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Left Orbital Myositis in a Patient with Crohn's Disease in Remission with Vedolizumab

Duanzhe Sun1, Fangjuan Gao1, Huanan Song1, Wei Li1, Lijun Zhang1, Xingyu Lu2, Lin Zhang1, Juan Liu1

1. Department of Gastroenterology, Guangzhou First People's Hospital, Guangzhou, China; 2. Department of Ophthalmology, Guangzhou Eye Hospital, Guangzhou, China.

CASE: Introduction. Orbital 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 extramuscular vessels. 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, ileal, Crohn's disease, currently controlled on vedolizumab, presented with two days of left eye pain, swelling, and difficulty with extraocular movements associated with nausea. She was initially seen by optometry 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 was started on pulse IV steroids with marked improvement by the next day. Workup for sarcoidosis, LGD disease, and Graves'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, she had no additional gastrointestinal complaints, fecal blood loss, or more than moderate inflammatory bowel disease activity on mg-CT Enterography. ER Enteroscopy was unremarkable and fluoro-oscopy performed with biopsies did not demonstrate any active disease, all 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 development of her Crohn's disease. Anti-TNF agents were not chosen since the patient had a history of primary non-response to infliximab.

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 clearly understood, though proposed mechanisms include immune complex formation due to cross-reactivity between colonic mucoproteins and extramuscular muscles. Diagnosis is best established by MRI, which shows characteristic hypersignal and contrast enhancement of the involved muscle. The first line treatment is high dose systemic steroids. Orally administered oxymetholone, which leads to symptoms in 3-4 days and a decrease in incidence of recurrence, long-term therapy is essential as there is no standard treatment that can be challenging given limited data for effective agents. Literature review shows antimetabolites 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

Daniele Sibilia1, Feagon Brian2, Hannahar Stephen3, Ivanovic Igor4, Ghosh Subrata5, Peterson AnnKatrin6, Hsu Steven7, Lee Ji Hwan8, Charles Longa9, Chikha Dendah10, Sanborn William11, D'Haens Greer12


METHODS: Patients in TOUCHSTONE received placebo or ozanimod (0.5 mg or 1 mg daily) for 12 weeks, followed by 24-week maintenance periods and could enter the optional open-label extension (OLE) with ozanimod 1 mg/day if they were non-responders 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 extended to all active patients who consented to roll 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 subscore) was assessed at all visits. Endoscopy was performed approximately annually in patient subsets, mainly at OLE weeks 56 and 104 for protocol amendments; total Mayo score (IMS, including pMS subscores plus endoscopy), endoscopic improvement (endoscopic subscore of ≤1), and histologic remission (Gebauer 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%) were in clinical remission (remission at week 52 for patients who were in remission at week 10), mucosal healing (endoscopic improvement plus histological remission), and durable clinical remission (remission at week 52 for patients who were in remission at week 10), respectively. Week 52 pMS clinical response and remission rates (observed case analysis) were 86%, 72%, 65%, and 53%, respectively, at week 104. ORI 82% and pMS showed a tendency to improve 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.

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

Feong Minjun1, Stone Mohy2, Forster Erin1

1. The J. Thomas Bell, Medical University of South Carolina, Charleston, United States. 2. United States.

BACKGROUND: The World 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 and symptomatic impacts on IBD patients.

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] 334, 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%, N = 502, P < 0.05). Additionally, 92% (79% CD and 82% UC) patients 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 78%, N = 484, P < 0.05).

Interestingly,