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.

PWE-034 ANTI-DIARRHEAL EFFECT OF BUDESONIDE (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.¹ 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,² the early anti-diarrheal effect of Budesonide (ENTOCORTTM) (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 safety and efficacy of ENT (9 mg/d; n=53) and Mesalazine (MZ) (3 g/d; n=53) were assessed, investigating CDAI score and Inflammatory Bowel Disease Questionnaire (IBDQ) at screening and 2, 4 and 8 weeks after treatment start (among other endpoints). Change of NSt, AP and IBDQ at week 2 to pre-dose were compared between the treatments in retrospective analyses of the dataset applying ANCOVA using baseline as covariate.

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

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

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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 chromoendoscopy (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 (ClinicalTrials.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.

Abstract PWE-035 Table 1

	0.2% (n=75)	0.03% (n=75)	P value
Per patient analysis			
Number of patients with dysplasia detected within colitic area	12	13	.666
Number of patients with dysplastic lesions detected within colitic segment	10 (13.3%)	10 (13.3%)	.265
Number of patients with dysplasia detected on random biopsies	3	6	.494
Per lesion analysis			
Total number of dysplastic lesions within colitic segment detected	12	13	.943
Mean withdrawal time	21.23 ± 6.69	16.36 ± 5.92	<0.001