RESULTS: Seventy-seven patients with CD and 68 patients with UC were evaluated compared to 55, 26/97, 26.8% vs nollent. Descriptive statistics were used to describe patient enrollment characteristics and were stratified by PROMIS status (moderate/severe ≤60 vs normal/mild <60) for Fatigue, Pain Interference, and Anxiety domain scores. Further investigation is needed to address the unmet medical needs in these patients.

PO39
Factors Associated with Impaired Patient-Reported Outcomes and Work Productivity Among Patients with Crohn’s Disease in Remission

Hudakman David1, Sauk Jenny2, Zhou Jie1, Harrison Ryan3, Kerti Samantha3, Emeanu-Kieloch4, Ahmad Harri5, Seoh Antonine6, Nguyen Joeh7, Cross Raymond8, Horst Sarah9,10
1NYU Langone Health, New York City, United States; 2Salix Pharmaceuticals, Bridgewater, NJ, United States; 3Corrona, LLC, Walhamb, United States; 4University of Maryland School of Medicine, Baltimore, United States; 5Vanderbilt University Medical Center, Nashville, United States; 6NYU Langone Health, New York City, United States; 7Ronald Reagan UCLA Medical Center, Los Angeles, United States; 8Bristol Myers Squibb, Princeton, United States; 9Corrona, LLC, Walhamb, United States; 10University of Maryland School of Medicine, Baltimore, United States.

BACKGROUND: We have previously observed poor patient-reported outcomes (PROMs) in patients with Crohn’s disease (CD). In this analysis, we investigated differences in enrollment characteristics between CD patients in remission reporting impaired PROMs vs those without impairment within the Corrona Inflammatory Bowel Disease Registry.

METHODS: Analysis included patients, enrolled in the Corrona IBD Registry from March 3, 2017 through September 3, 2019, with a diagnosis of CD who were in remission (defined as Harvey-Bradshaw Index ≤5) at the time of enrollment. Patient-Reported Outcomes Measurement Information System (PROMIS) and Work Productivity and Activity Impairment (WPAI) questionnaires were collected at enrollment. Descriptive statistics were used to describe patient enrollment characteristics and stratified by PROMIS status (moderate/severe, ≤60 vs normal/mild, <60) for Sleep Disturbance, Fatigue, Pain Interference, and Anxiety domains. Finally, a greater proportion of moderate/severe fatigue reported a history of extraintestinal manifestations such as arthritis (n = 20/103, 19.4% vs n = 60/493, 13.7%) and skin manifestations (n = 5/103, 4.9% vs n = 12/493, 2.7%). There were no meaningful differences in PROMIS scores (mild/normal vs moderate/severe impairment) in CD patients in remission on biologics with the exception of a lower proportion of patients with moderate/severe pain interference. The impaired PROMs group had differences in disease location and behavior, with more impaired patients reporting ideal disease location (n = 81/192, 42.2% vs n = 62/176, 35.2%), as well as a greater proportion with a greater penetration disease (n = 27/190, 14.2% vs n = 19/173,11.0%), compared with non-impaired patients. These patients were seen for reporting any work productivity loss or had elevated fatigue, anxiety, or pain interference were more likely to have a history of arthritis and anxiety. History of steroid use was seen more often in patients who reported impaired work productivity or had elevated fatigue, anxiety, or pain interference were more likely to have a history of arthritis and anxiety. History of steroid use was seen more often in patients who reported impaired PROMs scores. Further investigation is needed to address the unmet medical needs in these patients.

RESULTS: At the time of the study, a total of 812 CD patients were enrolled in the Corrona IBD Registry, of which 547 were in remission and included in the analysis. Compared with patients who reported normal/mild fatigue, patients with moderate/severe fatigue had a higher proportion of ileocolonic disease location (n = 41/103, 39.8% vs n = 174/493, 35.3%), this was also seen in the Sleep Disturbance and Anxiety domains. Patients with moderate/severe fatigue were younger (mean age, 42.5 vs 47.9 years) and were more likely to be obese (body mass index ≥30.2% vs 26.0%) than those with normal/mild fatigue. Additionally, a greater proportion of patients with moderate/severe fatigue reported a history of corticosteroid use (n = 33/34, 61.1% vs n = 156/325, 48.0%), a history of antibiotic use (n = 15/54, 27.8% vs n = 49/325, 15.1%), as well as a shorter duration of current IBD treatment (mean, 2.3 vs 3.3 years). These treatment trends were also seen in patients who reported moderate/severe pain or anxiety domains with a higher proportion of patients with moderate/severe fatigue reported a chronic biologic treatment (n = 23/54, 42.6% vs n = 109/325, 33.5%) compared with those who reported normal/mild scores. Overall, those in remission reporting any PROMs impairment were more likely to have a history of arthritis (n = 11/97, 11.3% vs n = 11/157, 7.0%), to have greater urgency of defecation (n = 26/97, 26.8% vs n = 24/157, 15.3%), and to be currently treated with corticosteroids (n = 11/97, 11.3% vs n = 115/70, 7.0%) compared with those who reported none. The same trends were seen in those reporting any Work Productivity Loss history of arthritis, n = 10/93 (10.8%) vs n = 10/144 (6.9%); urgency of defecation, n = 26/93 (28.0%) vs n = 23/144 (16.0%); and current corticosteroid treatment, n = 10/93 (10.8%) vs n = 10/144 (6.9%). In UC patients in remission reporting any Activity Impairment, the trend was seen for history of arthritis (n = 19/167, 11.4% vs n = 18/217, 8.3%), and urgency of defecation (n = 43/167, 25.7% vs n = 28/217,12.9%).

CONCLUSION: Despite being in remission based on partial Mayo Score, patients with UC who -0.43080, 0.0001) and self-esteem (R = -0.4063, P = 0.0007).

CONCLUSION: IB patients have impaired body image compared to the control group. Disease activity, quality of life and mood disorders were associated with impaired body image in IB patients.

PO37
Efficacy and Safety of 1-L NER1006 Bowel Preparation in Patients with Inflammatory Bowel Disease: Analysis of 2 Phase 3 Studies

Puppini David1, Oneto Caterina2, Allen Christopher3, Albers Craig4,5
1NYU Langone Health/ NYU School of Medicine, New York, New York, United States; 2Vanguard Gastroenterology, New York, New York, United States; 3Salix Pharmaceuticals, Bridgewater, United States; 4University of California Los Angeles, Irvine, United States.

BACKGROUND: NER1006 (Plenul®, Salix Pharmaceuticals, Bridgewater, NJ), a 1-L polyethylene glycol (PEG)-based bowel preparation, is indicated in the United States for colon cleansing in preparation for colonoscopy in adults. Colonoscopy is an important tool for the diagnosis, management and monitoring of patients with inflammatory bowel disease (IBD), and adequate bowel preparation is critical for effective performance of colonoscopy. The current data analysis was conducted to assess the efficacy and safety of 1-L NER1006 in an adult population who received this bowel preparation prior to colonoscopy, subgrouped by IBD diagnosis.

METHODS: NER1006 data were pooled from two phase 3, randomized studies (NOCT and MORA) of patients (aged 18-85 y) undergoing colonoscopy. Patients with ongoing severe, acute IBD were excluded. Patients received NER1006 as a 2-day evening/morning or 1-day morning/morning splitting regimen. Total NER1006 volume requirements were 64 oz or clear liquids ad libitum. Colon cleansing was assessed by treatment-blinded central readers. The 2 primary endpoints of the studies were overall bowel cleansing success rate and ascending colon/cecum high-quality cleansing rate. Overall cleansing success was defined as Harefield Cleansing Scale (HCS) grade A/B (score = 3/4 [ie, clear liquid/empty/ and clean] in all 5 colonic segments or score = 2 [ie, brown liquid/ removable meal or semi solids] for ≥1 segment with score 3/4 for remaining segments). High-quality cleansing in the ascending colon/cecum was defined as an HCS score = 3/4. Efficacy analyses were conducted in the modified full analysis set population, defined as all randomly assigned patients excluding those who failed to meet entry criteria post-randomization and who also did not receive any study drug. Safety was assessed in all randomly assigned patients in whom it could not be ruled out that they received ≥1 dose of NER1006 (per patient day). Safety was assessed through ≥7 ≥1 post-colonoscopy. Safety assessments included adverse event (AE) reporting, clinical laboratory evaluations, vitalsign measurements, and physical examinations; urinalysis and electrocardiogram were performed at screening and on the day of colonoscopy.

RESULTS: A total of 13 and 83 patients who did and did not have a medical history of IBD, respectively, were included in the pooled efficacy analysis, with a majority in each group receiving a 2-day split-dose regimen (61.5% and 66.8%, respectively). Overall cleansing success was achieved in 93.8% of patients with IBD and 92.7% of patients without IBD, and by WHO guidelines: 92.7% high-quality cleansing of the ascending colon/cecum was reported in 38.5% (5/13) of patients with IBD and 33.7% (274/813) of patients without IBD. Based on post-colonoscopy diagnosis, safety was analyzed for 12 patients with IBD. Only 1 patient with IBD (NER1006 1-L split-dose preparation) experienced an AE (mild) and was included in the study discontinuation analysis.

CONCLUSION: Data support the overall efficacy and safety profile of 1-L NER1006 as a bowel preparation in patients with IBD. Further studies in patients with IBD are warranted given the essential nature of careful mucosal evaluation for dysplasia surveillance and lesion detection in this patient population.

NOTE: Plenul® is a registered trademark of the Norgine group of companies used under license.