

concentration and prior anti-TNF experience.<sup>1</sup> Patients who were either anti-TNF-naïve or had an elevated baseline CRP achieved higher rates of remission than the general study population. In this post hoc analysis we examined whether patients who were anti-TNF-naïve and had an elevated CRP at baseline could achieve higher remission rates than those previously reported.

**Methods** Data from CHARM, a 56-week, randomised, placebo-controlled trial of ADA maintenance therapy, were analysed. All patients received open-label ADA during a 4-week induction period, and were then randomised to ADA (40 mg weekly or every other week [eow]) or placebo for a 52-week double-blind period. In this analysis, clinical remission at week 56 was determined for randomised responders (patients who had a decrease in CDAI  $\geq 70$  at week 4 compared with baseline) who were naïve to prior anti-TNF treatment, by baseline CRP subgroups (high:  $\geq 10$  mg/l, vs low:  $< 10$  mg/l), using non-responder imputation. Remission rates for patients treated with weekly or eow ADA were compared with rates for placebo-treated patients, using Fisher's exact test.

**Results** ADA treatment (weekly or eow) resulted in statistically significantly greater rates of clinical remission at week 56 compared with placebo treatment in each CRP subgroup of anti-TNF-naïve patients (Abstract PTU-110 table 1). The percentage of patients in clinical remission was greater in the high CRP subgroup for both weekly and eow ADA treatment.

Abstract PTU-110 Table 1 Clinical remission at week 56 in anti-TNF-naïve patients in CHARM

|                                | Placebo<br>n/N (%) | ADA 40 mg<br>eow<br>n/N (%) | p Value*<br>n/N (%) | ADA 40 mg<br>weekly<br>n/N (%) | p Value*  |
|--------------------------------|--------------------|-----------------------------|---------------------|--------------------------------|-----------|
| Baseline<br>CRP $< 10$ mg/l    | 6/46 (13)          | 17/49 (35)                  | 0.017               | 18/43 (42)                     | 0.004     |
| Baseline<br>CRP $\geq 10$ mg/l | 6/43 (14)          | 19/36 (53)                  | $< 0.001$           | 23/43 (53)                     | $< 0.001$ |

\*p Value vs placebo, from Fisher's exact test.

**Conclusion** In the CHARM trial, anti-TNF-naïve patients with baseline CRP  $\geq 10$  mg/l experienced greater rates of clinical remission, regardless of ADA dose frequency, compared with patients with baseline CRP  $< 10$  mg/l.

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PTU-111

**BASELINE C REACTIVE PROTEIN IS ASSOCIATED WITH DISEASE PROGRESSION IN PATIENTS WITH CROHN'S DISEASE**

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**Introduction** Elevated C reactive protein (CRP), a marker of inflammation, is known to correlate with Crohn's disease (CD) activity<sup>1,2</sup> and to be a predictor of disease relapse in CD.<sup>3,4</sup> However, in patients with moderate or severe CD it is not known whether CRP is associated with disease progression.

**Methods** This post hoc analysis evaluated the association of baseline (BL) CRP and change in CDAI over time in patients with moderate (CDAI  $> 220$  to  $\leq 300$ ) to severe (CDAI  $> 300$ ) CD who were randomised to the placebo group in the CHARM trial<sup>5</sup> (N=238). Patients received open-label adalimumab (ADA) induction (week 0: 80 mg; week 2: 40 mg) followed by blinded weekly placebo treatment from weeks 4–56, with switch to open-label ADA allowed after week 12 for disease flare. This analysis grouped patients by CD severity and BL CRP (severe, high: CDAI  $> 300$ , CRP  $\geq 10$  mg/l; severe, low: CDAI  $> 300$ , CRP  $< 10$  mg/l; moderate, high: CDAI  $\leq 300$ , CRP  $\geq 10$  mg/l; moderate, low: CDAI  $\leq 300$ , CRP  $< 10$  mg/l). Mean CDAI scores at each visit from weeks 4–56 were calculated for each subgroup, using last observation carried forward (after week 4) to handle dropouts or switch to ADA.

**Results** CDAI decreased from BL in all subgroups after ADA induction (Week 4, Abstract PTU-111 table 1). By week 56, the mean CDAI in all subgroups had increased compared with week 4, and was greater in patients who had higher CRP vs lower CRP at BL (244 vs 223, 306 vs 260, for moderate and severe groups, respectively). In patients with moderate CD and high CRP, week 12 and week 56 CDAI approached that of patients with severe CD and low CRP, despite BL differences in CDAI of over 90 points (week 12: 235 vs 243; week 56: 244 vs 260).

Abstract PTU-111 Table 1 Mean CDAI over time

|                              | Severe (CDAI $> 300$ )    |                              | Moderate (CDAI $\leq 300$ ) |                              |
|------------------------------|---------------------------|------------------------------|-----------------------------|------------------------------|
|                              | CRP $< 10$ mg/l<br>N = 60 | CRP $\geq 10$ mg/l<br>N = 87 | CRP $< 10$ mg/l<br>N = 70   | CRP $\geq 10$ mg/l<br>N = 44 |
| BL CRP, mg/l, median (range) | 2.5 (0.2–9.7)             | 33.6 (10.1–287.0)            | 4.2 (0.2–9.9)               | 31.4 (10.1–104.0)            |
| BL CDAI, mean (SD)           | 348 (46)                  | 370 (49)                     | 259 (24)                    | 254 (32)                     |
| Wk 4 CDAI, mean (SD)         | 243 (85)                  | 242 (96)                     | 162 (68)                    | 174 (70)                     |
| Wk 12 CDAI, mean (SD)        | 243 (102)                 | 286 (109)                    | 190 (85)                    | 235 (120)                    |
| Wk 56 CDAI, mean (SD)        | 260 (95)                  | 306 (114)                    | 223 (91)                    | 244 (116)                    |

**Conclusion** This post hoc analysis of disease activity and CRP demonstrates that an elevated BL CRP in patients with moderate or severe CD is associated with higher disease scores after 1 year. Disease activity over time in patients with moderate CD and higher CRP behaved similarly to that of patients with severe CD and lower CRP.

**Competing interests** J-F Colombel Shareholder with: Intestinal Biotech Development, Grant/Research Support from: Astra-Zeneca, Danisco, Danone, Dysphar, Ferring, Giuliani, Lesaffre, Mapi Naxis, Ocerra Therapeutics, Roquette, Schering-Plough, and UCB, Consultant for: Abbott Laboratories, ActoGenix NV, Albireo Pharma, Biogen Idec, Boehringer-Ingelheim, Bristol-Myers Squibb, Cellierix, Centocor, Chemocentryx, Cosmo Technologies, Danone France, Elan, Genentech, Giuliani, Given Imaging, GlaxoSmithKline, Merck, Millennium, NeoVacs, Ocerra, Otsuka American, PDL Biopharma, Pfizer, Ribo Vacs Biotech, Schering-Plough, Shire, Synta, Teva and Petah Tikva, Therakos, UCB, and Wyeth, Speaker bureau with: Abbott Laboratories, Astra Zeneca, Centocor, Elan, Falk, Ferring, Given Imaging, Otsuka American, PDL, Schering-Plough, Shire and UCB, W Sandborn Grant/Research Support from: Centocor Ortho Biotech, Abbott Laboratories, and UCB Pharma, Consultant for: Centocor Ortho Biotech, Abbott Laboratories, UCB Pharma, and Merck (previously Schering Plough), M Castillo Shareholder with: Abbott, Employee of: Abbott, B Huang Shareholder with: Abbott, Employee of: Abbott, Q Zhou

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**PTU-112 PRESENTATION, TREATMENT AND CLINICAL OUTCOME OF COLLAGENOUS AND LYMPHOCYTIC COLITIS OVER A 6-YEAR PERIOD IN A SINGLE UK CENTRE**

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**Introduction** Collagenous colitis (CC) and lymphocytic colitis (LC) are referred to collectively as microscopic colitis (MC). CC and LC represent an increasingly common cause of chronic diarrhoea. However, clinical and epidemiological data on these diseases are scarce and diagnosis is often delayed. Optimal treatment, especially of resistant cases, remains to be defined. We therefore aimed to investigate the incidence, presentation, treatment and outcome of patients from a single UK centre.

**Methods** Clinical data were retrospectively collected from electronic and paper records for all patients diagnosed with CC and LC at this institution from April 2004 to November 2011.

**Results** 104 patients were identified of which 68 (65%) had CC and 36 (35%) LC. The median age at diagnosis for MC was 70 years (range 36–90 years), with 18% being under the age of 55 years. The overall MC female to male sex ratio was 2.8:1. The incidence of MC rose tenfold during the study from 0.67 to 6.67 per 100 000 population/year. Presentation was similar between CC and LC with diarrhoea present in all cases and nocturnal diarrhoea in 41%, abdominal pain in 36%, weight loss in 34% and nausea in 12%. 58 (56%) were referred through the surgical pathway, often via 2-week-wait pathway. Diagnosis could be made from left sided biopsies in 96/102 (94%). The median number of days between histological diagnosis and commencement of treatment was 54 days with no significant difference between medical and surgical referral pathways. 46 (48%) patients were treated with budesonide with an immediate response in 42 (92%), though 54% of responders subsequently relapsed. The vast majority of budesonide sensitive patients responded to a further course of budesonide with continuing disease activity rare after a third treatment course. Budesonide was more likely to be started as first line treatment in the medical pathway compare to surgical. Of all cases, drug withdrawal was part of the treatment in 12 cases resulting in complete clinical remission in eight patients with a further two patients reporting a modest improvement. Six (6%) patients required long-term maintenance therapy, four with budesonide and two with azathioprine.

Abstract PTU-112 Table 1 Associations of CC and LC

| Association    | CC (%)   | LC (%) |
|----------------|----------|--------|
| Lansoprazole   | 23 (22%) | 6 (6%) |
| NSAIDs         | 27 (26%) | 9 (9%) |
| SSRIs          | 7 (7%)   | 5 (5%) |
| Coeliac        | 6 (6%)   | 0      |
| Current smoker | 12 (12%) | 4 (4%) |

**Conclusion** The incidence of both CC and LC increased over the period of the study in keeping with other European studies. A significant proportion of patients presented below the age of 55. Lansoprazole and NSAID use are both more common in CC than LC. Left-sided biopsies were sufficient for diagnosis in the vast majority of cases. Budesonide therapy is an effective strategy but long term maintenance therapy requires further investigation.

**Competing interests** None declared.

**PTU-113 QUALITY OF LIFE IN PATIENTS WITH ILEOANAL POUCH: A SURVEY COMPARING TWO DIFFERENT PATIENT POPULATIONS**

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**Introduction** Ileal pouch anal anastomosis (IPAA) is the standard restorative procedure for ulcerative colitis (UC) following colectomy. This operation is, however, associated with distinct rates of failure and complications. We performed a survey to evaluate the quality of life (QoL) after IPAA comparing patients followed up in two different teaching Hospitals in London (L), UK and Bologna (B), Italy.

**Methods** A total of 126 (71L+55B) UC patients received the questionnaire by mail or during clinic. The questionnaire was done according to the IBDQ and it was designed to assess pouch function, disease-specific adjustment, lifestyle aspects and psychological factors. 85 (43L+42B) patients (67%) returned it (M/F= 46/39; age 41±16 years); average pouch duration was 5–7 years.

**Results** There was no significant difference between L and B in terms of age, gender, marital status, pouch duration, bowel frequency (median 3–6 motions per day and 1–2 per night), experience of leakage (30% more than once a week) and need of additional surgery (0.05%). In L there were significantly more patients who had at least one episode of pouchitis (72%) compared to B (33%). L used significantly more alternative remedies (L 11% vs B 0%), antimotility drugs (L 44% vs B 30%), antibiotics (L 65% vs B 29%) and steroids (L 16% vs B 7%). No difference in immunosuppressant (18%) and VSL#3 use (22%). L patients regret having IPAA significantly more frequently (L 13% vs B 0.02%), cope less with the stoma (in L 39% hated it vs 0% in B), suffer more of unpredictability (L 51% vs B 19%), are less capable to hold the stool for more than 1 h (L 62% vs B 88%) and have more worrying thoughts (L 30% vs B 9%). B patients play sport significantly more frequently (B 76% vs L 53%). L and B reported similar QoL, well being, cheerfulness, ability to work, go on holiday and enjoy things they used to do; similar confidence in doing whatever they want and level of concern in finding a toilet.

**Conclusion** Our survey showed that in London patients developed more pouchitis and therefore used more medications. They cope worse with the pouch and regret more having had surgery. Interestingly in Italy patients play more sport, but the overall quality of life was the same. Extent and severity of disease prior to surgery, smoking and association with primary sclerosis cholangitis may play a role in the increase incidence of pouchitis in London, but these data were not available in our anonymous questionnaire. Different biologic behaviour and/or genetic background may contribute in this difference.

**Competing interests** None declared.