INTRODUCTION: We previously identified the need to develop educational materials to empower inflammatory bowel disease (IBD) patients to take care of their health and well-being. Based on patient input, we developed short educational videos that discuss: (1) how to be a self-advocate; (2) staying healthy beyond using medicines; (3) coping with IBD; and (4) shared decision making. We also created a video aimed at those who know someone with IBD that describes IBD patients’ disease experiences. We assessed the impact of the videos on patient engagement using the Patient Activation Measure (PAM) and on the level of empathy of their families and friends.

METHODS: We recruited IBD patients and people who know someone with IBD through Cint, an online survey research firm. IBD patients were randomized to watch one of the four videos developed for those with IBD and completed the PAM before and after watching the videos. Those who knew someone with IBD filled out a 9-item survey that measured their level of empathy for people with IBD before and after watching their respective video. We performed multiple logistic regression models to assess which factors are associated with improvements in PAM or empathy.

RESULTS: In total 776 IBD patients and 223 people who knew someone with IBD were recruited. The PAM increased on average 3.8 (CI 1.8 – 6.0) points after watching the videos that measured their level of empathy for people with IBD and before watching their respective video. We performed multiple logistic regression models to assess which factors are associated with improvements in PAM or empathy.

CONCLUSION: We developed five educational videos using a user-centered design approach for patients with IBD and their friends and family members. Patient engagement increased significantly after watching the videos and significantly higher levels of empathy were reported by family and friends. We now plan to widely disseminate these videos on social media and will track metrics such as views, shares, and comments.

S0814

Endoscopic Healing Index Is Inversely Correlated With Serum Inflimmabulm Concentrations in Crohn’s Disease Patients: A Retrospective Analysis of the TAILORIX Clinical Trial Cohort

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INTRODUCTION: Optimization of serum drug concentrations in anti-tumor necrosis factor (TNF) treated patients is a promising approach for treat to target strategies in Crohn’s disease (CD) patients. The endoscopic healing index (EHI) is a multi-protein serum biomarker test that was validated against endoscopy in adult CD patients and may aid repetitive endoscopic examinations. The aim of this study was to evaluate the relationship between the EHI and serum infliximab (IFX) levels and to correlate the results with endoscopy in patients from the TAILORIX clinical trial.

METHODS: EHI (scores ranging from 1-100) and IFX levels (homogeneous mobility shift assays) were measured at weeks 12, 14 and 54 (Prometheus Biociences, San Diego, CA). Samples at W12 and W54 were on the same day as endoscopy. Endoscopic remission (ER) was defined as simple endoscopic score for CD (SES-CD) of ≤2 with segment sub-scores ≤1 while endoscopic active disease (AD) was SES-CD >2. EHI <20 was considered with ER while EHI ≥20 and <30 were indicative of AD. Continuous variables (SES-CD or EHI) were compared using the Mann–Whitney test in patients at AGA recommended threshold low vs. high IFX cut-offs. ROC curves were used to identify optimal IFX thresholds that best corresponded with ER.

RESULTS: Serum samples (N = 269) from 105 patients (median age = 34 years [IQR, 22.5-45.8], 61.9% female) were included. SES-CD and EHI were significantly lower at week 14 in patients presenting with IFX levels greater than 5.94 μg/mL compared to those presenting with IFX lower than 5.94 μg/mL (Figure 1). Optimal IFX thresholds associated with ER post-induction (W14) were at 7 μg/ mL for both SES-CD or EHI endpoints (Figure 2).

CONCLUSION: EHI can be helpful as an adjunct to endoscopy. An IFX serum concentration of ≥7 μg/mL can be helpful as an adjunct to endoscopy. An IFX serum concentration of ≥7 μg/mL may be more optimal than the recommended 5 μg/mL when endoscopic healing of CD is used as a target of therapeutic intervention. Combination of EHI measurements and serum drug levels can allow for the simultaneous non-invasive assessment of the mucosal status and aid in treatment optimization.

REFERENCES

S0815

Effect of Mirikizumab on Inflammatory Biomarkers in a Phase 2 Study of Patients With Crohn’s Disease

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Figure 1. Box plots of SES-CD (A) and EHI (B) at weeks 14 and 54 in patients with serum IFX concentrations <5 vs. ≥5 μg/mL.
INTRODUCTION: Mirkamab (mini IL-23p19 antibody) is a humanized, IgG4 monoclonal antibody specifically targeting the p19 subunit of the IL23 cytokine. Prior studies have shown mink to have efficacy in psoriasis, ulcerative colitis, and Crohn’s disease (CD). High sensitivity C-reactive protein (hsCRP) is a known marker of acute inflammation which correlates with disease activity in the majority patients, while fecal calprotectin (FCP) correlates with mucosal inflammation and can be used as a reliable biomarker of mucosal healing [1].

METHODS: At baseline, subjects (N = 191) were randomized to a 2:1:1:2 allocation across 4 treatment arms (PBO, 200, 600, 1000 mg miki, administered intravenously (IV) at Weeks 0, 4, 8). Fecal samples and serum were collected for the assessment of FCP and hsCRP, respectively, at baseline (BL) and Week 12. Comparisons to placebo for continuous data were done using the normal approximation for the Wilcoxon two-sample test. For categorical data, a logistic regression analysis with treatment, geographic region, and prior biologic CD therapy (prior biologic experience of the patient) as factors was used with treatment, geographic region, and prior biologic CD therapy (prior biologic experience of the patient) as factors.

RESULTS: At Week 12, the percent change from BL in hsCRP was significantly greater in all miki groups compared to PBO (PBO: 0.0 [13.0%, 13.2%]; 200 mg miki: 13.0%, 200 mg miki: 28.6%, 600 mg miki: 33.3%, 1000 mg miki: 40.8% P < 0.05; FCP, 250 mg/kg miki: 0.0 [6.7%, 8.3%]; 200 mg miki: 14.3%, 250 mg/kg miki: 25.9%, 600 mg miki: 35.4%, 1000 mg miki: 40.8% P < 0.05; 1000 mg miki: 40.8% P < 0.05). The percentage of patients with normalized CRP (≤ 3 mg/L) or FCP (≤ 250, 100, and 50 mg/kg) levels was significantly higher after miki treatment compared to PBO, with the highest proportion of patients in the 1000 mg miki group (CRP: PBO 93%, 200 mg miki 4% mg/kg 6.7%, 600 mg miki 5.9%, 1000 mg miki 3.3%; P < 0.05; FCP: 250 mg/kg cutoff: PBO 13.0%, 200 mg 28.6%, 600 mg 33.3% P < 0.01, 1000 mg 40.8% P < 0.05).

CONCLUSION: The significant and dose dependent decrease of levels of hsCRP and FCP with miki treatment compared to PBO is consistent with results of clinical and endoscopic parameters and demonstrates the anti-inflammatory activity of miki. Notably, substantial proportions of patients had levels in a range observed in healthy subjects. [1] Dhaenens, et al. Inflamm Bowel Dis. 2012; 18: 2218–2224.