

severity. Patients completed RFIPC (a 25-item questionnaire about frequently reported worries/concerns in IBD) at each visit (6-month intervals). Responses are scored on a 10-cm visual analogue scale (0='no concerns' to 10='a great deal'; total score=mean of all items). Data are reported using descriptive statistics at baseline (BL, visit 1 [V1]), 1-year (V3), and 2-years (V5) and scores stratified by physician-assessed disease severity (in remission, mild, moderate, severe) at BL.

**Results** 63 patients were included (37 [59%] female; mean  $\pm$ SD age 43.4 $\pm$ 15.7 years; median time since diagnosis 126 days; physician-assessed severity: in remission 16 [25%], mild 18 [29%], moderate 18 [29%], severe 11 [17%]). Mean $\pm$ SD total RFIPC scores for all patients were 2.9 $\pm$ 2.3 (n=63) at V1, 2.7 $\pm$ 2.5 (n=40) at V3, and 2.2 $\pm$ 2.0 (n=35) at V5. At BL, mean $\pm$ SD RFIPC total scores by disease severity were: in remission 1.8 $\pm$ 1.7, mild 3.2 $\pm$ 1.9; moderate 2.6 $\pm$ 2.6; severe 4.8 $\pm$ 2.4. The changes from BL to V5, stratified by disease severity at BL, were: in remission -0.2 $\pm$ 1.0, mild -1.2 $\pm$ 1.4; moderate -0.7 $\pm$ 1.7; severe -2.2 $\pm$ 2.7. The specific concerns with the highest scores (mean RFIPC score >4.0) at BL were 'energy level', 'having an ostomy bag' and 'effects of medication'; the mean total scores for these items decreased between V1 and V5 for all patients. Of 5 UK sites, all had established multidisciplinary teams (MDTs) and 4 had a psychologist *in situ*.

**Conclusion** Despite all centres having MDTs and most having onsite psychologists, this subanalysis from ICONIC demonstrated a high burden of worries and concerns in early UC patients with more severe disease. Concerns were most notable at BL, appearing to decrease over time. The greatest concerns were with treatment and complications of UC, including energy levels, indicating fatigue remains an unmet need for UC patients.

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#### FIRST-LINE AZATHIOPRINE- ALLOPURINOL WITHOUT METABOLITE MONITORING IS AN EFFECTIVE AND SAFE LONG-TERM THERAPY FOR IBD

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**Introduction** The number of IBD patients experiencing a beneficial response from the first-line, low-cost immunosuppressive azathioprine (AZA) is too low due to high rates of adverse events. Co-administration with allopurinol has been reported to improve tolerability and might be an option as first-line therapy.

**Methods** The long-term efficacy, side-effects and safety of low-dose azathioprine with allopurinol (LDAA) was compared with AZA monotherapy (AZAm) in thiopurine-naïve IBD patients unguided by metabolite levels. Medical records of patients (identified from pharmacy dispensing records and an IBD database) were reviewed retrospectively. The primary outcome 'clinical benefit' was defined as: ongoing use of therapy without initiation of steroids, biologics or IBD-surgery. Secondary outcomes included disease activity scores, endoscopic findings,

withdrawal of concomitant therapy (including steroids), CRP and adverse events.

**Results** 166 LDAA and 118 AZAm patients ( $\geq$  90% having active disease) were included with a median follow-up of 25 and 27 months, respectively. Clinical benefit was higher in the LDAA cohort at both 6 months (74% vs 53%,  $p=0.0004$ ) and 12 months (54% vs 37%,  $p=0.01$ ). The overall median duration of beneficial response since commencement of therapy was 17 months (95%-CI 9 - 25) for LDAA therapy compared to 6 months (95%-CI 1 - 11) for AZAm. The lower efficacy of AZAm was explained by the median dose tolerated of 1.83 mg/kg (73% of most effective dose) and high percentage (45%) of patients discontinuing due to intolerance. Although elevated liver function tests and leukopenia were relatively commonly observed in the LDAA cohort, they only led to treatment withdrawal in 2% for both. Increasing allopurinol dosage from 100 to 200 - 300 mg/day significantly lowered liver enzymes in the majority (83%) of patients who had developed hepatotoxicity on LDAA.

**Conclusions** Optimisation of AZA therapy for IBD is mandatory as poor outcomes were observed in our AZAm cohort. LDAA without metabolite monitoring should be considered standard first-line immunosuppressive therapy, as we demonstrated a safe and effective profile in the long-term.

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#### RULING OUT INFLAMMATORY BOWEL DISEASE WITH FAECAL CALPROTECTIN: THE SOUTH AND WEST DEVON EXPERIENCE

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**Introduction** Faecal calprotectin (FC) testing in UK primary care is informing the diagnostic process where inflammatory bowel disease (IBD) is suspected but functional disease is likely (irritable bowel syndromes, IBS). Uptake of the regional IBD/IBS clinical pathway prompted laboratory adoption of an assay platform (Phadia 250 ELiA; ThermoFisher Scientific) offering more suitable batch sizes and facile sample preparation compared with ELISA while delivering similar analytical precision and range. Eighteen months later, comparison is made of FC diagnostic performance in the regional population *vs* published data, the clinical decision limit is reviewed and useful audit criteria established.

**Methods** Retrospective analysis of FC results ( $\mu$ g/g stool; analytical range 4-6000  $\mu$ g/g; imprecision [ $2\times$ CV] 12% at 20 $\mu$ g/g, 17% at 198 $\mu$ g/g) diagnostics reports and gastroenterology clinic letters. Letters were reviewed for all patients with results  $\geq$ 100 $\mu$ g/g or  $\geq$ 3 tests. Inclusion criteria: primary care patients 18.0-46.0y when tested, March 2018-November 2019. Exclusion criteria: known IBD, incomplete results or follow-up. Outcome measure: IBD diagnosis.

**Results** 2,962 FC results considered from 2,771 patients; of those with multiple results, 99% had only one repeat. 75% of tests in age range. 1,741 eligible results with complete follow-up. At 100  $\mu$ g/g (95% CI) PPV 36% (32-40%); NPV 100% (93-100%); sensitivity 95% (88-100%) specificity 92% (85-99%). ROC AUC 0.970 (0.957-0.982). IBD prevalence 4.1%. One false negative identified (isolated ileal Crohn's revealed by video capsule endoscopy.) 191 results 46-99  $\mu$ g/g indicated repeat; 27% repeated, 60% normalized

<46 µg/g. Median time (IQR) to repeat 35d (22–74.) 70 results 100–249 µg/g indicated routine referral; median wait for review 83d (54–160.) 130 results ≥250 µg/g indicated urgent referral; median wait 59d (40–105.) 18% had endoscopy directly ('straight to test.') 16% of results <46 µg/g still referred.

**Conclusions** This is the largest analysis of UK primary care FC testing to date that considers IBD specifically, as opposed to any organic intestinal disease, *versus* IBS. Comparing favourably to other published work, the assay platform and clinical pathway are fit for purpose in safely and effectively ruling out IBD. A 100µg/g cut-off is optimal based on the sensitivity×specificity product. Those with significantly raised results access secondary care more quickly; direct endoscopy rates appear low but data were incomplete. Repeat tests often normalize and repeats should be mandated for all positive tests. Sensitivity drops precipitously without an appropriate age limit; educating clinical users about pretest probability should minimize false negatives, streamline test workload and reduce unnecessary clinic utilization.

#### P168 TOFACITINIB IN ULCERATIVE COLITIS: EARLY REAL-WORLD EXPERIENCE IN SOUTHAMPTON

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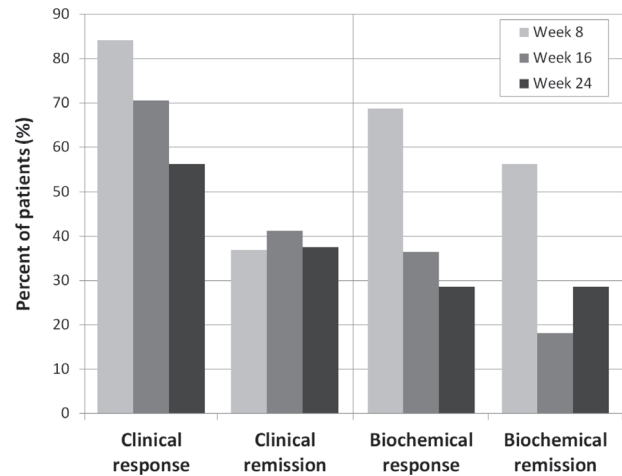
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**Introduction** The landscape of medical therapies for severe ulcerative colitis is widening. Tofacitinib, the first oral therapy and Janus kinase (JAK) inhibitor to be approved for this indication, was licensed in the EU in August 2018 and was approved for use in the NHS by NICE in November of that year. This is a description of the real-world experience of its effectiveness and patient reported outcomes in one IBD tertiary referral centre.

**Methods** Patients were reviewed every 8 weeks with safety blood monitoring, adverse event recording and effectiveness measured using faecal calprotectin (FC), abbreviated-UCDAI (a-UCDAI) and IBD-Control. A retrospective observational study was conducted using intention-to-treat analysis. A clinical response was defined as a fall of a-UCDAI from baseline or a value of ≤ 2. Clinical remission was defined as a score of ≤ 2. Biochemical response (only assessed where the baseline FC was more than 250µg/g) was defined as a fall of FC of at least 50% from baseline and remission as achieving a value of < 250µg/g.

**Results** All 22 patients treated with tofacitinib are included in this analysis. The mean age was 46 (SD ± 14) years, 27% were male and the median disease duration was 4.4 years (IQR 3.8–13). Rates of prior exposure to at least one anti-TNFα agent and vedolizumab were 86% and 64% respectively with 59% having received both. At baseline mean calprotectin was 2119µg/g, 14 patients had an a-UCDAI ≥ 7 and 12 patients were taking an oral corticosteroid.

At 8 weeks of treatment, 16 patients (84%) achieved a clinical response and 7 (37%) achieved clinical remission (figure 1). 38% of the 16 patients with 24 weeks follow-up at the time of analysis were in clinical remission at 24 weeks. Patient-reported outcomes showed a rapid



Abstract P168 Figure 1 Efficacy outcomes

improvement with all patients having an improved IBD-Control-8 score at week 8.

56% of patients were dosed with greater than 5 mg BD beyond week 8. Tofacitinib has been discontinued in 7 patients (4 primary non-response, 2 secondary loss of response and 1 due to an adverse event).

Tofacitinib was generally well tolerated and there were no venous thromboembolisms reported. There was 1 serious adverse event involving a suspected allergic reaction which resolved on discontinuation of tofacitinib.

**Conclusion** In this small group, that included a high proportion of complex patients, tofacitinib appears to be efficacious and well tolerated.

#### P169 LONG TERM ABDOMINAL DRAIN FOR PALLIATION IN ADVANCE LIVER CIRRHOSIS: SURVEY OF RISKS & BARRIERS

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**Introduction** Ascites is a leading cause of hospital admission in patients with cirrhosis, with up to a third developing refractory ascites (RA.) RA has a median transplant free survival of 6 months,<sup>1</sup> yet palliation remains sub-optimal and practice varies widely. Long term ascitic drains (LTAD) are standard of care in malignant ascites but there is a paucity of data to support this use in advanced cirrhosis. Our aim was to establish current views and practices of gastroenterologists and hepatologists towards LTAD as a palliative intervention in advanced cirrhosis.

**Methods** An electronic survey of 10 questions was designed by a focus group of four hepatologists with a special interest in palliative management of advanced cirrhosis. The survey included seven questions with fixed quantitative options and three exploratory questions with free text space. The survey was logged on survey monkey and distributed electronically via the BASL website and also to relevant departments in Brighton and North East London, with reminder emails in four and eight weeks.