Results Standard injection as per conventional endoscopic mucosal resection was initially performed. Then a suitably sized snare was selected and the snare tip was used to make a single incision with cut current lateral to the polyp. The snare tip was then anchored at the site of the incision and then the snare was slowly opened and simultaneously positioned around the polyp. Once the snare was adequately placed the polyp was resected. Histology revealed a tubulovillous adenoma with low grade dysplasia which was excised completely.

Conclusions This technique provides an easy and safe way to resect en-bloc flat, large and challenging colonic polyps.

PTH-079
Fully covered metal stent insertion for the treatment of refractory post endoscopic sphincterotomy bleeding
Yasmin Kassir*, Alvin Ochieng, Phillip Berry, Terence Wong Guy’s and St Thomas’ NHS Foundation Trust, London, UK

Introduction Bleeding is a common complication of endoscopic sphincterotomy (ES), occurring in 4% of cases. Fully covered metal stents (FCMS) are mainly indicated in the treatment of biliary strictures, bile ducts leaks and biliary stones. Recent studies have shown the value of fully covered metal stent placement in the management of post ES bleeding after failure of primary endoscopic interventions.

Treatment options have previously been limited to arterial embolisation or surgery in cases where conventional endoscopic therapy has failed. FCMS placement provides a less invasive means of achieving haemostasis through mechanical tamponade and may be a suitable option in patients whose bleeding has not been controlled with first line endoscopic management.

Methods We report a case of post ES bleeding refractory to conventional therapy, where haemostasis was achieved through placement of a temporary FCMS. A 27 year old man underwent therapeutic ERCP for choledocholithiasis in which precut sphincterotomy (with needle knife) resulted in bleeding. Initial management with local injections of adrenaline, endoclips and heater probe therapy were unsuccessful in achieving prolonged haemostasis and the patient became haemodynamically unstable, with melaena and Hb drop from 103 g/L to 56 g/L. The patient underwent a repeat ERCP in which a fully covered (10 mm/6 cm) metal stent (Wallflex, Boston) was inserted across the ampulla to tamponade the site of bleeding. The stent remained insitu and was removed 6 weeks post initial insertion, with no residual bleeding. Of note, the patient developed acute cholecystitis 48 hours post stent insertion, requiring urgent cholecystectomy. There were no post-operative complications.

Results Our case demonstrates the successful management of post ES bleeding with the use of FCMS placement, avoiding the need for arterial embolisation or surgery. Despite achieving haemostasis, our patient developed acute cholecystitis following stent placement, requiring urgent cholecystectomy. This has been reported in up to 10% of patients with FCMS for all indications. The patient remained well post operatively and stent was removed with no residual bleeding.

Conclusion Our case supports the proposed use of FCMS placement as second line management in post ES bleeding refractory to conventional endoscopic therapy. In applying this technique we avoided the use of arterial embolisation and its associated risks and complications, of particular importance in a young patient such as ours. There is a risk of cystic duct outflow obstruction in the application of covered metal stents, as our case highlights, and it is important to recognise this when considering this treatment modality.

IBD

OTU-001 IDENTIFICATION OF A NOVEL THERAPEUTIC AGENT FOR TREATING IBD GUIDED BY SYSTEMS MEDICINE

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Introduction There remains an unmet need in the treatment of IBD. The SysmedIBD project established a multi-disciplinary...
HLA-DQA1 CONTRIBUTES TO THE DEVELOPMENT OF ANTIBODY RESPONSE TO ETROLIZUMAB IN MODERATE TO SEVERE CROHN’S DISEASE


Abstract OTU-002 Figure 1 Immunogenicity by immunomodulator and HLA-DQA1*05 for infliximab and adalimumab.

Conclusion We have demonstrated that immunogenicity to anti-TNF is determined by HLA variants. Pre-treatment genetic testing might allow the use of individual risk profiles and targeted use of immunomodulatory therapies to deliver more durable, safe and cost-effective anti-TNF therapy.
severe Crohn’s Disease (CD) to determine safety and efficacy. Results of the Phase III BERGAMOT (NCT02394028) exploratory induction cohort are presented.

**Methods** Eligible pts with moderate to severe CD (refractory/intolerant to anti-TNFα agents, immunosuppressants, and/or corticosteroids) were assigned (2:2:1) etro 105 mg SC Q4W, etro 210 mg at wks 0, 2, 4, 8, and 12, or placebo (pbo) during a 14-wk induction period. Endpoints included CDAI remission (CDAI <150), CDAI-100 and –70 responses, PRO2 remission (weighted combined score ≤11, based on pt report of liquid/very soft stool frequency [SF] and abdominal pain [AP]), symptomatic remission (unweighted SF ≤3 and AP ≤1), and endoscopic improvement (≥50% reduction from baseline SES-CD) at wk 14.

**Results** 300 pts (73% aTNF-experienced) with moderate to severe CD (mean CDAI [SD], 315.6 [60.0]; mean SES-CD [SD], 14.1 [7.3]; median faecal calprotectin [range] 918 [30–15 451] μg/g; median C-reactive protein [range], 9.75 [0.2–148.0] mg/L) received etro 105 mg (n=120), etro 210 mg (n=121), or pbo (n=59).

Symptomatic remission was seen in a greater proportion of pts receiving etro 105 mg and 210 mg compared with pbo at wks 6, 10, and 14. More pts achieved endoscopic improvement with etro 105 mg and 210 mg compared with pbo at wk 14 (table 1).

CDAI remission at wk 14 was greater with etro 105 mg and 210 mg compared with pbo: 23.3% (17.6, 30.2), 28.9% (22.7, 36.1) and 16.9% (10.4, 26.4) respectively. PRO2 remission was achieved at wk 14 in 28.3% (22.1, 35.5), 28.9% (22.7, 36.1), and 20.3% (13.1, 30.2) respectively.

The frequency of adverse events with etro was comparable with pbo; no deaths, anaphylaxis or progressive multifocal leukoencephalopathy occurred.

**Conclusion** Treatment with etro was well tolerated and resulted in clinically meaningful endoscopic improvement in pts with moderate to severe CD. Rapid symptomatic remission was observed as early as wk 6 and sustained through wk 14. Enrolment into induction cohorts and the maintenance phase is ongoing.

**Abstract OTU-003**

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**Abstract OTU-004**

**SHALLOW WHOLE-GENOME SEQUENCING PREDICTS THE FUTURE CANCER RISK OF LOW-GRADE DYSPLASTIC LESIONS IN ULCERATIVE COLITIS**

1,2Abraham Al Bakir, 3Kathleen Curtius, 4Anne-Marie Baker, 1Theo SD Clarke, 1Morgan Moorghen, 1Marnix Jansen, 2Manuel Rodriguez-Justo, 1Simon Leedham, 1Ailsa Hart, 1Trevor Graham, 2Barts Cancer Institute, London, UK; 3IBD Unit, St. Mark’s Hospital, Harrow, UK; 4Pathology Department, St. Mark’s Hospital, Harrow, UK; 5Pathology Department, University College Hospital, London, UK; 6Wellcome Trust Centre for Human Genetics, Oxford, UK

The management of low grade dysplasia (LGD) in ulcerative colitis (UC) is uncertain due to the variable risk of progression to colorectal cancer (CRC). Chromosomal copy number alterations (CNAs) occur in colonic epithelial cells of UC patients who have developed CRC. The burden of CNAs in precursor LGD relative to high-grade dysplasia (HGD) and CRC has not been defined, and the correlation between LGD CNA burden and future HGD/CRC risk is unknown.

Shallow whole-genome sequencing is a novel, cost-effective technique for high resolution CNA assessment in formalin-fixed, paraffin-embedded tissue.

**Methods** We identified 19 UC proctocolectomy specimens with HGD/CRC, and analysed 77 neoplastic regions (36 LGD, 34 HGD and 7 CRC). We then analysed 13 'progressor' patients with 27 LGD lesions who subsequently developed HGD/CRC a median 427 days later (IQR 213–777), and 22 'non-progressor' patients with 26 LGD lesions who remained HGD/CRC-free >5 years later. The two patient groups are matched for age, gender, disease duration and LGD location.

Histological diagnosis was confirmed by two blinded pathologists. Shallow whole genome sequencing (0.1x) was performed using a standardised pipeline for epithelial cell enrichment, DNA extraction, library preparation, next generation sequencing and bioinformatic analysis.

**Results** A median 12% of the genome of LGDs from proctocolectomy specimens showed CNAs (IQR 4%–32%), compared to 23% in HGD/CRC (IQR 19%–42%, p=0.003). Similarly, the number of CNA events was greater in HGD/CRC compared to LGD (p<0.001). Multiple CNAs involving key driver genes were more frequent in HGD/CRC compared to LGD (adjusted p-values<0.05), including 8q gain (MYC loss, OR 17.2), 4q loss (OR 4.59) and 18q loss (DCC/Smad4 loss, OR 4.15).

**Abstract OTU-004**

Both the maximal total CNA burden and number of CNA events are greater in LGD of progressor than in LGD of non-progressors (p<0.01) as shown in the two violin plots.

**Abstract OTU-004 Figure 1**

**Abstract OTU-004 Figure 2**

10.1136/gutjnl-2018-BSGAbstracts.103
The Kaplan-Meier plot demonstrates that patients in this cohort bearing LGD with the 25% greatest CNA burden are significantly more likely to develop future CRC/HGD than the remaining 75% of patients (HR 5.1, p=0.001).

Conclusions LGD lesions demonstrate a surprising diversity in CNA burden, with some LGD lesions bearing CNA profiles indistinguishable from HGD/CRC. Shallow whole-genome sequencing has potential translational utility, by stratifying patients with LGD lesions according to risk of progression to HGD/CRC.

**OTU-005**

TARGETING EXPANDED GUT HOMING EFFECTOR T CELL LINEAGES IN GI-GVHD: A NEW THERAPEUTIC PARADIGM


Introduction Acute graft versus host disease may affect the gastrointestinal tract (aGI-GvHD) in up to 60% of haematopoetic stem cell transplant (HSCT) recipients who develop GvHD resulting in significant morbidity. Half of these patients will develop steroid refractory disease which is associated with high mortality (up to 90%) due to lack of safe and efficacious therapies. Here we test the hypothesis that the integrin α4β7/Madcam-1 pathway is clinically important in the pathogenesis of human aGI-GvHD.

Methods Prospective experimental study, recruiting HSCT recipients with aGI-GvHD (n=10) and controls [IBD (n=36) and non-IBD controls (n=32)]. Samples collected included peripheral blood and distal colonic biopsies. The α4β7 +CD4 +compartment was phenotyped with a multiparametric flow cytometry panel. MADCAM-1 and S100A8 (the calprotectin subunit; biomarker of intestinal damage) expression in the gut were tested with RT-PCR. Clinical data on aGI-GvHD patients treated with vedolizumab were prospectively collected.

Results Within the effector memory population (CD3 +CD4 +CD45RA-CD45RO+CCR7-) there was significant enrichment of α4β7 +effector memory cells in both inflammatory conditions (IBD: 24%±2.7, aGI-GvHD: 29%±6.5 as controls: 17%±1.1, both p<0.05). Analysis of each individual subtype of the effector T cell lineages demonstrated that β7 expression was especially enriched in Th1 (CXCR3 +CCR6-), Th17 (CCR6 +CXCR3-) and Th1/17 (CXCR3 +CCR6+) (p=0.0034). MADCAM-1 expression in aGI-GvHD is upregulated in comparison to non-IBD controls (fold change: 2 [0, 5], p=0.006)) and at similar levels with patients with UC [2 [0, 9]]. Levels of MADCAM-1 expression correlated to the expression of the calprotectin subunit S100A8 [r=0.90, 95% CI(0.54, 0.99), p=0.014]). Six patients with steroid refractory aGI-GvHD patients were treated with vedolizumab, a monoclonal antibody targeting α4β7. Five patients had a sustained clinical improvement (75% median reduction in clinical score, p=0.03) up to 6 months of follow up. These results compare favourably to other patients with steroid refractory aGI-GvHD treated at our centre with other second line treatments.

Conclusions For the first time, we show that aGI-GvHD is associated with significant expansion of gut homing effector lineages, most notably Th1 and Th17 cells. Interestingly the ligand for the α4β7 integrin (Madcam-1) is also highly expressed in gut tissue from aGI-GvHD patients, supporting further the therapeutic targeting of this gut homing pathway. Our promising clinical data on vedolizumab use have the potential to change the landscape of treatment in this condition.

**Abstract OTU-006**

THE INTERLEUKIN-6 RECEPTOR AS A DRUG TARGET IN INFLAMMATORY BOWEL DISEASE; A MENDELIAN RANDOMISATION STUDY

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Introduction Excessive production of interleukin-6 is associated with active inflammatory bowel disease (IBD). Blockade of the interleukin-6 receptor (IL6R) with a monoclonal antibody (tocilizumab) is licensed for treatment of rheumatoid arthritis. Clinical trials of IL6R inhibitors in IBD have been small in numbers, with varying efficacy. The IL6R SNP rs2228145 associates with a similar pattern of effects to tocilizumab therapy (higher soluble IL6R, lower c-reactive protein and fibrinogen), making it an attractive genetic instrument for drug target validation.

Methods We performed a two sample Mendelian randomization study using rs2228145 (a variant associated with impaired IL6R signalling) to evaluate the role of IL6R inhibition for primary prevention of IBD. Gene – soluble IL6R biomarker associations were estimated in 1650 individuals, as a proxy for defective IL6R signalling. Gene – IBD associations were estimated in 49 833 cases and 61 630 ancestry matched controls from publically available IBD genome wide association study (GWAS) summary statistics.

Abstract OTU-006 Abstract OTU006 Figure 1 Forest plot of odds ratios (OR) for Crohn’s disease (CD) and ulcerative colitis (UC) per doubling of soluble IL6R, used as a proxy for defective IL6R signalling as described elsewhere.

Results In a fixed effects meta-analysis of 26 788 cases with Crohn’s disease (CD), 23 045 with ulcerative colitis (UC) and 61 630 controls, genetically elevated soluble IL6R was
Filgotinib decreases inflammatory markers associated with endoscopic improvement in moderate to severely active Crohn’s disease

Introduction Filgotinib (FIL) is a JAK1-selective inhibitor currently in Phase III development for the treatment of ulcerative colitis and Crohn’s disease (CD). In a Phase II study in patients with moderately to severely active CD (FITZROY), ClinicalTrials.gov ID#NCT02048618), 10 weeks of treatment with FIL 200 mg once daily demonstrated significantly higher clinical remission rates compared with placebo. Here, we report treatment-induced changes in serum cytokines, C-reactive protein (CRP) and faecal calprotectin (FC) and investigation of the association of these biomarkers with endoscopic scores.

Methods Serum samples were acquired at baseline (BL), and Weeks 2, 4, and 10 and stool samples collected at BL and Week 10. Serum cytokines were measured by chemiluminescence, CRP by immunoturbidimetry and FC by Calprest+. Percent change of biomarkers from BL at post-treatment visits were compared between placebo (PBO) (n=44) and FIL-treated (n=128) patients using an ANCOVA model adjusting for BL biomarker levels and stratification factors (steroid use, prior anti-TNF exposure and BL CRP). Association of change in biomarkers with Week 10 endoscopic response (>50% decrease from BL in SES-CD score) was assessed by AUROC.

Results Biomarker levels at BL were comparable between PBO and FIL treatment groups, except IL-17A and VEGF-A which were higher in PBO (medians at 3.2 and 547.2 pg/ml vs. FIL group (1.3 and 389.6 pg/ml, p<0.05). FIL treatment induced reductions in FC (median% change of −30% to −35%), serum IL-6 (−11% to −20%) and serum VEGF-A (−8% to −12%) were observed at all time points. Decline in FC, CRP and VEGF-A in FIL-treated patients was observed at Week 2 and was significant compared with PBO-treated patients (p<0.05). No significant change was observed for IL-10, IFN-γ, and IL-8. No significant changes were observed in PBO-treated patients. In FIL-treated patients, a significant association was observed between the decrease in both systemic serum CRP and IL-6 and mucosal (FC) biomarkers and endoscopic response.

Conclusions Filgotinib treatment led to an early reduction in markers of systemic and mucosal inflammation that correlated significantly with endoscopic response.
Abstracts

of ‘naïve’ status (y or n) was static at ~50%; categorization of clinical indication consistently high at >80% of cases.

**Outcome measures** By Sept 17, Physician Global Assessment (PGA) was reported at 1053 initiation events for CD (62%) and UC 940 (66%); and at 1537 (97%) and 1248 (80%) post-induction reviews showing rapid adoption, but data for disease activity indices (HBI or SCAI) remained static at around 10%. The next upload (Feb 2018) contains almost 40 000 records from 63 sites and confirms continuing growth (analysis in progress).

**Conclusions** There has been significant increase in participation and in the breadth and depth of data being submitted to the UK IBD-R, particularly for biological therapies. Patterns of outcome data collection suggest clinical teams favour simple global outcome measures to formal activity indices – likely reflecting the added burden of administrating and recording the data. However, the feasibility of site-level reporting to support local biologics registries is now established.

_Funded by Crohn’s and Colitis UK_

**OTU-009** MODELING CASELOAD STANDARDS FOR IBD SPECIALIST NURSES IN THE UK

Isobel Mason*, Alison Leary. Crohns And Colitis UK, St Albin, UK

10.1136/gutjnl-2018-BSGAbstracts.108

**Introduction** The national standards for IBD care defined the numbers of nurse specialists required as 1.5 FTE per 2 50 000 population. The aim was to publish a new, robust, validated national standard and caseload.

**Methods** A consensus workshop of 15 IBD nurse specialists from across the UK met to check assumptions regarding workload and activity of this group. A 24-item questionnaire, exploring demographic data, caseload, workload and experience was developed. This was distributed through the RCN IBD Nursing Network. Data was modelled using descriptive statistics and pattern recognition.

**Results** 164 responses were received (55% response rate), 76% were from England. Responses were received from all four countries of the U.K. Most respondents covered a single (60%) or two (25%) hospital sites. 38% of respondents had less than 3 years experience working with IBD patients. 62% having four years plus experience. 32% had over ten years experience. 90% of the responding CNS were working solely in IBD. 82% reported spending 80% to 100% of their time on IBD. 51% worked with adult and transition patients. 72% of respondents worked full time. 84% of respondents regularly carried out unpaid overtime. The amount of unpaid overtime carried out equaled 17.6 FTE per week. Most common was ‘Clinical Nurse Specialist’. Grade 7 most common grade for respondents (65%). 61% received either no admin support or support for clinic letters only. The number of unfilled posts was estimated to be equivalent to 24.5 FTE. No respondents reported frozen posts. 43% of respondents had a prescribing qualification. 82% reported participation in CPD/education within the last 12 months. 63% of respondents had a higher caseload than the recommended level. Caseloads as high as 2000 patients plus were reported. Respondents generally had a positive experience of working in an MDT.

**Conclusions** This study recommends a caseload of 2.5 Full Time Equivalent (FTE) IBD specialist nurse per 2 50 000 population (a static caseload of 500 per FTE).

The original recommended caseload for IBD specialist nurses is 666 patients (or 1.5 FTE per 2 50 000 population) per FTE nurse. This does not allow for proactive management, advancing practice, cover arrangements and is not optimal for care.

There is a shortfall in the UK. 63% have much higher caseloads than the original recommended standard.

Compared to other specialities IBD specialist nurses have been working in specialist practice for less time (for example 52% had less than 7 years’ experience vs 25% of prostate cancer specialist nurses).

Considerable amount of unpaid overtime (4.13 hours per week each on average, equal to 17.6 FTE per week in total in this group). Worsened where administrative support is limited.

43% of respondents have a prescribing qualification only 14% have a Masters in advanced practice. To achieve a greater number of advanced practice nurses, this is an issue which needs to be addressed in light of the reduction in funding for continuing professional development nationally.

IBD specialist nurses generally have a positive experience of Multidisciplinary Team working (MDT) and feel able to fully contribute and advocate for patients within the MDT.

The role of the IBD specialist nurse is a complex case managing role involving interacting with many other specialties to deliver care for the patient population over their entire treatment pathway from pre diagnosis to continuing care.

**OTU-009** PATIENTS’ PERCEPTION OF Fecal CALPROTECTIN TESTING IN INFLAMMATORY BOWEL DISEASE: A MULTI-CENTRE PROSPECTIVE SURVEY

1Rahul Kalla, 2Ray Bapat, 3Simeon Vain, 4Gonzalo Hijos, 5Benjamin Crooks, 6G Moore, 7Veronica Hall, 8Suzanne Tatersall, 9George Lipscomb, 10Fredano Gomollon, 11Jorgen Jarsens, 12Sall Singh, 3Royal Bolton Hospital, Bolton, UK; 4Monash Health, Melbourne, Australia; 5Akerhus University Hospital, Laronskog, Norway; 6HEU Jozano Biesa, 7IS Aragon, Zaragoza, Spain

10.1136/gutjnl-2018-BSGAbstracts.109

**Introduction** Faecal Calprotectin is an established biomarker in the investigation and management of Inflammatory Bowel Disease (IBD). Despite its success, there appears to be practical issues with FC testing in clinical practice, including sample collection, sample delivery and processing delays. There are no studies exploring patients’ perception of faecal testing in IBD. We investigate patients’ perception of FC testing in clinical practice across centres in UK, Europe and Australia.

**Methods** A prospective patient survey was undertaken in an IBD unit in England from 12/2016 to 2/2017 and extended to 3 centres (Spain, Australia and Norway) from 07/2017 until 11/2017. Patients were asked to complete a 9-point based questionnaire in clinic which included diagnosis, patient demographics, previous FC testing, FC sample collection difficulty rating score (0–4) and preference to alternative methods of disease monitoring including blood tests and endoscopy. Predictors of FC testing difficulty were derived using multivariable logistic regression analysis. Continuous variables were categorised using integer cut points guided by the ROC curves and their relationship to the FC rating score.

**Results** A total of 585 patients with IBD completed the survey. There were 306 males (52%) with a median age of 43 years (IQR: 31–54). A total of 299, 279, and 7 patients had a...
Lack of standardised outcomes hampers effective analysis and comparison of data when comparing treatments in fistulising perianal Crohn’s disease (pCD). Development of a standardised set of outcomes would resolve these issues. This study provides the definitive core outcome set (COS) for fistulising pCD. 

**Conclusions**

Our study is the first to explore patients’ perceptions of FC testing as a routine biomarker in IBD across Europe and Australia. A significant 37% find FC testing challenging, in particular those aged <49 years with disease duration <35 months. Further qualitative studies understanding and addressing these practical issues may aid higher FC uptake in clinic.

**Methods**

Faeces was obtained from 63 donors (23 CD, 20 UC, 12 UC, 20 controls). Biopsies from the ileum and colon were obtained from 39 donors (21 CD, 18 UC). Biopsies were taken with a colonoscope to the level of the ileocaecal valve. Sequestration of the bacterial microbiome: few studies have looked at fungi (the mycobiome). Disturbance of Candida and Saccharomyces communities have been found and anti-saccharomyces cerevisiae antibodies (ASCA) may occur in CD. We aimed to characterise the fungal and bacterial communities in faeces of CD patients. We aimed to characterise the fungal and bacterial communities in faeces of CD patients. We aimed to characterise the fungal and bacterial communities in faeces of CD patients. We aimed to characterise the fungal and bacterial communities in faeces of CD patients. We aimed to characterise the fungal and bacterial communities in faeces of CD patients. We aimed to characterise the fungal and bacterial communities in faeces of CD patients. W

**Introduction**

Crohn’s disease (CD) is associated with a dysbiosis of the bacterial microbiome: few studies have looked at fungi (the mycobiome). Disturbance of Candida and Saccharomyces communities have been found and anti-saccharomyces cerevisiae antibodies (ASCA) may occur in CD. We found fungal metabolites in faeces of CD patients. We aimed to characterise the fungal and bacterial communities in the lumen and mucosa in IBD. 

**Methods**

Faeces was obtained from 63 donors (23 CD, 20 UC, 20 controls). Biopsies from the ileum and colon were obtained from 40 donors (18 CD, 12 UC, 10 controls). Metagenomic DNA was extracted and used for fungal 18S rRNA and bacterial 16S rRNA PCR. Amplicons were sequenced using Illumina MiSeq. Reads were quality filtered, trimmed, paired and OTUs were clustered. OTU table, fasta file, phylogenetic tree and metadata were used for statistical analysis. ASCA and calprotectin were measured by ELISA. 

**Result**

The faecal bacterial community is dysbiotic in CD; alpha diversity is low (figure 1), with beta diversity CD samples form a separate cluster (figure 2) and these are more phylogenetically conserved (figure 3). Disease distribution, ASCA and calprotectin explain some of the diversity. The mycobiome does not seem to be different in the faeces in CD and most samples have a high abundance of Saccharomyces. Other yeasts and moulds were also seen. Inter-kingdom co-occurrence network analysis shows few main clusters dominated by Firmicutes, but also Bacteroidetes and Actinobacteria, and two fungi: Malassezia and Aspergillus. 

**Abstracts**

DEVELOPING A CORE OUTCOME SET FOR FISTULISING PERIANAL

Crohn’s disease

Kapil Sahni, 1Phil Tozer, 1Samuel Adegbola, Matthew Lee, Nick Heywood, Angus McNair, Daniel Hind, Huha Yassin, Alan Lobo, Steve Brown, Shajj Sebastian, Robin Phillips, Philip Long, Ozan Faiz, Kay Crock, Sue Blackwell, Azmina Verjee, Alice Hart, Nicola Fearhead, ENiGMA Collaborators.

Introduction Lack of standardised outcomes hampers effective analysis and comparison of data when comparing treatments in fistulising perianal Crohn’s disease (pCD). Development of a standardised set of outcomes would resolve these issues. This study provides the definitive core outcome set (COS) for fistulising pCD.

Methods Candidate outcomes were generated through a systematic review and patient interviews. Consensus was established via a three-round Delphi process using a nine-point Likert scale based upon how important they felt it was in determining treatment success culminating in a final consensus meeting. Stakeholders were recruited nationally and grouped into three panels (Surgeons and Radiologists, Gastroenterologists and IBD specialist nurses, Patients). Participants received feedback from their panel (in the second round) and all participants (in the third round) to allow refinement of their scores.

Results A total of 295 outcomes were identified from systematic reviews and interviews that were categorised into 92 domains. 187 stakeholders (response rate 78.5%) prioritised 49 outcomes through a three-round Delphi study.

The final consensus meeting of 41 experts and patients generated agreement on an eight domain COS. The COS comprised three patient-reported outcome domains (quality of life, incontinence and a combined score of patient priorities) and five clinician-reported outcome domains (perianal disease activity, development of new perianal abscess/sepsis, new/recurrant fistula, unplanned surgery and faecal diversion).

Conclusion A fistulising pCD COS has been produced by all key stakeholders. Application of the COS will reduce heterogeneity in outcome reporting, thereby facilitating more meaningful comparisons between treatments, data synthesis and ultimately benefit patient care.
The mucosal bacterial community was dysbiotic and influenced by subject, disease distribution (figure 4) and diagnosis (figure 5). In terms of mycobiome, fewer viable reads were obtained, due to limited template. *Saccharomyces* was the most abundant fungi, but it was absent in some samples, other relevant genera were *Malassezia*, *Cladosporium*, *Aspergillus* and *Candida*. The last was found more often in controls.
Conclusions CD patients’ bacterial community is dysbiotic but fungi are not. *Saccharomyces* dominated most of faecal samples, but not biopsies. This implies it may not be a permanent resident of the mucosae. Fungi may arise from food: it is hard to discriminate what comes from food and what is active in the gut. The concept of a resident, symbiotic mycobiome needs further exploration.

**Abstract**

**OWE-010**

**Figure 5** NMDS weighted UniFrac (bacteria-all biopsies – diagnosis) R²=0.11 p=0.001

**Conclusions**

CD patients’ bacterial community is dysbiotic but fungi are not. *Saccharomyces* dominated most of faecal samples, but not biopsies. This implies it may not be a permanent resident of the mucosae. Fungi may arise from food: it is hard to discriminate what comes from food and what is active in the gut. The concept of a resident, symbiotic mycobiome needs further exploration.

**OBT-003**

**PAEDIATRIC CROHN’S DISEASE PATIENTS IN REMISSION HAVE A REDUCED SKELETAL MUSCLE PROTEIN BALANCE AFTER FEEDING**

1Gordon Moran, 1Amanda Walker, 1Aline Nixon, 1David Devadason, 2Rafeeq Muhammed, 3Kostas Tsintzas, 3Sian Kirkham, 5Francis Stephens. 1Nottingham University Hospitals NHS Trust; 2NIHR Nottingham Biomedical Research Centre; 3School of Life Sciences, University of Nottingham; 4Birmingham Children’s Hospitals; 5Sports and Health Sciences, University of Exeter

**Introduction**

Sarcopenia is common in active Crohn’s disease (CD) and still prevalent in remission. This can lead to fatigue, physical inactivity and poor quality of life but the aetiology is unclear. We aimed to investigate the association between sarcopenia and anabolic resistance (AR) and insulin resistance (IR), and the role of physical activity in age, gender matched children with CD.

**Methods**

18 fasted, male and female CD (on thiopurines+anti-TNFα) in deep remission (16 y, BMI=21) and 9 matched controls (Con) (16 y, BMI=21) drank a liquid meal (Ensure plus, 44 g CHO, 14 g PRO, 11 g fat) at t=0. Arterialised hand and venous forearm blood samples were collected concurrently and brachial artery blood flow measured at baseline and every 20 mins for 2 hours. Net balance of branched chain amino acids (BCAA) and glucose were derived, giving indices of skeletal muscle protein balance and IR. Subjects had a DEXA scan and handgrip dynamometer test on the day, and wore a pedometer and completed a food diary (for 3 days) to assess physical activity and food intake. Patient questionnaires (incl. IBD-fatigue) were completed.

**Results**

Net BCAA balance across the whole 2 hours was lower in CD vs Con (−0.1±0.2μmol/min vs 0.6±0.3μmol/min, p=0.05). Yet an initial response to feeding (t=0 to t=20) was exhibited by both CD (+1μmol/min) and Con

**Abstract**

**OWE-011**

**CLINICAL EFFECTIVENESS, SAFETY AND IMMUNOGENICITY OF ANTI-TNF THERAPY IN CROHN’S DISEASE: 12-MONTH DATA FROM PANTS**

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**Results**

1601 (49% male, median age 33 years [IQR 23–47]) eligible patients were recruited from 118 sites. Patients were treated with IFX (751 [47%]: REM, 200 [12%] CT-P13) or ADL (650 [41%]). Baseline characteristics included: median disease duration 3 years (IQR 1–10); steroids 27%, azathioprine 44%, mercaptopurine 8%, methotrexate 5%; median CRP in IFX 9 mg/L (IQR CI 3–24) and 6 mg/L (IQR 2–14) in ADL. PNR at week 12–14 was 21%, 21% and 26% in the REM, CT-P13 and ADL treated patients respectively. PNR was associated with older age (p=0.0004), higher BMI (p=0.03) and low DL (p<0.0001 for IFX and ADL): Week 54 remission rate was 40%, 40% and 34% of the REM, CT-P13 and ADL treated patients. At wk 54, the immunogenicity rate for REM, CT-P13 and ADL was 26%, 28% and 11% rising to 42%, 38% and 23% by 3 years respectively (IFX vs. ADL p<0.0001: REM vs. CT-P13 p=0.25). Immunogenicity was associated with non-remission at wk 54 (p<0.0001 for both IFX and ADL). Immunomodulator use reduced the risk of immunogenicity for both IFX (HR=0.37, p<0.0001) and ADL (HR=0.34, p<0.0001). 140 patients (9%) withdrew drug for SAEs including 5 who died, 3 from CD and 2 from possibly drug-related acute respiratory illness.

**Conclusions**

This is the largest prospective real-life study of anti-TNF therapy in IBD. We report the clinical effectiveness, safety and immunogenicity of REM, CT-P13, and ADL. This cohort provides a unique bioresource for multi-omics studies investigating personalised approaches to anti-TNF therapy.
Abstracts

V565, A NOVEL ORAL ANTI-TNF DOMAIN ANTIBODY, IMPACT OF IMPROVED ACCESS TO BIOLOGIC THERAPIES AND PHYSICIAN ENGAGEMENT ON EXCESS STEROID EXPOSURE


Background Steroid free remission is an important goal of IBD therapy. The aim of this study was to evaluate temporal changes in steroid prescribing in UK IBD outpatients in the context of major changes in UK prescribing guidelines and physician participation in audit and tailored service changes.

Methods Steroid use over the previous 12 months was recorded for unselected outpatient attenders against a definition of excess from ECCO guidelines. Data were collected from 7 centres that had completed a steroid assessment audit cycle in 2015, as well as from 12 new matched centres.

Results Data was collected for 2385 patients May-July 2017 and compared with 2015 data from 1176 patients. Overall disease distribution was 47.1% CD, 49.6% UC and 3.3% IBD-U, whilst 77.7% of patients were in clinical remission at the time of assessment. There was only a modest increase in patient exposure to anti-TNF from 2015 to 2017: 30.6% to 37.2% in CD (p=0.009) and 9.9% to 12.0% in UC (p=NS). Anti-integrin usage increased from 0.8% to 3.3% in CD (p=0.002) and from 1.6% to 2.4% in UC (p=NS). For centres taking part in the 2015 audit, steroid exposure rates fell from 30% to 23.8% (p=0.003) and steroid excess from 13.7% to 11.5% (p=NS). Steroid exposure and excess rates for sites that had not been part of the previous audit were significantly higher (31.0% excess, 17.1% exposure, p=0.0001 for both). There were no significant differences in important baseline characteristics of 2 groups of sites. Logistic regression analysis revealed independent predictors of reduced risk of steroid excess, after correction for disease severity. For CD these included treatment with anti-TNF therapy (p=0.04), treatment in a centre with regular IBD multidisciplinary team (MDT) meetings (p=0.01) and treatment in an original 2015 centre (p=0.02). For UC treatment in a 2015 centre was also significant predictor of protection (p=0.04) and treatment with thiopurine monotherapy a predictor of risk of excess (p=0.01); usage of anti-TNF therapy in UC did not reach significance for protection from excess.

Conclusions Changes in biologic access in the UK have resulted in only modest changes in prescribing behaviour and have not yet impacted significantly on excess steroid exposure in UC, unlike in CD. Participation in an audit cycle of steroid

ADTU-02

V565, A NOVEL ORAL ANTI-TNF DOMAIN ANTIBODY, REDUCES COLONIC MUCOSAL INFLAMMATION IN PATIENTS WITH UC

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Introduction Monoclonal antibodies to TNF transformed treatment options for patients with Inflammatory Bowel Disease (IBD). V565 is a novel oral anti-TNF domain antibody (Voraxpee) engineered to be resistant to intestinal proteases. It is in development as a potential oral treatment for IBD. In vitro it suppressed phosphorylation of tyrosine kinases and signalling proteins and inhibited the release of inflammatory cytokines following culture with biopsies taken from patients with CD (Crowe et al. 18th International Congress of Mucosal Immunology, July 19–22 2017, Washington DC, USA). It was safe and well tolerated after high single and multiple doses in healthy volunteers and patient volunteers with CD and resulted in high concentrations of active drug in ileal fluid and faeces.

Aims & Methods This open label study was designed to demonstrate that V565 enters GI mucosa and exerts a beneficial effect on inflammatory processes following oral dosing for 7 days to patients with Ulcerative Colitis. Patients with a Mayo score of 3–10 including an endoscopy score of ≥1 had up to 7 days of oral dosing with 555 mg tid V565. Sigmondoscopy with biopsies was performed before and after the dosing period. The primary outcomes of interest were presence of V565 in the mucosa and reduction from baseline in phosphorylation of tyrosine kinases and signalling proteins. Detection of V565 was determined by immunohistochemistry. Phosphorylation was determined using PathScan RTK signalling arrays (Vossenkaemper et al 2014. Gastroenterology 147:172–83).

Results Five patient volunteers were treated Due to visit scheduling, most received 6 days treatment. Presence of V565 was confirmed in the inflamed lamina propria and co-localised with CD14 + macrophages in post-treatment biopsies. Overall phosphorylation of the panel of kinases and signalling proteins was reduced by approximately 50% in four of the five patients. There were no treatment induced ADAs.

Conclusion V565, an oral anti-TNF domain antibody engineered to be resistant to intestinal proteases, was demonstrated bound to CD14 + macrophages in the lamina propria of UC patients and resulted in inhibition of mucosal inflammatory processes after 6–7 days oral dosing. The reduction of 50% in overall phosphorylation is similar to that seen in an earlier study of UC biopsy cultures with infliximab at a concentration of 67 nM (10 μg/ml), a serum concentration associated with mucosal healing (Ungar et al, Clin Gastroenterol Hepatol. 2016 Apr;14(4):550–557). These results provide encouragement that oral dosing with V565 will be a beneficial oral treatment option for patients with IBD.
Introduction Primary sclerosing cholangitis (PSC) is a chronic inflammatory condition of the bile ducts leading to fibrosis and end stage liver disease. A lack of robust non-invasive biomarkers has been hindering disease monitoring and development of optimal therapies. We have previously noted that the high levels of faecal calprotectin (fcal) seen in PSC-IBD patients belie the mild or quiescent intestinal inflammation. An unsupervised proteomics study identified biliary calprotectin as a potential biomarker. Here, we test the hypothesis that fcal is a marker of biliary injury in PSC.

Methods We analysed paired endoscopic activity data (UCEIS) and fcal results of patients with PSC-IBD (n=20) or UC (n=20) who underwent colitis surveillance in the context of a colitis surveillance pilot study. Relevant clinical data was recorded prospectively. Recruiting consecutive patients attending for ERCP (n=6) allowed for the concomitant testing of biliary and faecal calprotectin.

Results As expected, fcal strongly correlated with severity of mucosal injury (UCEIS) in UC [r=0.82, 95% CI(0.58, 0.92), p<0.0001]. However, the correlation was weaker in PSC-IBD [r=0.59, 95% CI(0.19, 0.82), p=0.006]. Moreover, in patients with PSC-IBD and quiescent colitis (UCEIS: 0–1) fcal concentration was significantly higher in comparison to UC patients with comparable endoscopic activity [279 ug/g (10, 1560) vs. 30 (10, 161), p=0.015]. A trend towards abnormal liver biochemistry was seen in those PSC-IBD with higher fcal [ALP: 250U/L (113, 561) vs. 83 (59, 170), p=0.06, GGT: 331 U/L (117, 1014) vs. 51 (29, 153), p=0.02, AST: 53 U/L (26, 85) vs. 37 (22, 43), p=ns]. UC patients with quiescent colitis and fcal >150 had a higher risk of colitis relapse in 12 months [HR=7.6, 95% CI[1.8, 33.6]] in comparison to those with fcal <150. However, in patients with PSC-IBD and quiescent colitis a fcal >150 was associated instead with a higher risk of cholangitis associated complications (need for antibiotics or stent insertion), HR=6.5, 95% CI[1.3, 33.9]. Strikingly, biliary calprotectin concentration showed a strong correlation with fcal concentration (r=0.90, p=0.04). Interestingly, immunostaining of biliary brushings for calprotectin demonstrated positive staining in cholangiocytes as well as neutrophils and macrophages.

Conclusion In patients with PSC-IBD and quiescent colitis the identification of a raised fcal is likely to herald complications of inflammation in the bile ducts rather than the colon. In this setting, fcal may be a valuable prognostic biomarker of cholangitis. Additionally, our data suggest that in PSC, the source of raised fcal may also be the damaged biliary epithelium.

ADTU-05 GUT MICROBIAL COMPOSITION IN THE MIGRANT SOUTH-ASIAN IBD POPULATION IN UK

Introduction Epidemiological studies have highlighted that the South Asian migrant population in UK have a comparable risk of developing IBD but with a more aggressive phenotype than the white Caucasian population. It remains unclear if this is due to environmental/lifestyle factors or differences in host genetics. The human gut microbiota is impacted by health status and diet and therefore represents a potentially adaptive phenotype that is influenced by the environment. As the gut microbiota has been shown to be different in the native South Asian population compared to those in developed countries, we aimed to investigate if there were ethnic differences in the microbiota in IBD patients.

Methods Stool samples were collected from South Asian (n=20) and Caucasian patients (n=46) with IBD attending outpatient clinics at University Hospital Birmingham along with healthy controls (n=17). DNA was extracted and the V4 hyper-variable region of the 16S rRNA gene amplified and sequenced. Analysis was performed on the QIIME pipeline using the GreenGenes database. Diversity analysis was corrected for false discovery rates.

Result Patients with IBD had a significantly different gut microbial composition in comparison to healthy controls as expected (p=0.01). Gut microbial diversity was reduced in IBD (p=0.001). A significant decrease in Firmicutes phylum was observed in patients with IBD in comparison to healthy controls which was primarily due a reduced abundance of communities from genus Faecalibacterium prausnitzii, Lachnospiraceae, Ruminococcus and Blautia (p<0.002). Within the IBD cohort, the alpha or beta diversity of gut microbiota was very similar for South Asians and Caucasian patients. No significant differences were seen at any taxonomic levels. Published literature have previously demonstrated that the gut microbiota in healthy South Asians living in the subcontinent was enriched with populations of Lactobacillus, Ruminococcus, and Bifidobacterium bacteria. In our South Asian IBD cohort these microbial communities were significantly reduced.

Conclusion This is the first study to date investigating the gut microbial composition in the migrant population with IBD in UK. The gut microbiota in South Asian IBD patients is similar to Caucasian IBD patients living in UK. Our findings suggest the need to explore further the role environmental factors in the development of IBD associated dysbiosis but also the role of host factors in pathogenesis.
Background Vedolizumab (VDZ) is a gut selective α4β7 anti-integrin approved for the treatment of UC and CD. We aimed to assess one year clinical and safety outcomes of VDZ.

Methods We previously reported 12 week outcomes using retrospectively collected demographic, clinical, and adverse effects data of patients treated with VDZ at 8 UK centres since 2014. We now report longer term outcomes, evaluating clinical response at week 12 and 52, using Physician Global Assessment, Harvey Bradshaw Index (HBI) and partial Mayo Score (pMS).

Results Of 203 patients, 135 had CD (96% anti-TNF experienced) and 68 UC (66% anti-TNF experienced). 101 received concomitant immunomodulator therapy and 97 received steroid bridging therapy.

Of 135 CD patients, 9 discontinued VDZ prior to week 12. At week 12, 38.5% were in PGA remission and 40.0% had a PGA response. Between week 12 and 52, a further 35 patients discontinued VDZ. At week 52 PGA remission and response were seen in 39.2% and 24.3% respectively. Mean HBI decreased from 9.2 (baseline) to 5.1 (week 12) and 5.2 at week 52 (p<0.01).

Of 68 UC patients, 3 discontinued VDZ prior to week 12. At week 12, 48.5% were in PGA remission and 42.6% had a PGA response. Between week 12 and 52, a further 9 patients discontinued VDZ. At week 52, PGA remission and response were seen in 67.2% and 16.4% respectively. Mean pMS decreased from 6.1 (baseline) to 3.1 (week 12) and 2.2 (week 52; p<0.01).

Adverse events were reported in 48 cases (24%) Of these 29 were infection related. Overall incidence of infection was 11.1 per 100 person-years of VDZ exposure.

Conclusion In our cohort of refractory (predominantly anti-TNF experienced) patients, VDZ proved to be safe and effective. Although at 12 weeks response/remission rates were similar in CD and UC, VDZ appeared to be more effective at maintaining remission for UC compared to CD. The incidence of infectious complications was lower than that seen with anti-TNF therapies (average 14 per 100 person-years).

Introduction Tofacitinib is an oral, small molecule JAK inhibitor that is being investigated for ulcerative colitis (UC). The efficacy and safety of tofacitinib was demonstrated as induction and maintenance therapy in 3 Phase 3, randomised, placebo-controlled studies (OCTAVE Induction 1, NCT01465763; OCTAVE Induction 2, NCT01458951; OCTAVE Sustain, NCT01458574) in patients (pts) with moderate to severe UC.1

Methods We present interim safety and efficacy data up to 3 years of treatment (as of 8 July 2016) from an ongoing Phase 3, multicentre, open-label, long-term extension study (OLE; NCT01470612) in pts who had completed or demonstrated treatment failure in OCTAVE Sustain, or who were non-responders after completing OCTAVE Induction 1 or 2. Pts in remission at Week 52 of OCTAVE Sustain received tofacitinib 5 mg twice daily (BID); all others received 10 mg BID. At Month 2, all pts underwent endoscopy, and non-responders from Induction were mandated to withdraw if no evidence of clinical response was shown. Remission was defined by a Mayo score ≤2 with no individual subscore >1, and rectal bleeding subscore of 0. Binary efficacy endpoints were derived from Mayo score, based on local-read endoscopic subscore.

Results 914 pts (5 mg BID, n=156 [17.1%]; 10 mg BID, n=758 [82.9%]) received ≥1 dose of study drug; 381 pts (41.7%) discontinued. The most frequent AE leading to discontinuation was worsening of UC. The most frequent treatment-emergent AEs by system organ class (both doses) were ‘infections/infestations’ and ‘gastrointestinal disorders’, and by preferred term were ‘nasopharyngitis’ and ‘worsening of UC’. Serious infections AEs were reported in 4 (2.6%) and 14 (1.8%) pts with 5 and 10 mg BID, respectively. Malignancies excl. NMSC were reported in 9 (1.2%) pts in the 10 mg BID group (no clustering of malignancy type); none were reported in the 5 mg BID group. No new safety risks were identified. Data as ‘as observed’ for remission and mucosal healing at Months 2, 12 and 24 are shown.

Conclusions In pts with moderate to severe UC who remained in the OLE study, no new safety concerns emerged compared with those observed with tofacitinib in rheumatoid arthritis. Efficacy results from this OLE study support sustained efficacy with tofacitinib 5 and 10 mg BID.

Funded by Pfizer Inc.

REFERENCE
ACHIEVING BIOCHEMICAL REMISSION IN CROHN’S DISEASE WITH ADA MONITORING

Introduction: Adalimumab (ADA) is a well-established treatment for Crohn’s disease (CD). Despite this limited data are available regarding the relationship of serum ADA levels, and antibodies to ADA (ATA) with clinical outcomes.

Methods: We performed a prospective cross-sectional study to investigate the association of serum ADA levels and ATA on clinical outcomes. Inclusion criteria were a diagnosis of CD and minimum of 12 weeks therapy. Patients were written to in advance of their next clinic visit and advised to omit their ADA dose if due within 72 hours from their appointment. Harvey Bradshaw Index (HBI), serum ADA levels/ATA, CRP and faecal calprotectin (FC) were simultaneously collected at clinic. Biochemical remission was defined as FC <200 μg/g in addition to CRP <5 mg/L.

Results: At the time of drug level testing, 259 patients were on ADA maintenance therapy. A total of 195 samples were available for analysis from 178 patients; matched HBI, FC and CRP were available for 171 patients. Median duration of ADA therapy was 2.4 years (IQR 1.2−4.3) with 37/178 (20.8%) patients receiving concomitant immunosuppression. Median ADA levels were higher in patients receiving weekly (n=53) (14.0 μg/ml, 8.0−17.4) vs. fortnightly dosing (n=123) (11.0 μg/ml, 7.0−14.5, p=0.0095). 29/178 (16.3%) patients were positive for ATA. A clear negative correlation was observed between ADA levels and ATA (Spearman’s r=−0.567, p<0.0001). Median ADA levels were 11.4 μg/ml (8.0−15.0), 5.0 μg/ml (4.0−6.6) and 1.0 μg/ml (0.8−2.0) at ADA <10 AU/ml, 10−50 AU/ml and >50 AU/ml, respectively (p<0.0001). Patients in biochemical remission (n=81/171; 47.4%) had significantly higher ADA levels (12.0 μg/ml, 10.0−15.7) than those with active disease (8.0 μg/ml, 4.8−12.5, p<0.0001). ROC analysis revealed a positive correlation between ADA levels and biochemical remission [AUC (95% CI) 0.71 (0.63−0.79), p<0.0001]. An optimum ADA level of >8.8 μg/ml was identified for predicting biochemical remission (82.7% sens, 55.6% spec, positive LR 1.86). ADA levels but not ATA independently predicted biochemical remission in a multivariable logistic regression model.

Conclusions: Higher ADA levels were independently associated with biochemical remission; levels of >8.8 μg/ml, higher than previously suggested, might be an appropriate target in the maintenance treatment of CD.

Abstract PTU-001 Table 1 Summary of safety and efficacy is the OLE study

**PTU-002 TREATING ILEOCOLONIC CROHN’S STRICTURES WITH REMOVABLE-SEMS: EFFICACY AND SAFETY, A LARGE SINGLE CENTRE EXPERIENCE**

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Introduction: Crohn’s patients have a greater than 70% lifetime risk of developing ileocolonic anastomotic strictures. (Rieder et al 2013) The usual management of these strictures has been with surgery or endoscopic balloon dilatation (EBD). Both risk of complications, with a reported perforation rate of 4% to 11% with EBD. (Morar et al. 2015) Stenting is a new alternative.

We present the largest UK series of Crohn’s patients undergoing removable self-expanding-metal-stent’ (SEMS) and report on the efficacy and safety of this technique.

Methods: Crohn’s patients were identified following MR Enterography. Ileocolonic fibrostenotic strictures were assessed for stenting within an IBD MDT setting. Strictures were examined colonoscopically at stent retrieval.

Results: Eighteen patients were considered for stenting. Four were not suitable, 2 had inflammatory strictures, 1 had an inaccessible, or stenting inappropriate based on endoscopist judgement. Strictures5 cm lengths were stented, with the Hannaro Diagmed HRC-20–080–230, 80 mm length’ stent under combined endoscopic and fluoroscopic guidance. Stents were removed between 6 and 10 days post insertion. Demographic and disease data was collected. All patients were followed up post-procedure median 70 (Range 18 to 122) weeks. Stenting success was defined as successful placement when endoscopically attempted. Therapeutic success was defined by whether the stented stricture could be crossed colonoscopically at stent retrieval.
ASKING ABOUT BOWEL CONTROL PROBLEMS IN IBD: RESULTS OF FACE-TO-FACE SCREENING VERSUS SELF-REPORTING

Patients with IBD have difficulty revealing concerns about bowel control problems to clinicians, who do not actively ask about this symptom despite clinical guidelines recommending active-case finding in high-risk populations. With no available evidence to advise clinicians on how to ask, we aimed to determine the results of face-to-face or self-reported screening to identify faecal incontinence (FI) in IBD patients. We also asked about patients’ desire for interventions to improve continence. FI was defined in this study as: ‘ever having accidental passing of stool, faeces, poo into your underclothes, that you are either unaware of at the time, or unable to control’.

Methods This cross-sectional survey used a study-specific questionnaire to screen participants at either face-to-face interview (by clinician/researcher) or anonymously (participant self-completed). Eligibility criteria: 18 to 80 years of age, confirmed diagnosis of IBD, no current fistula, no stoma, any level of disease activity. Disease activity was measured using the Harvey Bradshaw Index or the Simple Clinical Colitis Activity Index.

Results Of 1336 participants, 48% were male; mean age 43 years (range 18–80); 55% had Crohn’s Disease (CD), 41% ulcerative colitis (UC), 4% IBD unclassified. FI (occuring ever) was reported by 63% of 772 screened face-to-face and 56% of 564 self-report participants ($p=0.012$). A total of 38.7% of all respondents expressed interest in an intervention for FI. Patients with CD were more likely to report FI than those with UC ($p<0.005$). FI was reported by 49% of participants in remission, and by 59%, 83% and 93% of participants with mild, moderate and severe relapse of IBD respectively ($p<0.001$).

Conclusions Bowel control problems are very common in patients with IBD (including in remission) and these symptoms can be identified by face-to-face interview and postal screening. Interest in interventions for FI is expressed by 38.7% of patients with IBD.

REFERENCES
Improvement was 4 days (range 1–28). Table 1 outlines clinical information for the CSrefr and CSresp groups. Infection occurred in 10 episodes of IFX prescription (59%), 9 requiring antibiotics, including 2 cases of Pneumocystis jirovecii pneumonia.

Conclusions 35% of irD/C due to ipi +nivo is CS-refractory. In the CSrefr group, CS duration was longer, macroscopic colitis was more common and most pts developed an infection. Interestingly time to progression of disease was longer in the CSrefr group. Prospective clinical trials are warranted to evaluate whether early IFX may reduce the burden of CS in the management of irD/C without compromising disease control.

Abstract PTU-005 Table 1

<table>
<thead>
<tr>
<th></th>
<th>CSrefr (n=17)</th>
<th>CSresp (n=54)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N (range)</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>Ipilimumab</td>
<td>8 (47) 30 (56)</td>
<td>16 (6) 11 (7)</td>
</tr>
<tr>
<td>Nivolumab</td>
<td>1 (6) 9 (16)</td>
<td></td>
</tr>
<tr>
<td>Ipilimumab +ni-vo</td>
<td>8 (47) 11 (20)</td>
<td></td>
</tr>
<tr>
<td>Days from start ICI to onset of irD/C</td>
<td>41 - 45 -</td>
<td>45 -</td>
</tr>
<tr>
<td>Grade 1/2</td>
<td>1 (6) 14 (26)</td>
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</tr>
<tr>
<td>Grade 3/4</td>
<td>16 (94) 40 (74)</td>
<td></td>
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<tr>
<td>Median days from start of ICI to CS (range)</td>
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<td>5 -</td>
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<tr>
<td>Days from start CS to IFX</td>
<td>14 (1–180)</td>
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<tr>
<td>Median duration CS</td>
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<tr>
<td>Grade 1/2</td>
<td>160 (49)</td>
<td></td>
</tr>
<tr>
<td>Grade 3/4</td>
<td>79 (47) 28 (279)</td>
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</tr>
<tr>
<td>Extra treatment</td>
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</tr>
<tr>
<td>Macroscopic abnormality on FS</td>
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<td>76/22/41 54</td>
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<tr>
<td>Microscopic abnormality only on FS</td>
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<td>6/9/41 22</td>
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<td>Normal FS</td>
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<tr>
<td>Unknown FS result</td>
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<tr>
<td>Disease progression</td>
<td>12 (6) 42 (79)</td>
<td></td>
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<tr>
<td>Median days to progressive disease</td>
<td>170 -</td>
<td>101 -</td>
</tr>
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</table>

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

Abstract PTU-006 Figure 1

Reference
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 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 biological, 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-biological 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.


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.
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 histopathological data were recorded. Lower GI findings in this cohort were also analysed.

**Results** We reviewed 40 OGDs performed in our unit for melanoma patients who developed diarrhoea after starting treatment with ICPI patients. In all cases flexible sigmoidoscopy or colonoscopy was also performed. Inflammatory changes were common, including gastritis (40%) and duodenitis (17.5%). Importantly, even in the absence of macroscopically visible mucosal injury, there was a significant burden of microscopic inflammation, especially in the duodenum. In patients with a normal duodenoscopy, significant microscopic changes were present in 28% of patients. Significant histological abnormalities included chronic inflammation and/or increased intraepithelial lymphocytes (86%) and villous atrophy (71%), consistent with pathologically relevant mucosal immune activation. Abnormalities in the oesophagus were also common (32%), but were dominated by candidiasis (15%), likely secondary to high-dose steroids used to treat this challenging condition. All patients in this cohort of ICPI-induced diarrhoea patients investigated with OGD additionally underwent lower GI endoscopy, which confirmed the presence of colitis in 65% of patients. Importantly, upper GI disease was just as common in patients with a normal lower GI investigation (57%) as those with overt colitis (54%).

**Conclusions** There is a significant burden of upper GI pathology, including macroscopic and microscopic mucosal injury and excessive immune accumulation, most notably in the duodenum, in patients with diarrhoea secondary to ICPI therapy. Additional findings that altered management included oesophageal candidiasis (likely a side-effect steroid therapy, which is usually rapidly initiated as soon as patients present with diarrhoea). Importantly, upper GI pathology is just as common in patients without colonic disease. OGD should be part of diagnostic work up of patients developing diarrhoea in the context of ICPI therapy.

**Abstracts**

**PTU-010** PREVALENCE AND PHENOTYPE OF IBD ACROSS PRIMARY AND SECONDARY CARE: IMPLICATIONS FOR COLORECTAL CANCER SURVEILLANCE

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10.1136/gutjnl-2018-BSGAbstracts.128

**Introduction** Patients diagnosed with colonic IBD have increased risk of colorectal cancer (CRC). Colonoscopic surveillance reduces the risk of CRC-associated death through early detection; national/international guidelines recommend chromoendoscopy. We aimed to assess the burden of IBD in primary care unknown to our service and to identify patients eligible for surveillance.

**Methods** We conducted a population-based observational study across primary and secondary care to evaluate the incidence/ prevalence of IBD in our catchment. We identified cases from primary care using searches of practice databases and in secondary care using searches of hospital records. Case inclusion required a specialist diagnosis of ulcerative colitis (UC), Crohn’s disease (CD) or IBD unclassified. IBD was phenotyped according to the Montreal Classification and patients under the age of 75 years, who had been diagnosed with IBD with colonic disease involvement for more than 10 years, were deemed eligible for colonoscopic surveillance.

**Results** Patients from 48/49 GP practices within our catchment were included. We identified 3690 patients with IBD living within our catchment of which 12% (875/3690) were unknown to any local secondary care service. Overall, UC prevalence was 453/100 000 people (95% confidence interval 433–474), Crohn’s disease prevalence was 311/100 000 (95% CI 293–327), and IBD unclassified prevalence was 44/100 000 (95% CI 38–51). Patients managed solely in primary care, compared with those in secondary care, were older (mean age 60.9 vs 56.2 years, p<0.0001) and had longer disease duration (20.3 vs 14.2 years, p<0.0001). The proportion of UC out of total IBD was higher in primary care (69% vs. 58%, p<0.0001). A higher proportion of IBD patients in primary care than secondary care had undergone a colectomy (17% vs 5%, p<0.0001). Overall, 13% (388/2815) patients known to secondary care and 29% (257/875) of patients unknown to any secondary care services were eligible for colonoscopic surveillance, equivalent to approximately one colonoscopy list per week.

**Conclusions** We report one of the highest prevalence rates of IBD in Western Europe (1 in 124 patients). 12% of patients living in our immediate catchment area were unknown to our service; a third of these were eligible for colonoscopic colorectal cancer surveillance. Effective colorectal cancer surveillance programmes in IBD must target primary-care populations and not just known secondary care populations.

**PWE-001** EFFECTS OF EBV NAIVE STATUS ON TREATMENT DECISIONS IN IBD


10.1136/gutjnl-2018-BSGAbstracts.129

**Introduction** Thiopurines, through an association with Epstein Barr Virus (EBV), confer an increased risk of GI lymphoma when used to treat Inflammatory Bowel Disease (IBD), with EBV naïve individuals carrying a higher risk.

**Methods** We conducted a retrospective analysis of IBD patients undergoing EBV screening between June 2015 and June 2017 and extracted relevant data from electronic records.

**Results** Overall 359 patients underwent EBV screening in the specified period with 43 (12%) patients being identified as EBV naïve. The EBV naïve sample consisted of 27 (63%) males and 16 (37%) females, with a mean age of 40.
EVALUATING THE ROLE OF MR ENTEROGRAPHY IN THE MANAGEMENT OF PATIENTS WITH CROHNS DISEASE

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10.1136/gutjnl-2018-BSGAbstracts.130

Introduction Magnetic resonance enterography (MRE) is widely available and is being increasingly utilised in the management of patients with Crohn’s disease (CD). Free of ionising radiation, it is particularly valuable in sequential imaging. In addition, it is an attractive, non-invasive option in the investigation of patients suspected to have small bowel CD. We sought to investigate whether MRE in patients with CD alters patient management as well as its utility in the diagnosis of CD.

Methods PACS was interrogated to identify patients undergoing MRE across two sites in a trust from March to April 2017. Unique patient IDs were cross referenced with Telepath, Allscripts and Endobase databases for demographic data, results of faecal calprotectin (FC) and clinical outcomes. MR protocol was standardised and calprotectin measurement has been available since 2016.

Treatment change was defined as treatment initiation, escalation or cessation and referral for surgery. Patients being worked up for CD were those that had diarrhoea, abdominal pain or weight loss as their primary indication for MRE.

Results There were 111 MRE carried out over the 3 month period, mean age 38.2 (12–82), male 44 (39.6%), female 67 (60.4%). Of those 57 (51.3%) had established CD and 53 (47.7%) were for investigation of suspected CD. In this group, the results of the MRE influenced the management of 39 cases (68.4%) vs 18 (31.6%) with no change. 30 (52.6%) patients had a new treatment or treatment escalation, 6 (10.5%) had their treatment stopped and 3 (5.3%) were referred for surgery. 24 patients with CD had FC done within 2 months of MRE. Interestingly all of those with a FC <250 ug/g had a normal MRE (n=8).

In patients being worked up for CD, 42 (79.2%) of the MREs were normal and 2 (3.7%) were highly suspicious for CD, the rest showed non-specific inflammation and other findings including liver haemangioma, cholecystitis, jejunal diverticulitis and a carcinoid tumour. Surprisingly, MRE was used as the initial investigation in 9 (16.9%) patients, in which there was one case of cholecystitis but the rest were negative. As in patients with CD, no patient with a FC <250 ug/g had a positive MRE.

Conclusion MRE results influence treatment decisions in CD, facilitating changes in management including withdrawal of biologics. It is seemingly ineffective as a diagnostic test for small bowel CD and calprotectin may be more useful in that context. This study is limited by the exclusion of patients with Crohn’s disease who have not had MRE but these findings suggest potential cost savings if MRE is reserved for patients with CD suggested by other means such as faecal biomarkers or endoscopy.

Abstract PWE-001 Table 1

<table>
<thead>
<tr>
<th>No of patients screened (n)</th>
<th>Initial treatment agent considered</th>
<th>No of patients in whom treatment was altered (n)</th>
<th>Agent changed to</th>
<th>Average increased cost expenditure per patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>22</td>
<td>Thiopurine</td>
<td>12</td>
<td>Biologic</td>
<td>£9942*</td>
</tr>
<tr>
<td>6</td>
<td>Biologic</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>5</td>
<td>**</td>
<td>1</td>
<td>Biologic</td>
<td>£4112*</td>
</tr>
<tr>
<td>1</td>
<td>Combination therapy</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Of these 43 patients, 5 were excluded from further analysis as their EBV status was tested for reasons unrelated to IBD management and 4 were excluded as their treatment was altered for reasons other than their EBV status. Table 1 shows the breakdown for the remaining 34.

Table 1 Number of patients undergoing EBV screening for initial thiopurine or biologic therapy and the resulting number of patients in whom therapy was switched and the subsequent cost expenditure. *Calculated based on the cost of 12 months of treatment in a 70 kg individual **Patients underwent EBV screening as part of generic pre-screening bloods.

Of the 13 individuals who had their therapy switched 8 (62%) were male and 10 (77%) were Caucasian.

Conclusions Overall EBV naïve status resulted in initiation of therapy different to the initial agent considered in 38% of patients, producing an overall cost expenditure of approximately £1 23 416 with treatment more likely to be switched in male and Caucasian patients.

However, the absolute risk of lymphoma remains low and given the context, the average age of patients being associated with poorer prognosis and increased likelihood of subsequent antibody development to biologic therapy in patients without initial thiopurine treatment, is the practice of EBV screening in IBD management clinically relevant?

PWE-003 ACETARSOL IS AN EFFECTIVE OPTION IN THE MANAGEMENT OF REFRACTORY PROCTITIS

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Introduction There is an urgent need for superior topical therapy for mesalazine-refractory ulcerative proctitis. Two small preliminary cohort studies have suggested good clinical efficacy data for organic arsenic derivatives such as acetarsol in refractory ulcerative proctitis. Our aim was to describe the effectiveness and tolerability of acetarsol suppositories in a cohort of inflammatory bowel disease (IBD) patients.

Methods We performed a retrospective cohort study by prospectively reviewing maintained clinical records for all patients exposed to acetarsol at the IBD clinic in Nottingham University Hospitals from 2004 to 2017. Response was determined as clinical improvement or improvement in endoscopic appearance. Serum arsenic and C-reactive protein levels were reviewed when available. Non parametric statistical analysis
was performed. Data are presented as median and interquartile range.

Results 35 patients were prescribed acetarsol suppositories (28 with proctitis, 5 with left-sided colitis, 1 with diversion colitis and 1 with chronic pouchitis). Twenty were males with median age of 44 (34) years and disease duration of 7 (19) years. Nearly all patients had failed mesalazine or corticosteroid-based topical therapy with 20 (57.1%) being refractory to immunotherapy and 3 (8.6%) to anti-TNF therapy. Acetarsol 250 mg bd for at least 4 weeks was prescribed in 75% of the cases. Median treatment duration was 56 days (28). Sixteen patients were exposed to acetarsol more than once. 76.7% of patients achieved clinical response. 3/35 patients had an endoscopic assessment with two of three patients showing endoscopic improvement. 33.3% patients required treatment escalation following acetarsol exposure with two undergoing subtotal colectomy. Five patients (14.3%) stopped acetarsol due to side effects. One patient experienced vomiting, palpitations and sweating, and the other four experienced headache, vomiting, anal itching and paresthesia. Median serum arsenic level was 728.25 (872) nmol/l (<130 nmol/L). Serum arsenic levels were not correlated with patient clinical response nor the need for treatment escalation.

Conclusions Acetarsol suppositories could be an effective and tolerable option in the management of refractory proctitis. A definitive study is urgently warranted to thoroughly investigate the clinical efficacy and safety of this promising drug.

PWE-004 TAPERING WITH BUCONIODE – LABEL RECOMMENDATION VERSUS CLINICAL REALITY
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Introduction Symptoms of steroid withdrawal may be avoided in most patients by tapering the dose over time when deciding to discontinue treatment. Patients exposed to steroid therapy, even if only for a short period of time are very likely to have diminished hypothalamic-pituitary-adrenal (HPA) axis function. Despite primarily local action, budesonide can also affect the HPA axis. Tapering of budesonide allows the adrenal glands time to return to their normal patterns of secretion. This is a precaution and highlighted in the Entocort* Summary of Product Characteristics recommendation where it is stated ‘when treatment is to be discontinued, the dose should normally be reduced for the last 2 to 4 weeks of therapy’. The presented study was investigating tapering habits for budesonide prescriptions in Crohn’s disease (CD) among gastroenterologists in Europe.

Methods An online survey** was conducted among a total sample of 161 gastroenterologists in 8 countries. The data collection took place from November to December 2016. The physicians in the sample received a link to an online questionnaire (local language) on a secure platform via email. The questionnaire on prescribing practices included the following questions with regards to the use of budesonide for the treatment of CD: (i) Do you normally recommend tapering dose in the last 2–4 weeks of budesonide treatment? (ii) Do you recommend tapering over 2, 3, or 4 weeks? (iii) Do you recommend tapering to either 6 mg then 3 mg, straight to 3 mg or to 6 mg only?

Results Of the 161 gastroenterologists surveyed, the majority (81%) tapered when prescribing budesonide; the countries where the response rate was ≥80% included Finland (100%), Norway (88%), Czech Republic (82%), Denmark (82%) and Spain (80%). Most gastroenterologists tapered over a 4 week time period (78%), with a small minority over other time schedules (2 or 3 weeks). The most commonly used tapering schedule was 9–6–3–0 mg (91%), with only 5% and 4% of gastroenterologists tapering using a 9–6–0 mg and 9–3–0 mg schedule, respectively.

Conclusions The majority of gastroenterologists surveyed are adhering to the budesonide label recommendation of tapering over a 2–4 week period when prescribing budesonide. The reasons behind 20% of prescribers deviating from the product labels needs further research to be addressed.

* The rights to Entocort, including the rights to the trademark, are owned by Tillotts Pharma AG except for the USA. ** Financial sponsorship was provided by Tillotts Pharma AG.

PWE-005 VEDOLIZUMAB DOSE ESCALATION AS A WAY OF RECAPTURING RESPONSE IN PATIENTS WITH INFLAMMATORY BOWEL DISEASE
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10.1136/gutjnl-2018-BSGAbstracts.133

Introduction Increasing vedolizumab (VDZ) dosing frequency to recapture response has been shown to be effective in clinical trials but there is limited real-life data from the clinical practice. In this study we assessed whether VDZ dose escalation helped recapture response in a large cohort of patients in a tertiary referral IBD centre.

Methods A retrospective cohort study was performed by reviewing prospectively recorded clinical data for patients who received VDZ between November 2014 and October 2017. Patients who had sub-optimal response and had been escalated to 6 or 4 weekly infusions were identified. Data collected for demographics, previous biologic exposure, concomitant immunomodulators (IM), steroid use (SU), clinical disease activity for CD (HBI) and UC (SCCAI), and CRP levels at baseline, 12 and 24 weeks after dose escalation.

Of the total 139 patients on VDZ, 36 (27%) had been escalated to Q4 (30) or Q6 (6), of whom 5 were further escalated to Q4 (72% male, median age 44, previous biologics exposure 81%, 49% concomitant IM and 16% SU at time of escalation). 18 patients had CD (50%), 14 UC (39%), and 4 (11%) IBD-U which were included in the UC group for the purpose of analysis.

Duration of VDZ before and after dose escalation with a median of 7 m (ranges 0–22, 2–25 respectively). Currently 76% remain on VDZ after dose escalation (median 7 m after escalation).

Clinical response was defined as HBI or SCCAI reduction >3. Remission as HBI <5 or SCCAI <3. Paired HBI, SCCAI, CRP values at baseline, week 12 and 24 were compared using Wilcoxon signed-rank test

Results Patients with CD had a median HBI of 4 (range 0–27), 4 (0–29) and 3 (0–8), at baseline, 12 and 24 weeks.
In UC group, the median SCCAI was 6 (range 0–11); 4.5 (1–11), and 4 (0–10) at baseline, 12 and 24 weeks. CRP for both groups at baseline was a median of 6 (1–23), 5 (1–46) at w12, and 2 (1–17) at w24.

**Abstract PWE-005 Figure 1**

HBI and SCCAI at baseline, 12 and 24 weeks after dose escalation

Statistically significant differences were noted in the UC group between SCCAI at baseline and after 24 weeks (p 0.01) and overall CRP at baseline and 24 w (p 0.04).

Of all patients with clinically active disease at baseline (n=20), 5 achieved clinical response (25%), an additional 4 achieved clinical remission (20%).

**Conclusions** In a real life setting, increasing dosing frequency in patients with sub-optimal response to VDZ is effective in approximately half of patients and should be considered as an intervention.

**PWE-006 SMOKING IN UC IS ASSOCIATED WITH DECREASED THIOPURINE USE BUT NOT STEROID DEPENDENCY OR COLECTOMY**

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10.1136/gutjnl-2018-BSGAbstracts.134

**Introduction** Whilst smoking is established as a protective modifiable environmental risk factor for the development of Ulcerative Colitis (UC), the evidence for its impact on subsequent disease activity is conflicting. We therefore aimed to investigate the impact of smoking on clinical outcomes in the disease course of UC.

**Methods** Using a nationally representative clinical practice research database (CPRD), we identified incident cases of UC diagnosed between 2005 and 2014. Patients were grouped as: smokers, never-smokers or ex-smokers at UC diagnosis based on medical record codes for smoking status in the two years preceding UC diagnosis. Medical record codes were also examined to determine change in smoking status following diagnosis. We compared corticosteroid dependency (as defined in ECCO guidelines), thiopurine use and colectomy rates between these defined groups. Survival analysis, Cox proportional hazards analysis and logistic regression were used determine the risk of first thiopurine use, corticosteroid dependency and colectomy given smoking status.

**Result** We identified 4069 cases of UC over the study period. There were 1678 never smokers (41%), 329 smokers (8%), 1541 ex-smokers (38%) and 521 patients whose follow-up smoking status changed (13%). Multivariate regression analysis, adjusting for all covariates listed in table 1, demonstrated smokers had a significantly lower risk of thiopurine use compared to both never smokers (HR 0.52, 95% CI 0.27–0.97, p=0.04) and ex-smokers (HR 0.51, 95% CI 0.27–0.98, p=0.04). In contrast there was no difference in corticosteroid dependency (OR 0.83, 95% CI 0.44–1.75) or rates of colectomy (HR 0.4, 95% CI 0.53–3.02) in a multivariate analysis.

**Abstract PWE-006 Table 1** Univariate and multivariate Cox regression analysis for risk of Thiopurine use in patients with Ulcerative Colitis
A SYSTEMATIC REVIEW OF OUTCOMES AND ADVERSE CLINICAL OUTCOMES OF USTEKINUMAB IN RESISTANT CROHN’S DISEASE

Introduction Despite major progress in drug development for Crohn’s disease (CD) and advances in trial methodology, there is no internationally recognised core outcome set (COS). Poor standardisation in outcome reporting may impact negatively on translation of trials into practice. The suitability of traditional disease activity indices as primary end-points has been challenged, with growing interest in objective measures of inflammation. We undertook a systematic review to explore heterogeneity and time trends in the reporting of efficacy and safety outcomes in placebo-controlled randomised controlled trials (RCTs) of patients with CD.

Methods We searched MEDLINE, EMBASE, CINAHL and Cochrane Library from their inception to November 2015, for RCTs of adult CD patients with treated with medical or surgical therapies. We extracted information on efficacy and safety outcomes, definitions of end-points, and measurement instruments. To explore temporal trends studies were stratified by publication date (pre-2009 and 2009 onwards).

Results 181 RCTs comprising 23 850 patients. Trial focus: Induction of remission, 110 trials (60.8%), 104 medical and 6 surgical interventions. Maintenance of remission, 71 trials (39.2%). Biologics were intervention of interest in 33.7%, as either monotherapy or part of a combination therapy. 92.3% of trials reported clinical efficacy outcomes as a primary or secondary endpoint. CDAI was the dominant index, used to determine clinical response or remission in 63.5% of trials. However, there was heterogeneity, with 35 definitions of response or remission. CDAI <150 was the commonest end-point, but reporting reduced between periods (46.4% to 41.1% of trials), whilst CDAI100 reporting increased (16.8% to 30.4%). Reporting of objective measures of inflammation increased over time, but with lack of standardisation. Reporting of both histologic and endoscopic outcomes increased, from 3.2% to 12.5% and from 14.4% to 30.4% of RCTs, respectively. Biomarker reporting increased from 33.3% to 40.6% of trials. Patient-reported outcome measures (PROMs) were reported in 41.4% of trials with growth in reporting from 39.2% to 46.4%. Safety outcomes were reported explicitly in 35.4% of trials and reporting increased from 32.8% to 41.1%.

Conclusions As expected, the CDAI was the dominant composite index reported but there was significant variation in the selection and definition of clinical trial end-points in RCTs for CD between studies, and over time. Despite growing in reporting of objective measures of inflammation and in PROMs, there is much heterogeneity and lack of standardisation. This highlights the need for international researchers and clinicians to develop a COS for comparative effectiveness research in CD.

Clinical outcomes of ustekinumab in resistant Crohn’s disease: UK IBD tertiary referral centre ‘real-world’ experience

Introduction Ustekinumab (UST) binds to the p40 subunit of IL12 and IL23 to prevent IL12RB1 cell-surface receptor activation and thus inhibits downstream inflammatory signalling. It is approved for moderately to severely active Crohn’s disease (NICE TA456). We assessed the clinical outcomes and safety of UST in a ‘real-world’ cohort of refractory Crohn’s disease patients treated at a single UK centre.

Methods We retrospectively collected data from the electronic records of Crohn’s disease patients treated with UST at a single UK IBD tertiary referral centre. Patient demographics and adverse events were recorded. Clinical response to UST was evaluated at baseline and follow up using Harvey-Bradshaw Index (HBI) scores, C reactive protein (CRP), and faecal calprotectin (FC). Paired Student’s T Tests were used to determine statistical significance.

Results 26 patients (mean age 36 years; age 18–62 years; M:F ratio=1:1.6) with a variety of Crohn’s disease phenotypes (L1=8; L2=6; L3=12) were treated with UST. 9 patients (35%) had strictureing disease and 5 patients (19%) penetrating disease. All patients had failed at least one anti-TNF agent. 15 patients (58%) had failed two anti-TNF agents, and 11 (42%) had failed an anti-TNF and subsequent vedolizumab therapy. 7 patients (27%) received immunomodulatory co-therapy (AZA=5; MTX=2), and 11 (42%) received bridging steroids.

12 week data was available for 20 patients. At 12 weeks, mean HBI significantly improved (5 vs 9; p<0.05). There was reduction in mean FC (763 vs 1026; ns), but no change in mean CRP (14 vs 11; ns). 10 patients (50%) demonstrated subjective and objective (FC +/-CRP +/- endoscopic) response to therapy. 6 of these patients received bridging steroids, of which all had reduced and 4 had completed their steroid
course. Of all treated patients 2 discontinued UST (recurrence of a transitional cell carcinoma; primary non-response to therapy requiring surgery), and side effects were reported in 2 patients (Bell’s Palsy; lower respiratory tract infection).

Conclusions UST appears clinically effective and safe in this cohort of treatment-refractory Crohn’s disease patients after 12 weeks of therapy. Future work to combine ‘real world’ data and to assess longer term outcomes will help us to better understand and place the use of UST in the management of Crohn’s disease.

Abstracts

PWE-009 THE ACCURACY OF FECAL CALPROTECTIN MEASUREMENT FROM STOMA EFFLUENT IN PREDICTING CROHN’S DISEASE ACTIVITY

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10.1136/gutjnl-2018-BSGAbstracts.137

Introduction Faecal Calprotectin (FC) is a marker of neutrophil activity, and is sensitive at detecting gastrointestinal inflammation. FC levels >150 μg/g are considered to be associated with a higher risk of endoscopically active inflammatory bowel disease. Meta-analyses report that the sensitivity and specificity at predicting active Crohn’s disease (CD) using a cut off FC >50 μg/g is 83%–91% and 47%–53% respectively; for FC >150 μg/g, the sensitivity and specificity is 75% and 71% respectively. Whilst the use of FC from stoma effluent has been studied in the context of predicting allograft rejection after small bowel transplant, its use in IBD has not been assessed, even though many CD patients have stomas. The aim of this study is to assess the accuracy of FC from stoma samples.

Methods Consecutive patients with a stoma and CD were identified from a prospectively maintained clinical database. The FC from stoma effluent was categorised as: FC <50 μg/g, 50–100 μg/g, 100–150 μg/g and >150 μg/g. This was correlated to endoscopic and/or radiologic findings within 3 months of the FC result. An endoscopy was considered abnormal if the Simple Endoscopic Score for Crohn’s Disease (SES-CD) was ≥2 as rated by 2 blinded observers on the basis of the endoscopy report/pictures. An MRI or CT was considered abnormal if any evidence of active inflammation was reported.

Results 47 FC results were analysed from 29 CD patients with a stoma (M:F 12:15). 16/29 patients had intestinal failure. 25 samples were from an ileostomy, 18 from a jejunostomy and 4 from a colostomy. 18 patients had one sample, 5 had 2 samples, 3 had 3 samples and 2 patients had 4 samples assessed. The median time between FC and imaging was 40 days (range 2–93); and between FC and endoscopy was 56 days (range 6–91). 29 patients had a CT or MRI, 9 had an endoscopy and 9 had both. Of the 4 colostomy samples: 3 had FC of <150 μg/g and none had evidence of active disease; one had a FC of 1130 μg/g and moderate inflammation of a jejunal segment on endoscopy. Of the 43 ileostomy samples: 29 had FC <150 μg/g, of which 3 had active disease (false negatives).

The sensitivity at FC cut off of 50 μg/g and 150 μg/g was 80% and 73% respectively. The sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) for three FC cut offs are shown in Table 1.

Conclusion We report that stoma FC has a sensitivity and specificity which is similar to stool FC at all three cut offs. These results suggest that FC is a useful adjunct to clinical assessment and investigations, and a prospective trial in which there is a shorter interval between FC and the diagnostic test is required.

Abstract PWE-009 Table 1 The accuracy of FC at predicting small bowel Crohn’s disease activity

<table>
<thead>
<tr>
<th>Stoma FC cut off</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;50 μg/g</td>
<td>80%</td>
<td>47%</td>
<td>41%</td>
<td>83%</td>
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<tr>
<td>&lt;100 μg/g</td>
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<td>&lt;150 μg/g</td>
<td>73%</td>
<td>91%</td>
<td>79%</td>
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</tbody>
</table>

PWE-010 DEFINING INTERLEUKIN-27 EFFECTS ON THE EPITHELIAL BARRIER – A NEW THERAPEUTIC FOR IBD?

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10.1136/gutjnl-2018-BSGAbstracts.138

Introduction There is a clinical need for new and safer treatment options for inflammatory bowel disease (IBD). Interleukin-27 (IL-27) is an endogenous immunosuppressive cytokine through inhibition of Th2 and Th17 T cell responses and promotion of IL-10 secreting Tr1 T regulatory cells. Oral IL-27 clinically attenuates disease in several T cell and innate cell driven pre-clinical models of IBD. We need to translate this pre-clinical data to human IBD to underpin proof of concept for IL-27 as a new therapeutic for IBD. Our aim was to define IL-27 evoked responses in the human colonic epithelial barrier.

Methods A human colon derived epithelial organoid model was established from fresh colon tissue obtained through the Grassman Tissue Biorepository. Ethical approval was granted by the Biorepository Scientific Access Group. Isolated colonic crypts were grown in a 3D matrix with conditioned media and growth factors to maturity. RT-qPCR using TaqMan probes characterised organoid permeability gene expression (CLDN2, CLDN4, OCLN, CDH1, TJP1, ECM1) normalised to GAPDH and B2M following a 48 hour stimulation with recombinant IL-27 (rIL-27) (0, 50, 100 ng/ml). Data was analysed with the Livak method and one-way ANOVA. The impact of rIL-27 on colonic epithelial growth dynamics was established on Caco-2 and HT-29 cell lines, stimulated with 0, 50 and 100 ng/ml rIL-27, defined by (1) wound scratch assays over 72 hours with digital images of wound areas captured in 24 hour intervals and analysed with ImageJ software, and (2) tritiated thymidine incorporation proliferation assays stimulated for 48 hours.

Results rIL-27 evoked a differential epithelial permeability gene expression in human colonic organoids, with reduced expression of CLDN2 (p<0.01) and increased expression of CLDN4, OCLN, CDH1 and TJP1 (p<0.001) in a dose-responsive manner. rIL-27 led to an increased rate in epithelial wound restitution (p<0.001). In keeping with this, stimulation with rIL-27 over 48 hours increased the epithelial cell proliferation rate by up to 56% in Caco-2 (p<0.01) and 42% in HT-29 (p<0.001) cells.
Conclusion Our data demonstrates that IL-27 enhances epithelial barrier wound healing. Gene expression data suggests that cell-cell adhesion is enhanced through increased E-cadherin expression, with a reduction in permeability through decreased expression of claudin-2 (pore forming) and increase in claudin-4 (pore closing). Tight junction function is enhanced through increased expression of occludin and tight junctional protein-1. Further studies will define the IL-27 driven permeability related protein expression profile and impact on functional permeability in organoids and whether IL-27 is a potential new treatment for IBD.

**Conclusion**

Our data demonstrates that IL-27 enhances epithelial barrier wound healing. Gene expression data suggests that cell-cell adhesion is enhanced through increased E-cadherin expression, with a reduction in permeability through decreased expression of claudin-2 (pore forming) and increase in claudin-4 (pore closing). Tight junction function is enhanced through increased expression of occludin and tight junctional protein-1. Further studies will define the IL-27 driven permeability related protein expression profile and impact on functional permeability in organoids and whether IL-27 is a potential new treatment for IBD.

**PWE-011 THE PSYCHOSOCIAL EFFECTS OF INFLAMMATORY BOWEL DISEASE ON REPRODUCTIVE HEALTH – A SYSTEMATIC LITERATURE REVIEW**

Sahinder Purewal, 1Wladyslawa Czuber-Dochan, 2Sarah Chapman, 2Christian Selinger, Helen Steel, 3ProfMatthew Brookes. 1University of Wolverhampton, Wolverhampton, UK; 2King’s College London, London, UK; 3University of Bath, Bath, UK; 4Leeds Teaching Hospitals Trust, Leeds, UK; 5Royal Wolverhampton NHS Trust, Wolverhampton, UK

**Introduction**

Inflammatory bowel disease (IBD) is a chronic condition that can affect patients during their reproductive years. Previous studies report that IBD patients have high levels of pregnancy-related fears and voluntary childlessness. The aim of this project is to perform a literature review on the psychosocial effects of IBD on patients' reproductive health and investigate factors affecting family planning decisions.

**Method**

Six electronic databases (CINAHL, PsyInfo, EMBASE, Pubmed, Web of Science, ScienceDirect) were searched using a broad search strategy. Studies using qualitative, quantitative and mixed methods designs were eligible.

**Results**

Using Prisma-P, a total of 3600 records were identified through electronic databases, hand searching and contacting authors. After removing duplicates, 1806 titles were screened and 241 abstracts were reviewed. Of these, 79 full text articles were screened and 41 articles have been included. The studies design included cross-sectional surveys, qualitative, mixed methods and non-randomised controlled intervention studies. Synthesis of the data revealed that sexual dysfunction after surgery, specifically ileal pouch–anal anastomosis, is common for female patients. A small minority of female IBD patients do not use contraception and are at ‘risk’ for pregnancy. Knowledge regarding the effects of IBD on pregnancy and fertility is consistently poor and poor knowledge is associated with voluntary childlessness. Many patients report pregnancy-related fears and anxieties including concerns that IBD or medications may harm the baby or lead to a complicated pregnancy. Patients feared transmission of IBD to their offspring, which may lead to voluntary childlessness. Strategies to improve pregnancy and fertility knowledge (e.g., pre-conception counselling) are successful in reducing pregnancy-related anxieties. However, provisions of pre-conception counselling tend to be limited. The literature in this field is associated with a number of limitations including (a) small sample sizes; (b) low response rate for surveys; (c) the use of unstandardised and non-validated questionnaires; (d) few studies have included male samples and ethnic minority groups; and (e) lack of qualitative enquiry and longitudinal follow-up of patients.

**Conclusion**

The literature indicates that some patients with IBD experience sexual dysfunction, poor fertility and pregnancy-related knowledge, high levels of pregnancy-related fears, concerns and voluntary childlessness. Intervention to improve knowledge tends to be successful. This review has identified several psychosocial effects of IBD on reproductive health which need further investigation.

**PWE-012 SMALL BOWEL ULTRASOUND IN CROHN’S DISEASE: OUTCOMES IN A DISTRICT GENERAL HOSPITAL**

Robert Perry, Chia Sin Chey, Hein Htet, Fern Chilcott, Beverley Kirkham, Sarah Langlands, Gauraang Bhatnagar, Jian Wu. Frimley Health NHS Foundation Trust, Camberley, UK

**Introduction**

The joint ECCO and ESGAR evidence-based consensus guidelines for imaging techniques for inflammatory bowel disease IBD assessment recommends ultrasound (US) as one of the first-line tests for the investigation of Crohn’s Disease (CD). It is inexpensive, free of ionising-radiation and well tolerated. We looked at outcomes in SB US in our CD population.

**Methods**

Retrospective analysis of SB US for patients with known or suspected CD between June 2016 to February 2017 in Frimley Park Hospital. Data was collected from PACS, clinic letters and endoscopy reports.

**Result**

91 US scans in a total of 83 patients were performed by a single, dedicated GI radiologist (6 patients had more than one US). Patient age range 7–80 years (median 29 years); 53 female (64%), 30 male (36%).

21/91 (23%) US were performed for assessment of symptomatic flare in those with established CD. 16/21 (76%) had active disease on US (81% terminal ileitis; 63% stricture, 6.3% fistula, 6.3% abscess). Of these, 4 had MRE and 2 had colonoscopy which correlated with US findings. 11/16 (69%) had treatment escalation following US (55% started anti-TNF, 18% steroids, 9% Vedolizumab, 9% enteral, 9% surgery). US was the sole investigation prior to treatment escalation in 7 of these patients (64%).

24/91 (26%) US were performed in established CD patients to aid treatment decisions; 4 after recent steroid course (all started disease modifying treatment), 8 to assess patients on biologics, 2 to evaluate starting biologics, 6 to evaluate previous abnormal/inconclusive CT/MRI or colonoscopy, 2 periprocedurally, 1 for discordant symptoms and imaging; 1 for abnormal biochemistry.

6 US were undertaken after failure of terminal ileum intubation for established CD. 4/6 (67%) detected terminal ileitis and treatment subsequently escalated (1 started methotrexate, 1 anti-TNF, 1 Vedolizumab, 1 prednisolone).

46/91 (51%) US were performed for suspected CD. 11/46 (24%) showed active inflammation. 8 were ultimately diagnosed with CD. In this group, 2 had MRE, 3 had colonoscopy and 3 had both, all correlating with US findings. 35/46 (76%) did not show active inflammation but reported incidental findings including malignancy and gallstones.

**Conclusion**

This study demonstrates the useful role of SB US in the management of CD. Our results show that US led to changes in treatment including management of acute flares, alterations in medical therapy and assessing response to treatment in our Crohn’s cohort.

We recommend that SB US should be more widely utilised in such patients as it correlates well with gold standard
investigation and is able to provide complementary information to aid decision-making.

**PWE-013** FERACCRU® REAL WORLD EFFECTIVENESS STUDY IN HOSPITAL PRACTICE (FRESH): AN INTERIM ANALYSIS

1Fraser Cummings, 2Catherine Singfield, 3Lesley Jones, 4Joseph Hickey, 5Ian Beales, 6Aileen Fraser, 7Shaji Sebastian, 8Catherine Stansfield, 9Sam Hoque. 1University Hospital Southampton NHS Foundation Trust, Southampton, UK; 2Shield Therapeutics, London, UK; 3JH Associates, Marlow, UK; 4Nordic and Norwich University Hospitals NHS Foundation Trust, Norwich, UK; 5University Hospitals Bristol NHS Foundation Trust, Bristol, UK; 6Hull and East Yorkshire Hospitals NHS Trust, Hull, UK; 7Salford Royal NHS Foundation Trust, Salford, UK; 8Barts Health NHS Trust, London, UK

10.1136/gutjnl-2018-BSGAbstracts.141

**Introduction** Many patients with inflammatory bowel disease (IBD) experience iron deficiency anaemia (IDA), which can impact significantly on quality of life (QoL). Oral ferric maltol (Feraccru) is a novel iron complex licensed in the UK for the treatment of IDA in patients with IBD. The aim of this study is to understand the early experiences of Feraccru in patients with IBD and IDA in the UK, including treatment effectiveness, patterns of use and tolerability.

**Methods** FRESH is an ongoing observational cohort study conducted in 5 secondary care gastroenterology centres in the UK (up to 8 centres planned). Data were collected from hospital medical records for consenting adult patients (>18 years) with Crohn’s disease (CD), ulcerative colitis (UC) or unspecified IBD who were also diagnosed with mild or moderate IDA and initiated on Feraccru since June 2016. Patients with an IBD flare at time of study recruitment, and/or requiring corticosteroids to treat flares at time of Feraccru initiation were not eligible for the study. Interim data for the first 30 patients recruited to the study are presented.

**Results** The mean (SD) age of 30 patients at initiation of Feraccru was 42.2 (15.8) years and 37% (n=11) of patients were male. Of these patients, 50% (n=15) had CD, 43% (n=13) had UC and 7% (n=2) had IBD of unspecified type. The mean haemoglobin (Hb) level at initiation was 10.7 g/dL (standard deviation 12.1 g/dL). At 12 weeks after initiation of Feraccru (permitting a measurement window from 10 to 16 weeks), 62% (n=8) of 13 patients with a measurement recorded had normalised Hb levels (defined as Hb ≥12.0 g/dL for females and ≥13 g/dL for males).

Out of 30 patients who received Feraccru, 10% (n=3) discontinued by week 4 (+1 week) and 23% (n=7) by week 12 (+4 weeks). No patients discontinued Feraccru due to lack of efficacy.

**Conclusions** The first results from a study of the use and outcomes of Feraccru in UK clinical practice show that in the small sample less than half of patients had a recorded Hb measurement at 12 weeks after initiation of Feraccru. Of those who did, 62% had normalised Hb. This is comparable to results from the AEGIS phase III study where 66% patients achieved normalised Hb by 12 weeks.

**PWE-014** THE IMPACT OF THERAPEUTIC DRUG MONITORING DURING BIOSIMILAR INFlixIMAB SWITCH IN INFLAMMATORY BOWEL DISEASE

1Ravi Ranjan, 2Sally Myers, 1Linda Crisopo, 3Susan Ritchie, 4Frances Maw, 5Shaji Sebastian, 6Anjan Dhar. 1County Durham and Darlington NHS Foundation Trust, Darlington, UK; 2Royal Infirmary, Hull, UK

10.1136/gutjnl-2018-BSGAbstracts.142

**Introduction** Therapeutic Drug and antibody monitoring (TDM) is now an established strategy to manage patients with Inflammatory Bowel disease being treated with Biologic agents. Biosimilar switching of Originator Infliximab (IFX) is recommended by ECCO and BSG. The role of TDM during biosimilar infliximab switch is not well studied. This study aimed to analyse and compare IFX drug and antibody levels before and after switch.

**Aims** To study the impact of TDM on Biosimilar infliximab switching by detecting the proportion of patients who have sub-therapeutic drug levels and/or anti-IFX antibodies either before or 3 months after the switch, who would be considered as secondary loss of response (LOR).

**Methods** All patients with either Crohn’s disease (CD) or Ulcerative Colitis (UC) who were switched to Remsima, a biosimilar Infliximab in 2017 at the two hospital sites were included. Disease activity was assessed using Harvey-Bradshaw Index (HBI) or Simple Clinical Colitis Activity Index (SCAI). The most recent colonoscopy/radiological imaging and faecal calprotectin (FCP) was recorded. Pre and post-switch Infliximab and antibody levels were obtained. Concomitant use of immunomodulators (Azathioprine, Mercaptopurine or Methotrexate) was noted.

**Results** 119 patients had IFX Remicade switch to Biosimilar Inflectra or Remsima. 86 pts had CD and 32 had UC. 110 patients had pre-switch therapeutic drug and antibody monitoring, and 115 had post switch monitoring as well within 3 months. 67 pts had sub-therapeutic but detectable IFX drug levels prior to the switch with either mild or inactive clinical scores for both CD and UC. 19 patients had undetectable IFX drug levels, and post switch continued to have undetectable levels. 16 of these 19 patients had high anti-IFX antibodies suggesting that these patients were secondary loss of response who needed a change of their biologic to another agent. 11/86 patients had dose escalation to 10 mg/kg and then attained therapeutic levels. SCAI ranged between 0–9, mean 1.433, and HBI ranged between 0–12, mean 2, indicating that majority of patients were in remission. Post switch matched FCP showed 60 pts in remission with FCP <200 ug/g and 22 pts with FCP >250 ug/g.

**Conclusions** Therapeutic drug and antibody monitoring before and 3 months after Biosimilar switch detects secondary loss of response in patients maintained on scheduled IFX treatment in clinical and biochemical remission. It should be recommended over blanket switching as it may prevent unnecessary switching for some patients who are no longer responding the IFX or those who may merit a drug withdrawal.
CLINICAL EFFICACY AND SAFETY OF ANTI-TNF THERAPY IN INFLAMMATORY BOWEL DISEASE IN THE ELDERLY

Jonathan Digby-Bell, Haij Ibrahim, Fakhirah Badrulhisham, Nick Powell. Guy’s and St Thomas’ NHS Trust, London, UK

Introduction Many patients, especially the elderly, are excluded from clinical drug trials and little real-life data exists on the safety and efficacy of anti-TNF in this comorbid and difficult to treat group. We wanted to compare the clinical efficacy and safety of anti-TNF therapy in patients over 60 years in a tertiary IBD centre in London.

Methods We interrogated our IBD biologics database from January 2009 to November 2015 and performed retrospective data analysis until end of follow up in April 2017. Data was collected on demographics, biochemistry and clinical scores. For every ‘>60’ patient identified we randomly selected two ‘<60’ comparators.

Primary endpoints week 14 and week 54 steroid free clinical remission (Harvey Bradshaw Index<5 or Simple Colitis Activity index <3)

Secondary endpoint proportion of patients remaining on anti-TNF at the end of follow up

Results 29 patients (23 Crohn’s, 4 ulcerative colitis, 1 IBD unclassified) started anti-TNF aged ‘>60’ and 58 randomly chosen <60 years were selected for analysis

<table>
<thead>
<tr>
<th>Week 14 steroid free remission</th>
<th>Week 54 steroid free remission</th>
<th>Remain on anti-TNF at end of follow up (April 2017)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=58</td>
<td>n=29</td>
<td>Reasons for stopping biologic during study period</td>
</tr>
<tr>
<td>28/58 (88.3%)</td>
<td>8/16 (50%)</td>
<td>8 primary non-response</td>
</tr>
<tr>
<td>24/58 (85.5%)</td>
<td>12/29 (41.4%)</td>
<td>5 secondary loss of response</td>
</tr>
<tr>
<td>38/58 (85.5%)</td>
<td>16/29 (55.2%)</td>
<td>1 infusion reaction</td>
</tr>
<tr>
<td>30/58 (83.3%)</td>
<td>12/29 (41.4%)</td>
<td>1 remission</td>
</tr>
<tr>
<td>38/58 (85.5%)</td>
<td>16/29 (55.2%)</td>
<td>1 remission</td>
</tr>
<tr>
<td>30/58 (83.3%)</td>
<td>12/29 (41.4%)</td>
<td>1 severe fatigue</td>
</tr>
<tr>
<td>38/58 (85.5%)</td>
<td>16/29 (55.2%)</td>
<td>1 peripheral neuropathy</td>
</tr>
<tr>
<td>30/58 (83.3%)</td>
<td>12/29 (41.4%)</td>
<td>2 stopped attending</td>
</tr>
<tr>
<td>38/58 (85.5%)</td>
<td>16/29 (55.2%)</td>
<td>2 stopped attending</td>
</tr>
<tr>
<td>30/58 (83.3%)</td>
<td>12/29 (41.4%)</td>
<td>Anti-drug antibodies during follow up</td>
</tr>
<tr>
<td>38/58 (85.5%)</td>
<td>16/29 (55.2%)</td>
<td>35/8 (3.2%) – 3 infliximab</td>
</tr>
<tr>
<td>30/58 (83.3%)</td>
<td>12/29 (41.4%)</td>
<td>1 adalimumab</td>
</tr>
<tr>
<td>38/58 (85.5%)</td>
<td>16/29 (55.2%)</td>
<td>1 new cancer</td>
</tr>
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<td>1 infusion reaction</td>
</tr>
<tr>
<td>30/58 (83.3%)</td>
<td>12/29 (41.4%)</td>
<td>1 ileal perforation</td>
</tr>
<tr>
<td>38/58 (85.5%)</td>
<td>16/29 (55.2%)</td>
<td>2 infections</td>
</tr>
<tr>
<td>30/58 (83.3%)</td>
<td>12/29 (41.4%)</td>
<td>2 infections</td>
</tr>
</tbody>
</table>

Conclusions Only a small number of ‘>60’ patients started anti-TNF (29 out of greater than 650). This may reflect our local population, less severe disease or that clinicians favour non anti-TNF therapies in this older group.

Overall there was similar clinical efficacy at weeks 14 and 54 of anti-TNF therapy between the ‘young’ and ‘old’ groups.

There was a statistically significantly higher discontinuation rate after 1 year of therapy in the older group (p=0.043).

There were more adverse events in the older group (7/29), including 3 new cancer diagnoses, compared with the younger group (4/58).
cumulative dermatological effects, risk factors, time to event and outcomes are underway at our institution.

### Abstract PWE-017

**From Diarrhoea to Diagnosis: An Analysis of Faecal Calprotectin Use in an IBD Referral Pathway**

Rosemary Faulkes, Malik Magrabi, Gillian Townson, Megan Rees, Thomas Watkins, Katherine Richmond. Shrewsbury and Telford NHS Trust, Telford, UK

10.1136/gutjnl-2018-BSGAbstracts.145

**Introduction**
The volume of referrals to gastroenterology from primary care is steadily increasing. In order to prioritise appointments for suspected inflammatory bowel disease (IBD), a pathway for primary care assessment and referral of patients to a specialist IBD clinic was introduced in Telford and Wrekin in 2015, based on NICE guidelines. This took symptoms, baseline bloods and faecal calprotectin (FC) result into account. We reviewed the efficacy and outcome of referrals following implementation of the pathway.

**Methods**
A retrospective analysis of all patients in Telford and Wrekin who had a FC requested between September 2015 and September 2016. Electronic data were collected contemporaneously by the pathology laboratory on patients’ age, gender and FC result. Further retrospective analysis of the cohort assessed whether a referral was made, the outcome of the referral, including endoscopy findings if performed, and diagnosis. The cohort was divided into three groups based on the FC result: negative, indeterminate and positive. The number of referrals that followed the IBD pathway was recorded for each group.

**Results**
306 patients had FC requested over 12 months. Ages ranged from 1 to 88 years and 63% were female. 244 were referred to secondary care. The likelihood of being referred correlated with the absolute FC value (table 1).

<table>
<thead>
<tr>
<th>FC result</th>
<th>FC value</th>
<th>Patients referred</th>
<th>Patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>&lt;30</td>
<td>247</td>
<td>30</td>
</tr>
<tr>
<td>Negative</td>
<td>30–59</td>
<td>65</td>
<td>45</td>
</tr>
<tr>
<td>Indeterminate</td>
<td>60–149</td>
<td>82</td>
<td>56</td>
</tr>
<tr>
<td>Positive</td>
<td>&gt;150</td>
<td>112</td>
<td>84</td>
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</table>

Of those referred, there were 22 IBD diagnoses (table 2), giving an FC sensitivity of 90% and specificity of 63%.

### Abstract PWE-018

**New Guidance on Therapeutic Drug Monitoring; Potential Clinical and Cost Implications**

Richard Felwick, Heather Johnson, Hannah Dewhurst, Ernest Cadogan, Sean Weaver Chris, Simon McLaughlin. Royal Bournemouth Hospital, Bournemouth, UK

10.1136/gutjnl-2018-BSGAbstracts.146

**Introduction**
Biologic drugs are effective treatments in IBD, the use of therapeutic drug monitoring (TDM) is rapidly becoming part of routine clinical practice. The American Gastroenterology Association (AGA) and the Australian Gastroenterology Association have recently published guidance recommending the use of therapeutic drug monitoring in clinical practice. Recommendations on the minimum trough level for Infliximab differ between these two guidelines. The AGA recommends a level >5 μg/ml, whilst the Australian guidance suggests >3 μg/ml. To date there are no published recommendations from ECCO or BSG. In patients with active disease and sub-therapeutic trough levels we shorten the dose interval from 8 to 4 weeks.

**Aim**
To review the clinical and cost implications of introducing these guidelines into clinical practice at a large district general hospital.

**Methods**
We maintain a prospective IBD database and have used TDM routinely since 2014. Data on the use of TDM from 2016 to 2017 were reviewed. Age, Sex, disease type, and disease activity were reviewed. Results of drug levels in the active disease and remission group were compared and the cost implications of intensifying drug treatment to achieve recommended trough levels calculated. The costs were calculated for escalating all patients below recommended levels to dosing every 4 weeks.

**Results**
Biosimilar Infliximab (Remsima) trough level data was available for 167 patients. Mean age = 42, Range 18–81. 133 (80%) had Crohn’s disease and 34 (20%) UC. 118 had inactive disease at the time of TDM, whilst 49 had active disease. Of those with inactive disease 78/118 (66%) had an Infliximab TL <3 μg/L and 104/118 (88%) had a level <5 μg/L. In patients with active disease 33/49 (67%) had a TL <3 μg/ml and 40/49 (82%) a level <5 μg/ml. Across both groups antibodies were present in 72 (43%). The annual cost for maintaining all 167 patients on biosimilar infliximab (5 mg/kg) was calculated at £521,040, (assuming a standard dose of 5 mg/kg). If all patients with a TL <3 had treatment intensified the total annual drug cost would be £2,055,080 (+77%). If all patients <5 μg/ml were intensified the annual cost rises to £1,045,200 (+100%). If only those patients with active disease and <3 μg/ml were escalated the annual cost rises to £6,411,600 (+23%) and £6,666,400 (+28%) if those <5 μg/mL were escalated.
Conclusions In our cohort of 167, 62% (n=104) of patients had a TL below the recently published recommended guidelines (5 µg/ml) yet were in a clinical remission. Therefore following these guidelines would lead to a significant increase in drug spend which may not translate into improved clinical outcomes; since in this cohort only 24% with sub-therapeutic levels had active disease. Escalating only those with active disease may represent a more acceptable financial solution but too will lead to an increase in drug spend.

Abstract PWE019 Table 1  Day one results

<table>
<thead>
<tr>
<th>Patient scoring</th>
<th>Total score</th>
<th>No. of patients</th>
<th>Responders (%)</th>
<th>Non-responders (%)</th>
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<tbody>
<tr>
<td>0-1</td>
<td>29</td>
<td>23 (79.3)</td>
<td>6 (20.7)</td>
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<tr>
<td>2-3</td>
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Abstract PWE019 Table 2  Patient scoring

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Abstract PWE020  INITIAL EXPERIENCE OF A RAPID ACCESS ULTRASOUND IMAGING CLINIC IN INFLAMMATORY BOWEL DISEASE

Introduction Although less widely used than MRI in UK practice, Ultrasound offers a number of advantages in the assessment of inflammatory bowel disease. It is quick to perform and requires minimal preparation allowing it to be performed at short notice. It is dynamic and clinically interactive allowing immediate correlation of patient’s symptoms with imaging findings. It provides assessment of disease activity/complications together with dynamic assessment of functional obstruction. Results are immediately available allowing instantaneous clinical decision making. We present our initial experience of using Ultrasound in a rapid access imaging clinic and its effects on patient management.

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LOCAL EXPERIENCE OF VSL#3 USE IN POUCHITIS

James Gulliver, Stephen Lewis, Walter Douie. Plymouth Hospitals NHS Trust, UK
10.1136/gutjnl-2018-BSGAbstracts.149

Introduction Pouchitis can affect up to 50% of patients following ileal pouch-anal anastomosis (IPAA). Broad spectrum antibiotics are the mainstay of treatment. In 2003 a randomised study of 36 patients showed remission rates of 85% at 1 year with the probiotic VSL#3. In 2005 a US study of 31 patients in clinical practice failed to replicate these results. A Cochrane review found low quality evidence to support the use of VSL#3 in maintaining remission for chronic pouchitis.

We retrospectively evaluated the use of VSL#3 in our teaching hospital, to see if the efficacy demonstrated in the earlier study could be replicated.

Methods We interrogated our surgical database for patients undergoing IPAA between 2003 and 2014. Paper and electronic records were reviewed for details of pouchitis episodes, their investigation and subsequent management. Diagnosis was classified as probable with clinical evaluation only, or definitive based on histological confirmation. Results were tabulated, analysed non-parametrically and presented as medians and interquartile ranges.

Results Pouchitis was diagnosed in 27% of IPAA patients. This cohort had an average age of 48 years and a female preponderance of 1.2:1. The median duration to first episode was 43 months (34–75). The diagnosis was probable in 29% and definitive in 71% of patients. Antibiotics (metronidazole in 100%, ciprofloxacin in 13%) were prescribed in 66.7% of patients.

14 patients (58%) were commenced on VSL#3 following their pouchitis (Figure 2). Of those with confirmed recurrent pouchitis, two thirds remain on VSL#3 but use repeated antibiotic courses to settle flares. The median duration of follow up was 92.5 months (48–75).

Conclusions This study evaluated the use of VSL#3 over a longer follow up than those published previously. VSL#3 was efficacious in only 22% of the cohort. Accepting the limitations of this small study, the data suggests VSL#3 has little effect in maintaining remission in pouchitis post IPAA. These results correlate with the earlier US study where 19% of patients demonstrated efficacy at 8 months. Larger studies are recommended to review the benefits of VSL#3 in this cohort, with specific reference to degrees of severity and numbers of previous episodes of pouchitis.

REFERENCES

PWE-022 GUT-HOMING TH17 CELLS ARE SELECTIVELY TARGETED BY VEDOLIZUMAB AND MAY PREDICT CLINICAL RESPONSE IN IBD

10.1136/gutjnl-2018-BSGAbstracts.150

Introduction Trafficking of inflammatory lymphocytes to the gut plays a central role in IBD pathogenesis. We analysed the profile of circulating gut homing effector memory T cell subsets in IBD patients. We also evaluated the impact of treatment with Vedolizumab, a monoclonal antibody that binds to integrin α4β7 and prevents binding to its ligand MadCAM-1, thereby preventing lymphocyte migration to the gut.

Methods Using multi parametric flow cytometry, we analysed the gut homing (β7+) effector T-cells (CD3+CD4+CD45RO+CD45RA-CCR7-) including different functional lineages: Th1 (CXCR3+CCRx6-); Th2 (CXCR3-CCR6+CCR7+); Th17 (CXCR3-CCR6+) and Th1/17 (CXCR3+CCR6+) from peripheral blood (PB) of healthy controls (HC, n=42) and IBD (n=34) patients, including a prospective analysis of new starters of vedolizumab. Peripheral blood was taken from patients before their first dose of vedolizumab and at each subsequent infusion.

Results Compared to HC, the proportion of Th1 cells within the gut homing compartment was significantly decreased in PB of IBD patients (median HC 27.3% vs IBD 44%, p<0.0006). In contrast, the proportion of Th17 cells within the gut homing compartment was significantly increased (HC 12% vs IBD 19%, p<0.003). This difference was most striking in ulcerative colitis. There was no significance difference in Th1/17 or Th2 cells in IBD vs HC.

In the longitudinal analysis, there was minimal impact on gut homing Th1 cells in vedolizumab treated patients (comparison between baseline and week 8), however, the gut homing Th17 compartment increased over the same time period (from 19.3% at baseline to 29.7% at week 8). The proportion of gut homing Th17 was significantly higher in vedolizumab treated patients at week 8 in comparison to infliximab (n=3) treated IBD patients (37.3% vs 18.3%, p<0.02). There was no change in the proportion of Th1 cells expressing β7 in these groups. Intriguingly, preliminary data indicated that clinical response to vedolizumab (30% fall in HBI or SCCAI at week 8) was associated with a significantly higher median number of Th17 cells expressing β7 compared to non-responders (responders: 46.8% vs non-responders: 29.7%, p<0.04).

Conclusions IBD is characterised by an expansion of circulating gut homing Th17 cells, which is yet further increased...
following institution of vedolizumab therapy. The magnitude of change could also differentiate between responders and non-responders to treatment, raising the possibility that this test could be used as an early warning biomarker to aid decision making in clinical practice.

**PWE-023 TSTT (TRIAGE TO STRAIGHT TO TEST) IMPROVES EARLY DIAGNOSIS OF INFLAMMATORY BOWEL DISEASE**


10.1136/gutjnl-2018-BSGAbstracts.151

**Introduction** It is well known that there is a considerable delay in establishing diagnosis of inflammatory bowel disease, in case of Crohn’s disease it about 4–9 months and in case of Ulcerative is about 4 months. Barts health NHS trust is one of the pioneers in establishing TSTT (‘straight to test’) service to reduce the wait until a definitive diagnostic test in patients with LGI symptoms. The aim of the study to look at whether this STT service improves early diagnosis of inflammatory bowel disease.

**Methods** In STT service, routine referrals are vetted and prioritised by specialist colorectal nurses using information from the GP referral letter and patient-reported history during telephone assessment. However, it can be expedite to investigate within 2 weeks due to the onset and severity of their symptoms, particularly patients with symptoms suggestive of inflammatory bowel disease (IBD) including raised faecal calprotectin levels.

**Results** 1531 patients have been triaged since July 2013 with 813 (53%) female 718 (47%) male respectively. The mean age of the patients is 51 years (range 16–94). Based on telephone triage, 56% were triaged to colonoscopy, 13% had flexible sigmoidoscopy. Only 32.5% of TSTT were upgraded to 2 weeks wait. In total, 355 (23.2%) had any pathology encountered. Out of all pathology, 101 (28.5%) of these found to have new diagnosis of IBD. The mean age of these patients is 42 years (range 85–17) and the average waiting time on the TSTT pathway is only 17 days. Of the remaining, 74% of non-upgraded patients (excluding 6% DNA), 25% had pathology of which 10% had already diagnosed IBD with a mean age of 43 range 85–34 years and waited an average time on the TSTT pathway of only 32 days. There is a significant difference in between in picking up pathology between upgraded triage and traditional 18 weeks pathways 17 days vs. 32 days (p<0.001).

**Conclusion** These data suggest that there is significant improvement in diagnosing inflammatory bowel disease early through TSTT pathways. It appeared to be significantly more early diagnosis can be achieved if triage can be upgraded after telephonic discussion with the triage nurse.

**REFERENCE**


**PWE-024 EFFECTIVENESS OF ANTI-INFLAMMATORY THERAPY IN IMMUNE CHECKPOINT INHIBITOR-INDUCED DIARRHOEA/COLITIS**

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**Introduction** Immune checkpoint inhibitors (ICPI), including monoclonal antibodies targeting CLTA-4 (e.g. ipilimumab) and PD-1 (e.g. nivolumab) have transformed the treatment landscape for cancer. However, their success is hampered by the high incidence of immune-mediated toxicity. ICPI-induced diarrhoea/colicity, resembling some aspects of IBD, occurs in up to 46% of patients and is the most common cause of ICPI discontinuation and death. Presently, treatment of ICPI-induced colitis is ad hoc, but typically involves systemic steroids, with biologics (most commonly anti-TNF) used as rescue therapy. ICPI use is anticipated to increase substantially in coming years, and expert gastroenterology input, and development of evidence-based treatment algorithms is now urgently needed. Our aim was to conduct a systematic review on the effectiveness of anti-inflammatory therapy in the management of ICPI-induced diarrhoea/colicity.

**Methods** Relevant databases including Medline (PubMed and OVID), EMBASE, Web of Science and Cochrane were searched up to September 2017. Inclusion criteria included adult cancer patients treated with at least one dose of an ICPI, and reported outcome data following anti-inflammatory drug management of diarrhoea. Two independent reviewers assessed eligibility of studies.

**Results** After reviewing 1838 studies, 26 met the inclusion criteria (15 original articles, 11 abstracts), of which 17 (65%) were retrospective studies. A total of 983 patients had diarrhoea and/or colitis. 16 studies reported on anti-CTLA-4 therapy (ipilimumab or tremelimumab), 4 on anti PD-1, and 6 on both (either anti-CTLA-4 or anti-PD1) or combination therapy. 558 (57%) patients were treated with corticosteroids, with clinical response reported in 333 (62%). However, reporting of the corticosteroid dose, type and regimen used was inconsistent.

297 (30%) patients with steroid refractory disease received infliximab with good response rates (86%)- although response rates were only reported for 188 patients.

A single case series reported vedolizumab to be effective in the management of 6 out of 7 steroid refractory patients.

**Conclusions** ICPI-induced diarrhoea/colicity is a significant complication of cancer immunotherapy and engagement with specialist gastroenterology services are now urgently needed to improve outcomes. Systematic review of therapeutic experience in this setting indicates that about two-thirds of patients respond to high-dose steroids, and rescue therapy with biologics captures response in most patients. Given the predicted expansion in use of ICPI in cancer, better quality clinical data are needed to inform standardised treatment protocols.
Abstract PWE-025 Figure 1

Endoscopic assessment more closely reflected response to intravenous steroids than stool frequency. 96% of those with mild endoscopic disease responded to IV steroids, compared to 40% of those with severe endoscopic disease (p<0.001). 70% of those with stool frequency <4/day responded to steroid therapy compared to 62% of those with >6 stools/day (p=0.028). Endoscopy was performed on day 2 on average (IQR 1–3) (figure 1).

Those requiring surgery had a shorter disease duration compared with those responding to IV steroids (median 0.13 years vs 1.5 years, p=0.09 Kruskal-Wallace). The median length of admission was 7.5 days (IQR 6–16) and surgery was performed on day 9 (IQR 8–12) on average. Age, sex, disease extent at diagnosis and smoking status were similar between groups.

Conclusions 20% of patients admitted to hospital for IV steroid treatment for active UC required urgent colectomy during admission. Response to steroids was greater in those with less severe endoscopic disease with a clearer relationship between endoscopic severity and response than stool frequency on admission. Those requiring surgery were likely to have a shorter disease duration on admission. These data emphasise

Abstract PWE-026

Endoscopy is superior to stool frequency in predicting response to steroids in acute ulcerative colitis

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the need for a timely endoscopic assessment for all patients admitted with acute colitis.

PWE-027 SELF-MEDICATION WITH ORAL CORTICOSTEROIDS IN AMONGST PATIENTS WITH INFLAMMATORY BOWEL DISEASE

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Introduction Corticosteroid (CS) overuse and dependency has been highlighted as a key clinical outcome in the management of inflammatory bowel disease (IBD) in a recent national audit1. Whilst data regarding clinician prescribed CS is available2, little is known about the magnitude of self-prescribed CS amongst IBD patients, and we therefore aimed to investigate self-prescribing habits.

Methods Patients attending the IBD clinic at a teaching hospital between November 2017 and February 2018 were included in the study and invited to complete an 18-item questionnaire, designed to determine CS self-medication in the previous 12 months. The questionnaire defined: patient demographics, disease behaviour, and CS prescriptions in the last 12 months. A pilot questionnaire was initially administered to ensure validity and robustness.

Results 100 patients participated in the survey. In total, 8 (8.0%) reported self-medicating with CS in the last 12 months, with the majority (n=6) having a diagnosis of ulcerative colitis. All these individuals had been diagnosed with IBD for at least 11 years. In most cases (n=7), CS were remaining from previous medical prescriptions, with 1 patient reporting having purchased CS online. Reasons given for self-medicating included difficulty in seeing a clinician (n=3) and a desire for greater control of their own symptoms (n=3). The self-medicating dosage regimen varied significantly between individuals, from 5 mg to 60 mg prednisolone daily, taken for durations between 5 to 21 days. Of the total patients who participated in the survey, 40 (40.0%) had not suffered with a flare-up in the previous 12 months.

Conclusions Nearly one-tenth of the study population reported self-medication with CS over the past year. These findings underscore the importance of enquiring about CS self-medication in the IBD clinic, which may otherwise go undetected. Self-prescribing may indicate refractory disease and a need for treatment escalation.


PWE-028 PERSISTENCE OF BIOLOGIC THERAPY AND MAPPING OF SEQUENTIAL BIOLOGICS: RESULTS OF A SINGLE CENTRE COHORT

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Background Biologic therapy has revolutionised the treatment of IBD in the last 20 years. There is limited data on the patient journey through multiple lines of biologics and mapping this to outcomes. We aimed to establish the prevalence of biologic use in a single tertiary IBD centre and assess outcomes defined by biologic persistence.

Methods Retrospective review of electronic health records (TrakCare) was performed on all patients who have received infliximab (IFX), adalimumab (ADA), vedolizumab (VEDO) or ustekinumab (UST) in Edinburgh from January 1999 to October 2017. We collected data for demographics, phenotyping details and duration of treatment. Kaplan–Meier survival curves and log-rank analyses were used to compare time to either discontinuation or resectional surgery.

Result 841 patients were identified who have had biologic therapy for IBD. Median interval from diagnosis to biologic was 4.9 years (IQR 1.3–11.0). The multiple combinations of biologics used is displayed in Figure 1. 665 CD patients (79.7% of total) were treated with biologics; 486 received IFX (73.1%), 169 ADA (25.4%) and 10 VEDO (1.6%) as first line therapy. Second line therapy was required in 238 patients and consisted of ADA 189 (79.4%), IFX 25 (10.9%), VEDO 18 (7.6%) and UST 6 (2.5%). Third line therapy was required in 57 patients, VEDO 41 (74.5%) and UST 14 (25.5%). 3 (0.5%) patients received fourth line therapy with UST. In the CD cohort persistence of treatment on ADA was longer than IFX when used as first line treatment; median 2373 vs 1430 days (p=0.0189).

Abstract PWE-028 Figure 1
Introduction Since 2012, a supported, self-help and management programme (SSHAMP) at the Luton and Dunstable University Hospital, has allowed over 950 IBD patients with stable symptoms to be managed safely within the community by encouraging self-management. IBD-SSHAMP is supported by consultants and specialist nurses through telephone clinics, relieving pressures on the hospital based outpatient clinic system. Both IBD-SSHAMP patients and those who continue to be under traditional hospital-based outpatient clinic care, also have access to online support via an IBD web-portal provided by Patients Know Best (PKB). We were keen to see if the different forms of support provided differences in the perception of their disease control and health-related quality of life (HRQoL).

Method Between 2013 and January 2017, an estimated 575 patients had registered with PKB and 950 were on IBD-SSHAMP. A series of questionnaires were completed anonymously by 260 patients between January – July 2017. Measures included depression, anxiety, health-related quality of life, psychological flexibility and illness perception. Approximately 60% of patients completing the questionnaires receive traditional hospital outpatient care (n=158), with around 30% of those registered for additional online PKB support (n=46) comprising the PKB group and 70% (n=112) not registering for PKB and comprising the control (normal) care group. Of the 40% IBD-SSHAMP patients (n=101), 52% also registered for PKB (n=53) comprising the SSHAMP+PKB group. The remaining patients (n=48) were the SSHAMP only support group. Various univariate comparisons between the normal-care group and the 3 supported groups were undertaken as well as multivariate regression analysis.

Results In this patient cohort, women tended to respond more and there was a higher proportion of Crohn’s disease in the females and compared to UC within the men. The proportion of men and women in the different patient groups was similar except that men were slightly over-represented in the normal (OPA)-care group and women in the SSHAMP +PKB group. Women had significantly lower HRQoL scores than men and scored worse on most psychological measures. CD diagnosis correlated with worse overall HRQoL and fatigue measures. The SSHAMP patient group had significantly better overall HRQoL and social-emotional HRQoL scores than the normal-care group. There were no significant psychological differences between PKB web-users and the normal-care group, although high PKB registration was observed amongst the SSHAMP group, particularly by younger female patients with Crohn’s disease.

Conclusion Multiple sequential biologic use is becoming increasingly common and this will accelerate with the increasing use of anti-integrin and anti-IL12/IL23 therapies. Mapping the sequence of biologic use and linking this to outcomes is a priority for IBD research.
Introduction Anaemia is the most prevalent extra-intestinal manifestation of inflammatory bowel disease (IBD), affecting up to 66% of inpatients admitted with a flare of IBD. European guidelines published in 2015 define clear management priorities for such patients. Here we present a re-audit of the regional guidelines published in 2015 define clear management priorities for such patients.1 Here we present a re-audit of the practice of a large teaching hospital following introduction of a local guideline based on the European consensus.

Methods We retrospectively identified and analysed the case notes of all patients admitted to North Bristol NHS Trust between 2015 and 2017 presenting with a flare or new diagnosis of IBD. Data collected included patient demographics, admission haemoglobin (Hb) and ferritin levels, and prescription of oral or intravenous iron during admission. These data were compared to a historical dataset from 2014 prior to the local guideline introduction.

Result 25 patients (mean age 53.2 years (SD 20.8), 11 (44%) female) were identified that matched the selection criteria and had both pre- and post- intervention. In anaemic patients with ferritin values under 100 µg/L, more patients had an iron infusion prescribed (33.3% vs 16.7%) and iron deficiency anaemia was more commonly mentioned on discharge summaries (66.7%) vs 33.3%) compared to the pre-guideline population, but this did not reach significance (p=0.519 and 0.292 respectively). No improvement was seen in whether ferritin was checked during admission (p=0.111). Hb negatively correlated with length of stay (p=0.006), corroborating findings from the pre-intervention cohort.

Conclusion Since adopting European guidelines on the investigation and management of anaemia in IBD practice at our Trust has improved, but not significantly so – clearly there is more work to do. Our findings will be reviewed at local clinical governance meetings. This will be accompanied by further clinician education and a review of our electronic ‘order set’ so necessary investigations can be requested on IBD patients at the front door.

References

PWE-032
GOLIMUMAB IN ULCERATIVE COLITIS: A MULTI-CENTRE REAL WORLD EXPERIENCE
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Introduction Golimumab (Simponi) is a TNFα inhibitor approved for patients with ulcerative colitis (UC) since 2013. Pre-clinical work showed superiority to both infliximab and adalimumab in mechanism of action. Initial trial data showed 51% achieved clinical remission by week 6% and 47% by week 54. However there is no real world data to correlate these findings. We aimed to assess the effectiveness of golimumab in a real world setting.

Methods A retrospective multicentre study was conducted between 2014 to date. Data was obtained from 5 hospitals around the West Midlands, UK. Inclusion criteria included patients with a diagnosis of moderate to severe ulcerative colitis (endoscopic Mayo score ≥2.) Dosing was weight dependent (≤80 kg=50 mg 4-weekly;>80 kg=100 mg 4-weekly following an induction dose). Data was collected using patient notes and endoscopy reports. Fisher’s exact test was used for statistical significance.

Results There were a total of 56 patients with a mean age of 39.2 years (M=39; F=17). The majority of patients had left sided disease (48%; n=27) followed by pancolitis (45%; n=25) and proctitis (7%; n=4). 64% were on concurrent immunosuppressants. The mean duration of golimumab treatment was 12 months. One patient developed deranged liver function tests on golimumab. They were switched to vedolizumab. Twenty-two patients (39%) showed endoscopic and clinical remission (proctitis n=3; left sided n=9; pancolitis n=10). There was no statistically significant difference between disease extent and remission (p=1.00). Of these 22 patients, 17 patients were on the higher dose of 100 mg, with a statistical significance between the dosing (p=0.03). Three patients who were initially on 50 mg and relapsed had their dose increased to 100 mg. They remain in remission. Of the 50% (n=28) who switched biologic therapy, 23 were to vedolizumab, 1 to infliximab and 4 to adalimumab. Despite changing to vedolizumab, 3 (13%) patients still required surgery. Patients switched to adalimumab and infliximab are currently in remission. In total, 14% (n=8) required surgery, of which 3 patients had emergency surgery.

Conclusion Golimumab has not proven as effective in our real world data. Two important inferences were made from this study. Firstly, of those patients that went into remission, 75% were on the higher dose of golimumab. This may be secondary to higher trough levels; however therapeutic drug monitoring is currently unavailable in the UK for golimumab. Secondly, 5 patients who were switched to an alternative anti-TNF, where drug monitoring is available, had a good clinical response. This leads us to propose that drug-monitoring is of clinical importance and should be available for golimumab in the UK to help maintain clinical remission.

Abstracts

PWE-033
THE OUTCOMES OF THERAPEUTIC DRUG MONITORING (TDM) IN A NON-TERTIARY SETTING
Aditi Kumar, Jayne Slater, Beth Bates, Judith Jones, Shaniqa De Silve. Russells Hall Hospital, Birmingham, UK

Introduction Biological therapy is now well established for the treatment of inflammatory bowel disease (IBD). Even though the majority of patients respond to treatment, up to 46% of patients will lose response within twelve months of initiating
therapy, TDM has become increasingly beneficial and cost effective in altering management of patients.

Methods We performed a retrospective study of all patients with IBD at the Dudley Group NHS Trust UK who were on either infliximab or adalimumab and had TDM carried out from 2015 onwards during the course of their disease. Patient notes, blood tests, endoscopy reports and clinic letters were used for data collection.

Results 99 patients had TDM carried out at least once whilst on biological therapy. The levels were done either as a routine check or due to patient symptoms (reactive check). 84 patients had Crohn’s disease and 15 had ulcerative colitis. The majority of patients were on adalimumab (n=70, 71%). Of the levels that were taken, 16 (16%) had loss of response due to antibody formation, which resulted in 12 (12%) patients changing within class of biologic therapy and 4 (4%) who were switched to out of class. 5 (5%) patients had below therapeutic levels and all had their doses escalated appropriately. 11 (11%) patients had a raised level, which led to dose reduction. Of the 77 patients whose levels were therapeutic, 4 patients had their dose escalated due to patient symptoms, 8 patients switched drug (4 had ongoing disease on endoscopic or radiological assessment and 4 had persistent symptoms) and 4 were initiated to step-down therapy. 61 patients continued on the drug and dose they were initiated on. As a result of TDM 38% of patients had an alteration to their treatment, with 16% of these patients receiving biological therapy with no benefit due to antibody formation.

Conclusion Routine drug levels led to change in therapy thereby affecting patient management early on, facilitating disease control in a very complex group of patients. In our study, 21% with therapeutic levels still had a change in therapy indicating levels should not be taken only when questioning loss of response but should be done routinely in all patients on biologic therapy.

Abstracts

PWE-034 ANTI-DIARRHEAL EFFECT OF BUDERONIDE (ENTOCORT) IN CROHN’S DISEASE AND IMPACT ON QUALITY OF LIFE

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Introduction Budesonide exhibits anti-diarrheal activity independent of its anti-inflammatory effects. The number of bowel movements per day has a great influence on the general well-being and quality of life of patients (also in Crohn’s Disease (CD)). In post-hoc analyses of a Phase III study in CD, the early anti-diarrheal effect of Budesonide (ENTOCORT™)(ENT) was evaluated.

Methods Number of liquid or very soft stools (NSt) and abdominal pain rating (AP) are subscores of the Crohn’s Disease Activity Index (CDAI) score. In a Japanese multi-centre, double-blind, randomised pivotal study in patients with active CD, the early anti-diarrheal effect of Budesonide (ENTOCORT™)(ENT) was evaluated.

Results The number of liquid and very soft stools in ENT treated patients significantly decreased within 2 weeks treatment compared to MZ (–7.1±12.3 (ENT) vs. –2.5±6.8 (MZ), mean ±SD, p=0.02) whereas there was no significant effect on abdominal pain, respectively (–1.8±4.3 vs. –1.2 ±3.7, p=0.25). In parallel, total IBDQ (17.3±19.7 (ENT) vs. 7.4±17.2 (MZ, p=0.01) and subscore in emotional function (5.6±8.4 vs. 2.0±7.2, p=0.02) significantly improved more in the ENT treated patients compared to MZ.

Conclusions Budesonide (ENTOCORT™) reduced the frequency of liquid and very soft stools significantly better than Mesalazine within 2 weeks of treatment. This reduction of diarrheal symptom results in a quicker improvement of Quality of Life in CD patients treated with Budesonide (ENTOCORT™) as compared with Mesalazine.

REFERENCES

PWE-035 HDCE USING 0.03% VERSUS 0.2% INDIGO CARMININE FOR DETECTING DYSPLASIA IN IBD COLITIS SURVEILLANCE. RCT INTERIM-ANALYSIS


Introduction Patients with ulcerative colitis (UC) and Crohn’s colitis are known to have an increased risk of colorectal cancer compared with that of the background population. The recent SCENIC consensus statement endorses high definition chroendoendoscopy (HDCE) with targeted biopsies for dysplasia detection but required more evidence regarding optimal dye concentrations and mode of delivery. No trials have previously studied this. Our aim was to compare 0.2% indigo carmine (IC) using a spray catheter with that of 0.03% IC via a foot pump, for dysplasia detection in patients undergoing surveillance in IBD colitis.

Method A parallel group randomised controlled trial (Clinical-Trials.gov ID: NCT03250780) in which patients undergoing surveillance endoscopy for IBD colitis were randomised into either HDCE using 0.2% IC using a spray catheter or HDCE using 0.03% IC via a foot pump. HD scopes (Olympus CF-HQ290L) and processors (Elite CV 290) were used. Two expert GI histopathologists confirmed presence of dysplasia. Time of withdrawal and ampoules of IC were also recorded.

Results There were 75 patients in each arm (total n=150). Baseline characteristics including colitis phenotype, disease duration, BSG risk category, number of biopsies, concomitant PSC and previous dysplasia were similar in both arms. Dysplasia within the colitic area was found in 12 patients (16.0%) in the 0.2% IC group and 13 patients (17.3%) within the 0.03% IC group, p=0.666 (table 1). Withdrawal was significantly (p<0.001) quicker in the 0.03% IC group (16.36 ±5.92, 95% CI 14.9–17.7) than in the 0.2% IC group (21.23 ±6.69, 95% CI 19.7–22.8). The 0.03% IC group used significantly less IC ampoules (2, IQR 2–3) compared with 0.2% IC group (5, IQR 4–5.25), p<0.001. Dysplasia on random biopsies only, was found in 3.3% (n=5) of the cohort. Univariate analysis for dysplasia on random biopsies showed association
with BSG high-risk category group (p<0.001), concomitant PSC (p=0.033) and having previous dysplasia (p<0.001).

Conclusion There is no significant difference in dysplasia detection between 0.2% and 0.03% IC concentration. 0.03% IC seems to be on average 5 min quicker and uses less ampoules of IC. There maybe still a place for random biopsies in patients defined by the BSG as high-risk.

### Table

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**PWE-036 A PROSPECTIVE AUDIT OF THE 2017 ESPEN GUIDELINES ON MICRONUTRIENT TESTING IN QUIESCENT IBD PATIENTS**

1Morag MacMaster, 1Christina Thomson, 2Dinesh Talwar, 4Fiona Stefanowicz, 3Konstantinos Gerasimidis, 4Daniel Gaya. 1Gastroenterology Unit, Glasgow Royal Infirmary, UK; 2Department of Human Nutrition, University of Glasgow, UK; 3Scottish Trace Element and Micronutrient Research laboratory, Glasgow Royal Infirmary, UK.

**Introduction** ESPEN guidelines advise regular screening for micronutrient deficiencies in patients with inflammatory bowel disease (IBD). This is rarely undertaken in UK and in the presence of active disease and systemic inflammation, plasma micronutrient concentration is complicated by the influence of acute phase response. We prospectively audited the micronutrient profile in an IBD cohort in clinical remission attending the OPC.

**Methods** 54 IBD patients in remission were identified between September 2017 and January 2018 with a Harvey Bradshaw Index<4 or partial Mayo score <2. Micronutrient screen was performed for Vitamin B1, B2, B6 and B12, Vitamin A, Vitamin E, Vitamin C, Vitamin D, Vitamin K, Selenium, Magnesium, Copper, Ferritin, Zinc, Manganese and Folate. Serum albumin and CRP were measured and faecal calprotectin was also tested.

**Results** 33 patients had Crohn’s disease with the majority Montreal A2 (15), L2 (15), B1 (23), 21 patients had UC or IBDU with majority Montreal A2 (12), E2 (10). Low levels of Vitamin B2 were identified in 2 (2%); Vitamin B6 in 10 (19%); Vitamin B12 in 6 (11%); Vitamin A in 1 (2%); Vitamin C in 9 (17%); Vitamin D in 39 (72%); Ferritin in 3 (6%); Zinc in 10 (20%) and Folate in 4 (8%). 3 (6%) patients had low levels of Selenium, Magnesium and Copper. Vitamin E, Vitamin B1 and Manganese were within normal range in all patients. To rule out the effect of acute phase response on blood micronutrient levels, a subgroup of 27 (50%) patients with albumin >34 g/L, CRP <20 mg/L and faecal calprotectin <250 mg/kg were analysed. Low levels of Vitamin B2 were identified in 1 (4%); Vitamin B6 in 4 (15%); Vitamin B12 in 2 (8%); Vitamin A in 1 (4%); Vitamin C in 2 (7%); Vitamin D in 20 (74%); Copper in 2 (7%); Ferritin in 1 (4%); Zinc in 4 (15%) and Folate in 2 (7%). Magnesium was within normal range in all patients. A few patients had high Vitamin B1 (1), Selenium (1) and Manganese (3).

Spearman rank correlation analysis showed positive significant correlations between faecal calprotectin with Vitamin B2, Magnesium, Copper, Ferritin and manganese; CRP with serum Selenium and Copper; and Albumin with Vitamin B2, Vitamin A, Vitamin D, serum Selenium, Copper, Ferritin and Zinc.

**Conclusions** While we identified a substantial number of IBD patients with micronutrient deficiencies, a proportion of these may be an epiphomenon of the acute phase response. We propose that micronutrient screening only be performed in IBD patients with disease in ‘deep’ remission.

**PWE-037 ACUTE SEVERE ULCERATIVE COLITIS (ASUC) OUTCOMES AREN’T ALTERED BY ADMISSION TO A TERTIARY REFERRAL CENTRE**

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**Introduction** First-line treatment for ASUC with IV steroids is routinely given in UK hospitals. We sought to establish if initial treatment in a tertiary referral centre affected outcome. We examined all admissions with ASUC within Lothian and compared outcomes between those initially treated at the tertiary referral centre: Western General Hospital (WGH) and those treated at the other two acute hospitals in the health trust: Royal Infirmary of Edinburgh (RIE) and St. John’s Hospital (SJH). We assessed response to steroids and second-line medical therapy and the likelihood of requiring surgery during the index admission.

**Methods** Admissions to NHS Lothian were identified using the ICD-10 code K51 between November 2013 and November 2016. If a patient was admitted more than once during this time only the first admission was used. 159 patients were included. 105 (105/159; 66.0%) were admitted to WGH, 14 (14/159; 8.8%) were admitted to RIE and 40 (40/159; 25.2%) were admitted to SJH. Female: male split was 60 (37.7%):99 (62.3%). Mean age at admission was 41.7 years (range 16.3–86.75).

**Results** 71.4% (75/105) were successfully treated with IV steroids at WGH compared with 63.0% (34/54) at RIE and SJH (p=0.364; OR=1.471). 37.0% (20/54) of patients treated for ASUC at the other hospitals in NHS Lothian required transfer to WGH for further management. There was wide variation in the proportion of ASUC patients referred from the two referring hospitals: 45% (SJH, 18/40) and 14.2% (RIE, 2/14). There was no significant difference in the proportion of patients requiring medical rescue therapy (Infliximab or Ciclosporin) when comparing those admitted to WGH 23.8% (25/105) and those admitted to RIE and SJH 33.3% (18/54) (p=0.1412; OR=0.625). Of those requiring second line medical therapy 48.0% (12/25) responded in the tertiary centre compared with 50.0% (9/18) in those admitted to other
hospitals, and therefore did not require surgery (p=0.6609; OR=0.923). At WGH 16.7% (5/30) required surgery after failing IV steroids without being given second line medical therapy. Compared with 10% (2/20) of those transferred from surrounding hospitals (p=0.8029; OR=1.8).

Conclusions In Lothian, although there is no statistical difference in response to IV steroids whether treatment was started in a tertiary referral centre or not, there was a trend towards a greater success at WGH. There was no statistical difference in response to second line medical therapy between the two groups. Although numbers are small there is a trend to patients in the tertiary referral centre being more likely to proceed directly to surgery upon steroid failure. This could be due to the input of the surgical team at an earlier stage.

Conclusions Most cases of anaemia were IDA, and more episodes of ID than IDA were found. An equal number of CD and UC patients had IDA, but non-anaemic ID was more common in UC than CD patients. As only 57% of haematinic tests fulfilled the minimum requirement to detect ID in anaemic IBD patients (Hb combined with ferritin plus CRP) ID/IDA may be significantly underdiagnosed conditions in IBD. However, these findings are limited due to the small, real-world, dataset.

An adapted Registry Webtool may allow easy data collection though there are challenges in completing data input during consultations. Iron status could therefore be better monitored if haematinics were a default part of the IBD Registry dataset, allowing for quality improvement.
Orally-delivered encapsulated FMT is the preferred route of administration and future work should explore the utility and efficacy of this route.

**PWE-040** MICROSCOPIC COLITIS AND PROTON PUMP INHIBITORS – USE OF THE NULL HYPOTHESIS

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10.1136/gutjnl-2018-BSGAbstracts.168

Introduction Many studies have shown a strong association with proton pump inhibitor (PPI) usage and the development of microscopic colitis (MC). Due to the association of PPIs with diarrhoea there is a risk of confounding bias due to increased investigation with colonoscopy and biopsies. This has resulted in a controversy in case-control studies with regard to using a control group from the background population (BP) or a control group with investigated chronic diarrhoea (ICD). This abstract evaluates the use of the null hypothesis for MC and PPIs with relation to published case-control studies of MC and PPIs and with discussion of potential mechanisms.

Methods The Null Hypothesis for MC and PPIs can be categorised according to MC being largely clinical and investigated or a largely subclinical uninvestigated disease.

Hypothesis 1: PPIs and MC are unrelated and MC is always overt and investigated by colonoscopic biopsies.

Hypothesis 2: PPIs and MC are unrelated and MC is always subclinical.

For age and sex matched groups – those with clinical MC (hypothesis 1) that are detected will have the same percentage on PPIs as those from the background population (BP), whereas those with subclinical MC (hypothesis 2) that are detected will have the same percentage on PPIs as those with investigated chronic diarrhoea (ICD).

Results There are 6 published case-control studies and a recent abstract that provide adjusted odds ratios (AORs)/odds ratios (ORs) for PPIs and MC. Some of the larger studies have divided MC patients into the two subgroups; collagenous colitis (CC) and lymphocytic colitis (LC).

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<td>Bonderup 2017 (abstract)</td>
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Conclusions MC is unlikely to be always investigated and there is some evidence that MC can be detected in asymptomatic individuals. However, it is also unlikely that MC is largely subclinical and not investigated. All but one case-control studies have shown increased AORs for MC and PPIs for BP controls and similarly in 2 of 3 studies for ICD controls. The only study not showing an association included only 26 cases with MC and a very high usage of PPIs in the control BP of 45%. The mechanisms of how PPIs may cause MC are unclear but theories include increased intestinal epithelial permeability, alteration of colonic bacterial flora and increased production of collagen by colonocytes. The association of MC with medications including PPIs should not be ignored and cessation of potentially causative medications requires consideration.

**PWE-041** ALTERATION IN SMALL BOWEL MOTILITY, GUT PEPTIDES AND PATIENT’S SYMPTOMS IN ACTIVE CROHN’S DISEASE

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Introduction Intestinal inflammation in Crohn’s disease (CD) is associated with an increase in Polypeptide YY (PYY), Glucagon-like peptide 1 (GLP-1) and cholecystokinin (CCK). CD patients experience postprandial fullness and nausea. These symptoms may be linked to the increase in plasma gut peptides levels and alterations in intestinal motility.

Our aims are to quantify gut peptide, small bowel motility and patient symptom response to a standard test meal using Magnetic Resonance Imaging (MRI).

Methods Subjects underwent baseline and postprandial MRI scans, symptom questionnaires and blood sampling (GLP-1, PYY, CCK) at intervals for 270 min following a test meal: soup (400 g) (Heinz, Wigan, UK); (kcal) 51, protein 1.5 g, carbohydrate 4.7 g, fat 2.9 g per 100 g.

MRI scans were performed using a 1.5T Philips Achieva MRI scanner. Gastric volume, small bowel water content (SBWC) and small bowel motility were assessed using MRI. Patients also underwent a standard contrast enhanced clinical MR enterography (MRE) and MaRIA score applied to quantify disease activity. All subjects gave informed written consent. Trial registration number: NCT03052465. Data is presented as mean +/-SEM.

Results CD patients showed a significantly (p<0.05) slower fasting small bowel motility (50±6 a.u.) compared to HV (77±10 a.u.). Postprandial SBWC was significantly greater in CD than HV (measured as area under the curve CD: 18452, HV: 13760, p<0.05). Fasting PYY (CD: 236±16 pg/mL, HV: 118±11 pg/mL, p<0.0001) and GLP-1 (CD: 50±8 pg/mL, HV: 13±3 pg/mL, p<0.0001) were significantly higher in CD compared to HV with this difference persisting at each time point of the study (p<0.0001). The meal induced a significant increase (p<0.0001) in fullness, bloating and abdominal pain scores in patients (28.4±4 mm, 22.5±3 mm and 12.2±2 mm respectively) compared to HV (12.2±4 mm, 3.8±3 mm and 1±2 mm respectively). No differences were noted in gastric volumes, CCK concentration and postprandial motility.
Conclusion The decrease in fasting small bowel motility noted in CD may be ascribed to the increased fasting GI peptides. Understanding the physiological changes in disease groups will allow us to identify the key biomarkers for pharmacological modulation to improve patient symptoms.

Profile biomarker

PWE-043 MANAGING ACUTE SEVERE COLITIS IN A DISTRICT GENERAL HOSPITAL

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Introduction Following a critical incident in the care of a patient with acute severe colitis (ASC) we audited practice against the European Crohn’s and Colitis Organisation (ECCO) standards for ASC. Performance was compared to the 2014 Inflammatory Bowel Disease (IBD) Audit. Since 2014 gastroenterology inpatient care changed to consultant of week instead of a single consultant. This improved discharge rates (top 4 in England for acute admission targets) but may have disrupted quality of care for more complex conditions like IBD.

Methods Adult coding database searched for ‘colitis’ from 01/01/2016–31/10/2017. Admissions<48 hours excluded. Discharge letters were searched for ASC cases and notes then reviewed. Admissions with ASC were audited against the ECCO standards.

Results
- 40 admissions with ASC (30 patients – 2 had 3 and 8 had 2 admissions)
- 17 saw gastroenterologist day 1 (median day 2, range 1–4)
- 39 went to gastro ward
- 32 had abdominal xray on day 1
- 1 had flexi sig day 1, 12 had lower GI scope pre-admission, 18 during admission (median day 3, range 1–11) and 9 had none
- 34 had IV hydrocortisone on day 1 (median day 3, range 1–6)
- 26 had Ca/vit D
- All had low molecular weight heparin (LMWH)
- 14 saw dietician, 33 had MUST scored
- 24 saw IBD nurse
- 13 saw stoma nurse
- 6 saw surgeon on day 1 (median day 2, range 1–14) and 15 did not get referred
- 10 required surgery – 7 done by a colorectal surgeon (6 laparoscopically, 4 open)
- Median surgery day 9 (range 2 – 23 from admission)
- 1 on biologic pre-admission
- 2 had surgery on readmission
- 3 based on clinical features
- 3 not responded to biologic
- 1 not clear
- Biologics given to 10 patients – 2 day 3, 1 day 4, 6 day 5 and 1 day 6 (2:8 between adalimumab:infliximab). No ciclosporin. 90% did not need surgery.

Conclusion In 2014 our trust data showed we performed on par with National audit. In 2017 we were equivalent to or outperformed the National figures for:
- Care on a specialist ward (98% vs 69%)
• Nutritional assessment (80% vs 82%)
• Dietician review (45% v 40%)
• Prescribing LMWH (100%)
• IBD nurse review (60% vs 66%)

We performed below the IBD audit for:
• Sigmoidoscopy in 72 hours (28% vs 99%)
• Prescribing Ca/vit D (65% vs 74%)
• Median time to surgery (9 vs 7.5 days)

Important standards of IBD nurse and dietician review maintained. Delay in endoscopic evaluation and therefore time to surgery indicate there has been a slipping of standards in ASC care. This may be related to less direct ward continuity.

Our data show a drop in performance (access to endoscopy and time to surgery). They have allowed us to critically appraise our acute IBD service thus leading to care delivery change and an education package for medical and surgical directorates. A repeat audit is planned in 24 months to demonstrate quality improvement as a result of this.

The IBD BioResource

PWE-044 PROGRESSING FROM GENETICS TO FUNCTION AND CLINICAL TRANSLATION IN CD & UC
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10.1136/gutjnl-2018-BSGAbstracts.172

Introduction The Inflammatory Bowel Disease (IBD) Bioresource was established by the UK IBD Genetics Consortium and the NIHR Biobank in 2016 to expedite the clinical translation of recent genetics advances and support important IBD research. It recruits patients from hospitals UK-wide, the aim being to enlist 25 000 participants who can be further invited for future research studies based on genotype and/or phenotype. DNA samples will also be used in on-going IBD genetics analyses by the UK IBD Genetics Consortium.

Methods The Main cohort comprises individuals with established Crohn’s Disease (CD) and Ulcerative Colitis (UC). Both clinical and self-reported phenotype data are collected, alongside plasma, serum and DNA samples for whole Genome Sequencing. The Inception cohort aims to recruit a sub-set of 1000 individuals newly diagnosed with IBD that will provide more detailed sampling, unconfounded by drug treatment or effects of surgery and includes stool, biopsy tissue and whole blood for RNA. This cohort offers a unique resource to undertake transcriptomic, meta-genomic, metabolomic and proteomic studies and facilitate research into determinants, predictors and biomarkers of IBD disease course and treatment response. In addition to Stage 1 recruitment, the IBD Bioresource panel can be accessed by any researchers (both academic and commercial) with ethically approved proposals and may involve a range of possible options, such as access to raw data, samples or recall of genotype-selected participants to donate further samples or trial novel therapies.

Results 24 months in, we have 59 hospitals active and ~30 in set-up.

Main Cohort over 8000 patients have been recruited – CD/UC 4,390/3,832.

CD phenotypes: extent – 31% ileal, 32% ileo-colonic, 31% colonic, 28% with peri-anal involvement; behaviour – 68% inflammatory, 21% stenosing and 11% penetrating.

5048 (61%) have been prescribed thiopurines and 2324 (28%) required treatment cessation. 3842 (47%) have received anti-TNFa therapy.

45% CD and 5% UC have required surgery. Most subjects are recruited in medical gastroenterology clinics so there are biases in this dataset. We will provide updates and breakdown of numbers at the meeting and discuss downstream stage 2 studies.

Inception Cohort has been launched and is being rolled out nationally.

Conclusion The IBD Bioresource and its network are on course to generate an accessible platform of patients and their data that will facilitate high quality translational IBD research.

PWE-045 VEDOLIZUMAB RESULTS IN REDUCED HOSPITALISATION AND STEROID USE OVER 1-YEAR: RESULTS FROM THE SCOTTISH VEDOLIZUMAB COHORT
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10.1136/gutjnl-2018-BSGAbstracts.173

Introduction The GEMINI trials and an increasing body of real-world data have demonstrated the effectiveness and safety of vedolizumab (VDZ) in IBD. However, there is limited available data about its effect on hospitalisations and steroid use. Our aim was to address this in a large real-world cohort of IBD patients from across Scotland.

Methods A multicenter retrospective cohort analysis of medical records was performed across 7 Scottish healthcare trusts. Primary outcomes were hospitalisation rates and overall steroid use in patients remaining on VDZ. Secondary outcomes were safety and intention to treat steroid free remission rates in patients with active disease. All data were prospectively collected as part of routine clinical care. Baseline demographics, clinical scores (HBI or Partial Mayo), faecal calprotectin (FC), endoscopy and radiology at 3, 6 and 12 months were recorded where available. Active disease was defined as endoscopic or radiographic evidence of disease or FC >200 mcg/g. Clinical remission was defined as HBI <5 or Partial Mayo<2. Biochemical remission was defined as FC <200 mcg/g.

Results 340 (137 UC and 203 CD) patients were included in the primary analysis with a median follow-up of 9.4 months. Hospitalisation rates per patient-year were 0.60, 0.67, 0.36 and 0.16 at baseline, 3, 6 and 12 months of treatment respectively. Total number of hospitalisations reduced by 52.5% from 204 (12 months prior to VDZ) to 97 (12 months after VDZ). Proportion of patients on concomitant steroids reduced from 39.7% to 16.7% (n=332), 8.1% (n=270), 9.3% (n=194) at 3, 6 and 12 months respectively. In patients with active CD (n=153, 75.4%) steroid free clinical and steroid free biochemical remission rates were; 54.4% and 30.2% at 3 months; 47.7% and 32.1% at 6 months; 28.6% and 33.9% at 12 months. In patients with active UC (n=112, 81.8%)...
steroid free clinical and steroid free biochemical remission rates were; 57.4% and 40.9% at 3 months; 51.6% and 39.1% at 6 months; 37.5% and 41.2% at 12 months. Our cohort received >2066 VDZ infusions, 2 (0.6%) patients developed infusion reactions, 9 (2.6%) patients developed serious infections and 17 (5.0%) serious adverse events.

Conclusions VDZ is associated with reduced hospitalisation and steroid use over 1 year. Steroid free remission rates and safety profile is in keeping with the published literature.

TH17 CELLS DOMINATE THE COLONIC MUCOSAL IMMUNE RESPONSE IN PRIMARY SCLEROSING CHOLANGITIS ASSOCIATED COLITIS

PWE-046

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Introduction Primary sclerosing cholangitis (PSC) is an idiopathic chronic cholestatic liver disease associated with ulcerative colitis (UC). PSC is thought to be a consequence of a genetically predisposed, dysregulated immune response and unknown factors including the gut microbiome. The colonic mucosal immune response in PSC associated colitis (PSC-UC), however, has been poorly defined. In this study, we analysed the characteristics of colonic mucosal CD4 T cells in patients with PSC-UC.

Methods Colon biopsies were collected from patients with PSC-UC (n=13), UC (n=10) and controls (n=20). One patient with PSC-UC and one patient with UC was on biologics. Three patients with PSC and three with UC had colonic inflammation. Lamina propria mononuclear cells were analysed by flow cytometry.

Results PSC-UC and UC were characterised by a significantly higher frequency of colonic mucosal CCR6 + CD161 + Th17 cells compared to controls (17.5% vs 11.1%; p=0.009%) and 21.02% vs 11.1%; p=0.01 respectively). CCR6/CXCR3 + CCR5 + Th1 cells were significantly lower in PSC-UC compared to controls (15.46% vs 24.50% respectively; p=0.01). CD127+CD25+FoxP3+T regulatory cell frequencies was elevated and CCR6/CXCR3+CXCR3- Th2 frequencies were reduced only in UC compared to controls (7.6% vs 4,38%; p=0.007%) and 14.84% vs 8.77%; p=0.02 respectively). Significantly increased frequencies of IL17 producing CD4 cells were observed in both PSC-UC and UC compared to controls (7.75% vs 4.77%; p<0.001% and 7.23% vs 4.70%; p=0.006 respectively). Although there were no differences in TNFRα and IFNγ producing CD4 cells, patients with PSC-UC had a significantly higher frequency of IL17/IFNγ dual producing CD4 cells compared to controls (2.79% vs 4.76% respectively; p=0.03). Correlation analysis of PSC-UC and controls demonstrated that Th17 frequencies positively correlated with increasing frequencies of IL17 producing cells and negatively with Th1 (p<0.05).

Conclusions Our study demonstrates for the first time that the colonic mucosal immune response in PSC-UC is characterised by significantly higher Th17 cells and lower Th1 cells compared to controls. Patients with PSC-UC have higher IL-17 and IL17/IFNγ dual producing CD4 cells. Our findings highlight the need to explore the role of key players such as the gut microbiome in mucosal T cell homeostasis and Th1/Th17 plasticity in PSC.

THERAPEUTIC DRUG MONITORING FOR INFlixIMAB & ADAlimumab IN IBD: PRACTICE PATTERNS, UNDERSTANDING & INTERPRETATION

PWE-047

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Introduction The use of therapeutic drug monitoring (TDM) for infliximab and adalimumab in the treatment of inflammatory bowel disease (IBD) is becoming increasingly commonplace. In cases of non-response (primary or secondary) TDM can provide a clearer understanding of the cause of treatment failure and offer a rationale for steps taken to recapture response. However, several factors regarding its use remain uncertain such as minimum therapeutic thresholds, the relevance of antidrug antibodies found in the presence of detectable drug, and the benefits of TDM during remission.

Methods We designed a survey that included 5 TDM-based clinical scenarios, for which the ‘most appropriate’ responses were based on the Building Research in IBD Globally (BRIDGE) groups’ Anti-TNF Optimizer (http://www.bridgeibd.com/anti-tfn-optimizer). This resource combines available TDM evidence with expert consensus. A link to our online survey tool was sent to various IBD clinician groups in June 2017 including members of the British Society of Gastroenterology, Royal College of Nursing IBD Network and the gastroenterology special interest group of the UK Clinical Pharmacy Association.

Results We received 142 responses. Of these, 110 (77%) were complete, comprising 50 (45%) consultants, 30 (27%) trainees, 25 (23%) IBD nurse specialists and 5 (5%) gastroenterology pharmacists, and were used for analysis. Over half (61, 55%) only carry out TDM in non-response. The remainder use TDM routinely, during stable maintenance therapy for patients in remission. Only 15 (14%) respondents reported being clear and confident in their understanding of the difference between drug-sensitive and drug-tolerant assays. Moreover, most (82, 75%) were unsure as to which type their laboratory uses. Lower therapeutic thresholds used by clinicians were variable (figure 1).

Consultants, high-frequency TDM users (>3 requests/month) and clinicians with larger anti-TNF cohorts (>100 patients) were significantly more likely to select the ‘most appropriate’ answer to at least 1 of the 5 TDM scenarios (figure 2).

Conclusions These results demonstrate marked heterogeneity in the practical use, understanding and interpretation of biologic TDM in IBD. Biologic decision-making, informed by TDM, should involve consultation with experienced clinicians who are frequent TDM users, ideally, as part of a multidisciplinary, biologics-focused IBD meeting.
THE NATURE OF CHECKPOINT INHIBITOR-ASSOCIATED LOWER GASTROINTESTINAL TOXICITY: A SINGLE CANCER CENTRE EXPERIENCE

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10.1136/gutjnl-2018-BSGAbstracts.176

Introduction Immune checkpoint inhibitors (CPI) are a standard of care for various cancers however can cause unpredictable toxicity, notably of the lower gastrointestinal (GI) tract. As continued expansion of their use is anticipated, we sought to investigate the ‘real world’ frequency and characteristics of such toxicity.

Methods We conducted a retrospective case-note review of patients treated with ≥one dose of either nivolumab monotherapy (N), pembrolizumab monotherapy (P), sequential pembrolizumab/ ipilimumab (P-I) or combination nivolumab + ipilimumab (n+I) between 01/03/2016 – 28/02/2017. Toxicity (tox) was graded using NCI Common Terminology Criteria for Adverse Events v4.03. Statistical comparisons used Student’s T-test or Chi Squared tests with Bonferroni corrections.

Results 141 patients were treated (49 female, 34.8%), mean age of 64.6 years. 71, 33 and 37 (50.3%, 23.4% and 26.2%) had melanoma, lung and renal cancers respectively. 83 received P (58.9%) while 39 (27.7%) received N with only 11 (7.8%) and 8 (5.7%) receiving n+I or P-I respectively.

Of these, 29 had any grade GI tox. Their mean age (65.7 years), female proportion (34.4%) and proportion with melanoma, lung or renal cancers (55.2%, 20.1% and 24.1% respectively) did not significantly differ from the 112 patients with no GI tox.

However, 6 (20.6%) vs 2 (1.8%) received P-I and 5 (17.2%) vs 6 (5.4%) received n+I in the GI and no-GI tox cohorts respectively which was significantly different (p=0.001 and 0.036 respectively). Only 2 (7.1%) in the GI tox cohort had initial progressive disease compared to 47 (46.1%, p<0.001).

In the GI tox cohort, 17 had grade 1 (G1) tox, 5 G2 and 7 G3/4. When comparing the G3/4 to G1 cohort there was a trend towards younger age (54.3 vs 67.7 years), treatment with P-I or n+I (71.5 vs 17.8%) and higher CRP (100 vs 62 mg/L).

The rate of G3/4 toxicity was similar to the reported literature. For n+I, 5/11 (45.5%) had any grade GI tox with 3/11 (27.3%) having grade 3/4.

Finally, of those with G3/4 tox, 4 had documented fever at presentation, only 1 had haematochezia and all had diarrhoea of ≥5 x/day. All required IV methylprednisolone but 3 received alternate routes initially (2 oral, 1 rectal). Three patients required infliximab with only 1 requiring ≥1 dose.

Conclusions A significant proportion of patients develop lower GI tox with CPI. They were more likely to have been treated with ipilimumab containing regimens and to have a favourable response to therapy although this may have been confounded by the higher use of n+I in this cohort. The rate of G3/4 toxicity was similar to the literature. Some patients are initially treated with oral/rectal steroid; they may benefit from earlier IV therapy. Infliximab as a single dose is usually effective.
Transient hypophosphatemia may occur in response to rapid cellular proliferation due to transcellular shift of phosphate from the extracellular fluid into cells whereas longer lasting hypophosphatemia described after treatment with low IV iron seems related to renal phosphate wasting mediated through an increase in the phosphaturic hormone fibroblast growth factor (FGF23). This analysis was done to investigate whether phosphate levels need to be considered during treatment with iron isomaltoside.

**Methods** The data presented here is from a pooled analysis of IBD patients from 3 clinical trials of iron isomaltoside performed in IBD patients with IDA. Outcome measures were s-phosphate and adverse drug reactions linked to low levels of serum phosphate. Intact FGF23 (iFGF23) was measured in a subgroup of patients.

**Results** 255 patients (89 men, 166 women) were included in the analysis. Cumulative doses of ≤1000 mg or >1000 mg iron isomaltoside were administered in 189 and 66 patients, respectively.

Hypophosphatemia (s-phosphate <2 mg/dL) was observed in 7.9% and 6.1% in patients dosed with ≤1000 mg and >1000 mg iron isomaltoside, respectively (p=0.8) and 7.4% for the total population. The drop in phosphate was typically just below 2 mg/dL, appeared one week after the iron infusion and was normalised two weeks after the infusion. These events were asymptomatic, not reported as adverse events, and assessed as non-clinically significant. No severe hypophosphatemia (s-phosphate <1 mg/dL) was observed.

No increase in iFGF23 was seen throughout the study in the subgroup of patients (n=21) where it was measured.

**Conclusions** No severe hypophosphatemia was observed in IBD patients treated with iron isomaltoside and the small dip in s-phosphate observed among 7.4% of the patients was independent of dose. Signs of iFGF23-induced renal phosphate wasting were not observed in the sub-population of patients examined.

The majority of testing was for suspected loss of response (46%) and partial response (15%). In contrast fewer were for post-induction (10%) and yearly reassessment (15%), of whom 80% had documented inactive disease. 17% had experienced an infusion reaction around the time of testing.

For Adalimumab patients (figure 1), 4 had prior ADA to Infliximab. 71% had a co-prescribed immunomodulator (IM). The mean time from treatment initiation to ADA detection was 23 months. After ADA detection, 8 (38%) had their Adalimumab therapy continued. Of these, 5 (62%) had dose escalation, of whom 2 had successful ADA suppression and durable remission of 15 and 23 months after initial ADA detection (drug level 1.1 and 4.7 ug/mL respectively). The remaining 3 had persistent ADA at next testing. Of the 19 who discontinued Adalimumab, 32% required a third line out of class biologic.

For Infliximab patients (figure 2), 61% had a co-prescribed IM. The mean time from treatment initiation to ADA detection was 17 months. After ADA detection, 9 (24%) continued on Infliximab. Of these, 5 had successful ADA suppression and sustained remission of 14–27 months to the end of the study (drug levels 2.9–9.6 ug/mL). Of the 33 who had a switch in class of biologic, 52% achieved remission. However, 9% subsequently required a third line and 6% a fourth line out of class biologic.

For both groups, neither a high or low level of ADA, nor duration of biologic pre-testing were predictive of outcome.

**Conclusions** Our study shows some of the challenges in therapeutic drug monitoring when LOR is suspected. When ADAs were detected, most patients required a biologic switch in or out of class, and/or surgery, in line with consensus algorithms. However, it appears that in some cases a durable ADA suppression following dose escalation is possible and should be considered when there are limited other therapeutic options.
to relieve pouch related symptoms. Patients with PPI treated with a biologic were followed up until last clinical encounter. Outcomes included the presence of PPI following biologic therapy, pouch failure defined by the need for an ileostomy, and remission of PPI defined by the absence of any PPI on endoscopic and histological assessment within a year of biologic therapy.

**Result** There were 30 patients in our cohort. The median age at diagnosis of IBD was 27 years old (range 6–48). The median time from pouch formation to diagnosis of pre-pouch ileitis was 81.5 months (range 1–147). The median length of time a patient was on biologics at the censoring of the study was 12 months (range 2–62).

On last endoscopic follow-up, 21/30 (70%) still had endoscopic and histological evidence of PPI, seven had achieved remission and two had no endoscopic follow-up. In our cohort 11 patients had an ileostomy after a median time from starting a biologic of 25 months (range 14–91). Of those who had their UC reclassified to CD, 3/10 (30%) had pouch failure compared with 8/19 (42%) who had UC (p=0.72).

**Conclusion** Biologics fail to achieve endoscopic and histological remission of PPI in the majority of patients. In a small proportion of patients, they may help to prevent deterioration in symptoms. In a large proportion of patients with pre-pouch ileitis, surgery may be required despite biologic use.

### PWE-052 LONG TERM OUTCOMES OF INITIAL IFX THERAPY FOR INFLAMMATORY POUCH PATHOLOGY: A MULTI-CENTRE RETROSPECTIVE STUDY

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**Introduction** Restorative proctocolectomy is considered the procedure of choice in patients with UC refractory to medical therapy. Inflammation of the pouch is a common complication and in some cases fails to respond to antibiotics, the mainstay of treatment. In such cases, corticosteroid, immunomodulatory or biologic treatments are an option. However, our understanding of the effectiveness of IFX for both chronic pouchitis and Crohn’s-like inflammation are based on small studies.

**Methods** This was an observational, retrospective, multi-centre study to assess the effectiveness of IFX for inflammatory disorders related to the pouch. The primary outcome was the development IFX failure defined by primary non-response or secondary loss of response to IFX.

**Result** 38 patients were included. 20/38 (53%) who were initiated on IFX for inflammatory disorders of the pouch had IFX failure, 4/38 (11%) had primary non-response and 16/38 (42%) had secondary loss of response with a median follow-up of 265 days (range 82–2119). Of those that had IFX failure 10/20 (50%) avoided an ileostomy by switching to an alternative biologic. In total, 28/38 (74%) avoided an ileostomy, of these, 17/38 (45%) continued on their IFX after a median follow-up of 311 days (42–3968), 5/38 (13%) were changed to Adalimumab after a median follow-up of 498 days (1–1544), 4/38 (11%) were changed to Vedolizumab after a median follow-up of 569 (251–1138), 1 achieved histological remission and stopped all treatments at 251 days and 1 was maintained on methotrexate and multiple antibiotics after 3968 days.

**Conclusions** After initial IFX therapy over half will fail first line IFX, of those that fail half can avoid an ileostomy by switching to an alternative biologic. Patients should be counselled about a high incidence of failure and alternatives should be considered.

### PWE-053 BIOFEEDBACK IN PATIENTS WITH ILEOANAL POUCH DYSFUNCTION: A SPECIALIST CENTRE EXPERIENCE

Jonathan Segal*, 1,2Heyson Chan, 1Brigette Collins, 1Omar Faz, 1Professor Alisa Hart, 1,2Susan Clark, 1St Mark’s Hospital, Harrow, UK; 2Department of Surgery and Cancer, Imperial College, London, UK.

**Introduction** Restorative proctocolectomy is performed in patients with ulcerative colitis refractory to medical therapy, UC related neoplasia, and in some patients with familial adenomatous polyposis. Incontinence can occur in up to 12%–31% of patients with an ileoanal pouch. Evacuatory difficulty in the absence of mechanical or anatomical abnormality is uncommon and management options are limited. Incontinence and evacuatory disorders associated with the ileoanal pouch can be particularly problematic and difficult to treat using conventional therapies.

Biofeedback therapy is a behavioural treatment which is non-invasive and offers a non-surgical approach as an alternative or adjunct for patients with functional bowel disorders. The theoretical basis for biofeedback is ‘learning through reinforcement’ or ‘operant conditioning’.

**Methods** This was a retrospective single centre study. We reviewed the notes of all patients attending for biofeedback at our institution between January 2012 and October 2017, and identified all those that did so for ileoanal pouch related problems. We recorded patient reported subjective improvements following biofeedback. The validated International Consultation on Incontinence Questionnaire was used to assess improvement in incontinent symptoms and the evacuatory disorder questionnaire was used to assess improvement in evacuatory disorders.

**Result** Twenty-six patients with ileoanal pouch related problems underwent biofeedback. Based on patients’ feedback at next clinical encounter following biofeedback, nine reported much improvement, 11 reported some improvement and six reported no improvement. In the group treated for incontinence, quality of life improved significantly from a median pre-treatment score of 80 to a post-treatment score of 41 (p=0.01) (table 1). Biofeedback reduced pain, bloating, straining and laxative use in patients with evacuatory disorders.
Abstract PWE053 Table 1 Incontinence disorder using objective scoring system (n=5) ICIQb Scores

<table>
<thead>
<tr>
<th>Domain</th>
<th>Pre-biofeedback score (median, range)</th>
<th>Post biofeedback score (median, range)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bowel pattern</td>
<td>62 (49–62)</td>
<td>46 (39–62)</td>
<td>0.12</td>
</tr>
<tr>
<td>Bowel control</td>
<td>82 (33–102)</td>
<td>53 (11–76)</td>
<td>0.21</td>
</tr>
<tr>
<td>Non-scored</td>
<td>22 (17–35)</td>
<td>29 (12–29)</td>
<td>0.35</td>
</tr>
<tr>
<td>Quality of life</td>
<td>80 (62–98)</td>
<td>41 (30–55)</td>
<td>0.01</td>
</tr>
</tbody>
</table>

Conclusions Biofeedback is associated with significant improvement in quality of life as well as possible improvements in symptoms related to both incontinence and evacuatory disorders. It is probably an underused service. Further larger prospective studies are required to assess the efficacy of biofeedback in pouch related dysfunction.

Abstract PWE054 INFLEXIMAB THERAPEUTIC DRUG MONITORING IN IBD VIRTUAL BIOLOGICS CLINIC LEADS TO DURABLE RESULTS

1Christian Selinger, 1Marco Lentl, 1Tanya Clark, 1Helen Rafferty, 1David Graice, 1Alex Ford, 1Anthony O’Connor, 2Tariq Ahmad, 1John Hamlin, 1Rebecca Sagar. 1Leeds Teaching Hospitals Nhs Trust, Leeds, UK; 2Royal Devon and Exeter Foundation Trust, Exeter, UK

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Introduction We have previously shown that therapeutic drug monitoring (TDM) of infliximab (IFX) trough levels and anti-drug antibodies (ADAs) can aid decision making for patients on biological therapy, in conjunction with clinical symptoms, disease history and investigations. The aims of this follow-up study were to evaluate 1 year outcomes of patients who had decisions changed on the basis of TDM results in our original study, and to test the hypothesis that TDM-based decisions to alter or stop IFX treatment are safe and durable.

Methods In our original study, a blinded treatment decision was first made, without knowledge of IFX trough and ADAs. Immediately after this, TDM results were released and a final treatment decision was recorded. For this study we collected long-term clinical outcomes 12 months after the decision. We compared patients with changed treatment decisions with those where the decision to continue IFX remained unchanged. We defined changed decision groups as (I) IFX stop, (II) switch to other biological therapy, and (III) continue IFX with adjusted dose or interval. Events of interest were hospitalisation for IBD or further changes to biological therapy.

Results Of 190 patients reviewed in virtual biologics clinic 54 (28%) had decisions changed in the light of results of TDM. Of the 136 patients with an unchanged decision, 128 who continued IFX as previously dosed were used as the comparator group. There were no differences in hospitalisation rates between 3 changed decision groups (I, p=1), (II, p=0.2), (III, p=0.4) and the unchanged decision comparator group. There were no differences in hospitalisation rates compared patients with changed treatment decisions with those who continued IFX therapy unchanged. TDM-based decisions about IFX treatment that incorporate the clinical picture can safely alter therapy without exposing patients to an increased risk of hospitalisation or need for subsequent changes to biologic therapy.

Abstract PWE055 CURRENT SMOKING TRENDS IN BRITISH IBD PATIENTS IN THE AGE OF E-CIGARETTES

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10.1136/gutjnl-2018-BSGAbstracts.183

Background Cigarette smoking has a very detrimental effect on the course of Crohn’s disease (CD) while data on ulcerative colitis (UC) are conflicting with some studies suggesting a potential protective effect. Smoking trends have changed dramatically changed over the last decades in the United Kingdom with the introduction of a smoking ban in public buildings and the advent of e-cigarettes. We aimed to describe current smoking rates in IBD patients compared to the general population and to ascertain any effects of smoking on disease course.

Methods Self-reported smoking status was elicited in consecutive IBD out-patients and clinical data (phenotype, demographics, treatment history, current disease status) were extracted from the electronic hospital patient record. Office of national statistics 2015 data for the general population were used as the comparator.

Results Of 375 patients (mean age 44.7 years; mean disease duration 10.7 years) 50% suffered from CD, 42% from UC and 8% from IBD-U. Current drug exposure included: 70 mesalazine, 109 thiopurine, 8 methotrexate, 44 infliximab, 34 adalimumab, 6 Vedolizumab and 45 patients were on steroids. Current disease activity was remission (42.4%), mild (41.1%), moderate (14.9) and severe (1.6%). Of 200 ever cigarette smokers 144 had stopped and 56 continued cigarette use, while of 30 ever e-cigarette users 14 had stopped and 16 continued. All e-cigarette users had previously smoked cigarettes and 10 had stopped smoking completely after e-cigarettes.

Conclusion Our study demonstrates that changes to IFX treatment based on TDM were durable. Patients with a decision to stop, switch, or continue with an adjusted IFX dose experienced comparable clinical outcomes with those who continued IFX therapy unchanged. TDM-based decisions about IFX treatment that incorporate the clinical picture can safely alter therapy without exposing patients to an increased risk of hospitalisation or need for subsequent changes to biologic therapy.
Crohn’s disease patients were more likely to smoke cigarettes (19.9% vs 8.1%) or e-cigarettes (4.1% vs 3.4%) compared to UC/IBD-U patients (p=0.026).

Infliximab use was more common in cigarette smokers (13.2%) and e-cigarette users (21.4%) vs non-smokers (11.2%); p=0.016. Adalimumab use was more common in cigarette smokers (16.9%) and e-cigarette users (7.1%) vs non-smokers (7.6%); p=0.023. The need for previous surgical resection was higher in cigarette smokers (44.2%) and e-cigarette users (35.7%) vs non-smokers (26.8%); p=0.035.

Compared to the general population the proportion of current cigarette smokers (14.9% vs 17.2%) and e-cigarette users was similar in our cohort (4.26% vs 4%).

Conclusion IBD patients show similar smoking behaviour as the general population with 4% using e-cigarettes. The detrimental effect of smoking remains evident in our cohort. IBD patients use e-cigarettes as replacement for cigarettes or as an intermediate step for smoking cessation with no de-novo e-cigarette use in our cohort. Some health authority propose that e-cigarettes are less harmful to health than cigarettes. There are however little data on the effect in IBD. Large scale, prospective studies examining the effects of e-cigarette use are required.

Abstract PWE-056 Table 1

<table>
<thead>
<tr>
<th>Delivery</th>
<th>CD</th>
<th>UC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginal delivery</td>
<td>11</td>
<td>2</td>
</tr>
<tr>
<td>Caesarean section without perianal disease</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Perianal disease with obstetric indication for Caesarean section</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

Abstracts

PWE-056 MANAGEMENT AND OUTCOMES OF PREGNANCY IN PATIENTS WITH INFLAMMATORY BOWEL DISEASE IN JOINT OBSTETRIC/IBD CLINIC

Methods Patients with IBD were identified when they booked for their maternity care between 22/2/15–16/7/16. Data was collected retrospectively via both paper notes and online electronic patient record. We obtained information regarding patients’ IBD including diagnosis, medications used during pregnancy and previous surgical history. In addition, Obstetric data was collected, including method of conception, number of live births, miscarriage, terminations, birth weight, pre-term delivery, congenital abnormalities and maternal mortality.

Results We found that there was a higher incidence of foetal loss in our cohort after booking visit than would be expected in the general population. In our group of IBD patients only 17% of Crohn’s patients underwent a caesarean section, whilst it was 50% in the UC cohort. One patient with CD delivered pre-term having stopped her anti-TNF therapy early in pregnancy against her physician’s advice. 73% patients in our population delivered at term with good outcomes.

Conclusions It is important for patients to maintain remission during pregnancy by strictly adhering to their medications. Medications used for the management of IBD are safe to take during the conception period and during first two trimesters of pregnancy with the exception of methotrexate and thalidomide. Patients with IBD can be at increased risk of miscarriage.

PWE-057 USING AN EVIDENCE-BASED, EXPERT CONSENSUS TOOL TO GUIDE BIOLOGIC DECISION-MAKING IS ASSOCIATED WITH FAVOURABLE OUTCOMES

Introduction Treatment with biologic agents is costly and the mechanisms available for inflammatory bowel disease (IBD) remain limited. It is important to optimise the benefit and cost-effectiveness of their use. Therapeutic drug monitoring (TDM) is a strategy to help achieve this, through the measurement of drug and anti-drug antibody concentrations. The Building Research in IBD Globally (BRIDGe) groups ‘Anti-TNF Optimizer’, an online tool that helps interpretation of TDM and clinical decision-making.

Methods We performed a retrospective study of IBD patients on infliximab (IFX) or adalimumab (ADA) at our institution, undergoing TDM between Jan 16-Mar 17. TDM was performed using a drug-tolerant ELISA (IDKmonitor, Immunodagnostik). Disease activity was defined by the combination of clinical symptoms and evidence of biochemical (CRP >10; FCP >150), endoscopic or radiological activity. Clinical decision-making was compared to recommendations made by the BRIDGe ‘Anti-TNF Optimizer’ tool, which suggests that objective evidence should be sought in all cases of suspected primary non-response (PNR) and loss of response (LOR).

Subsequent disease course was evaluated using a Physicians Global Assessment (PGA), which took into account clinical, biochemical, endoscopic and/or radiological activity and the need to progress to surgery. Outcomes were described as
favourable’ or ‘unfavourable’. Groups were compared using Fisher’s exact test (GraphPad Prism V7.0a).

Results 60 patients were included: 30 IFX and 30 ADA. Indications for TDM: LOR 45 (75%), PNR 8 (13%), routine monitoring during remission 7 (12%). Objective evidence of inflammation was sought in all 53 cases of LOR/PNR and found present in 42 (79%). Two patients were lost to follow up and were not included in the final analysis. Of these 40, subsequent clinical management was in keeping with BRIDGe recommendations in 19 (48%).

Of the 19 LOR/PNR patients managed as per BRIDGe recommendations, 15 (79%) achieved a subsequent favourable outcome. The rate of subsequent favourable outcome in the group who were not managed in accordance with BRIDGe was significantly lower at 3/21 (14%, p<0.0001).

Conclusions The rate at which objective evidence of inflammation was sought amongst our patients with symptoms suggestive of PNR/LOR was good. However, clinical decision-making deviated from BRIDGe recommendations in majority of cases and this appeared to adversely impact disease course. Results therefore, suggest that using an evidence-based, expert consensus, online tool to guide biologic decision-making with the results of biologic TDM provides benefit in IBD outcomes.

Abstract PWE-057

PWE-058 FACTORS ASSOCIATED WITH INFLAMMATORY BOWEL DISEASE ASSOCIATED COLORECTAL CANCER AND DAMAGE ASSOCIATED MUCOSAL LESION DETECTION


Introduction Colonoscopic surveillance is indicated for the detection of premalignant damage associated mucosal lesion (DALMs) and colorectal cancer (CRC) in patients with chronic inflammatory colitis of greater than 10 years duration. We reviewed all cases of DALM and CRC detection in our IBD cohort over a 4 year period and compared against current BSG guidance for high risk groups (2010).

Methods The pathology reporting system of Imperial College Healthcare NHS Trust was interrogated for SNOMED 11a codes for IBD and dysplasia or CRC (D6214, D6216, D6255 and M7400) between 1/9/12–1/1/17. The case notes of these patients were reviewed and those with adenoma related dysplasia excluded. The indication for the detecting procedure was recorded.

Surveillance practice during this time was measured by recording all colonoscopies performed for the indication of IBD (colitis, Crohn’s disease, colitis – ulcerative or IBD assessment) over a 9 year period (1/9/07–1/1/17) from the endoscopy reporting system (Scorpio, Emis Health, UK) of Imperial College Healthcare NHS Trust. The surveillance interval of each individual patient was calculated. A subgroup of 20 patients within this cohort were sampled for case notes review to identify the reasons for inappropriate surveillance.

Results Dysplasia and IBD was detected in 59 individuals, 42 were adenomas and excluded, leaving 7 DALMs detected. Three (42%) were not detected during surveillance (two<10 years from symptom onset, one bowel cancer screening program). Two (29%) had cancer. Four (58%) were recognised as DALMs under white light endoscopy, three (42%) were detected on random biopsy, none were detected with dyespray. Adherence to the 2010 guidelines in these patients was 85%.

1289 individuals with 2256 colonoscopies were identified. Low/moderate/high risk groups were 78 (60%)/382 (29%)/125 (9.7%) respectively. Interval adherence in this cohort was 82%. 20 patients were selected for case notes review. The mean age was 49 (range 31–72). Three patients had colectomy (2 refractory colitis, one DALM) and one patient moved out of area during the studied period. 72 colonoscopies were performed with 52 intervals recorded. Seven (13%) intervals were scheduled over the recommended time (mean 333 days). These were all at the patient’s request. 30 intervals (58%) were performed before there intended date (mean –347 days). The most common reason for this was inappropriate yearly surveillance.

Conclusions DALMs were detected in 0.5% of IBD patients undergoing colonoscopy. Almost half of these were not detected during scheduled surveillance, which may support the shorter intervals used by some clinicians.
TRAVELLING WITH INFLAMMATORY BOWEL DISEASE (IBD): BARRIERS, FEARS, CONCERNS AND SUGGESTIONS FOR SUPPORT

Amet Soussieres, Varun Philip, Andrew Poullis. St George’s Hospital NHS Trust, London, UK

Introduction IBD can act as a barrier to overseas travel due to concerns about travel related morbidity. This study aims to identify barriers, fears and concerns of IBD patients with regards to travel and possible areas of support from the IBD team.

Method 136 IBD patients were selected using convenience sampling. They completed a questionnaire focused on travel with IBD and specific travel issues (decision to travel, insurance, pre-trip advice, vaccination, previous flares while abroad, high altitude travel, assistance while overseas).

Result 136 patients completed the questionnaire, 70 were male (51.4%), 73 had Crohn’s Disease, 53 had Ulcerative Colitis (UC), 3 had Indeterminate Colitis and 7 were unsure. 56.6% of patients were taking 5-ASAs, 52.9% were on immunosuppressant therapy and 20.6% receiving biologics. 89% had travelled abroad since their IBD was diagnosed, 30% reported IBD limited their travel and 40% said it affected their choice of destination. 61% worried about healthcare problems abroad. 7% were refused health insurance and 47% had travelled abroad uninsured. 9% travelled uninsured due to their current diagnosis of IBD. Only 64% felt that they had received adequate pre-travel medical advice. 78% wanted advice from their doctor for future travel. 60% were unaware that taking immunosuppressant medication could affect their vaccinations and 63% on immunosuppressant therapy of biologics claimed they were uninformed of the need to avoid live vaccines. 12% received live vaccines prior to travel. Suggestions for travel help: 91% requested a written/electronic prescription for their journey, 75% wanted specific management advice, 68% a written management plan. 68% felt a doctor’s note could help them secure health insurance. 38% of patients who travelled abroad were suffering/recouping from a flare and 18% travelled despite being within a week of a flare. 92% were unaware that high altitudes could precipitate a flare. 27% travelled to high altitude destinations and of these 46% experienced a flare whilst travelling or within 4 weeks of travel. 72% were unaware of the ‘Can’t Wait Card’ and 96% never heard about the IBD passport website.

Conclusion IBD has a big impact on travel for a broad range of reasons. Refusal of health insurance, coupled with higher premiums could explain why many IBD patients travel abroad uninsured. Providing a doctor’s note confirming fitness to travel was a popular solution chosen by patients. A majority were interested in doctors providing written management plans and prescriptions prior to their travel. Despite over half of the study being on immunosuppressant therapy, most were unaware of avoiding live vaccines whilst taking them. Better advice from health care professionals makes this entirely avoidable. Most IBD patients were unaware that high altitudes may precipitate flares. A large majority were unaware of the ‘Can’t Wait Card’ and IBD passport services. Pre-emptive discussions around travel plans should be part of the IBD clinic review.
**Introduction** Guidelines support endoscopic assessment of mucosal healing in Crohn’s disease before a change in therapy. [Gomollon, J Crohn’s Colitis 2016] A recent study has shown that the PillCam Crohn’s (PCC, Medtronic, Dublin, Ireland) has a better diagnostic yield than ileocolonoscopy [Lighton, Gastrointest Endosc 2017] and that colon capsule (for which the same bowel preparation is used) is better tolerated [Ojidu, European J Gastroenterol Hepatol, in press]. We report the first experience of PCC in routine clinical practice.

**Methods** Data was collected prospectively in Sheffield and South Tyneside hospitals. Montreal classification was used (ileal:L1; colonic: L2; ileocolonic: L3; upper GI: L4; B1: non-stricturing/penetrating; B2: stricturing; B3: penetrating). All patients passed an Agile patency capsule (Medtronic).

**Results** Eighteen patients (median age 33 years, 38.9% male, known Crohn’s in 83%) had PCC. Indications were: symptom assessment (77.8%), assess response to treatment (11.1%), consideration of stepping down therapy (16.7%). Patients with established Crohn’s had L1 (53.3%), L2 (13.3%), and L3 disease (33.3%) which was uncomplicated (40%), stricturing (46.7%) and penetrating (13.3%). Patients were on medical treatment in 73.3%. PCC changed staging of disease in 33% of cases (L1 to L3 n=1, B2 to B1 n=3 and B1 to B2 n=1). One of three patients with suspected Crohn’s disease subsequently had endoscopic confirmation (L3 B1). PCC was normal (5/18), revealed L1 disease alone (8/18), L2 disease alone (1/18) and L3 disease (5/18). There were three incomplete procedures, all with an otherwise normal visualised colon. No capsule retentions occurred. Follow up data was available in 11 patients. Of eight patients with symptoms, five had active disease and three no or minimal activity. Of the five, three had a step-up in treatment, one had adalimumab temporarily suspended due to a perianal abscess and management continues to be discussed in one patient on maximal medical therapy. Other causes of symptoms were sought in the patients with inactive disease. Three patients had no symptoms, one had active disease and a step up in treatment, two had no or minimal activity of whom one continued therapy due to poor prognostic factors and one was already on no treatment (PCC being performed to provide supportive evidence of a diagnosis made in childhood). No patient known to have Crohn’s has been referred for further small bowel imaging or colonoscopy. Conclusion PCC provides a single visit assessment of both small and large bowel which was useful in guiding patient management without complications.
Results A total of 45 pregnancies in 44 women were identified. 18 women have Crohn’s disease (CD) and 26 ulcerative colitis (UC). Most women were on some treatment with only 4 being on none. 21 women were on 5-ASA (oral, topical or both). 7 women were on thiopurines. 8 women were on biologics (Infliximab 3, adalimumab 4, vedolizumab 1). 5 women were on biologics and thiopurines (3 adalimumab, 2 infliximab). Biologics were stopped at 28 weeks in 6/8 women, 1 woman stopped at 20 weeks and in one case it was necessary to continue Adalimumab throughout the pregnancy.

2 patients needed treatment with prednisolone due to flare up during pregnancy. One woman was diagnosed with UC during pregnancy and required prednisolone. One woman with severe perianal CD needed surgical drainage during pregnancy.

All pregnancies resulted in live births. Mean birth weight was 2303 g. 7 women had emergency caesarean section (CS), 9 women elective CS and 5 had instrumental deliveries. The commonest indications for elective CS were obstetric or maternal choice and emergency CS foetal distress or failure to progress. There were 5 preterm deliveries (<37 weeks), 4 spontaneous, 1 emergency. There was one birth with severe intrauterine growth retardation (IUGR) secondary to a large placental haemorrhage at the beginning of the pregnancy and 1 duodenal atresia.

One woman on infliximab and azathioprine developed listeria sepsis 10 days after the last infliximab infusion at 28 weeks. This was identified and treated appropriately, the pregnancy continued to term with no foetal complications.

Average number of clinic visits was 3. There were a total of 115 appointments with a rising trend as the clinic became established and better known to GPs and midwives.

Conclusion This study showed that a combined IBD-obstetric clinic improves adherence to treatment and guidelines with good pregnancy outcomes. Patient feedback is that they value this combined approach both in terms of the medical/obstetric expertise and in terms of convenience.

Abstract PWE065 Table 1 Relationship between ATI status and IFX trough levels at first maintenance dose n=50

<table>
<thead>
<tr>
<th>ATI status</th>
<th>IFX trough level (mg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Undetectable (&lt;0.8)</td>
</tr>
<tr>
<td>Positive</td>
<td>6</td>
</tr>
<tr>
<td>Negative</td>
<td>7</td>
</tr>
<tr>
<td>Total (%)</td>
<td>13 (26)</td>
</tr>
</tbody>
</table>

Conclusion At first maintenance dose, nearly a third of patients had developed positive ATI. These patients have lower IFX levels and a higher risk of treatment failure by the second maintenance dose. Therefore, TDM following induction therapy may be important in identifying patients who require rapid treatment alteration.

Abstract PWE066 MICRONRNA SIGNATURES CAN DIFFERENTIATE BETWEEN INFLAMED AND NON INFLAMED COLONIC MUCOSA OF ULCERATIVE COLITIS PATIENTS

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Introduction Ulcerative colitis (UC) is a form of inflammatory bowel diseases (IBD) which are chronic, relapsing and idiopathic disorders of gastrointestinal tract. The aetiology of IBD has not been defined yet but a complex interplay of microbial, genetic and environmental factors is known to play role in its pathogenesis. Recently, microRNAs have emerged as an epigenetic regulator of inflammation during IBD. MicroRNA target the genes involved in major signalling pathways and regulate there expression thereby affecting the overall inflammatory pathway. In this study we looked at the miRNA.
profile of inflamed and non-inflamed regions of UC patients. We also studied the biological relevance of this dysregulated expression by looking at the potential targets of these miRNA and the biological pathways involved.

Methods To investigate the expression profile of miRNAs we collected the colonic mucosal biopsies from the endoscopically inflamed and non-inflamed regions of UC patients. Colonic biopsies were also collected from control individuals. The differential expression of miRNA was studied by microarray and qRT-PCR. The potential targets of miRNA were predicted using bioinformatics tools such as TargetScan, miRDB, DIANA-MicroT, microrna.org and Pictar. The pathways involved were identified by mirPath v.3:DIANA TOOLS.

Results The miRNA profile of inflamed colonic mucosa was found to be significantly different from the non-inflamed one in microarray. The real time analysis showed a significant upregulation in the expression of miR-125b and miR-223 in the inflamed colonic mucosa as compared to non-inflamed mucosa. TRAF6 which is a potential target of miR-125b and an important signalling molecule of NFkB pathway, showed a significant downregulation in UC patients as compared to controls. Similarly, IKK alpha which is targeted by miR-223 showed a significant downregulation in its expression in UC patients.

Conclusions Our study indicates the spatial expression of miRNA during UC and their biological relevance. MiR-223 showed a disease independent behaviour therefore, it could be developed as a biomarker for UC. Studying these miRNAs and the signalling pathways in detail, could provide better insight of disease pathogenesis and provide scope for their use in therapeutics.

PWE-067 HEALTHCARE RESOURCE UTILISATION AND QOL IN PATIENTS WITH UC BY DISEASE SEVERITY: ICONIC BASELINE DATA

Sjin van Haaren, Subrata Ghosh, Laurent Peyrin-Biroulet, Francesc Casellas, Ciara O’Shea, Wan-Ju Lee, Brandee Pappalardo, Joel Peterson. Abbie, North Chicago, UK, College of Medical and Dental Sciences University of Birmingham, Birmingham, UK; Nancy University Hospital, Nancy, France; Hospital Universitari Vall d’Hebron, Barcelona, Spain

Introduction ICONIC is a prospective, multi-country (n=33) observational study, assessing cumulative burden in adult ulcerative colitis (UC) patients (pts) under routine care. Assessments of healthcare resource utilisation (HCRU), disease severity and impact on quality of life will be captured at 6 month intervals through 2 years. This analysis evaluated baseline (BL) HCRU, work productivity, and quality of life among UC pts with different level of disease severity.

Methods Pts with early UC (diagnosed ≤36 months) were enrolled irrespective of disease severity or treatment. For this analysis, we evaluated pts stratified by physician assessment of disease severity into severe, moderate, mild and remission groups. BL characteristics described: Simple Clinical Colitis Activity Index (SCCAI), UC-related HCRU measured during the 6 months prior to study enrollment (i.e., visits to treating physicians or other IBD-associated healthcare professionals, emergency room (ER) visits, hospitalizations and hospital admissions for surgeries); Health Related Quality of Life (HRQoL), pt-reported employment/UC-related sick leave status and Work and Productivity Activity Index (WPAI:GH; including work time missed (absenteeism), impairment while working (presenteeism), overall work productivity impairment, and daily activity impairment domains).

Results A total of 1816 UC pts were enrolled; mean ±SD age was 38.5±14.6 years and 833 (45.9%) were female. At BL, 230 pts (12.7%) were in remission, 672 pts (37.0%) had mild UC, 668 pts (36.8%) had moderate UC, and 234 (12.9%) had severe UC. Compared to pts in remission, pts with moderate to severe UC had 1.8 to 2.6-fold higher rates of hospitalizations and 1.6 to 2.5-fold higher rates of ER visits over the past 6 months. Pts with moderate and severe disease were associated with lower SIBDQ scores and higher WPAI:GH domain scores (i.e., greater impairment on work productivity) than pts with mild disease or those in remission.

172 (9.5%) pts reported to be unemployed at BL. 183 (10.1%) reported sick leave at BL. Sick leave time ranged from <2 months (59.6%), 2–4 months (12.6%), >4 months (22.4%).

Conclusion The direct and indirect burden of UC is substantial, as measured by healthcare resource utilisation and work-life impact. Pts with moderate and severe UC not only were associated with higher rates of urgent care in hospitalisation and ER visits, but also with poorer quality of life, higher unemployment, sick leave and impaired work productivity than pts with mild UC or in remission. For pts with mild UC, despite comparable HCRU to pts in remission, increased impact on work productivity remains a concern.

PWE-068 ADVERSE EVENTS IN ELDERLY INFLAMMATORY BOWEL DISEASE PATIENTS MANAGED WITH ANTI-TNF THERAPY

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Introduction In a population with an increasing life expectancy, a sizable proportion of inflammatory bowel disease (IBD) patients are elderly. The management of IBD often requires immunosuppressing anti-tumour necrosis factor (anti-TNF) drugs which add to the immunosuppressive effects of ageing. Evidence for the safety of anti-TNF therapy in the elderly is scarce. Our objective was to assess the safety of anti-TNF therapy in the elderly considering their co-morbidities and immunomodulators (IM).

Methods Retrospective single centre study The IBD database of a large teaching hospital was interrogated for patients aged >65 years who had been prescribed infliximab or adalimumab. Patient electronic records were reviewed along with general practice prescribing records. Data was collected on co-morbidities, IM use, hospitalisations, significant adverse events (any reaction requiring discontinuation of the anti-TNF), and antibiotic prescriptions. Charlson Co-Morbidity index (CCD) was calculated.

Results 80 patients (51 female) aged >65 received either infliximab (n=50) or adalimumab (n=30). Crohn’s disease (n=70) was more common and 34 patients were on a concomitant IM. The median duration of follow-up (FU) was 4 years and the median duration of therapy was 14 months. There were 5 deaths during FU, 4 after cessation of anti-TNF (2 pneumonias, 1 chronic obstructive pulmonary disease, 1 malignancy) and 1 patient was still on an anti-TNF (Crohn’s related malnutrition). Seven patients developed cancer, 5 still on an anti-TNF and the other two were one and two years...
post-cessation of anti-TNF. Of the 5 patients who developed cancers on an anti-TNF, all 5 restarted their anti-TNF after treatment of the cancer. Eight patients (10.5%) required hospitalisation due to what was felt to be an anti-TNF related event (7 infective, 1 allergic reaction). Patients on an IM had a 15.4% chance of anti-TNF related hospitalisation vs 4.4% in those not on a concomitant IM (p=0.09). Concomitant IM use had no statistical impact on the risk of developing a cancer (9.1% on an IM vs 6.5% not on an IM, p=0.49). Of those that required antibiotics, IM use did not seem to increase this risk (p=0.43). Thirty one percent of those that stopped their anti-TNF (n=50) did so because of an adverse event. When CCI=0 was compared with a CCI >0, they were no more likely to still be on an anti-TNF after 12 months.

Conclusions In this series, we were unable to demonstrate a relationship between co-morbidities and tolerance of anti-TNF therapy. There was, although not reaching statistical significance, a relationship between concomitant IMs and risk of hospitalisation due potential anti-TNF related events. Elderly patients are more likely to stop anti-TNFs than the younger populations used in larger trials. Concomitant IMs must be carefully considered to reduce the risk of adverse events.
ETROLIZUMAB INDUCTION IN MODERATE/SEVERE ANTI-TNF INTOLERANT/REFRACTORY (IR) UC: THE HICKORY OPEN-LABEL INDUCTION (OLI) TRIAL

Introduction HICKORY OLI evaluated the safety and efficacy of etrolizumab (etro) via independent, centrally-read endoscopy, patient (pt)-reported outcomes, and inflammatory biomarkers in pts who are IR to aTNFs.

Methods Pts received etro 105 mg injected SC every 4 weeks (14 week induction). Mayo clinical scores (MCS) based on endoscopic score (ES), and pt-reported rectal bleeding (RB) and stool frequency (SF) were assessed at baseline (BL) and week 14. Clinical response: ≥3 point and 30% reduction of MCS from BL and ≥1 point decrease in RB or RB ≤1. Remission: MCS ≤2 with individual subscores≤1 and RB=0. Endoscopic improvement: ES ≤1. RB remission: RB=0; SF remission: SF ≤1 with >1 point reduction from BL. The% decline from BL in RB and SF at week 14 was also calculated.

Results HICKORY OLI enrolled 130 UC pts; 45% had previously failed >1 TNF antagonist. BL disease activity included MCS score, 9.4; median C-reactive protein (CRP), 6.6 (95% CI: 2.9, 14.5) g/dL; and median faecal calprotectin (FC), 1778 (95% CI: 898, 3452) mg/kg.

At week 14, etro treatment was associated with clinical response in 30.8% of pts; remission in 12.3%; ES ≤1 in 23.9%; RB remission in 32.3%; and SF remission in 35.4%. 43.9% of pts had ≥1 point improvement from BL in the ES score, and improved ES scores were associated with increased rates of RB and SF remission. Among pts with ES=0, 100% reported RB ≤1, and 90% reported SF ≤1 (table 1). Pts who achieved either SF or RB remission or ES ≤1 also demonstrated >50% geometric mean reduction in CRP (BL ≥2.87 mg/L) and >70% geometric mean reduction in FC.

Conclusions TNF antagonist-experienced pts with moderate-severe UC and high disease burden treated with open label etro for 14 weeks achieved clinically meaningful clinical response and remission and endoscopic improvement. Pts who had a decline in ES ≥1 achieved higher rates of RB and SF remission and greater reductions in inflammatory biomarkers. Recruitment to HICKORY continues in a randomised, placebo controlled induction cohort and a randomised maintenance phase is ongoing.

Abstract PWE071 Table 1 Lower ES at week 14 was associated with higher SF and RB remission rates (N=130)

<table>
<thead>
<tr>
<th>Improvement in ES from BL (%)</th>
<th>No Improvement from BL (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=57</td>
<td>n=73</td>
</tr>
<tr>
<td>Week 14</td>
<td></td>
</tr>
<tr>
<td>RB=0</td>
<td></td>
</tr>
<tr>
<td>n=10</td>
<td>n=21</td>
</tr>
<tr>
<td>RB=1</td>
<td></td>
</tr>
<tr>
<td>n=19</td>
<td>n=26</td>
</tr>
<tr>
<td>RB=2</td>
<td></td>
</tr>
<tr>
<td>n=12</td>
<td>n=15</td>
</tr>
<tr>
<td>SF=0</td>
<td></td>
</tr>
<tr>
<td>n=30</td>
<td>n=33</td>
</tr>
<tr>
<td>SF=1</td>
<td></td>
</tr>
<tr>
<td>n=60</td>
<td>n=33</td>
</tr>
<tr>
<td>SF=2</td>
<td></td>
</tr>
<tr>
<td>n=10</td>
<td>n=33</td>
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</tbody>
</table>

Abstract PWE072 PHARMACY TECHNICIAN IN THE IBD TEAM MAINTAINS PATIENT SAFETY WHilst FREEING UP PHARMACISTS AND PHYSICIANS

Introduction We previously demonstrated that incorporating a pharmacist into the Inflammatory Bowel Disease (IBD) team releases doctors’ time and improves the consistency and safety of drug monitoring and counselling. We now take the next logical step, by recruiting a pharmacy technician to do the routine drug monitoring and other duties under the supervision of the specialist pharmacist, thereby freeing up clinicians time. We present the outcome of this 3 month pilot.

Methods • Provide a blood monitoring service for immunosuppressant therapies of 524 patients on thiopurines and 419 patients on biologics
• Manage the weekly ordering of infusion medication and other duties under the supervision of the specialist pharmacist, thereby freeing up clinicians time.

Result • A total of 260 patients were monitored of which 63 patients (24%) needed to be contacted to provide the blood test
• 48 referrals (18.4%) were made to the gastroenterology pharmacist:
• 27 patients (10.3%) due to drug levels outside therapeutic ranges or antibodies
• 9 patients (3.5%) had deranged liver function tests
• 5 patients (1.9%) had leucopaenia
• 7 patients (2.6%) had either raised FCLP levels or anaemia
• Biological medication for 259 patients (average of 20 patients per weekly clinic) was dispensed, ensuring cold chain procedure and accurate stock control. Using the Aspecic Non-Touch Technique (ANTT) infusions were prepared, maximising vial sharing, releases nursing staff to undertake cannulation and pharmacists to monitoring and review patients.
• 42 VBIC patients were asked to provide a FCLP sample and bloods 2 weeks prior to VBIC. IBD scores were collected during a phone call.

• A total of 17 SCP were sent to patient GP’s.

• All data was entered on the in house database for easy review by the MDT.

Conclusions A competent pharmacy technician can safely take over the majority of the drug monitoring and infusion preparation, previously done by our pharmacist. Released funds of £13 K (lower staffing cost) and cost savings £36 K (vial sharing) per year are projected.

This represents an increased cost saving, freeing up nursing time and releasing the pharmacist to deal with identified problems and advanced roles within the team (e.g. outpatient clinics, prescribing, helpline queries, counselling patients, TDM) which in turn releases clinicians’ time (ECCO 2015 Abstract P306). In addition this audit has identified the on-going need for active monitoring of the medications as 1/5 of patients had abnormal results and 1/4 had to be chased up to undertake monitoring at the appropriate interval.

Liver

OWE-012 NATIONWIDE POPULATION-BASED EVALUATION OF MORTALITY AND CANCER-RISK IN YOUNG PATIENTS WITH ULCERATIVE COLITIS/PRIMARY SCLEROSING CHOLANGITIS

Introdution Advancing age is proposed as a risk factor for mortality in primary sclerosing cholangitis (PSC) (Trivedi*Weismuller* et al. Gastro. 2017). However outcomes against a matched control population need evaluation. Our aim was to provide data-driven prioritisation of unmet need by comparing pts. with ulcerative colitis (UC) and coexisting PSC vs an age-matched cohort with UC alone in a stratified outcomes’ analysis.

Method A population-based study was performed via linkage to the national Hospital Episode Statistics registry, which records every adult (>18 y of age) hospital attendance, admission or clinic event within England since 2006. Across the entire registry we captured all incident cases of UC alone (group I); and UC with an established diagnosis of PSC, or UC diagnosed with PSC subsequently (group 2). Case finding/definition was as per Jess et al (Gastro 2012), by applying ICD10 codes for UC overall (inclusion K51), UC/PSC more specifically (inclusion K51 +K83.0) and excluding other causes of liver injury (K70–77, K80.3/4, B16–19). Cases were captured till 03/2015; follow-up ending 1y thereafter. Event rates (colectomy, colorectal cancer [CRC], liver transplantation [LT]/death, and all-cause mortality) were stratified according to age strata at UC diagnosis.

Results Over 10 years, 1 28 694 incident UC cases were identified (annualised incidence/100,000 population: 23.8 in 2006; rising to 25.1 in 2015). Of this group, 2124 were diagnosed with PSC at some point (incidence in 2006 and 2015: 0.29 and 0.4, respectively). Observing the UC cohort in entirety, we observed 210 1 sr LT (206 in group 2), 9413 individuals who came to colectomy, 1,208 CRC cases, and 11 177 pt. deaths. The leading cause of mortality was coronary disease (1%) in group 1; whereas liver-related death (5.9%), cholangiocarcinoma (4.6%) and CRC (1%) predominated in group 2. The incidence rate ([IR]/1000-pt.yrs.) was greater in the UC/PSC group for colectomy (17.3 vs 13.7), CRC (5.6 vs 1.5), LT/death (38.5 vs 15.1), and all cause mortality (26.4 vs 15.1); \(p<0.001\) for all. Time-dependent Cox regression validated the negative impact of PSC onset for each endpoint (time-dependent adjusted hazard ratio: 1.62, 3.31, 2.47 and 1.62, respectively; \(p<0.001\) for all). Compared to UC alone, the standardised incidence ratio (SIR) for CRC was greatest in UC/PSC of young presenting age (<40 y); a 7-fold increase (figure 1A). This contrasted to pts. diagnosed above age 40 (SIR ~4). Although absolute mortality rate was elevated in older ages (figure 1B) it was in young pts. with UC/PSC that the contrast vs UC alone was most evident for 5 year. (1.6% vs 0.4%) and 10 year. survival (3.6% vs 0.6%); a 4 and 6-fold increase, respectively. Indeed, standardised mortality (SMR) was the greatest for patients diagnosed age \(\leq\)40 years., and plateaued with older age at diagnosis (figure 1C).

Abstract OWE-012 Figure 1 a) standardised incidence rate of all clinical events b) absolute mortality rates c) standardised mortality rate over time per age group