subpopulations in which to employ various dosing strategies of ustekinumab for chronic pouch disorders.

P029

Left Ocular Mysitis in a Patient with Crohn’s Disease in Remission with Vedolizumab

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CASE: Introduction. Ocular myositis (OM) is a rare ocular extra-intestinal manifestation (EIM) of inflammatory bowel disease (IBD). It can present with a myriad of ophthalmologic symptoms including pain and swelling due to acute or recurrent inflammation of one or more extraocular muscles. We present the case of a young female with Crohn’s disease (CD) who developed OM.

CASE DESCRIPTION: A 26-year-old female with a three year history of inflammatory bowel disease (IBD), ileal, Crohn’s disease, currently controlled on vedolizumab, presented with two days of left eye swelling, pain, and difficulty with extraocular movements associated with nausea. She was initially seen by ophthalmology who prescribed topical prednisolone drops for presumed anterior uveitis, but her symptoms continued to progress and she presented to the hospital. Labs including ESR and CRP were normal. MRI of orbits showed abnormal signal and enhancement of the left medial rectus muscle consistent with inflammatory myositis. She started on pulse IV steroids with marked improvement by the next day. Workup for sarcoidosis, LGE disease, and Grave’s disease was negative. Oral steroids were continued on discharge with repeat MRI 4 months later showing near resolution of her orbital inflammation, but she still continued to endorse persistent pain in her left eye requiring steroid therapy. Throughout this course, she had no additional gastrointestinal complaints, febrile, or laboratory abnormality. MR Imaging showed minimal MRI enhancement on fat-suppressed T1 weighted imaging. ER Imaging performed with biopsies did not demonstrate any active disease, consistent with remission of CD. Given her persistent ocular symptoms and inability to wean off steroid therapy, 6-mercaptopurine was added to the gut-specific agent vedolizumab as a steroid-sparing agent to control the exacerbation of her Crohn’s disease. Anti-TNF agents were not chosen since the patient had a history of primary non-response to inlimumab.

DISCUSSION: Although ocular extra-intestinal manifestations including episcleritis and uveitis can present in up to 10% of patients with IBD, OM is very rare and has only been described in isolated case reports. Data shows a predominance in females and a higher incidence in CD than ulcerative colitis. Symptoms can vary, and include orbital pain, swelling, diplopia, and ophthalmoplegia. OM appears to be independent from bowel inflammation in the majority of cases, and can precede gastrointestinal symptoms or present during remission of CD. The pathophysiology is not yet fully understood, though proposed mechanisms include a complex formation due to cross-reactivity between colonic mucroproteins and extraocular muscles. Diagnosis is best established by MRI, which shows characteristic hyperintensive and contrast enhancement of the involved muscle. The first line treatment is high-dose systemic steroid therapy, which, while effective in the short term, may result in rapid recurrence of incidence of recurrence, long-term therapy is essential though can be challenging given limited data for effective agents. Literature review shows antimalabites can be a safe and effective steroid-sparing treatment. Although there is limited data for the newer biologic therapies, anti-TNF agents have been historically used with success. An individualized approach to treatment is necessary, with consideration of prior biologic exposure as well as adverse effects.

P030

Ozanimod Efficacy, Safety, and Histology in Patients with Moderate-to-Severe Ulcerative Colitis During Maintenance in the Phase 3 True North Study


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BACKGROUND: Ozanimod is a sphingosine-1-phosphate receptor subtype 1 (S1P) modulator that has demonstrated safety and efficacy in patients with moderate-to-severe ulcerative colitis (UC) in the randomized, placebo-controlled, phase 2 TOUCHSTONE study (NCT01647516). This analysis presents data from the extension period of TOUCHSTONE, with ≥4 years of follow-up.

METHODS: Patients in TOUCHSTONE received placebo or ozanimod (0.5 mg or 1 mg daily) during the 8-week induction and 24-week maintenance periods and could enter the optional open-label extension (OLE) with ozanimod 1 mg/day if they were nonresponders at the end of the induction period, lost response during the maintenance period, or completed the maintenance period. Eligible patients entered the OLE between May 2015, March 2015. In 2019, the OLE was ended and all active patients who consented rolled over to a phase 3 program. During the OLE, patients were followed for safety and efficacy at weeks 4, 8, 12, and 12-week intervals thereafter. Partial Mayo score (pMS, comprised of stool frequency, rectal bleeding, and physician’s global assessment subscores) was assessed at all visits. Endoscopy was performed approximately annually in patient subsets, mainly at OLE weeks 56 and 104 per protocol amendments; total Mayo score (MS, including pMS subscores plus endoscopic), endoscopic improvement (endoscopic subscore of ≤1), and histologic remission (Gebes score 1). Biomarkers of disease activity were assessed (C-reactive protein [CRP], all visits; fecal calprotectin [FCP], OLE week 8, end of study).

RESULTS: Of 170 patients entering the OLE, 123 (72%), 102 (60%), 84 (49%), and 71 (42%) completed OLE weeks 56, 104, 152, and 200, respectively. Using non-responder imputation (NRI) for missing data, pMS clinical response and remission rates at week 56 were 71% and 55%, and 41% and 37%, respectively, at week 200. IMS clinical response and remission rates (observed case analysis) were 68% and 41%, respectively, at week 104. CRP ≤2 mg/L and pMS decreased substantially over time, plateauing at 1 treatment-emergent adverse events (TEAEs) were UC flare (4%), anemia (1%), and ischemic stroke (1%); no serious TEAEs of cardiac arrhythmias or macular edema were reported.

CONCLUSION: Data from the TOUCHSTONE OLE demonstrate durable efficacy by clinical, endoscopic histologic, and biomarker measures with ozanimod 1 mg/day. No new safety risks were identified with ≥4 years of follow-up.

P032

The Symptomatic and Psychological Impacts of COVID-19 Outbreak on IBD Patients - A Patient Survey in a Tertiary Referral Center

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BACKGROUND: The Worldwide Health Organization declared COVID-19 a pandemic in March 2020. It has been presumed that immunosuppressed people, including Inflammatory Bowel Disease (IBD) patients, are more vulnerable to contracting infection. Additionally, the pandemic is expected to increase levels of fear and anxiety among people due to knowledge gaps and persistent social isolation. However, the effect of COVID-19 on IBD patients remains unknown. We hypothesized COVID-19 would have negative psychological impacts on IBD patients, who are already burdened with symptoms of IBD.

METHODS: After obtaining IRB approval, we identified IBD patients with at least one clinic visit at MUSC IBD Center in the past 5 years and invited them to participate in a brief anonymous survey via REDCAP.

RESULTS: We invited 1504 eligible patients and received 502 responses (Crohn’s disease [CD] = 331, ulcerative colitis [UC] = 140) from June to July 2020. A total of 238 (72%) CD patients and 88 (63%) UC patients felt more anxious since the outbreak and had a significantly higher rate of symptom worsening compared to patients who were not anxious (32% vs 8%, P = 0.052). Additionally, many (79% CD and 68% UC) patients were worried they were more vulnerable to COVID-19 infection, but only approximately half (54% CD and 42% UC) discussed their concerns with their health care providers (HCP). Patients who discussed their concerns had a higher rate of feeling supported compared to those who did not (92% vs 79%, N = 484, P < 0.05). Interestingly,
During the 12-month follow up period: anti-TNF agent change, anti-TNF discontinuation, escalation of anti-TNF dose, or reduction of anti-TNF dose. Logistic regression was used to identify any associations between baseline characteristics and composite persistence, as well as to compare treatments using certolizumab pegol as the reference value.

RESULTS: For the 4,265 anti-TNF naïve patients, the initial therapy consisted of 54% infliximab, 43% adalimumab, and 3% certolizumab pegol. Composite persistence was 67% for infliximab, 57% for adalimumab, and 52% for certolizumab pegol (P < 0.0001). After adjusting for other model covariates, patients treated with infliximab had a significant increase in composite persistence (P = 0.0001), while differences in composite persistence were not significantly different for adalimumab. For the 880 patients switching anti-TNF agent, 41% switched to infliximab, 36% to adalimumab, 20% to certolizumab pegol, and 3% to other agents. The composite persistence in patients switching agents was lower than that observed in treatment-naïve patients. Composite persistence was not significantly different between the groups (adalimumab 53%, certolizumab pegol 50%, infliximab 45%, other agents 42%, P = 0.1581). After adjusting for other model covariates, patients switching to adalimumab had an increase in persistence (P = 0.0423). Differences in persistence were not significant when switching to infliximab.

CONCLUSION: Composite persistence, as defined by stable and continuing anti-TNF therapy, was lower after 1 year across all sub-populations. No single agent provided consistently higher composite persistence in both treatment-naïve and treatment-experienced patients.

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Rates of Anti-TNF Drug Persistence in Patients with Crohn's Disease
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BACKGROUND: Crohn's disease (CD) is an inflammatory bowel disease with steadily increasing incidence over the past several decades. Three anti-tumor necrosis factor (TNF) agents (infliximab, adalimumab, and certolizumab pegol) have demonstrated efficacy in treatment of patients with moderate to severe CD who inadequately respond to treatment with corticosteroids, thiopurines, and/or methotrexate. The aim of this study was to determine differences in persistence for 2 sub-populations of patients with CD treated with anti-TNF agents: anti-TNF naïve patients, and patients switching to another agent.

METHODS: The study population for this retrospective analysis was drawn from real world administrative claims data for patients enrolled in Medicare or commercial regional health plans from January 1, 2010 to September 30, 2018 with a diagnosis for CD and at least one pharmacy or medical claim for a TNF agent in the treatment of CD. Excluded were patients with 12 months of baseline data with no anti-TNF treatment were considered anti-TNF naïve and assigned an index date of the first medical or pharmacy claim for an anti-TNF agent. Patients with claims for 2 or more anti-TNF agents during the claim’s evaluation window were considered anti-TNF experienced patients and assigned an index date of the first pharmacy claim or pharmacy claim prior to the anti-TNF agent than previously observed. Both sub-populations were followed for 12 months beginning on the index date. Study groups were assigned based on the anti-TNF agent used on the index date. A composite outcome of persistence was defined as patients without any of the following outcomes: discontinuation of anti-TNF therapy, change in anti-TNF therapy, escalation in anti-TNF dose, or reduction in anti-TNF dose. The composite outcome was defined as an important clinical measure of successful treatment.

RESULTS: A composite outcome of persistence was observed in 63% of anti-TNF naïve patients on anti-TNF drug persistence in patients with moderate to severe CD, with the highest rate of persistence observed in patients who initiated infliximab. Infliximab, adalimumab, and certolizumab pegol showed significantly higher rates of persistence compared to patients with no prior anti-TNF Naïve exposure. Rates of anti-TNF drug persistence were 57% for infliximab, 51% for adalimumab, and 42% for certolizumab pegol, with the infliximab group showing a statistically significant increase in persistence compared to adalimumab and certolizumab pegol (P = 0.0002 and P = 0.0013, respectively). Rates of persistence were also significantly higher for patients who received infliximab as their first anti-TNF agent compared to those who switched from another TNF agent (P = 0.0002). In patients who switched to another TNF agent, persistence rates were 51% for adalimumab and 42% for certolizumab pegol, with no significant difference in persistence between these groups.

CONCLUSIONS: Rates of persistence for anti-TNF drug therapies in patients with CD were high, with the highest rates observed in patients who initiated infliximab. Infliximab showed significantly higher rates of persistence compared to adalimumab and certolizumab pegol. Infliximab also showed a statistically significant increase in persistence compared to adalimumab and certolizumab pegol in patients who switched from another TNF agent. These findings are important for understanding the persistence of anti-TNF therapy in patients with CD and may inform clinicians on the best initial choice of anti-TNF therapy for individual patients.