prior to the index, with a mean total daily supply of 102.5 days (1 biologic) and 113.0 days (2 biologics). Among OCS users during baseline, the average prednisone-equivalent daily dose was 32.5 mg (1 biologic cohort) and 29.3 mg (2 biologics cohort). Use of OCS decreased to 25% (1 biologic cohort) and 23% (2 biologic cohort) 6 months after TOF initiation. Mean PDC with TOF over the first 6 months follow-up was 0.74 in both cohorts with median PDC of 0.89 (1 biologic) and 0.82 (2 biologic).

CONCLUSION: Among UC patients starting TOF in a real-world cohort, half had been exposed to 2 or more biologics. Post-initiation adherence was generally high and OCS utilization decreased regardless of the number of previous biologics. These findings provide insights into early real-world utilization and experience with a new therapeutic for moderate to severe UC.

PO22

Utilization Patterns of Infliximab Originator vs Infliximab Biosimilar in US Veterans

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BACKGROUND: The study objective was to describe utilization of infliximab (IFX) products, including the infliximab originator Remicade (IFX-origin) and biosimilars Inflectra (IFX-dyyb), and Ben Felix (IFX-abda), during a 6-month follow-up period. METHODS: Data were collected from national Veterans Affairs (VA) administrative and electronic medical record datasets between September 1, 2016 to December 31, 2019. The index date was the first infliximab biosimilar dispensation date from the study period. Veterans were required to be enrolled in the VA for >60 days prior to their index date. Veterans were sub-grouped according to their history of infliximab exposure prior to the index date (IFX-origin or IFX-experienced) and disease indication (Crohn’s Disease (CD), Ulcerative Colitis (UC), Rheumatoid Arthritis (RA), Ankylosing Spondylitis (AS), Psoriatic Arthritis (PsA), Psoriasis (PsO), and Others). The distribution of patients on each IFX product was assessed over time. Persistence on the index product and proportion of patients switching to a different IFX product were determined. Other measures of IFX utilization included the average age-weighted base, cumulative dose, the number of dispensed doses, and proportion of doses covered (PDC).

RESULTS: Among 5,227 veterans, the mean age was 54.5 (95% CI: 53.6-55.4) years and 88.4% (87.6-89.2) were male. 72% (71.6-73.2) had a degree beyond high school. Among 4,027 respondents, 63% (61.8-64.6) were employed. For the 3,080 respondents with income data, 42% (40.8-43.9) earned ≤$10,000, 16% (14.9-17.7) earned between $10,001 and $20,000, 23% (21.7-24.8) earned between $20,001 and $30,000, and 13% (11.9-14.7) reported having an income of more than $30,000. The average annual income was $17,000. 51% of patients reported having lost work time due to IBD.

CONCLUSION: The results of the study suggest that the Puerto Rican IBD cohort is a diverse one in terms of level of education and income. Compared to the general Puerto Rican population for 2017, unemployed and unemployed IBD patients have an almost identical level of education, showing no remarkable difference. Unemployed patients with a degree beyond high school account for 47%, roughly equal to the general population at 46%, and unemployed patients with high school or a lower level constitute 33%, compared to 54% of the general population. Employed patients with a degree beyond high school represent 42%, native to 64% of the general population, and employed patients with high school or a lower level amount to 33%, compared to 36% of the general population. Yearly income in IBD patients is varied. Nonetheless, there is an evident difference amongst the patients and the general population. The average yearly income of the general population was $27,532, as opposed to $17,000 for the IBD cohort. The noticeable difference of $10,532, coupled with the number of patients that reported having work time lost due to IBD, may signify a disparity in the labor setting, compared to the general population.

PO24

Medical Decision Support System in the Diagnosis of Ulcerative Colitis

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BACKGROUND: An increase in the number of patients with ulcerative colitis (UC) occurs with a change in the modern lifestyle and is referred to as the “westernization” of lifestyle and nutrition. The aim of the study was to develop a model for supporting medical decisions in the diagnosis of UC, based on a set of anamnestic signs. METHODS: A survey was conducted in the form of an interview after receiving informed consent of respondents. The questions of the survey were combined according to the following characteristics: Type of work and occupational hazards, Lifestyle, Nutritional factors. The sample consisted of 81 patients (42 men and 39 women) aged from 18 to 79 years. A comparison was carried out between the control group of healthy respondents comparable in age (U = 13,38, P = 0.1760) and gender (2I = 0.0037) and the group of patients with UC. The control group consisted of 39 healthy individuals (14 men and 25 women) aged from 22 to 77 years. The median age of respondents in the process. After we obtained binary choice models for each of the groups and determined the clipping regions, we calculated type 1 and 2 errors. The clipping region for each model was selected individually. We built a general model in the form of a neural network.

RESULTS: We identified no variables among the markers of the “hygiene hypothesis” and medication intake that could influence the occurrence of UC. After removing insignificant variables from the model of “psychological stress”, the statements “Perhaps I am a nervous person” (coefficient -0.296901; variable 0.0041) and “Connection between illness and the stressful condition” (coefficient 0.683475; variable 0.0000) became significant. In the model “Nut- rition factors”, the significant variables were “Regular consumption of spicy food” (coefficient 0.188398; variable 0.0060). “Excessive consumption of sugar with tea and coffee” (coefficient 0.483434; variable 0.0002), “Insufficient consumption of vegetables daily” (coefficient -0.006935; variable 0.0001) and “Poor milk tolerance” (coefficient 0.825448; variable 0.0013). In the model “Type of work and occupational hazards”, the significant variables were “Occupational employment” (coefficient 1.825389; variable 0.0000) and “Occupational employment” (coefficient 2.608838; variable 0.0000). The last level also went through the procedure for building a binary choice model. The models “Type of labor and occupational hazards” (coefficient 1.492367; variable 0.0010) and “Psychological stress” (coefficient -1.825389; variable 0.0000) turned out to be significant.

CONCLUSION: We developed a model to support medical decisions based on a set of anamnestic data, which improves the efficiency of the UC diagnosis.

PO25

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


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BACKGROUND: Ozanimod is an oral sphingosine-1-phosphate (SIP) receptor modulator that selectively targets S1P1 and S1P3. Ozanimod has previously demonstrated efficacy and safety in patients with ulcerative colitis (UC) in a phase 2 study (TOUCHSTONE). Here we report data from a 10-week induction period in the phase 3, double-blind, True North study (NCT02435992). The aim of this study was to evaluate the efficacy and safety of ozanimod in inducing and maintaining remission in patients with moderate-to-severe UC. Results from the maintenance period are reported separately.

CONCLUSION: Ozanimod was well tolerated and demonstrated efficacy and safety in patients with ulcerative colitis (UC) in a phase 2 study (TOUCHSTONE). Here we report data from a 10-week induction period in the phase 3, double-blind, True North study (NCT02435992). The aim of this study was to evaluate the efficacy and safety of ozanimod in inducing and maintaining remission in patients with moderate-to-severe UC. Results from the maintenance period are reported separately.
METHODS: Adults with moderately-to-severely active UC (total Mayo score 6-12 with a Mayo subscore ≥2 and on oral aminosalicylates or corticosteroids) were randomized to 2:1 to receive oral ozanimod (1 mg equivalent to ozanimod 0.92 mg) or placebo once daily during a 10-week randomized induction period. Randomization was stratified by prior tumor necrosis factor inhibitor (TNFi) use at screening and by disease location (rectal, ileal, or ileocolonic). The primary outcome was the proportion of patients in clinical remission using the 3-component Mayo score (rectal bleeding score = 0, stool frequency score ≤1 and decrease from baseline ≤1, and endoscopy subscore ≤1) at week 5. Ranked key secondary endpoints were proportions of patients with clinical response (based on 3-component Mayo score), endoscopic improvement (Mayo endoscopic subscore ≤1 without friability), and mucosal healing (endoscopic improvement plus histological remission).

Histologic remission was a pre-specified secondary (non-ranked) endpoint. RESULTS: A total of 645 patients were randomized to receive ozanimod (n = 429) or placebo (n = 216). 94% and 97% of patients completed the induction period in the ozanimod and placebo groups, respectively, achieved clinical remission (difference, 12.4% [95% CI 7.3-17.5]; P = <0.0001). All key secondary efficacy endpoints showed statistically greater improvements with ozanimod vs placebo. Clinical response was achieved in 47.8% vs 25.9%, endoscopic improvement in 27.3% vs 11.6%, and mucosal healing in 12.8% vs 3.6% for ozanimod vs placebo (all P < 0.001). A significantly greater proportion of patients achieved histologic remission with ozanimod (defined as Geboes ≤2, 18.2% vs 7.4%; Geboes ≤1, 34.7% vs 18.3%; and Geboes ≤1, 26.3% vs 11.1% for ozanimod vs placebo, respectively; P < 0.001 for all). In patients with prior TNFi exposure, the proportion of patients achieving clinical remission favored ozanimod but was not significant vs placebo (100% vs 46.4%, P = 0.395), while the proportion of patients with clinical response was statistically superior for ozanimod (36.9% vs 18.5%, P = 0.008) at week 10. The most common treatment-emergent adverse events (TEAEs) for patients who received ozanimod vs placebo, respectively, were anemia (4.2% vs 5.6%), nasopharyngitis (3.5% vs 1.4%), and headache (3.9% vs 1.9%). Cardiovascular events were infrequent and included bradycardia (0.5% vs 0%) and hypertension (1.4% vs 0%). Serious TEAEs occurred in 4.0% vs 3.2%, respectively. Serious infections occurred in <1% per group.

CONCLUSION: Ozanimod induction for 10 weeks in patients with moderate-to-severe UC resulted in statistically significant improvements in clinical remission, clinical response, endoscopic improvement, mucosal healing, and histologic remission. Ozanimod was well tolerated and no new safety signals were observed.

P026
Assessment of Contributing Factors for Fistula Development in Patients with Inflammatory Bowel Disease Treated by Proctocolectomy with Ileal Pouch-Anal Anastomosis

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BACKGROUND: In patients with inflammatory bowel disease (IBD), surgical intervention is sometimes required due to medically refractory colitis or the development of neoplasia, and restorative proctocolectomy with ileal pouch-anal anastomosis (IPAA) is the most common procedure of last resort. Deep inflammatory and granulomatous changes thought to be unique features of CD. Deep inflammation included ulcerations, fissures, and lymphoid aggregates observed below the level of the mucosa. Fishier’s test was used for univariate analysis to assess factors contributing to fistula development. Logistic regression analysis was performed as a multivariable analysis including variables with a P-value < 0.10 in the univariate analysis.

RESULTS: We reviewed 1,359 pouchoscopies from 426 IBD patients who underwent proctocolectomy with IPAA and who subsequently underwent pouchoscopies at the University of Chicago between January 2007 and December 2019. We reviewed the endoscopic findings in different anaatomic areas of the pouch (the antherliment, inlet, “tip of the J”, proximal and distal pouch, anastomosis, rectal cuff, anal canal, and perianal area). Endoscopic phenotypes were classified into 5 main categories (1) antherliment, (2) inlet involvement, (3) diffuse inflammation of the pouch body, (4) ciffits, and (5) pouch with fistulas. This analysis included pouches with any type of fistulas that developed ≥6 months after ileostomy takedown. We assessed clinical data and pathological findings of the resected colon including deep, focal inflammation, and granulomas generally thought to be unique features of CD. Deep inflammation included ulcerations, fissures, and lymphoid aggregates observed below the level of the mucosa. Fishier’s test was used for univariate analysis to assess factors contributing to fistula development. Logistic regression analysis was performed as a multivariable analysis including variables with a P-value < 0.10 in the univariate analysis.

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