Abstract PTU-005 Table 1 CS-refractory versus CS-responsive patients

	CSrefr (n=17)		CSresp (n=54)	
	N	%	N	%
	(range)		(range)	
Ipi	8	47	30	56
Nivo/pembro	1	6	9	16
Ipi+nivo	8	47	11	20
Days from start ICI to onset of irD/C	41	-	45	-
Grade 1/2	1	6	14	26
Grade 3/4	16	94	40	74
Median days from start of D/C to CS (range)	5	-	5	-
Days from start CS to IFX (1–100)	14	-	NA	-
Median duration CS	-	-	-	-
Grade 1/2	160	-	49	-
	(160–160)		(6–295)	
Grade 3/4	79	-	47	-
	(28–279)		(6–204)	
Extra treatment (vedolizumab)	1	6	0	0
Macroscopic abnormality on FS	13/17	76	22/41	54
Microscopic abnormality only on FS	1/17	6	9/41	22
Normal FS	2/17	12	7/41	17
Unknown FS result	1/17	6	3/41	7
Disease progression	12	67	42	79
Median days to progressive disease	170	-	101	-

NB: 1 patient who had CS but unknown status re IFX is not included

PTU-006 INCIDENCE OF IMMUNE CHECK POINT INHIBITOR INDUCED DIARRHOEA/COLITIS- EXPERIENCE FROM A MULTI-CENTRE COHORT

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Background Immune checkpoint inhibitors (ICIs) including anti-CTLA-4 (e.g. ipilimumab (ipi)) and anti-PD-1 antibodies (e.g. nivolumab (nivo)) have improved outcomes in many cancers. However their use is complicated by ICI-related diarrhoea/colitis (irD/C), a common cause of morbidity and ICI discontinuation. The National Cancer Institute's Common Terminology Criteria for Adverse Events (CTCAE) has been used to grade irD/C according to frequency of bowel movements over baseline. Grade 1–2 represents mild-moderate disease, grade 3–4 severe disease and grade 5 represents death. In clinical trials diarrhoea/colitis is more common in regimes using anti-CTLA-4 agents.¹ There are few real world data reported in the UK.

Methods Electronic medical records were reviewed for melanoma patients (pts) at The Royal Marsden Hospital (RMH) and melanoma, renal and lung cancer pts Guy's and St Thomas' Hospital (GSTT), receiving at least one ICI dose between 2011–2016. Clinical outcome data included class of ICI therapy and CTCAE grade of diarrhoea.

Results 651 ICI treatment courses were administered mostly for melanoma (100% RMH, 53% GSTT). 285 (44%) received anti-CTLA-4 monotherapy, 288 (44%) anti-PD-1 monotherapy, and 77 (12%) combination ipi +nivo. The incidence of all-grade irD/C was 27% for anti-CTLA-4 therapy, 12% for anti-PD-1–34% for ipi +nivo. The incidence of severe irD/C (grade 3–5) was 12% in anti-CTLA-4 monotherapy, 4% in anti-PD-1 therapy and 26% in combination therapy (figure 1). There was one only death reported in a pt who developed colitis following treatment with anti-CTLA-4 monotherapy.

Abstract PTU-006 Figure 1

Conclusion This is the largest cohort of data reporting the incidence of irD/C involving real-world patients. Compared to trial data, the incidence of all-grade diarrhoea was slightly lower but the incidence of severe disease was higher in all treatment groups, particularly with ipi +nivo. Given the expansion of ICIs in other cancer types and use as an adjuvant therapy, there is an urgent need to engage gastroenterology services and to develop evidence-based management algorithms for treatment of irD/C.

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PTU-007 A RETROSPECTIVE MULTICENTRE STUDY COMPARING INFLIXIMAB AND ADALIMUMAB FOR MAINTENANCE OF REMISSION IN ULCERATIVE COLITIS

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Introduction Anti-tumour necrosis factor (TNF) therapy has revolutionised ulcerative colitis (UC) treatment, particularly in

moderate-to-severe disease. However, these drugs tend to perform less well in the maintenance of remission. Route of administration may influence efficacy and network meta-analyses of trial data indicate a superiority of intravenous drugs (IV; Infliximab; IFX) over subcutaneous (SC; adalimumab; ADA). We conducted a retrospective multicentre case-control study to compare the efficacy of these two drugs.

Methods Patients administered IFX or ADA as their first biologic, identified from therapy databases of five UK hospitals, were included, if they had completed induction dosing and entered maintenance. Patients receiving IFX as 'rescue' therapy were excluded. Data was collected for pre-biologic disease activity (Simple Clinical Colitis Activity Index (SCCAI), C-reactive protein and calprotectin) and throughout anti-TNF therapy. The primary end-point for comparison was the number of patients in clinical remission at 52 weeks (combined features of continuing IFX or ADA therapy and SCCAI score ≤ 3). Data was collected for duration of therapy, or up to last follow-up, if beyond 52 weeks.

Results 78 IFX (40.3 ± 14.6 years, 33F) and 63 ADA (36.8 ± 14.6 years, 27F) patients were analysed. There were no statistically significant differences in demographics or pre-biologic disease activity between the two groups. At 52 weeks, 58 (74%) IFX patients and 29 (46%) ADA patients remained on therapy ($p=0.009$) and in remission (26 (33%) vs 5 (8%), $p=0.0003$). Primary non response was the reason for treatment cessation in 15 (24%) ADA patients and 4 (5%) IFX patients ($p=0.0012$).

Conclusions Our results from a real-world cohort mirror those produced in the network meta-analyses of clinical trials for these agents, suggesting that IFX is superior to ADA in UC maintenance of remission, demonstrated by improvement in SCCAI scores and treatment continuation at 52 weeks. There were no significant differences in colectomy rates, hospital admission for acute flares or adverse events in the study timeframe.

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PTU-008 INTERLEUKIN 23 AS A NON-INVASIVE TEST OF DISEASE SEVERITY IN PATIENTS WITH ULCERATIVE COLITIS

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Introduction Studies have found increased expression of IL-23 in inflamed and non-inflamed mucosa of patients with ulcerative colitis (UC). This study was done to evaluate serum interleukin-23 as a non-invasive test for ulcerative colitis disease and assessed its correlation with the disease severity.

Methods A prospective case-control study where 80 patients were recruited, and allocated into two groups:

Group I: included forty patients diagnosed with UC by clinical, endoscopic and histopathologic features.

Group II (control group): included 40 patients without UC, matched in age and gender, who had colonoscopy for various

indications but had a normal colonoscopy and normal histopathology.

In patients with UC, disease severity was assessed using the Mayo Scoring System for assessing UC activity. Serum IL-23 level was quantified using Quantikine Human IL-23 Immunoassay by R and D Systems Europe, Ltd. ELISA kit. IL-23 levels were compared in the 2 groups, also correlation with severity was obtained.

Analysis of the data was done using SPSS (Statistical System for Social Science version 16). Kruskal Wallis test was used to compare the 2 groups regarding quantitative nonparametric variables. Spearman correlation was used to rank variables positively or inversely. Receiver operating curve (ROC) was used to find the best cut off and validity of IL-23. The one-way ANOVA test was used to assess the relationship between the severity of UC and IL-23 levels.

Results Patients with UC had higher level of interleukin 23 (234.5 ± 161 pg/mL) compared to controls (54.2 ± 15 pg/mL). A positive correlation was found between the level of IL-23 and disease severity. A cut off value of IL-23=68 pg/mL was the best to differentiate between cases and controls. Performing the receiver operating characteristic curve (ROC) revealed that the best cut off values of IL-23 to identify the severity of ulcerative colitis were 105 pg/mL for mild cases (80% sensitivity), 200 pg/mL for moderate cases (60% sensitivity), and 270 pg/mL for severe cases (81% sensitivity).

Conclusion Our findings reinforce the suggestion that IL-23 level measurement may be of value as a non-invasive test in the diagnosis and disease severity assessment in patients with UC. Further studies on a larger scale would be needed to evaluate whether this could be used for monitoring of response to treatment. In view of IL-23 antagonists currently being studied in UC patients, the predictability of response to IL-23 antagonists guided by IL-23 levels is an area that could be explored.

PTU-009 UPPER GASTROINTESTINAL INFLAMMATION IN PATIENTS WITH IMMUNE-CHECKPOINT INHIBITOR INDUCED DIARRHOEA

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Introduction Immune Checkpoint inhibitors (ICPi) have revolutionised the management of melanoma, non-small cell lung cancer and renal cancer. They block receptors expressed by immune cells that reduce immune activation. 'Turbo-charged' immune cells deliver augmented anti-tumour immunity (hence the striking efficacy of these anti-cancer agents), but comes at the cost of immune mediated side effects. Immune-mediated damage to the gut is a common and serious side effect of ICPi therapy. Endoscopic and histological findings in the lower gastrointestinal (GI) tract have been described (colitis is a common feature), but little is known about manifestations in the upper GI tract.

Methods We performed a retrospective analysis of all patients presenting with diarrhoea following treatment with ICPis (ipilimumab, nivolumab, pembrolizumab or combination therapy) who had been investigated with OGD. Endoscopic and