiosis in the gut. There is no known treatment to cure AS. Here, we report incidental improvement in AS in 2 patients with irritable bowel syndrome predominant diarrhoea (IBS-D) who received faecal microbiota transplant (FMT).
Case Description/Methods: Case one: Female, 47 years of age, with known IBS-D, presented with recurrent abdominal pain, explosive diarrhoea 5 time a day, nocturnal bowel motions and urgency. At the same time, she was on salazopyrin and arava for her AS with limited improvement in symptoms. Stool testing was for positive *Clostridium difficile* toxin and she received 2 fresh FMT's (one via colonoscopy, one via enema) in 2016. Testing 1 month after FMT treatment was negative to *Clostridium difficile* toxin. The patient had no ongoing gastrointestinal (GI) symptoms. She also reported significant improvement in AS symptoms (specifically reduction in excruciating pain in lower back and hip). After 5 years, her IBS-D symptoms relapsed and she had another 2 FMTs (one via colonoscopy, one via enema) which resulted in improvements in GI symptoms and more improvement in AS than previous FMTs. Her CRP and ESR levels were normal pre and post treatment.
Case 2: Male, 68 years of age, with known IBS-D received fresh 2 FMTs (one via colonoscopy, one via enema) in 2005 for treatment of IBS-D. Prior to treatment he had abdominal pain, cramps and loose motion and AS symptoms including excruciating pain in the sacroiliac joint. He was on infliximab and analgesics for his AS. After FMT treatment, he reported resolution of all GI symptoms and AS symptoms. His pre and post CRP levels were 100 and 2.6 and ESR levels were 18 and 7 respectively. In 2009, he had antibiotic treatment for sinusitis and his GI symptoms relapsed. He had a further 5 FMTs, again with complete recovery of GI symptoms and continued AS remission.
Discussion: We observed short-term and long-term improvement in AS symptoms after treating patients with FMT. Future prospective trials are required to confirm FMT as a treatment for AS.