

approx. £119,000 for investigations and consultations. Using a Caldetect® (Preventis, GmbH) point of contact FC test, it was estimated that a saving of £89,000 could be achieved. A pathway for investigating chronic diarrhoea using Caldetect® was designed and implemented in the community (population 150,000) between September 2011–March 2012. (this will be presented). FC results were categorised using manufacturer cut-offs of <15 ug/g, 15–60 ug/g and >60 ug/g. Patients with FC results of 15–60 and >60 were deemed to have an inflammatory process and referred to Gastroenterology Clinics. Cost analysis was carried out using the 2010–11 tariffs for the NHS.

**Results** 142 Caldetect® tests were carried out in Primary Care during this pilot phase. Of these, a negative result (< 15 ug/g) was present in 89, with 36 tests being > 60 ug/g. 3 tests were at the intermediate level and 14 tests could not be accurately reported. Negative results were managed in primary care as IBS. A monthly cost savings of £6100 was calculated taking consultation and endoscopy tariffs into account.

**Conclusion** This pilot study demonstrates the feasibility and cost effectiveness of a Pathway for decision making and a point-of-care faecal calprotectin test in rationalising referrals to Gastroenterologists for chronic diarrhoea.

**Disclosure of Interest** A. Dhar Speaker bureau with: Shire Pharmaceuticals, Warner Chilcott UK, S. Lee: None Declared, H. Borthwick: None Declared, P. Nair: None Declared, C. White: None Declared

**PTU-058** ONE YEAR LIKELIHOOD OF RELAPSE IN ULCERATIVE COLITIS (UC) IS PREDICTED BY MUCOSAL APPEARANCE BUT NOT BY FAECAL CALPROTECTIN: DATA FROM THE CODA STUDY OF ONCE DAILY VERSUS THREE TIMES DAILY ASACOL

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**Introduction** Faecal calprotectin (FC) has become a useful marker of mucosal healing, with studies showing raised levels predictive of relapse<sup>1,2,3</sup>. These studies did not assess mucosal healing however, so did not compare calprotectin with mucosal appearance as predictors of relapse.

**Methods** In the CODA (Colitis Once Daily Asacol®) trial of once daily (OD) Asacol® (three 800 mg tablets) vs one 800mg tablet taken three times daily (TDS), 213 UC patients in remission for >4 weeks, but relapse in the past 2 years, were recruited. Baseline FC (Phical ELISA kit) was collected and rectal sigmoidoscopy (sig) score at baseline, and relapse or 1 year (using the modified Baron score: 0 = normal; 1 = erythema, decreased vascular pattern; 2 = marked erythema, absent vascular pattern, friability, erosions; 3 = spontaneous bleeding, ulceration). At entry patients had no symptoms of active disease, with a sig score of 0 or 1. Follow-up was for 1 year or until relapse (symptoms of active disease with a sig score of 2 or 3). Demographic factors, concomitant drugs, FC, sig score, CRP, and adherence were evaluated in a Cox regression model of time to relapse.

**Results** (Shown as median[IQR] unless stated otherwise). Remission duration prior to entry was 6.0 [3–12] months. Disease extent was extensive (30.0%), Lt. sided (54.9%), proctitis (13.6%). At entry FC was 78mg/kg stool [23.3–159.4], sigmoidoscopy score 0 (70.9%), 1 (29.1%). All were taking mesalazine, and 11.7% thiopurines. Baseline FC was higher if sig score was 1 (109[38–335]) than if 0 (62[21–120]),  $p = 0.001$ , but did not differ according to disease extent or medication (including aspirin ( $n = 18$ ) and occasional NSAIDs ( $n = 6$ )). Remission rates at one year were 62% overall (68.9% in OD and 55.5% in TDS group). Factors associated with

time to relapse were explored in a Cox proportional hazards model, with baseline FC dichotomised at 150mg/kg stool (as by Costa *et al*). Relapse risk was 2.5 times higher in those with baseline sig score 1 compared to score 0 (95% CI 1.32–4.76,  $p = 0.005$ ). Age, concomitant medication, previous duration of remission, disease extent, smoking, trial medication adherence and baseline FC (cut off at 150 mg/kg stool or as a continuous variable) did not remain in the final model.

**Conclusion** In this study, sigmoidoscopy appearance at baseline was the sole factor predicting relapse over 1 year of maintenance mesalazine 2.4g, whereas calprotectin level was not a predictor, perhaps because of wide variability in this group of patients. FC may have more value in measuring relative change in individual patients.

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**PTU-059** ADALIMUMAB THERAPY REDUCES HOSPITALIZATION AND COLECTOMY RATES IN PATIENTS WITH ULCERATIVE COLITIS AMONG INITIAL RESPONDERS

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**Introduction** Two double-blind, placebo-controlled trials (ULTRA 1 and 2) revealed that adalimumab (ADA) therapy significantly reduces hospitalisation and non-significantly decreases colectomy rates in patients with moderate to severe ulcerative colitis (UC).<sup>1</sup>

**Methods** We assessed the effect of an ADA 160/80/40 mg treatment regimen on risk reduction of all-cause and UC-related hospitalisation and colectomy in these 2 trials among initial ADA responders. The pooled dataset included 963 patients (480 ADA, 483 placebo [PBO]). Hospitalization and colectomy events were based on safety reports reviewed by 2 gastroenterologists who were blinded to treatment. Conservatively, hospitalizations from initial ADA non-responders (per Mayo score at Week 8) through Week 8 were counted, but were censored after Week 8 to reflect the clinical practise pattern of continuing treatment in initial ADA responders. Risk and number of hospitalizations were compared between groups using person-year (PY)-based incidence rates (IRs) and Poisson regression, respectively; Z-scores were used to assess statistical differences.<sup>2</sup>

**Results** 35% and 34% reductions in the number of patients hospitalised and number of hospitalizations for any reason, respectively, were observed with ADA therapy vs. PBO (table,  $P < 0.05$  for both comparisons). When UC-related hospitalizations were compared, reductions for rate (50%) and number (54%) of hospitalizations were both statistically significant, too.

**Conclusion** Initial ADA-responders had a significantly lower risk for UC-related and all-cause hospitalisation compared with PBO. Reduction of all-cause hospitalisation is unique for ADA compared with any other anti-tumour necrosis factor agent. A non-significantly lower colectomy rate in patients receiving ADA vs. those receiving PBO was also observed.

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## Abstract PTU-059 Table

Hospitalization and Colectomy Rates in ULTRA 1 and 2: Week 8 ADA Responders

Patients	ADA		PBO		RR (ADA/PBO)	P-Value
	n/PYs at Risk	IR (n/PYs at Risk)	n/PYs at Risk	IR (n/PYs at Risk)		
All-cause hospitalisation	46/260.4	0.18	58/222.3	0.26	0.68	.047 <sup>a</sup>
UC-related hospitalisation	29/266.5	0.11	49/223.6	0.22	0.50	.002 <sup>a</sup>
Colectomy	6/271.9	0.02	11/231.7	0.05	0.46	.122 <sup>a</sup>
Hospitalizations	E/PYs	IR (E/PYs)	E/PYs	IR (E/PYs)	RR(ADA/PBO)	
All-cause	55/272.7	0.20	71/232.8	0.31	0.65	.021 <sup>b</sup>
UC-related	32/272.7	0.12	59/232.8	0.25	0.48	<0.001 <sup>b</sup>

IR, incidence rate; PYs at Risk, time at risk in patient years; n, number of patients with event; E, total number of events; RR, relative risk.

<sup>a</sup>Z-score and normal approximations.

<sup>b</sup>Poisson regression with time offset.

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### PTU-060 PHENOTYPIC CHARACTERISATION OF INFLAMMATORY BOWEL DISEASE IN SOUTH ASIANS IN THE UNITED KINGDOM-INSIGHTS INTO A SHIFTING LANDSCAPE

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**Introduction** The aetiology of inflammatory bowel disease (IBD) remains elusive. The increasing incidence of IBD in developing countries and immigrant populations appears to outpace what genetic influences alone could instigate. There is a relative dearth of literature on the phenotypic characteristics of South Asian immigrant populations. The aim of our study was to define the clinical phenotype of IBD in South Asians in North-West England.

**Methods** We conducted a retrospective study of 102 patients of South Asian origin attending IBD clinics at our hospital. Clinical data including demographics, disease characteristics (Montreal classification), treatment and blood results were obtained using electronic case records.

**Results** Of 106 patients reviewed, 55 were male. The median age was 38 years (range 16–80) and mean disease duration was 9.5 years. Seventy-six patients had ulcerative colitis (UC) and 30 had Crohn's disease (CD). Five patients were current or ex smokers (4.7%). Seventeen patients had extra-intestinal manifestations of IBD (16.0%). Of UC patients 37 had pancolitis, 34 left sided disease and 5 had proctitis. Of patients with CD, 3 had ileal disease, 11 colonic disease and 16 had ileocolonic disease. Five CD patients had stricturing disease, 10 had penetrating disease (6 also stricturing) and 15 had non-penetrating, non-stricturing disease. Perianal disease was noted in 3 at diagnosis and in 5 subsequently. Eighty four patients received steroids, topical steroids (31), 5-ASA (99), topical 5-ASA (31), azathioprine (56), 6-mercaptopurine (4), cyclosporine (2), methotrexate (10), infliximab (21) and adalimumab (10). Fifty eight patients received at least one immunomodulatory therapy

with the median time to use being 12 months (range 0–276 months). Thirteen patients (7 CD, 3 UC) required surgery (3 total colectomy, 10 subtotal). Mean time to surgery was 4 years (range 0–13 years). Seventeen patients had disease progression leading to Montreal reclassification (median time 60 months; range 1–216 months).

**Conclusion** We noted a higher prevalence of UC with predominantly pancolonic disease and a significant proportion of CD with penetrating or stricturing disease. The majority of patients required immunomodulatory therapy. Epidemiologic insights from such populations may provide further clues in defining an aetiological paradigm for IBD and should form an important area of further research. A case control study exploring differences is underway at our institution.

**Disclosure of Interest** None Declared

### PTU-061 VITAMIN D DEFICIENCY IS WIDELY PREVALENT IN SOUTH ASIAN PATIENTS WITH INFLAMMATORY BOWEL DISEASE

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**Introduction** There has been resurgent interest in recent years in the pro-hormone vitamin D in its role and plausible effects on immune regulation and inflammatory bowel disease (IBD). We postulated a wide prevalence of vitamin D deficiency in South Asian patients with implications for the control of their IBD. The aim of our study was to review vitamin D assessment in a South Asian IBD cohort.

**Methods** We conducted a retrospective review of 102 South Asian patients attending IBD clinics in our institution. Clinical data including demographics, disease characteristics (Montreal classification) and therapy were obtained from electronic record review. Serum 25-hydroxyvitamin D (25-OHD) concentrations were recorded in all patients tested and in all having serial measurements.

**Results** Of 106 patients reviewed, 55 were male. The median age was 38 years (range 16–80) and mean disease duration was 9.5 years. Seventy-six patients had ulcerative colitis (UC) and 30 had Crohn's disease (CD). Five patients were current or ex smokers (4.7%). Vitamin D status was assessed in 52 patients (49%), 26 had serial measurements. Median 25-OHD was 10.25 (range 3.3–44.4). Fifty one patients had levels < 25 ng/ml consistent with deficiency and all 52 had insufficient levels < 50 ng/ml. Of the patients with deficiency 35 had UC and 16 had CD. Of the UC patients, 18 had pancolitis, 13 had left sided disease and 4 proctitis. Of the CD patients 5 had penetrating disease and 4 had stricturing disease. Forty-three of the deficient patients had received