

provide input into areas such as VTE prophylaxis, delivery method and folic acid dosing. IBD indications for caesarean section seem to be poorly understood by a sizable minority. A basic framework to inform service set-up, and better education on the available clinical guidance for clinicians, is required to ensure consistent identification and review of patients and high quality care.

P147 SAFETY AND EFFICACY OF USTEKINUMAB FOR CROHN'S DISEASE (CD): THE CROSS PENNINE EXPERIENCE

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Background Ustekinumab was approved by NICE in 2016 for adults with moderate to severe CD. Real world data are required to establish effectiveness of therapy where restrictive inclusion and exclusion criteria from trials are not routinely applied.

Methods This retrospective audit of clinical data included all patients treated with Ustekinumab for CD at 8 North West England and Yorkshire hospitals that form the Cross Pennine IBD Initiative. The dataset included medical history, treatment history, phenotype and disease activity (at 3 and 12 months). Remission was defined as Physician Global Assessment (PGA) of 0 and response by PGA of 1.

Results The cohort comprised of 259 patients (160 females, mean age 39.99, mean disease duration 11.78 years) with active Crohn's Disease. The majority (n=137) had ileocolonic, 65 colonic and 57 ileal disease distribution. Eighty six (33.2%) had inflammatory, 78 (30.1%) stricturing and 95 (36.7%) penetrating disease behaviour. Perianal disease was noted in 32.1% and 46% had had a previous bowel resection. Previous treatment history included Infliximab in 73%, Adalimumab in 80.7% and Vedolizumab in 30.1% with 35.5% having been exposed to 1, 40.5% to 2 and 22.4% to 3 previous biologics. Steroid exposure at baseline was 36.7%.

At 3 months 89 (34.4%) had achieved remission and 84 (32.4%) had a clinical response. By 12 months 65 (25%) patients had discontinued Ustekinumab, 63 (24.3%) were in remission and 34 (13.1%) in response (outcomes not available for 37.6%). Bowel resections were required in 20 and perianal surgery in 6 cases. 84% of patients were given 8-weekly sc ustekinumab.

Adverse events included headaches (8), joint pains/arthritis (8), body rashes/urticaria (6) and flu type symptoms (5). Serious adverse events included hospitalisations with infection (17), gastrointestinal operations (26), CD flare (46), abdominal pain (6), medical admissions (8). There was one death from a pre-existing primary malignant melanoma, 3 cases of newly diagnosed cancers (1 small bowel adenocarcinoma, 1 breast cancer, 1 hepatocellular carcinoma), and 2 recurrences of previous known cancers (1 basal cell carcinoma of the skin, 1 bladder transitional cell carcinoma).

Conclusion In this large real-world study of patients with long disease duration and highly refractory CD we found that Ustekinumab was clinically effective and safe in line with expectations from clinical trials. Further analysis of predictors of

response may help clinicians' decision making on biologic choices for CD.

P148 AN INTERVENTION BUNDLE LEADS TO QUALITY IMPROVEMENT IN ENDOSCOPIC REPORTING OF ULCERATIVE COLITIS

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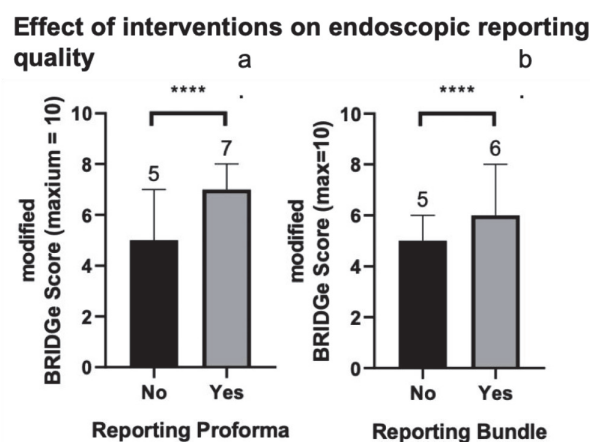
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Introduction Macroscopic mucosal healing is an established therapeutic target in ulcerative colitis (UC) and can be objectively measured using endoscopic indices. The Mayo Endoscopic Subscore (MES) and UC Endoscopic Index Score (UCEIS) are validated scores that can guide clinical decision making and prognostication. This multi-centre study aimed to assess the use of these indices in the endoscopic assessment of UC and whether an intervention bundle impacts reporting quality.

Methods We retrospectively reviewed 1160 endoscopy reports for UC patients across 7 London centres (April-October 2019), evaluating the use of 10 reporting elements recommended by the *Building Research in Inflammatory Bowel Disease Globally* (BRIDGe) group. In addition to the MES (recommended by BRIDGe), we included the UCEIS as an alternative index.

We segregated endoscopists according to specialty, level of training and interest in inflammatory bowel disease (IBD) and compared the number of BRIDGe elements in reports between groups. We then implemented an intervention bundle at a single centre and compared index use pre- and post-intervention. The bundle included integrating a proforma into reporting software, training on endoscopic indices (online and face-to-face) and posters in endoscopy suites. Statistics: Chi squared for categorical variables and Mann-Whitney U for continuous variables.

Results The use of endoscopic indices was higher in centres with a pre-existing reporting proforma compared to centres without (77.7% (202/260) vs 44.4% (400/900), $p < 0.0001$), and after implementing an intervention bundle at a single centre (110/190 (57.9%) pre-intervention vs 117/168 (69.6%) post-intervention, $p = 0.03$). Both the proforma and bundle



Abstract P148 Figure 1 Modified BRIDGe score at a multiple sites without and with a reporting proforma and b. single site before and after implementation of a reporting bundle (median, inter-quartile range) **** $p < 0.0001$

improved BRIDGE scores (7/10 vs 5/10, $p < 0.0001$ and 6/10 vs 5/10, $p < 0.0001$, respectively) (figure 1).

Endoscopic indices were used more frequently by gastroenterologists compared to other specialists (544/1002 (54.3%) vs 58/158 (36.7%), $p < 0.0001$), non-consultants relative to consultants (272/455 (59.8%) vs 330/705 (46.8%), $p < 0.0001$) and clinicians with an interest in IBD (282/477 (59.1%) vs 320/683 (46.9%), $p < 0.0001$). When comparing non-consultants to consultants with an interest in IBD, use of endoscopic indices was more comparable (272/455 (59.8%) vs 189/357 (52.9%) ns).

Conclusion Implementing a UC reporting proforma as part of an intervention bundle results in quality improvement in endoscopic reporting. Our results also support running dedicated lists for UC assessment, carried out by gastroenterologists with an interest in IBD. High quality reporting achieved by implementing this strategy may translate to improved clinical decision making and patient outcomes.

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THERAPEUTIC DRUG MONITORING OF VEDOLIZUMAB FOR PATIENTS WITH INFLAMMATORY BOWEL DISEASE: REAL WORLD EXPERIENCE

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Introduction Vedolizumab (VDZ) is a humanised monoclonal IgG-1 antibody that is used in the treatment of inflammatory bowel disease (IBD). Unlike with anti-TNF therapy the benefit of therapeutic drug monitoring (TDM) of VDZ remains debatable. A number of trials have suggested that VDZ trough levels post induction of >18 – 20 $\mu\text{g/ml}$ are associated with better clinical outcomes.^{1 2} However, data regarding levels in the maintenance phase is less convincing but likely to be lower.¹ Real-world data is lacking, and the use of Vedolizumab drug monitoring is not widely used outside tertiary centres.

The aim of this study was to evaluate our current practice at a busy London district general hospital.

Methods A retrospective study of all patients undergoing VDZ TDM at our unit between July 2017 and December 2019. Data collected included indication and timing of level, value and whether the level resulted in a change in management.

Results 67 patients were established on VDZ between July 2017 and December 2019. 15 patients (22.4%) had VDZ levels performed with 4 patients undergoing more than one level during this time giving a total of 22 levels performed. Levels were undertaken in the majority of patients for secondary loss of response (LOR) (16/22). A small number were taken during maintenance (4/22), post induction (1/22), and after recapturing response (1/22). Out of the 22 drug levels analysed, 10 (45.5%) were classified as trough levels (within 1 week of a VDZ infusion). Trough levels ranged between 5 $\mu\text{g/ml}$ and 32.7 $\mu\text{g/ml}$ with a median of 15.8 $\mu\text{g/ml}$. We used a cut-off of 18 $\mu\text{g/ml}$ when interpreting levels. All trough levels taken were performed due to LOR. 6 (60%) levels taken in 4 patients were <18 $\mu\text{g/ml}$ with the remaining 4 levels ≥ 18 $\mu\text{g/ml}$.

The outcomes of the 4 patients who had sub-therapeutic trough levels were analysed. 2 patients recaptured response after either a course of corticosteroids or optimising 5-ASA therapy. 2 were switched to other therapeutic options (Infliximab and Ustekinumab).

A further 3 non-trough levels (in 2 patients) analysed were sub-therapeutic. 1 recaptured response after optimisation and 1 responded to a 3 month period of escalated 4-weekly VDZ therapy. All patients with levels ≥ 18 $\mu\text{g/ml}$ have continued VDZ therapy with good response.

Conclusions In our real-world setting, using a cut-off of <18 $\mu\text{g/ml}$ for levels carried out in LOR is helpful in identifying the need to either escalate/optimize or switch agent. However, VDZ levels are being underutilised and are only being taken as trough in 45.5% of patients. There remains uncertainty as to how maintenance levels should be interpreted and national guidance after more studies would be welcome.

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ADALIMUMAB THERAPEUTIC DRUG MONITORING – DOES TIME OF TESTING MATTER?

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Introduction Whilst anti-TNF drugs such as adalimumab (ADL) have revolutionised the management of Inflammatory Bowel Disease treatment outcomes are not universally favourable with 30% primary non response (PNR) and 46% secondary loss of response (SLOR) rates reported^{1,2}. Therapeutic drug monitoring (TDM) – measurement of serum drug levels (DL) and anti-drug antibodies - has become popular with clinicians who use it to optimize biologic therapy through serum DL guided dose adjustment. Conventionally TDM is based on the interpretation of trough DL, obtained by drawing a blood sample immediately prior to the next drug dose. Obtaining an ADL trough DL can be challenging as the drug is administered as a subcutaneous injection usually in the patient's own home. The aim of this project was to determine the current use of non-trough ADL TDM in clinical practice and determine whether timing of ADL TDM in relation to next planned dose is clinically important.

Methods All ADL DLs performed in 2018 in the Scottish Biologic TDM service³ were identified. DLs were included for patients in sustained clinical remission (SCR), on 40 mg every other week dosing, and if time from last dose was ≤ 14 days. TDM performed during induction and for PNR or SLOR were excluded, as were patients on nonstandard dosing or with missing data on dose and interval. Results were analysed by quartile according to time from the last drug dose.

Results 338 DLs were included. Median DL is 8 $\mu\text{g/ml}$ (range <0.4 – 36). Median time from last dose is 12 (range 0–14) days. The 1st quartile (n=83, median 5 (range 0–7) days) had a median DL of 8.2 $\mu\text{g/ml}$ (<0.4 – 28.1). The 2nd quartile (n=90, median 11 (8–12) days) had a median DL of 7.9 $\mu\text{g/ml}$ (<0.4 – 36). The 3rd quartile (n= 80, 13 days from last dose) had a median DL of 8 $\mu\text{g/ml}$ (<0.4 – 28.1). 4th quartile samples (n= 85, 14 days from last dose – true trough DLs) had a median DL of 8 $\mu\text{g/ml}$ (<0.4 – 34.8). No relationship was