PMO-47 CLIPPER (BECLOMETHASONE DIPROPIONATE) AS A TREATMENT FOR CHECKPOINT INHIBITOR INDUCED ENTEROCOLITIS

^{1,2}James Alexander*, ^{1,2}Hajir Ibraheim, ¹Camellia Richards, ²Ben Shum, ³Polychronis Pavlidis, ²Andrew Furness, ^{1,2}Julian Teare, ⁴Ally Speight, ³Sophie Papa, ^{1,2}Nick Powell. ¹Imperial College, London; ²Royal Marsden Hospital, London; ³King's College, London; ⁴Newcastle Upon Tyne Hospitals NHS Foundation Trust, Newcastle Upon Tyne

10.1136/gutjnl-2021-BSG.186

Introduction Systemic corticosteroids, the mainstay of treatment for immune checkpoint inhibitor (CPI) induced enterocolitis, are associated with complications including life-threatening infection. The topically-acting oral corticosteroid Beclomethasone Dipropionate (BD) is an effective treatment for mild to moderate flares of ulcerative colitis, and has fewer side effects than systemic corticosteroids. In this study, we hypothesised that BD is a safe and effective treatment for mild and microscopic CPI enterocolitis.

Methods We performed a retrospective analysis of all patients who started BD for CPI enterocolitis at three UK cancer centres between November 2017 & October 2020. All patients underwent endoscopic assessment and biopsy. The initial regimen of BD was 5mg once daily for 28 days. The primary outcome was clinical remission at 28 days, defined as a return to baseline stool frequency. Secondary outcomes included the rates of adverse events and clinical relapse after BD cessation.

Results Twenty-two patients (14 male) with a median age of 64 (range 45-84) were treated with BD. At baseline, ten patients (71%) had an increase in stool frequency of greater than 3 per day above baseline (CTCAE grade 2 or more) and the median number of loose stools in a 24-hour period was six. 11 (50%) patients were dependent on systemic corticosteroids prior to starting BD. Baseline sigmoidoscopy showed mild inflammation (loss of vascular pattern, mucosal granularity, small erosions) in eleven patients (50%) and normal findings in eleven patients (50%). Twenty patients (91%) had histopathological features of inflammation. There were no adverse events attributable to BD. All 22 patients (100%) had a clinical response to BD and 21 (95.5%) achieved clinical remission with a return to baseline stool frequency. 10 patients (45.5%) had symptomatic relapse on cessation of BD, five (22.7%) within seven days of stopping. All 10 relapsing patients recaptured response on restarting BD.

Conclusions Topical BD is an appealing alternative option to systemic immunosuppressive treatments to treat colonic inflammation. In this study, BD was safe and effective at inducing remission in mild and/or microscopic CPI induced enterocolitis. Further randomised studies are needed to confirm these findings and determine the optimum dosing regimen.

PMO-48 BOTH SINGLE AND MULTIPLE SWITCHING BETWEEN INFlixIMAB BIOSIMILARS CAN BE SAFE AND EFFECTIVE IN IBD

¹Rachael Barrett*, ¹Spyros Siakavellou, ¹Nikolas Plevris, ¹Julia Gauci, ¹Laura Lucaci, ¹Ian Amott, ¹Lynne Merchant, ^{1,2}Gareth-Rhys Jones, ¹Lauranne Derikx, ^{1,2}Charles Lees. ¹The Edinburgh IBD Unit, Western General Hospital, Edinburgh, UK; ²Centre for Genomics and Experimental Medicine, Institute of Genetics and Molecular Medicine, University of Edinburgh, Western General Hospital, Edinburgh, UK

10.1136/gutjnl-2021-BSG.187

Introduction There is extensive data on the safety and effectiveness of switching from originator infliximab to biosimilar infliximab. However, there is relatively little data regarding biosimilar-biosimilar infliximab switch nor on multiple switching. In our tertiary IBD unit, we have now undertaken two managed switch programs for infliximab: 1) Remicade to CT-P13 in 2016 and 2) CT-P13 to Zessly in Q1 2020. We now report the 6 months experience of this second switch.

Methods All IBD patients treated with CT-P13 underwent an elective switch to Zessly from March to May 2020. Patients were identified in a prospective biologic prescription database. IBD phenotype, CRP, drug survival, infliximab drug and antibody levels and faecal calprotectin (FCAL) data were collected before and 6 months after switch. Protocol driven treatment adjustments were made in specialized multidisciplinary virtual biologics clinic.

Our main aim was to investigate the outcomes following a switch from an IFX biosimilar CT-P13 (Remsima) to another biosimilar Zessly in IBD, with the primary outcome being drug persistence.

Results Overall, 229 IBD patients (CD=165 UC/IBDU=64) were switched from CT-P13 to Zessly. 67/229 (29.2%) patients had been started on Remicade and switched to CT-P13 four years previously, therefore this was their second biosimilar switch ('double switch'). Drug persistence was excellent at 94.3% for the overall cohort with no significant difference ($p=0.26$) seen between the CT-P13-Zessly (single switch - 93.2%) or Remicade-CT-P13-Zessly groups (double switch - 97%). Nine patients (3.9%) needed a dose increase. No differences were observed between CRP ($\leq 5\text{mg/L}$), FCAL ($\leq 250\text{mcg/g}$) or clinical (CD: HBI ≤ 4 , UC: pMayo Score ≤ 1) remission rates comparing before and 6 months post Zessly switch. This was observed for both the total cohort and the single/double switch subgroup. Trough infliximab levels also remained stable pre- and post-switch in both switch subgroups as well as in the total cohort ($p = 0.11$). Five patients (3.1%) developed new infliximab antibodies after switching from CT-P13 to Zessly, all from the single switch group. 11 patients (4.8%) were switched to another biologic category due to loss of response. Two patients (0.8%) stopped treatment secondary to adverse events (1 due to severe infection and 1 due to exacerbation of arthritis).

Conclusions Switching between CT-P13 and Zessly did not affect treatment efficacy, pharmacokinetics and safety. Moreover, this held true in a double switch group originally treated with Remicade.

PMO-49 PATIENT PERCEPTIONS ABOUT CAUSES OF FLARE IN IBD: BASELINE RESULTS FROM THE PREDICT STUDY

¹Spyros Siakavellou*, ^{1,2}Lauranne Derikx, ¹Lisa Derr, ¹Linda Williams, ¹Nikolas Plevris, ³Nathan Constantin-Cooke, ¹Kate Covil, ¹Gareth-Rhys Jones, ¹Charlie Lees, ¹PREDICT Writing Group. ¹The Edinburgh IBD Unit, Western General Hospital, Edinburgh, UK; ²Inflammatory Bowel Disease Center, Department of Gastroenterology and Hepatology, Radboud University Medical Center, Nijmegen, The Netherlands; ³MRC Human Genetics Unit, Institute of Genetics and Molecular Medicine, University of Edinburgh, Edinburgh, UK

10.1136/gutjnl-2021-BSG.188

Introduction Patient reported outcomes are important endpoints in Inflammatory Bowel Disease (IBD) management, but patient perceptions of the causes of disease flare are unknown and thus may reveal novel areas for future study.

Methods The PREdiCCt study (<https://www.predicct.co.uk>) is the largest prospective study of the causes of IBD flare. 2629 patients in clinical remission were recruited from 48 UK sites and followed for 2 years with detailed assessment of environmental and dietary factors via monthly questionnaires. 1946 (74%) patients completed the baseline questionnaires. We present here the results of the baseline questionnaire analysis of patient perceptions of disease flare, derived from a list of 17 putative causes from the literature and their own experience via free text input.

Results In total 1,946 IBD patients [male=852, Crohn's disease (CD)=1000; Ulcerative Colitis/IBD unclassified (UC/IBDU)=946, age 45.8 ± 15.5 (mean $\pm$ SD in years)] gave their opinion about factors initiating a flare (Figure 1). The commonest causes reported were stress (n=1359, 69.8%), dietary changes (n=911, 46.8%), alcohol use (n=385, 19.8%), sleep disturbances (n=331, 17%) and that their medication stopped working (n=308, 15.8%). CD participants were more likely to identify dietary changes (50% vs 43%, $p < 0.001$) and menstruation (16% vs 10% of female patients, $p < 0.001$) as flare triggers than UC/IBDU participants, while UC/IBDU participants more frequently reported loss of response to medication as a trigger for flare (9% vs 5% for CD participants, $p < 0.001$). CD patients with small bowel involvement were more likely to name dietary changes (61% vs 42%, $p < 0.001$), travel (14% vs 9%, $p = 0.016$) and smoking (4% vs 1%, $p = 0.04$) as flare triggers. When compared by gender, the ranking of causes was identical but female participants were more likely to identify stress (77% vs 65%, $p < 0.001$) and antibiotic use (12% vs 6%, $p < 0.001$) as reasons for disease relapse compared to male participants.

Abstract PMO-49 Figure 1 Reported causes of flares by diagnosis

Conclusions Stress, dietary changes and alcohol use were identified as the main causes of flare by patients with dietary changes more frequently reported in CD (especially those with small bowel involvement). The impact of environmental and dietary factors in the development of flare is being further investigated with ongoing longitudinal data collection in the PREdiCCt Study.

PMO-50 FACTORS INDEPENDENTLY ASSOCIATED WITH FATIGUE IN IBD: RESULTS FROM THE PREDICCT STUDY

¹Lauranne Derikx*, ¹Spyros Siakavellas, ²Daniel Gaya, ³Kamal Patel, ⁴Charles Murray, ⁵Jonathan MacDonald, ⁶Christopher Lamb, ⁷Nick Kennedy, ⁸Paul Henderson, ¹Charlie Lees. ¹The Edinburgh IBD Unit, Western General Hospital, Edinburgh, UK; ²Glasgow Royal Infirmary, Glasgow, UK; ³St Georges, London, UK; ⁴Royal London Free, London, UK; ⁵Greater Glasgow and Clyde, Glasgow, UK; ⁶Newcastle Royal Victoria Infirmary, Newcastle, UK; ⁷Royal Devon and Exeter, Exeter, UK; ⁸Edinburgh Royal Sick Children, Edinburgh, UK

10.1136/gutjnl-2021-BSG.189

Introduction Fatigue is one of the most common symptoms in IBD resulting in decreased quality of life, impaired work productivity, and higher societal costs. However, little is known about its etiology and pathophysiology. We aimed to estimate the prevalence of fatigue and to identify predictive factors for fatigue.

Methods The PREdiCCt study is the largest prospective study of the causes of IBD flare. 2629 patients in clinical remission were recruited from 48 UK sites. 1946 (74%) patients completed the baseline questionnaires. We assessed the prevalence of fatigue at baseline using a single item from the IBD Control questionnaire. To identify predictors for fatigue, we performed univariable and multivariable analyses including demographic, biochemical, environmental and psychosocial

Abstract PMO-50 Table 1

Variable (n [%], or median [IQR])	UNIVARIABLE ANALYSES			MULTIVARIABLE ANALYSES		
	Often lack energy – yes (n=759)	Often lack energy – no (n=1034)	P-value	OR	95% CI	P-value
Female sex	504 (66.4)	508 (49.1)	<0.001	2.4	1.5-3.8	<0.001
Current smoker	57 (8.9)	45 (4.9)	0.002			
IBD type (CD)	431 (57.2)	492 (48.0)	<0.001			
Laboratory values	360 (62.8)	588 (76.5)	<0.001	2.1	1.3-3.5	0.004
1. CRP <5 mg/L	136 (127-145)	140 (131-148)	<0.001			
- Haemoglobin (g/L)	6.3 (5.3-7.8)	6.0 (5.0-7.2)	0.011			
- White cell count ($\times 10^9/L$)	56 (27-106.5)	66 (36-116)	0.011			
- Ferritin (ug/L)	6.5 (4.3-10.5)	7.3 (5.0-10.9)				
- Folate (ug/L)						
Clinical remission (HBI<4, pMayo<2)	287 (71.8)	482 (82.7)	<0.001			
Depression (HADS>9)	224 (30.0)	49 (4.8)	<0.001	6.2	2.9-13.3	<0.001
Anxiety (HADS>9)	336 (45.0)	165 (16.2)	<0.001	1.8	1.1-3.0	0.031
Physical activity (GPAQ<600)	207 (27.6)	193 (18.8)	<0.001			
Sleep quality (PSQI>5)	633 (90.2)	693 (69.9)	<0.001	2.5	1.4-4.6	0.002