RESULTS: Seventy-seven patients with CD and 68 patients with UC were evaluated compared to 155 healthy people. The mean age was higher in the IBD group (P = 0.012). Family income (P = 0.0093) and alcoholism (P < 0.0001) were higher in the control group. There was no difference in quality of life (P = 0.6990), anxiety symptoms (P = 0.3117) or self-esteem (P = 0.7611), but depressive symptoms were more frequent in the IBD group (P = 0.008). Body image was impaired in the IBD group (P = 0.0007). The variables associated with body image in the IBD group were disease activity in CD (P = 0.33457, P = 0.0074), disease activity in UC (P = 0.27732, P = 0.0055), quality of life assessed by IBDQ (P = 0.52408, P < 0.0001), SF-36 (P = 0.92905, P = 0.0001), anxiety (P = 0.287829, P = 0.0005), depression (P = 0.37041, P = 0.0002) and self-esteem (P = -0.4308, P = 0.0001). The variables associated with body image in the control group were male gender (R = -0.1919, P = 0.0130), quality of life (SF-36) (R = -0.42172, P < 0.0001), anxiety (R = 0.253865, P = 0.0012), depression (R = 0.32871, P = 0.0001) and self-esteem (R = -0.4068, P = 0.0001).

CONCLUSION: IBD 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 IBD patients.

PD07

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

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BACKGROUND: NER1006 (Plenvu, 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 follow-up colonoscopy in 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, sub-grouped 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 split-dosing regimen. Total NER1006 volume requirements were 64 oz plus clear liquids ad libitum. Colonoscopy was performed at screening and on the day of colonoscopy. Overall cleansing success was defined as Harefield Cleansing Scale (HCS) grade A/B (score 3/4 [ie, clear liquids/empty and clean] in all 5 colonic segments or score ≥ 2 [ie, brown liquid/removable semi-solid stools] 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 randomized 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 randomized assigned patients in whom it could not be ruled out that they received ≥1 dose of NER1006 (per patient diary). Safety was assessed through ≥7 days post-colonoscopy. Safety assessments included adverse event (AE) reporting, clinical laboratory evaluations, vital sign 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 92.3% (12/13) of patients with IBD and 88.7% (721/813) of patients without IBD. High-quality cleansing in the ascending colon/cecum was reported in 85.3% (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-day split-dose regimen) experienced an AE (mild nausea) and the result in study discontinued.

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: Plenvu is a registered trademark of the Norgine group of companies used under license.