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溃疡性结肠炎(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 findings from the pre-intervention cohort. 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.

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.

Conclusion Golimumab has not proven as effective in our real world data. Two important differences 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.

References

PWE-033 THE OUTCOMES OF THERAPEUTIC DRUG MONITORING (TDM) IN A NON-TERTIARY SETTING

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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. 1 patient 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.

**Abstract 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 CD2 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 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 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 resulted in a quicker improvement of Quality of Life in CD patients treated with Budesonide (ENTOCORT™) as compared with Mesalazine.

**Conflicts of interest** The study was sponsored by Tillotts Pharma AG, Rheinfelden, Switzerland. All authors declare that they have no conflicts of interest.

**REFERENCES**


**Abstract PWE-035 Table 1**

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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.