Abstracts

**P021**
Utilization Patterns of Infliximab Originator to 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 Benelux (IFX-aba), during a 6-month follow-up period.

**METHODS.** We selected 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 during the study period. Veterans were required to be enrolled in the VA for ≥65 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).

**RESULTS.** The percentage of IFX users on a biosimilar increased throughout the study period. Use of OCS decreased to 25% (1 biologic 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 6-month 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.

**P022**
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 this 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; Markers of the hygiene hypothesis (presence of pets in childhood, attendance at kindergarten, breastfeeding in childhood, number of children in the family); Psychological stress; Nutritional factors. The main group consisted of 81 patients (42 men and 39 women) aged 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 (21 = 2.72, P > 0.05) and the group of patients with UC. The control group consisted of 39 healthy individuals (14 men and 25 women) aged from 22 to 59 years. The median age of patients with UC was 46.7 (28.5–52.0) years. We used the Mann-Whitney U test, and the calculation of I and statistics to describe and compare the groups. We built binary choice models in the “Eviews 11” program using the Logit-model. Variables with P values > 0.05 were excluded from the model. After the we obtained binary choice models for each of the groups and determined the clipping region, 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 -0.296621; variable 0.0041) and “Connection between illness and the suffered stress” (coefficient 0.683475; variable 0.0000) became significant. In the model “Nutrition factors,” the significant variables were “Regular consumption of spicy food” (coefficient 0.121655; variable 6.0698) and “Exact intake of sugar with tea and coffee” (coefficient 0.048343; variable 0.0022), “Insufficient consumption of vegetables daily (coefficient -0.006935; variable 0.0001) and “Poor milk tolerance” (coefficient 0.825848; variable 0.0013). In the model “Type of work and occupational hazards,” the significant variables were “Occupational employment” (coefficient 0.149237; variable 0.0010) and “Physical psychological stress” (coefficient -1.82558; 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.

**P023**
Lower Income Levels in Puerto Ricans with IBD: A Sociodemographic Characterization of a Hispanic Cohort

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**BACKGROUND.** The prevalence of Inflammatory Bowel Diseases (IBD) is rapidly increasing in Hispanics, but there is limited information regarding sociodemographic characteristics of this cohort. Factors such as education, employment status, and income may provide insight as to how the IBD population compares to the general population. In recent years, Puerto Rico has reported an increase in the prevalence of IBD. We aim to describe a Puerto Rican cohort.

**METHODS.** The study subjects were Puerto Ricans participating in EPI reconciliation, a multicenter study of IBD in Latin America. After consent, a questionnaire with sociodemographic and medical questions was administered. Variables analyzed were age, sex, IBD diagnosis, education, income, and employment status. Results were compared to the Puerto Rican Department of Labor and Human Resources 2017 statistics regarding these variables. The study was approved by the IRB.

**RESULTS.** 160 patients were recruited. The mean age was 39 years. 87 were men (54%) and 73 were women (46%). 115 patients had CD (72%) and 45 had UC (28%). 44% reported being employed, 25% were unemployed, 17% were students, and 14% were retired. 5% of patients had only elementary school education, 7% achieved middle school, 31% completed high school, and 57% obtained a degree beyond high school. For the 70 employed patients, 67% had a degree beyond high school. For the 40 unemployed patients, only 47% had obtained education beyond high school. In terms of yearly income (US$), the median income for 145 patients, excluding the 15 full-time students, 19% of patients reported having no income, 23% earned between $1,000 and $10,000, 29% had an income between $10,000 and $20,000, 36% earned between $20,001 and $30,000, and 13% reported having an income of more than $30,001. 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, employed 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% compared to 54% of the general population, and a notable number of 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 higher 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.

**P024**
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 (S1P) 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 (NCCT2433992). 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.

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METHODS: Adults with moderately-to-severely active UC (total Mayo score 6-12 with a Mayo endoscopy subscore ≥2 and on oral aminosalicylates or corticosteroids) were randomized 2:1 to receive oral azathioprine (HCl) mg (equivalent to azathioprine 0.92 mg) or placebo once daily during a 10-week randomized induction period. Randomization was stratified by prior tumor necrosis factor inhibitor (TNFi)- and infliximab use at screening. At the end of the induction period 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 10. Rank-ordered 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 azathioprine (n = 429) or placebo (n = 216). 94% and 92% of patients achieved the induction endpoint (P = 0.14 and P = 0.16, respectively) in the azathioprine 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 azathioprine 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 3.8% for azathioprine vs placebo, respectively (P < 0.001 for all). In patients with prior TNFi exposure, the proportion of patients achieving clinical remission favored azathioprine but was not significantly different vs placebo (100% vs 46.4%, P = 0.039), while the proportion of patients with clinical response was statistically superior for azathioprine (36.9% vs 18.3%, P = 0.008) at week 10. The most common treatment-emergent adverse events (TEAEs) for patients who received azathioprine vs placebo, respectively, were anaemia (4.2% vs 5.6%), nausea/vomiting (3.5% vs 1.4%), and headache (3.9% vs 1.9%). Cardiovascular events were infrequent and included bradycardia (3.9% 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: Azathioprine 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. Azathioprine 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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TARGET-IBD is a longitudinal cohort of patients receiving care at 34 community and academic practices in the United States. Patients with IBD enrolled between July 24, 2017 and August 17, 2020 were included in this analysis. To be included, patients were required to initiate a biologic drug of interest during the study period, with no biologic use in the 6 months prior to initiation. If less than 10 participants were treated with a given therapy class, they were excluded from multivariable analyses. The primary outcome was calculated as time (continuous months) from biologic therapy initiation was 4 years among patients with UC and 5 years among patients with CD; 92% of patients with UC were biologic naive, as were 74% of patients with CD. Among all 856 patients, 268 (31%) discontinued therapy during the study period. The median time to discontinuation or censoring was 10.6 months (IQR 4.1-18.6 months). In multivariable analysis patients with UC, discontinuation was less likely in patients treated with an anti-integrin (Flazzaro Ratio [HR] 0.51, 95% CI 0.30-0.86) relative to anti-tumor necrosis factor alpha (anti-TNF), adjusting for disease duration, concomitant methotrexate/thiopurine use, and C-reactive protein. Patients with CD using anti-integrin or IL-12/IL-23 inhibitors were less likely to discontinue therapy compared to patients treated with anti-TNF (HR 0.66, 95% CI 0.43-1.02); this difference was not statistically significant after adjusting for disease duration, age at diagnosis, disease location, and history of perianal fistula. The most frequent reasons for treatment discontinuation were primary non-response/lack of efficacy (21%), secondary non-response/lack of efficacy (31%), and side effects of therapy (23%). Development of antibodies was specifically noted among 10% of participants as a cause of treatment discontinuation.

CONCLUSION: In a multicenter cohort of patients with IBD, nearly one-third discontinued biologic treatment. The most common reason for discontinuation was secondary loss of response followed by side effects, then primary non-response. Primary non-response and secondary loss of response remain concerns in the treatment of patients with CD and UC, and continued emphasis on proactive strategies to maintain durability of therapies should be considered.

P028
Outcomes of Standard and Intensified Dosing of Ustekinumab for Chronically Failing Pouch Disorders
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BACKGROUND: Patients with chronic antibiotic-refractory pouchitis and Crohn’s disease of the pouch are often treated with biologics. Data regarding the efficacy of ustekinumab therapy dosing (weekly, every 4 weeks (q4w), or every 6 weeks (q6w)) and intensification of dose in the 6-month post-operative period is limited. We sought to assess outcomes of standard and intensified ustekinumab dosing and identify factors associated with clinical response among patients with chronic pouch disorders.

METHODS: This retrospective cohort study included adults initiated on ustekinumab for chronic pouchitis between January 1, 2016 and March 1, 2020. Electronic medical data were reviewed to obtain demographic and clinical data. The primary outcome was physician-reported clinical response 2-4 months after ustekinumab initiation (q4w or q6w) or dose intensification (q8w or q4w). The secondary outcome was time to dose intensification. Additional outcomes included pouch excision with or without perianal dehiscence, pouch failure, and pouch disease activity index (PDAI), IBID-related hospitalization, improvement in quality of life, and discontinuation of chronic antibiotics. Univariable logistic and cox regression were used to identify characteristics associated with primary and secondary outcomes, respectively.

RESULTS: 46 patients were initiated on ustekinumab for pouchitis (n = 6), cuffitis (n = 4), or CD of the pouch (n = 36). Outcomes after initiation were as follows (denominators vary due to missing data or insufficient follow-up time): 80.4% (37/46) of patients had a physician-reported clinical response at 2-4 months, 50.0% (23/46) underdose intensification after a median of 223 days, 8.7% (4/46) had a partial intensification after a median of 771.5 days, 59.3% (26/44) had an improvement in PDAI clinical subscore at 2-4 months, 16.2% (6/37) were hospitalized within 12 months, 53.6% (15/28) of those who underwent pouchosis after initiation had improvement in pouch inflammation, and 30.8% (4/13) of patients on chronic antibiotics discontinued antibiotics within 12 months. Logistic regression demonstrated that female sex (OR 10.5, 95% CI 1.02-92.7; P = 0.03) and pouch fistula (OR could not be calculated, 37.8% clinical response vs. 0.0% no clinical response; P = 0.04 by Fisher’s exact test) were positively associated with clinical response after initiation and cannabis use (OR 0.15, 95% CI 0.03-0.75; P = 0.02) was inversely associated with clinical response. Cox regression demonstrated that higher baseline PDAI at IBD diagnosis (HR 0.94, 95% CI 0.90-0.99; P = 0.01) and younger age at initiation (HR 0.96; 95% CI 0.92-0.99; P = 0.04) were associated with shorter time to dose intensification. After dose intensification to q4w or q6w, there were similar rates of clinical response at 2-4 months (61.0%, 26/43; 58.1%, 24/41), improvement in PDAI clinical subscore at 47.6% (24/47), 46.7% (24/47) at 2-4 months. One patient experienced an adverse event (acneiform reaction), leading to ustekinumab discontinuation 807 days after dose intensification. On logistic regression analysis, no baseline characteristics were significantly associated with clinical responses after dose intensification.

CONCLUSION: While ustekinumab was effective for the majority of patients in our cohort, nearly 50% ultimately required dose intensification, which was effective in recapturing response for most patients. Larger, prospective studies are needed to determine the optimal