CLINICAL REPORT: ASFJ, 15 years old, male, obese, admitted to the Pediatric ward due to suppurative and painful buttock injuries, started two years ago, coinciding with the onset of puberty, with periods of improvement and worsening. Patient reported occasional diarrhea with 4 bowel movements a day, without mentioning blood or mucus. There was no growth of germs in the cultures performed. Therapy employed did not improve the condition. The patient underwent biopsy of the lesions, which showed granuloma sketches (no necrosis, no foreign body granuloma characteristics), suggesting a cutaneous manifestation of Crohn’s disease. Computed tomography (CT) with enterotomography visualization pattern without evidence of lesions. Colonoscopy showed no alterations and serial biopsies did not indicate acute inflammatory symptoms. Anorectal ultrasonography showed complex fistulas in the upper, middle and lower anal canal, suggesting perineal aggression secondary to CD. In a joint decision between gastroenterologists, pediatricians, dermatologists and coloproctologists, it was decided to introduce Adalimumab, but with slight improvement. Symptoms became more exuberant after two months, with extensive involvement of the perineum and buttocks, with apparent secondary bacterial infection. Proceeding with new hospitalization, antibiotic therapy (ciprofloxacin and clindamycin) and new biopsies, which this time also showed foreign body granulomas, suggestive of SH. Patient had significant improvement of symptoms with antibiotic therapy for 3 months, associated with corticotherapy. Adalimumab was prescribed after antimicrobial therapy to reduce infectious risk.

DISCUSSION: The differential diagnosis between perianal CD and SH is a challenge, often delaying treatment. Although SH is admitted by EIM of CD, association in this disease phenotype is rare, as demonstrated by the study by Kamal N. (2016), where the association of CD and SH was investigated over a 10-year period, and only found 15 patients where 73% had perianal CD. Biological anti-TNF therapy may be effective, although many cases still require surgical intervention. In the case of undiagnosed SH, immunosuppressive therapies may aggravate a subclinical infectious process existing to the patient a poor clinical outcome, as in the case presented. Multidisciplinary assessment is critical and patient revaluations should be early, especially in pediatric patients where the disease may cause functional and psychological impairment.

P078

Obstructive Giant Inflammatory Polyp as a Manifestation of Crohn’s Disease

Rodrigo Ramírez del Pilar1, Tomas Cortes Espinosa2, Jesús Lópezm Gómez2, David1, Reinisch Walter2, Greuter Thomas3, Vavricka Stephen4, Kotze Paulo Gustavo5, with hyperplasia of the muscular layer and granulomatous non-casing lesions consistent with the cavity, and no signs of intestinal perforation. The histopathology report was chronic transmural IBD rectosigmoid colon. There was also a formation of a pericolonic abscess draining to the abdominal the intestinal lumen, and therefore the main di exploratory laparotomy was performed with Dilatation of intestinal loops and hydro-aerial levels were noted in the abdominal radiography. An Anorectal ultrasonography showed complex...

P079

Real-World Prescribing Patterns of Certolizumab in the Treatment of Crohn’s Disease

Timothée Riffet1, Chris Fourment2, Samantha Kater3, Lucinda Van Angelen4, 1Texas Digestive Disease Consultants, Southlake, TX; 2Hailix Infusion Therapy, Sugar Land, TX.

BACKGROUND: Certolizumab (CZP) is a pegylated anti-tumor necrosis factor (TNF) agent approved for the treatment of moderate-to-severe Crohn’s disease (CD). CZP therapy has proven effective and well-tolerated for biologic-naive patients, as well as anti-TNF-experienced patients with secondary non-response or intolerance. CZP is also the preferred anti-TNF during pregnancy. We sought to describe real-world prescribing patterns of CZP in the treatment of CD.

METHODS: We performed a retrospective cohort study of CD patients treated with CZP at a large multicenter gastroenterology private practice since drug approval in 2014. Data collection included demographics, diagnosis, treatment history, and reason for CZP use. CZP use was classified as one of the following: first-line anti-TNF, prior anti-TNF non-response or intolerance, payer requirements, and/or pregnancy considerations.

RESULTS: A total of 59 patients receiving CZP for the treatment of CD were identified. Mean age was 48 ± 16.1 years and 42 (71%) were female. Median CZP treatment duration was 26 [IQR 9-59] months. Forty-four (78%) patients had private insurance, 12 (20%) were enrolled in Medicare or Medicaid, and 1 was uninsured. Nine (15%) patients were bio-naive. Of the 50 (85%) biologic-experienced patients, 22 were previously treated with 1 agent, 23 received 2 previous agents, and 5 patients received 3 or more previous agents. Reasons for CZP use were as follows: prior anti-TNF non-response (75%), pregnancy considerations in 8 (14%), payer requirements or cost considerations in 6 (10%), first-line anti-TNF use in 4 (7%), and other reasons in 2 (3%). To date, 26 (44%) patients remain on CZP with a median treatment duration of 48 [IQR 31-59] months.

CONCLUSION(S): We described real-world utilization of CZP. In our cohort, CZP was most commonly prescribed to biologic-experienced patients with prior anti-TNF non-response or intolerance.

P080

Extraintestinal Manifestations at Baseline, and Effect of Tofacitinib in Patients With Moderate to Severe Ulcerative Colitis in the OCTAVE Program

Rubin David1, Reinsch Walter2, Greuter Thomas3, Vavricka Stephen4, Kotze Paulo Gustavo5, Pinheiro Maciá1, Pan Haiyun7, Maller Eric2, Fellmann Marc3, Lawendy Norwin4, Modesto Irene5, Lichtenstein Gary6, 1University of Chicago Medicine, Chicago, IL; 2Medical University of Vienna, Vienna; 3University Hospital Zurich, Zurich; 4Zentrum für Gastroenterologie und Hepatologie AG, Zurich; 5Catholic University of Pará, Cuiabá, Brazil; 6Pfizer Inc, São Paulo, Brazil; 7Pfizer Inc, Collégialle, PA.

BACKGROUND: Extraintestinal manifestations (EIMs) occur in approximately one-third of patients with ulcerative colitis (UC) (1). Tofacitinib is an oral, small molecule JAK inhibitor for the treatment of UC. The effect of tofacitinib on EIMs is currently unknown. We explore whether tofacitinib treatment impacts EIMs in patients with moderate to severe UC enrolled in the Phase 3 OCTAVE clinical program.

METHODS: We report data from three double-blind, placebo-controlled, Phase 3 studies in patients with moderate to severe UC: two 8-week induction studies (tofacitinib 10 mg twice daily [BID] on placebo, OCTAVE Induction 1&2, NCT01465763 and NCT01458951) and a 52-week maintenance study (tofacitinib 5 or 10 mg BID or placebo, OCTAVE Sustain, NCT01458574). The frequency and proportion of pre-defined quiescent prior and active EIMs at baseline, and the change from baseline in EIMs at the end of the treatment period (Week 8 or Week 52), or at early termination, were evaluated in patients with non-missing data.

RESULTS: Overall, 1139 and 592 patients were randomized into OCTAVE Induction 1&2 and Sustain, of which 27.0% and 9.0% had a history of quiescent prior or active EIMs, respectively. At Week 8 of OCTAVE Induction 1&2, 4.6% of tofacitinib-treated patients experienced a change (improvement, worsening, or new occurrence) from baseline in EIMs. At Week 52 of OCTAVE Sustain, 4.6%, 3.1%, and 7.3% of patients in the tofacitinib 5 mg BID, tofacitinib 10 mg BID, and placebo groups experienced a change from Sustain baseline in EIMs, respectively. The most frequent active EIMs at Induction baseline were peripheral arthritis (11.2% of patients [127/1135]), sacroiliitis (1.0% of patients [11/1135]), and ulcer ophthalmia/trantasoma (0.5% of patients [7/1535]). In OCTAVE Induction 1&2, similar proportions of patients in each treatment group with active baseline peripheral arthritis experienced no change (tofacitinib 10 mg BID, 78/96 [81.3%]; placebo, 24/28 [85.7%]) or an improvement (13/96 [13.6%] and 4/28 [14.3%, respectively) from baseline at Week 8. The (3.3%) tofacitinib-treated patients experienced worsening of symp toms compared with no placebo-treated patients. At OCTAVE Sustain baseline, 20 patients had active peripheral arthritis. The majority of these patients experienced no change in their peripheral arthritis at Week 52 (tofacitinib 5 mg BID, 5/6 [83.3%]; tofacitinib 10 mg BID, 2/5 [46.7%]; placebo, 9/11 [81.8%]). Two tofacitinib-treated patients experienced an improvement at Week 52 (tofacitinib 5 mg BID, 1/6 [16.7%]; tofacitinib 10 mg BID, 1/3 [33.3%]) and no tofacitinib-treated patients reported a worsening of symptoms. Two placebo-treated patients (2/11 [18.2%]) reported a worsening of symptoms and none reported improvement.

CONCLUSION(S): In OCTAVE Induction 1&2 and OCTAVE Sustain, 27.0% and 9.0% of patients experienced EIMs at baseline, respectively. The most common active EIM was peripheral arthritis, for which the majority of patients in Induction and Sustain reported either no change or improvement from baseline. These post-hoc analyses should be interpreted with caution; they limited by low patient numbers and collection of data via a predefined EIM list which did not include a specific arthralgia category (or arthralgia may have been recorded as peripheral arthritis). Additional studies are required.