

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

identified between observed DL and the time of DL testing ($\rho = -0.3162$, $p = 0.23$).

Conclusion It is not necessary to use trough DLs when performing ADL TDM for individuals in SCR. This data should give clinicians the confidence to use opportunistic ADL TDM testing in a clinical setting. Further work should be undertaken on non-trough testing of ADL DLs in other clinical scenarios.

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ANTI-DRUG ANTIBODIES TO INFLIXIMAB: A COMPARISON OF FREE ANTI-DRUG ANTIBODY MEASUREMENT

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Introduction Infliximab (IFX) is a biologic drug that inhibits the action of the pro-inflammatory cytokine, TNF α , which is implicated in the pathogenesis of inflammatory bowel disease (IBD).

IFX has revolutionised the care of IBD patients, but response to the drug is not universal. Primary non-response to IFX treatment occurs in up to 30% of IBD patients while up to 46% of patients develop secondary loss of response.^{1 2}

Development of anti-drug antibodies (ADAs) against IFX is considered a significant risk factor for the loss of response to treatment, hence the measurement of ADAs as part of therapeutic drug monitoring is an increasingly utilised tool.

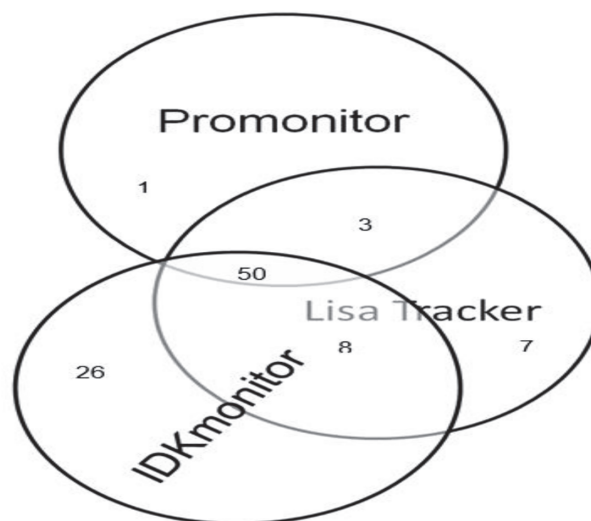
The detection of ADAs varies widely depending on the type of assays used. The aim of this study was to determine the qualitative concordance of three commercially available ELISA kits for measurement of free ADAs to IFX on the Grifols Triturus analyser.

Methods 150 patient samples with low IFX drug levels ($\leq 0.6 \mu\text{g/ml}$) were analysed for free ADAs using Promonitor, Lisa Tracker and IDKmonitor kits on the Grifols Triturus automated ELISA analyser.

Results Kappa coefficient (κ) analysis indicated a moderate agreement between the Promonitor and IDKmonitor assays ($\kappa = 0.484$ (95% CI, 0.357 to 0.611)) and the IDKmonitor and Lisa Tracker assays ($\kappa = 0.485$ (95% CI, 0.348–0.621)) as well as substantial agreement between the Promonitor and Lisa Tracker assays ($\kappa = 0.768$ (95% CI, 0.667–0.870)). Figure 1 shows the distribution of samples identified as free ADA positive by each kit.

Conclusion Although broad qualitative agreement was found between the three kits, they should not be used interchangeably for patient management.

All kits appear amenable for utilisation in a high-throughput laboratory though a true quantitative comparison between



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these kits was precluded by the absence of any certified reference material for free ADAs to IFX.

Further research is required to estimate the impact of free ADAs on efficiency of IFX treatment and patient management.

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LOW RATES OF SUBTHERAPEUTIC DRUG LEVELS ARE OBSERVED WITH PROACTIVE THERAPEUTIC DRUG MONITORING OF ADALIMUMAB

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Introduction The new BSG IBD guidelines¹ advocate therapeutic drug monitoring (TDM) of adalimumab (ADL) in clinical practice. Testing can be reactive (rTDM) or proactive (pTDM). The most effective strategy remains unclear. Since 2018, a TDM service based at Queen Elizabeth University Hospital, Glasgow, has provided access to TDM testing across Scotland.² Additional clinical information collected prospectively at the time of TDM has been used to develop a national TDM database. This study aimed to assess the use of ADL pTDM, examine the DL results observed with ADL pTDM and explore factors associated with results above and below the commonly accepted therapeutic drug level (DL) target of $5 \mu\text{g/ml}$.

Methods ADL TDM results with available supplementary clinical information performed between 01/01/18–30/09/19 were identified from the TDM database. Sub-analysis was performed for all pTDM test results.

Results 1627 ADL TDM tests were identified. pTDM testing accounted for 979(60.1%) tests. Median DL was $8.7 (<0.4 > 36) \mu\text{g/ml}$. 789(80.6%) had DL $> 5 \mu\text{g/ml}$, 380(38.9%) of these had DL $> 10 \mu\text{g/ml}$. 190(19.4%) had low DL result < 5