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

P029

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

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CASE: Introduction. Ocular myositidis (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 extracocular 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, 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 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 started on pulse dose IV steroids with marked improvement by the next day. Workup for sarcoidosis, LGD 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 case, she had no additional gastrointestinal complaints, fecal blood, or weight loss. MR Imaging of her orbit was unremarkable and fluoro-luminescoscopy 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 EIM 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 oculus extra-intestinal manifestations including episcleritis and uveitis can present in up to 10% of patients with IBs, 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 well understood, though pro-inflammatory cytokines and abnormal complex formation due to cross-reactivity between colonic mucoproteins and extracocular muscles. Diagnosis is best established by MRI, which shows characteristic hyperintensity and contrast enhancement of the involved muscle. The first line treatment is high-dose systemic steroids, with methotrexate, which leads to symptomatic improvement. The incidence of recurrence, long-term therapy is essential though it 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 History in Patients with Moderate-to-Severe Ulcerative Colitis During Maintenance in the Phase 3 True North Study

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BACKGROUND: Oxanimod is a potent, selective, sphingosine-1-phosphate receptor subtype 1 agonist (S1P1), which is currently approved for the treatment of relapsing-remitting multiple sclerosis. This is a real-world open-label extension of the phase 2 TOUCHSTONE study (NCT02167451), which included patients with moderate-to-severe UC who achieved clinical remission with ozanimod 1 mg/day. To further evaluate efficacy and safety of ozanimod, we report results from a multi-center real-world study in patients with UC who achieved clinical remission on ozanimod 1 mg/day.

METHODS: We conducted an open-label extension study of patients with moderate-to-severe UC who achieved clinical remission on ozanimod 1 mg/day. Patients who entered the open-label extension (OLE) with ozanimod 1 mg/day were re-randomized in a 1:1 double-blind manner to double-blind main-tenance treatment with ozanimod 1 mg/day or matching placebo. Additional patients who responded to ozanimod during induction were re-randomized in a 1:1 double-blind manner to double-blind maintenance treatment with ozanimod 1 mg/day or matching placebo after 8 weeks of induction therapy. All patients received ozanimod 1 mg/day for up to 32 weeks in advance of re-randomization. Through the OLE study, a total of 457 patients who responded to ozanimod during induction were re-randomized to double-blind maintenance treatment with either ozanimod (n = 230) or placebo (n = 227), of which, 80.0% and 54.6%, respectively, completed the study. For the primary endpoint, 37.0% and 18.5% of patients in the ozanimod and placebo groups, respectively, achieved clinical remission (difference, 18.6% [95% CI, 10.8-26.4]; P < 0.0001). All key secondary endpoints were statistically significant for ozanimod vs placebo (P < 0.005 for all). In addition, a significantly greater proportion of patients achieved histologic remission with ozanimod (defined as Geboes <2, 33.5% vs 16.3%; Geboes 0-1, 53.2% vs 22.3%; P < 0.0001 for all). In patients with prior TNFi exposure, the proportions of patients achieving clinical remission (28.9% vs 10.1%) and clinical response (35.3% vs 24.6%) were greater for ozanimod vs placebo (P < 0.001 for both). The most common treatment-emergent adverse events (TEAEs) for patients who received ozanimod vs placebo, respectively, were increases in alanine aminotransferase (4.8% vs 0.4%) and headache (3.5% vs 0.4%). The most common serious TEAE was flare of UC (0.4% vs 4.0%).

CONCLUSION: Ozanimod for up to 52 weeks in patients with moderately-to-severely active UC showed benefit on clinical, endoscopic, histologic, and mucosal healing endpoints. Significantly more patients achieved clinical and histologic remission with ozanimod maintenance therapy vs placebo. No new safety signals were observed.