Abstract O8 Table 1 Per protocol outcomes, including cross-over (Primary endpoints in bold)

	Remission 10w	Remission maintained to 6 m	Remission maintained to 12 m	Rem. &/or response 10w	Remission 4wk
AB/HCQ	**7/27**	**6/24 (plus 3 10wk responders in rem @ 6m)**	**3/23 (plus 1 10wk responder in rem @ 12m; plus 1 clin rem but WD UTI)**	15/27	8/30
Budesonide	**10/34**	**1/32 P=0.035 (preset significance threshold of P= 0.02 to allow for multiple testing)**	**1/31**	13/34	9/37

(Entocort CR 9 mg/day 8 weeks, then 6 mg/day 2 weeks and 3 mg/day 2 weeks) or antibiotics/hydroxychloroquine (AB/HCQ) - oral ciprofloxacin 500 mg bd, doxycycline 100 mg bd, hydroxychloroquine 200 mgs tds for 4 weeks, followed by doxycycline 100 mg bd and hydroxychloroquine 200 mgs tds for 20 weeks. Use of anti-TNF in the previous 3 months was an exclusion. Primary endpoints were remission (CDAI </=150) at 10 weeks, remission maintained to 24 weeks, and remission maintained to 52 weeks. Patients not responding by 10 weeks were invited to cross-over onto the alternative therapy.

Results 59 patients were recruited across 8 sites, lower than target (100) as recruitment slowed due to widening access to biologics. Including cross-over, 39 patients received AB/HCQ and 39 received budesonide. No significant differences were seen comparing AB/HCQ with budesonide at 10, 24 or 52 weeks on either intention-to-treat or per protocol analysis (see table 1). Withdrawals by 10 weeks due to adverse events were seen in 16 AB/HCQ and 7 budesonide. When patients on AB/HCQ who responded at 10 weeks and later remitted were included, 9/24 patients were in remission at 24 weeks and 4/23 at 52 weeks. No correlation was seen between response to AB/HCQ and ASCA/OmpC status.

Conclusions The long term remissions seen with AB/HCQ are encouraging and justify a phase 3 study.

O9 STOP-COLITIS PILOT: PROSPECTIVE, OPEN-LABEL, RANDOMISED STUDY COMPARING NASOGASTRIC VERSUS COLONIC FMT DELIVERY IN ULCERATIVE COLITIS

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10.1136/gutjnl-2020-bsgcampus.9

Introduction Although faecal microbiota transplantation (FMT) appears to hold therapeutic potential for ulcerative colitis (UC), the optimal administration route and dose of FMT is unknown. This pilot trial aimed to identify the optimal route of administration to further test in an RCT.

Methods In this prospective, three-centre, open-label, randomised study (STOP-Colitis pilot), we compared delivery of FMT via the naso-gastric (NG) or colonic (COLON) route in adult patients with active UC. Participants were administered 8 infusions of FMT over an 8 week period. Clinical response was defined as ≥3 point and ≥30% reduction in Mayo score at week 8 compared to baseline. Clinical remission was defined as Mayo score of ≤2, with no subscore >1 at week 8. The primary outcome was based on clinical response and safety at weeks 8 and 12, along with qualitative assessment of acceptability.

Results 30 participants were randomised between March 2018 and April 2019; 16 to NG; 14 to COLON. 8 in NG arm and 2 patients in the COLON arm withdrew from the study before completion. Clinical response was achieved in more participants who received FMT via COLON compared with NG (9/12 [75%] vs 2/8 [25%]; adjusted relative risk [RR] 2.94 [95% CI, 0.84, 10.30]). Clinical remission was observed in more participants undergoing FMT via COLON compared to NG (6/12 [50%] vs 2/8 [25%] respectively; RR 1.89 [95% CI, 0.51, 6.99]). IBDQ and SF-36 scores at week 8 and 12 were similar in NG and COLON groups. Qualitative analysis showed greater patient and clinician acceptability for colonic delivery. There were three serious adverse events (one considered a serious adverse event) in 2 participants in the NG arm, and none in the COLON arm.

Conclusion This pilot study suggests that in patients with active UC, FMT delivered via the COLON route appears to be safe and better tolerated with signals suggesting greater efficacy compared to the NG route. A randomised, double-blind, placebo-controlled trial of colonic delivery of FMT is now underway to determine clinical efficacy and safety.

O10 NORMALISATION OF CALPROTECTIN WITHIN 12-MONTHS OF DIAGNOSIS IS ASSOCIATED WITH REDUCED DISEASE PROGRESSION IN CROHNS

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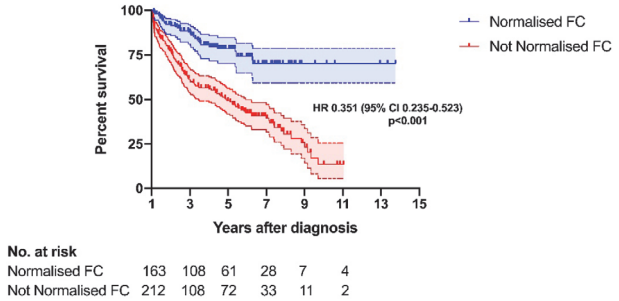
10.1136/gutjnl-2020-bsgcampus.10

Introduction Faecal calprotectin (FC) demonstrates excellent correlation with endoscopic inflammation. In addition, a treatment-decision algorithm for Crohn's disease (CD) incorporating FC outperforms and improves 12-month mucosal healing



Abstract O10 Figure 1

compared to a strategy based on symptoms alone. The aim of this study was to determine whether normalisation of FC (<250 µg/g) within 12-months of diagnosis is associated with a reduction in disease progression in CD.

Methods This was a retrospective cohort study performed at a tertiary IBD centre. All incident cases of CD diagnosed between 2005–2017 were identified. Patients with a FC measurement of >250 µg/g at diagnosis who also had at least 1 follow up FC measured within the first 12-months of diagnosis and >12 months of follow up were included. The primary endpoint was a composite of progression in Montreal disease behaviour (B1 to B2/3 or B2 to B3 or new perianal disease), surgery or hospitalisation.

Results A total of 375 patients were included with a median follow up of 5.3 years (IQR 3.1–7.4). Normalisation of FC (<250 µg/g) within 12 months of diagnosis was confirmed in 43.5% (n=163/375) of the cohort. On multivariable Cox-proportional hazards regression analysis, individuals who normalised their FC within 12 months of diagnosis had a significantly lower risk of composite disease progression (HR 0.351, 95% CI 0.235–0.523, p<0.001) (figure 1). In addition, normalisation of FC was the only predictor that remained significant for all of the separate progression end-points (progression in Montreal behaviour/new perianal disease: HR 0.250, 95% CI 0.122–0.512, p<0.001; hospitalisation: HR 0.346, 95% CI 0.217–0.553, p<0.001; surgery: HR 0.370. 95% CI 0.181–0.755, p=0.006). Patients initiated on a biologic within 3 months of diagnosis were significantly more likely to normalise their FC within 12 months of diagnosis (OR 4.288, 95% CI 1.585–11.0601, p=0.004).

Conclusions Normalisation of FC by 12-months of diagnosis is associated with a reduced risk of disease progression in CD. The immediate implication for healthcare providers and patients is that by ensuring resolution of mucosal inflammation - using FC as a proxy target - within 1 year of diagnosis has a dramatic effect on disease course.

O11 OUTCOMES OF GP OUTREACH PROGRAMME OFFERING COLONOSCOPIC SURVEILLANCE FOR IBD PATIENTS MANAGED IN PRIMARY CARE

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10.1136/gutjnl-2020-bsgcampus.11

Introduction Colonoscopic surveillance in IBD patients can reduce the development of colorectal cancer (CRC) and the rate of CRC-associated death. We recently reported that 27% of IBD patients living in East Devon are managed exclusively in primary care of whom about 23% maybe eligible for colonoscopic surveillance. We devised an outreach programme, whereby we invited primary care physicians to enrol these patients in a colonoscopic surveillance programme.

Methods In December 2017 we contacted 37 general practices, where 161 patients with UC who were eligible for surveillance had been identified. Each practice was sent a letter explaining the goals of the project, a link to the National Institute for Healthcare and Clinical Excellence (NICE) guidance for CRC surveillance in IBD patients and patient information booklets. We informed the practices of their eligible patients and asked them to refer patients for secondary care IBD consults if appropriate. We included an outcome form that captured whether the patient was referred, was deemed inappropriate for surveillance, had surveillance elsewhere, had declined surveillance, or was no longer registered at the practice.

Results Sixty-five percent of practices (24/37) responded and we received responses for 57 of 161 (35%) potentially eligible patients. Thirty-five (61%) patients were referred to our IBD service; 7 (12%) patients declined surveillance; 7 (12%) patients were deemed by their GP to be unfit for surveillance and 5 (10%) were no longer registered at the identified GP practice; 2 (4%) had surveillance arranged elsewhere and 1 (2%) patient had died. Amongst the 35 patients referred to secondary care; 22 (63%) underwent surveillance colonoscopy, 12 (34%) declined surveillance after discussion or did not attend their booked appointments and one is awaiting colonoscopy. Half of patients who had a colonoscopy had active inflammation. We diagnosed one CRC He was an elderly man with a locally invasive signet ring caecal tumour, without distant metastases, who went onto to have a curative right hemicolectomy without complication.

Conclusions Patients with longstanding IBD are frequently managed exclusively in primary care and maybe overlooked for colonoscopic CRC surveillance. There is a need to implement processes to facilitate identification and recall of patients eligible for surveillance across primary and secondary care.

O12 REVERSION TO BASELINE MICROBIOME FOLLOWING SUCCESSFUL COURSE OF EXCLUSIVE ENTERAL NUTRITION IN PAEDIATRIC CROHN'S DISEASE

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10.1136/gutjnl-2020-bsgcampus.12

Introduction To characterise the microbiome composition and functionality in paediatric Crohn's disease (CD) patients during a course of exclusive enteral nutrition (EEN) and subsequent food-reintroduction

Methods CD patients were recruited between August 2014-June 2016. Patients were treated with an 8 wk course of EEN. Clinical disease activity was defined using the weighted paediatric Crohn's disease activity index (wPCDAI). Serial faecal samples were collected prior to EEN, at 30d and 56d of EEN, and two further samples were collected post-EEN (17d