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PTU-056 PREGNANCY OUTCOMES IN PATIENTS WITH CROHN'S DISEASE: LESSONS FROM AUDIT IN A SPECIALIST IBD CLINIC

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Introduction Crohn's disease (CD) affects mainly people in their reproductive years. Concerns regarding family planning are the impact of CD on fertility and course of pregnancy, transmission to the offspring, issues concerning drug safety, mode of delivery and congenital anomalies. Published data is reassuring but awareness of outcomes locally can provide data regarding possible additional benefit from specialist obstetric medicine service.

Methods Pregnant patients with CD were identified through the Electronic Patient Record System. Data were collected from

October 2008-November 2012. Further information on outcomes was gathered from individual consultation with patients.

Results 80 pregnancies in 57 patients with CD were identified. 10 patients currently pregnant, 9 patients (13 pregnancies) with incomplete data were excluded. Therefore, pregnancy outcomes of 57 pregnancies/38 patients (mean age: 30.7 years) were analysed. 31/38 (82%) of patients had luminal disease, 7/38 (18%) perianal disease. 36/38 (95%) conceived naturally, 1/38 (2.5%) by assisted reproduction, 1/38 (2.5%) by IVF. 25/57 (44%) pregnancies were on no treatment in early pregnancy, 4/57 (7%) on biologics [Infliximab 3/4 (75%), Adalimumab 1/4 (25%)], 6/57 (10%) on biologics + thiopurines (TPN), 6/57 (10%) on TPN, 6/57 (10%) on TPN + 5-ASA, 7/57 (12%) on 5-ASA, 2/57 (3.5%) on steroids and 1/57 (1.7%) on elemental diet. 15/57 (26%) pregnancies had flares, of which 5/15 (33%) continued throughout pregnancy. 5/15 (33%) occurred in the 1st trimester, 4/15 (27%) in the 2nd, 1/15 (7%) in the 3rd. Of all pregnancies with flares, 9/15 (60%) were on no CD therapy. The mean week of delivery was 39.5 weeks (36–42). 32/46 (70%) of deliveries were vaginal and 14/46 (30%) by Caesarian section (CS). Of CS, 8/14 (57%) were planned due to perianal disease 5/8 (63%) or obstetric indication 3/8 (37%). Pregnancy outcomes were: live births 46/57 (81%), miscarriages 10/57 (17%), termination 1/57 (2%). The mean birth weight (BW) of the newborns was 3 kg (1.9 kg–5.1 kg). 4/46 (11%) of the babies were of low BW (<2.5 kg). Neonatal issues were recorded in 5/46 (11%); 1 diabetes mellitus, 2 cardiac anomalies, 1 with viral infection at 8 days, 1 cot death. Of the miscarriages, 5/10 (50%) were on no CD therapy and 4/10 (40%) flared in early pregnancy. The termination was due to use of medication unrelated to CD that could potentially cause congenital anomalies.

Conclusion The number of pregnancies in a specialist IBD clinic is high up to 20/year in this series highlighting a potential additional service need. A specialist obstetric medicine service can provide reassurance regarding safety of drugs in pregnancy, which in turn may reduce flare rates and result in good pregnancy outcomes. Observed outcomes did not fall outside that expected from larger reported series.

Disclosure of Interest None Declared

PTU-057 POINT-OF-CONTACT FAECAL CALPROTECTIN (FC) TESTING IN DIARRHOEA HELPS DECISION MAKING FOR REFERRAL TO GASTROENTEROLOGISTS: A PRIMARY CARE PILOT STUDY IN NORTH EAST ENGLAND

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Introduction Faecal Calprotectin (FC) is a cytosolic protein belonging to the S-100 family of calcium binding proteins found in neutrophils. It is excreted in the intestinal lumen in inflammatory conditions of the gut and can be used to distinguish irritable bowel syndrome (IBS) from other inflammatory bowel conditions such as colitis, diverticulosis, etc. Point-of-contact qualitative FC tests are now available and can be used in primary care to aid decision making for referrals to gastroenterologists for young patients presenting with chronic diarrhoea.

Methods Aims To assess the feasibility and cost effectiveness of a primary care Pathway using a point-of-contact FC Test (Caldetect®) to aid decision making for referrals to gastroenterology in young patients presenting to their primary physicians with chronic diarrhoea. **Methods:** Primary Care data indicated that approximately 253 referrals are made annually to gastroenterologists from Primary Care to assess patients < 60 years presenting with diarrhoea, costing

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.

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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^{1,2,3}. 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).¹

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.²

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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