



Abstract P110 Figure 1 Model schematic
CDAI, Crohn's disease activity index

UK clinical guidelines, consisting of sequences of immunomodulator followed by biologic upon relapse ('step-up' treatment), 2) targeted therapy guided by PredictSURE, whereby patients identified as high-risk receive sequences of anti-TNF biologic treatment followed by other biologic classes upon relapse ('top-down' treatment), figure 1. Parameters were informed by patient data from PredictSURE clinical studies and the literature.

Results Top-down treatment guided by PredictSURE resulted in an incremental cost-effectiveness ratio (ICER) of £7,179 per quality-adjusted life year (QALY), with £1,852 incremental costs and 0.258 incremental QALYs vs. standard of care generated over a 15-year time horizon. Additional costs relating to earlier biologic use were offset by reductions in the costs of flares, hospitalisations and surgery. Incremental QALYs were driven by increased time spent in remission and improved quality of life from reduced flares and surgery. The model was most sensitive to the time horizon, rates of mucosal healing on top-down vs. step-up therapy, the costs of hospitalisation and the costs and quality of life in the severe disease health state.

Conclusion Modelling shows that upfront use of biologic guided by PredictSURE could substantially improve clinical outcomes for high-risk patients by increasing remission rates and reducing flares, surgery and treatment escalations. The ICER for PredictSURE was well below the £20-£30 k/QALY threshold used by the UK National Institute for Health and Care Excellence (NICE). Top-down treatment guided by PredictSURE would not only represent a treatment paradigm shift for CD patients but would also be a highly cost-effective use of resources in the UK National Health Service.

P111

STEROID AND ANTIBIOTIC PRESCRIBING RATES IN UK PATIENTS WITH ULCERATIVE COLITIS ON VEDOLIZUMAB VS ANTI-TNF

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Introduction This study evaluated corticosteroid and antibiotic prescribing during the first 12 months of first-line biologic therapy in patients with ulcerative colitis (UC) initiated on vedolizumab (VDZ) compared with patients initiated on anti-tumour necrosis factor- α (anti-TNF) agents.

Methods A multicentre, retrospective observational study was conducted in six United Kingdom secondary care centres. Eligible consenting patients were aged ≥ 18 years at initiation, without primary fistulising disease or acute severe disease. Patients were matched for age, gender, Montreal classification of disease extent and steroid use at initiation.

Results The study included 56 patients initiated on VDZ and 56 patients initiated on anti-TNF (table 1). During the overall 12 month post-initiation observation period, patients initiated on VDZ and anti-TNF were prescribed a median of 1.0 (interquartile range [IQR] 0.0–4.8) and 2.0 (IQR 0.0–7.8; Mann-Whitney U test $P=0.16$) courses of corticosteroids, respectively. During the post-initiation maintenance period (week 14 to month 12), 37% (95% confidence interval [CI] 24%–49%; $n=52$) of patients initiated on VDZ and 57% (95%CI 44%–70%; $n=53$; $\chi^2 P=0.039$) of patients initiated on anti-TNF received at least one course of corticosteroids. During the overall 12 month post-initiation observation period, patients initiated on VDZ and anti-TNF were prescribed a median of 0 (range 0–4) and 0 (range 0–2; Mann-Whitney U test $P=0.42$) courses of antibiotics, respectively. During the post-initiation maintenance period, 11% (95%CI 3%–19%; $n=56$) of patients initiated on VDZ and 16% (95%CI 6%–26%;

Abstract P111 Table 1 Characteristics at initiation of first-line biologic

Characteristics at initiation	VDZ (n=56)	Anti-TNF (n=56)
Age (years), mean (standard deviation)	46.8 (16.9)	45.7 (17.5)
Female, n (%)	25 (45%)	25 (45%)
Disease duration (years), median (IQR)	6.9 (3.1–13.6)	4.7 (1.8–14.9)*
Montreal classification, n (%)	5 (9%)	5 (9%)
E1	29 (52%)	29 (52%)
E2	22 (39%)	22 (39%)
E3		
On corticosteroids	31 (55%)	31 (55%)

*Mann-Whitney U-test $P=0.27$

$n=56$; $\chi^2 P=0.41$) of patients initiated on anti-TNF received at least one course of antibiotics.

Conclusions During the post-initiation maintenance period of first-line biologic therapy in patients with UC, patients initiated on VDZ were significantly less likely to be prescribed corticosteroids than matched patients initiated on anti-TNF agents. Numerically less patients on VDZ received antibiotics, however this did not reach significance.

P112

IMPACT OF THERAPEUTIC DRUG MONITORING ON OUTCOMES FOR PATIENTS WITH INFLAMMATORY BOWEL DISEASE

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Introduction Anti-tumour necrosis factor α biological drugs have proven efficacy in the management of inflammatory bowel disease (IBD). Among infliximab and adalimumab treated cohorts, primary non response occurs in up to 30% and secondary non response occurs in up to 46% of patients. Therapeutic drug monitoring (TDM) is a useful tool for optimising drug dosing and modification. The aim of this study is to assess the appropriateness and effectiveness of TDM in IBD patients in a large UK district general hospital.

Methods This was a retrospective study. Patients with Crohn's disease (CD) and Ulcerative Colitis (UC) on infliximab and adalimumab were identified from 2017 – 2019. Clinician's response to TDM results were monitored. CRP and faecal calprotectin up to 3 months before and after TDM with appropriate management were recorded. Hospital admission and surgery rates were compared between the TDM and non-TDM cohorts. Wilcoxon signed rank and Mann-Whitney test were applied to determine statistical significance.

Results 364 patients were included (281 CD, 73 UC, 10 IBD-unclassified; 204 on infliximab, 160 on adalimumab). 209 (57.4%) patients were tested for TDM at least once during their follow up. Indications for TDM included proactive (85/209), worsening symptoms (103/209), worsening biochemistry (15/209) and worsening endoscopy (6/209). The median infliximab level was 5 μ g/mL. Antibodies to infliximab were present in 34% of patients. The median adalimumab level was 9 μ g/mL. Antibodies to adalimumab were present in 22% of patients.

88.5% of patients had an appropriate management plan based on their TDM results. This included no change (118/209), increase in dose/frequency (33/209), adding an immunomodulator (13/209), switching within class (22/209), switching out of class (17/209) and drug discontinuation (6/209).

Mean CRP before TDM was 22.5 and after TDM 5.2. TDM followed by appropriate management elicited a significant reduction in CRP ($Z = -5.1, P<0.01$). Mean faecal calprotectin before TDM was 692.1 and after TDM 250.5. TDM followed by appropriate management elicited a significant reduction in faecal calprotectin ($Z = -5.0 P<0.01$). Fewer patients in the TDM group required hospital admission (14.4%) and surgery (8.1%) compared to the non-TDM group (hospital admission (24.5%) and surgery (19.3%)) $p<0.05$.

Conclusion CRP and faecal calprotectin significantly reduced after TDM and appropriate management. Hospital admissions

and surgery were significantly less in the TDM group. There are limitations due to retrospective design and confounding factors; we acknowledge the TDM group tended to have closer monitoring, which may have led to better outcomes. This study demonstrates TDM as a powerful tool in personalised care for inflammatory bowel disease.

P113

THE USE OF VEDOLIZUMAB IN A SECONDARY CARE DGH SETTING; REAL WORLD EXPERIENCE AND OUTCOMES

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Introduction To evaluate the clinical and biochemical outcomes of patients with inflammatory bowel disease to Vedolizumab at a District General Hospital

Methodology Retrospective cohort study assessing 55 patients administered Vedolizumab between 2015 and 2019. Demographics and clinical information were recorded. Response was determined using Harvey Bradshaw (HB) and partial Mayo score (pMS). Baseline indices and serum CRP were recorded at (i) prior to commencement, (ii) 6 months, and (iii) 12 months. A clinical response was determined by a decrease in pMS and HB of at least 3 points for UC and CD respectively or to a score below 5.

Results A total of 55 patients (33 CD, 22 UC) were found on our electronic records. A total of 44(18 UC, 26 CD) were included with 11 patients excluded as they had started within 6 months of study commencement.

Mean age for UC was 45.2 years and CD was 42.8 years, 15/18(83.3%) UC patients and 20/26 (76.9%) CD patients had prior anti TNF exposure. 56% (5/9) of all those TNF naïve were found to have a response at 6 months.

UC group

Mean CRP reduction at 6 and 12 months was -7.1 and -6.3 respectively. Mean pMS prior to treatment 5.8 and at 6 months was 4.8. At 6 months, 6% (n=1/18) were responders, 61% (11/18) were partial responders and 33% (n=6/18) were non responders. 67% (n=12/18) completed 12 months treatment when 8%(n=1/12) were responders, 58% (n=7/12) partial responders and 33% (n=4/12) were non responders.

CD group

Mean CRP reduction at 6 and 12 months were -7.7 and -7.2 respectively. Mean HB prior to treatment 7.7 and at 6 months was 5.7. At 6 months, 19%(n=5/26) were in clinical remission, 15% (n=4/26) were responders, 46% (n=12/26) were partial responders and 19% (n=5/26) non responders. 65% (n=17/26) completed 12 months treatment, of those 23.5% (n=4/17) were in clinical remission, 17.6%(n=3/17) were responders, 41% (n=7/17) were partial responders and 17.6% (n= 3/17) were non responders.

Reasons for stopping treatment in all patients: treatment was stopped prior to completion of 12 months in 15/44(34%) patients. This included need for surgery 4.5% (2/44), abnormal liver function tests 9%(n=4/44), intolerance 18% (8/44), and pregnancy 2.2% (1/44).

Conclusion Our results reflect similar safety and efficacy of Vedolizumab to published data. Vedolizumab was generally well tolerated with no serious adverse effects.