Results: The study included 182 patients (UC: 97, CD: 85), all previously exposed to at least one biological therapy. As shown in Table 1, patients with CD receiving or not receiving the additional dosing at week ten were comparable in terms of disease activity at weeks 0 and 6, while patients with UC receiving the dosing at week 10 experienced higher disease activity at week 0 but not week 6. The overall efficacy of vedolizumab in UC and CD stratified according to treatment with the optional dosing at week ten is summarized in Figures 1 and 2, demonstrating no statistically significant difference among patients receiving or not receiving vedolizumab at week 10. Furthermore, the optional dosing of vedolizumab at week 10 (odds ratio (OR)=0.23 (95%CI 0.03-1.17), and OR=0.68 (95%CI 0.22-2.04)), was not associated with CR at week 52 among patients with UC and CD, respectively.

Conclusion: Vedolizumab is effective in achieving short and long-term CR and SCR in patients with treatment-refractory UC and CD. This study emphasizes that supplementary dosing at week 10 did not improve long-term outcomes.

Table 1: Association between the severity of ulcerative colitis and Crohn’s disease and supplementary dosing of vedolizumab at week 10

| Week 0 | Week 6 |
|--------|--------|
|       | Univariate analysis | p-value | Univariate analysis | p-value |
| Crohn’s disease | | | | |
| CRRA=2 | 1.47 (0.40-4.61) | 0.50 | 5.33 (1.16-23.10) | 0.04 |
| FC=250 μg/L | 2.00 (0.45-10.91) | 0.38 | 0.26 (0.01-1.82) | 0.24 |
| CRP>5 mg/L | 2.13 (0.96-7.17) | 0.21 | 1.08 (0.25-4.60) | 0.91 |
| Ulcerative colitis | | | | |
| CRRA=2 | 1.27 (0.43-3.75) | 0.67 | 3.10 (0.96-10.52) | 0.06 |
| FC=250 μg/L | 1.87 (0.40-4.30) | 0.43 | 2.8 (0.31-0.38) | 0.40 |
| CRP>5 mg/L | 0.95 (0.18-5.54) | 0.95 | NA | NA |

COVID 19 infection in IBD patients treated with biologic therapy-experience from tertiary center in Serbia

A. Sokie Milutinovic* MSc- PhD, M. Jevtic, S. Jovicic
1Clinical Centre of Serbia, Clinic for Gastroenterology and Hepatology, Belgrade, Serbia, 2University of Belgrade, School of Medicine, Belgrade, Serbia

Background: COVID 19 pandemic is caused by newly discovered coronavirus that started end of December 2019 and is ongoing. Patients with severe forms of Crohn’s disease (CD) and ulcerative colitis (UC) treated with biologic therapy are considered to be at increased risk of infectious diseases due to the immunosuppressive effect of biologic drugs. Available guidelines recommend that biologic therapy is continued during the pandemic. Since data on COVID 19 infection in this subgroup of IBD patients is limited we aimed to assess presence of risk factors related to virus transmission, incidence and severity of COVID 19 infection in patients on biologic therapy in tertiary center in Serbia.

Methods: Study was conducted in Clinic for Gastroenterology and Hepatology, Clinical center of Serbia. We included 263 IBD patients on biologic therapy in the study (mean age 41±13, 142 males). There were 162 CD and 101 UC patients. Standardized questionnaire was used to assess presence of different risk factors relevant for virus transmission and also symptoms and severity of disease if patient was infected with COVID 19.

Results: Out of 263 patients 41 (22 CD, 19 UC) was COVID 19 positive. Mean age of COVID 19 positive patients was 43±14, 19 were...
males and 22 females. In COVID 19 positive group 26 patients were on anti-TNF therapy (15 on infliximab and 6 on adalimumab), while 15 were treated with vedolizumab. Risk factors for COVID 19 infection were use of public transportation (p<0.05), active disease (p<0.05), residency in capital city (p<0.05) and presence of COVID 19 infection in a household member (p<0.05). Other factors such as age, sex, blood type, use of conventional immunosuppressive therapy and class of biologic drug did not differ between infected and uninfected group. Pneumonia was diagnosed in 7 patients (17%) and hospital admission was necessary in 4 cases (9.7%). All hospitalized patients were using corticosteroids due to relapse of IBD. Most common symptoms of infection were fever in 26 (63.4%), tiredness in 19 (46.3%) and loss of taste and smell in 17 (41.4%) patients. All patients recovered successfully and none needed mechanical ventilation.

Conclusion: Use of biologic therapy during COVID 19 pandemic is safe in IBD patients. Since we did not observe any fatal outcomes and all patients had mild to moderate COVID 19 presentation it is possible that biologic therapy, especially anti-TNF, has a protective role in preventing cytokine storm during COVID 19 infection.

P423
Treatment escalation and associated cost in German Ulcerative Colitis patients treated with advanced therapies

N. Picker1, H. Patel2, T. Wilke1, L. Rosin1, B. Bokemeyer*†
1Ingress Health, HWM GmbH, Wismar, Germany, 2Galapagos, nv, Mechelen, Belgium, 1IPAM, e.V., Wismar, Germany, 3Galapagos, Biopharma Deutschland GmbH, Munich, Germany, 4Interdisziplinäres Crohn Colitis Center Minden und Medizinische Klinik I- Universitätsklinik Schleswig-Holstein- Campus Kiel, Gastroenterologische Praxis Minden, Minden, Germany

Background: Advanced therapies used in moderate-to-severe Ulcerative Colitis (UC) may show a secondary loss of response (LOR) over time, requiring patients to undergo dose escalation or switching. Our study aimed to investigate the frequency of dose escalation in real-world practice and evaluated the associated cost.

Methods: Using German claims data (AOK PLUS) including prescription data, we identified UC patients by either at least two confirmed outpatient diagnoses or one primary inpatient diagnosis (ICD-10 K51). Analyzed patients initiated an advanced therapy (anti-TNF, vedolizumab, tofacitinib) between 01/01/2015-30/06/2019. Therapy escalation was defined as dose increase exceeding the recommended maintenance dose according to product labels by more than 150%. Time to first escalation was analyzed using a Kaplan-Meier estimation. The observation ended with the discontinuation of index therapy + 90 days, or loss to follow-up, whatever occurred first. End of therapy was determined in case of a supply gap of >60 days or switch of the advanced therapy. Patients with a follow-up < 6 months were excluded. Direct UC-related resource use and costs accounting for hospitalizations, outpatient treatment, drug costs according to pharmacy sales prices were reported per patient-year (PY).

Results: Among 574 UC patients who initiated an advanced therapy, 328 patients (median age: 37 years; female: 52.1%; biologic-naive: 85.4%) with sufficient follow-up time (median: 12.2 months) were identified. Of these, 59 patients (19%) were dose-escalated within the first year, whereas 73 patients (22%; anti-TNF: 61; vedolizumab: 12) were found to experience a therapy escalation during the whole follow-up time (average daily dose during maintenance therapy: adalimumab: 5.3 mg, infliximab: 14.6 mg, golimumab: 3.7 mg, vedolizumab: 11.1 mg, tofacitinib: n/a). Total observed direct cost related to UC amounted to €39,514/PY (95%-CI: 37,469-41,558), with €37,369/PY (34,852-39,885; Figure 1) caused by UC-related medication (95%). In comparison, UC-related total direct costs and drug costs for patients without any observable escalation were much lower (€30,425/PY [29,672-31,178]; p-value <0.001 and €28,066/PY [27,230-28,902]; p-value <0.001). Frequency of hospitalizations due to UC (0.3 [0.2-0.5]) vs. 0.4 [0.3-0.5]; p-value: 0.947) and gastroenterologist visits (2.1 [1.6-2.6] vs. 2.3 [2.1-2.5]; p-value: 0.361) were similar among both groups.

Conclusion: Nearly one-fifth of observed patients required therapy escalation in the first year, most likely due to secondary LOR. This results in higher UC-related costs. Payers should consider rates and costs of dose escalations when evaluating the cost-effectiveness of advanced therapies.

P424
Treatment persistence of first-line anti-TNF therapy in patients with inflammatory bowel diseases: results from a real-world study over 20 years

A. Blesl*, L. Binder1, C. Hogenauer1, H. Wenzl1, A. Borenich2, G. Pregartner3, A. Berghold2, S. Mestel1, P. Kump1, F. Baumann-Durchschein1, W. Petritsch1
1Medical University of Graz, Division of Gastroenterology and Hepatology, Graz, Austria, 2Medical University of Graz, Institute for Medical Informatics- Statistics and Documentation, Graz, Austria

Background: Anti-TNF therapy is still the most frequently used first-line biologic treatment in inflammatory bowel disease (IBD). This study aimed to determine length of treatment persistence and to describe reasons for discontinuation of first-line anti-TNF therapy used in the standard care of IBD patients.

Methods: A single-center, real-world, retrospective study including IBD patients (Crohn’s disease (CD), ulcerative colitis (UC), IBD unclassified (IBD-U)), who received an anti-TNF therapy in the last 20 years at the study center, was conducted. Length of first-line anti-TNF therapy, differences in treatment duration between infliximab (IFX) and adalimumab (ADA) and between CD and UC, reasons for discontinuation, side effects leading to cessation, treatment following first-line anti-TNF therapy, rates of surgery and death, and factors being associated with treatment failure were assessed.

Results: 586 patients were identified as having received first-line anti-TNF therapy at the study center. 48 patients were excluded due to shortness of available data. 538 patients (CD: 367, UC: 147,