Abstract P152 Table 1

	No. of DLs (% of total)	No. with ADA (%)	No. on non standard dose (%)	No. on CI(%)	Median DL (mcg/ml)
DL < 5µg/ml	190(19.4)	109(57.3%) 4 ADA not done	35(18.4)	46(24.2)	2.9(<0.4–4.9)
DL > 5µg/ml	789(80.6)	61(7.7) 332 ADA not done	195(24.7)	240 (30.4)	9.8(5->36)

mcg/ml. 109(57.4%) with DL <5 mcg/ml had positive ADL anti-drug antibodies (ADA). 35 (18.4%) with DL < 5µg/ml were on non-standard dosing of ADL compared with 195 (24.7%) with DL >5µg/ml. Table 1 summarises pTDM results by drug level.

Conclusion Low rates of subtherapeutic DL result are observed when using a pTDM strategy for individuals with IBD treated with ADL. ADAs may be associated with low DLs but more evidence is needed to demonstrate this. 19.4% had low DLs despite being in clinical remission. They may benefit from early reassessment including repeat TDM to consider dose escalation to achieve DL >5µg/ml or conversely drug withdrawal may be an option. Furthermore 380 individuals in remission with DL >10µg/ml who may be suitable for dose de-escalation as part of a pTDM strategy were identified. A prospective, observational study to evaluate long-term clinical outcomes associated with rTDM vs. pTDM strategies within the Scottish TDM service is ongoing.

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P153 LOW RATES OF SUBTHERAPEUTIC DRUG LEVELS ARE OBSERVED WITH PROACTIVE THERAPEUTIC DRUG MONITORING OF INFLIXIMAB

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Introduction Recommendations for use of therapeutic drug monitoring (TDM) in clinical practice are set out in the 2019 BSG IBD guidelines.[1] Reactive (rTDM) or proactive (pTDM) strategies may be used. To date there is little good quality evidence to support routine use of pTDM testing for patients in ongoing clinical remission. Since 2018, a biologic TDM service has provided testing to IBD teams across Scotland.[2] Additional clinical information collected prospectively at the time of testing has been used to develop a national TDM database. This study aimed to assess the current use of pTDM with infliximab (IFX) in the Scottish Biologic TDM service, examine the DL results observed with IFX pTDM and explore factors associated with results above and below the commonly accepted therapeutic IFX drug level (DL) target of 3µg/ml.

Methods IFX TDM results with available supplementary clinical information performed between 01/01/18–30/09/19 were identified from the TDM database. All pTDM results and associated data were identified for cohort analysis.

Results 1331 IFX TDM tests were identified. pTDM testing accounted for 705(52.9%) results. Median DL was 5.9 (<0.3->43) µg/ml. 546(77.4%) had DL > 3µg/ml, 235 (33.3%) had DL >8µg/ml. 159(22.6%) had low DL result <3µg/ml. 39(24.5%) with DL <3µg/ml had positive IFX anti-drug antibodies (ADA). Only 43(27%) results with low DL reported escalated dosing regimes (>5 mg/kg every 8 weeks) compared with 273(59.2%) test results with DL >3µg/ml

Conclusion In this cohort analysis of IFX pTDM test results low rates of subtherapeutic DL were observed. Low DL results were associated with lower rates of IFX dose escalation but not with use of concomitant immunomodulator or presence of ADAs. Escalated treatment doses of IFX were observed in 50% of tests with a DL >3µg/ml which suggests that pTDM is being used as a tool to dose optimise IFX therapy in an effort to maintain clinical remission.

Disclosure Biogen GmbH contributed funding for this research. Authors had full editorial control and approval of all content.

Abstract P153 Table 1 summarises pTDM results by DL category

	No. of DLs (% of total)	No. with ADA (%)	No. on escalated IFX dosing (%)	No. on concomitant immunomodulator (%)	Median DL (µg/ml)
DL < 3µg/ml	159(22.6)	39(24.5)	42(27.1)	91(42.8)	1.5(<0.3–2.9)
DL > 3µg/ml	546(77.4)	144(26.4) *207 ADA not done*	272(49.8)	263(48.2)	7.15(3->43)

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P154 VEDOLIZUMAB DRUG LEVELS ARE NOT ASSOCIATED WITH OUTCOMES OR DISEASE ACTIVITY IN INFLAMMATORY BOWEL DISEASE

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Introduction Treatments in inflammatory bowel disease(IBD) include anti-TNFα and anti-integrin biologics. Therapeutic drug monitoring(TDM) supports clinical decision making and improves outcomes with anti-TNFα drugs[1,2]. It is unclear if TDM offers benefits with vedolizumab(VDZ), and there are no clinical guidelines for its use[3]. The aim of this study was to identify if drug levels(DL) are associated with clinical

outcomes and markers of disease activity in VDZ treated patients.

Methods All VDZ DLs performed since introduction of testing at our unit in December 2018 were retrospectively identified. Target DLs of >30 µg/ml during induction (≤ 14 weeks since treatment initiation (TI)) and >10 µg/ml in maintenance (>14 wks after TI) were agreed based on available published data. Dose information, timing of DL, lab results and disease activity scores were obtained from electronic patient records and paired with the DL dose. Calprotectin was included if recorded within 3 months of DL. Patients were classified as in remission or mild, moderate or severe active disease according to partial Mayo Score for ulcerative colitis and Harvey Bradshaw Index for Crohn's disease. Sub-analysis was undertaken according to timing of testing in relation to TI.

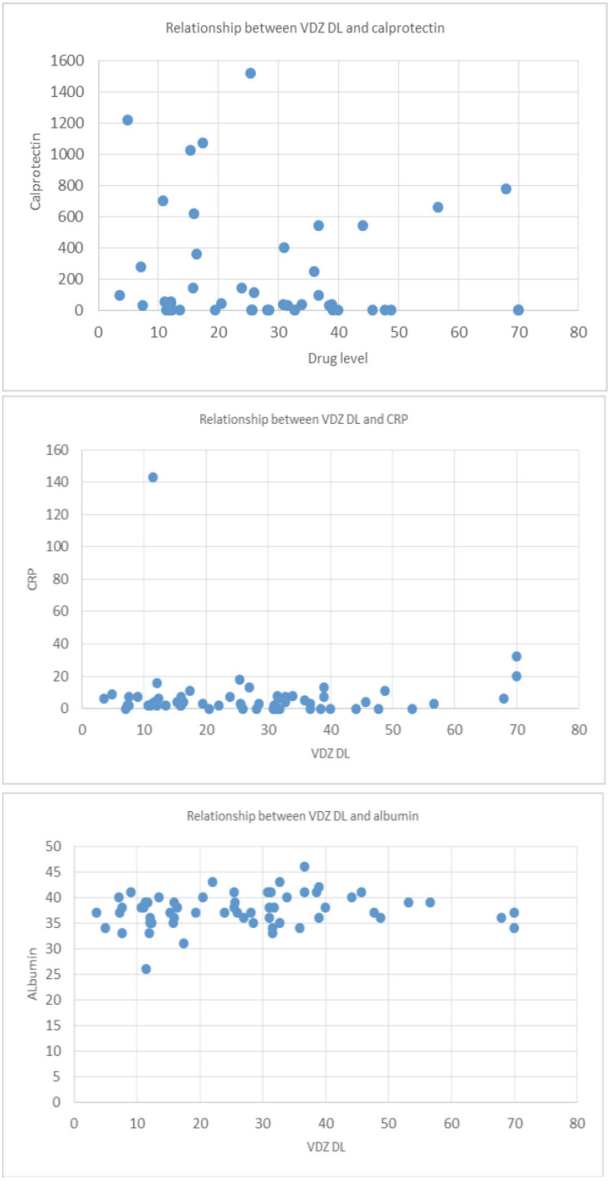
Results 60 pre-dose trough VDZ levels were identified from 41 patients. Median VDZ level was 25.7 µg/ml (<3.5->70). Median time from TI to first VDL DL was 36 weeks (4.6–184). No relationship was identified between VDZ levels and biochemical markers of disease (figure 1).

14(23.3%) TDM were performed during induction. 6/14 (42.8%) had subtherapeutic DLs; 3 in remission, 1 mild, 2 severe disease. The remaining 8/14(57.1%) had therapeutic DL; 3 mild, 3 moderate, 1 severe disease, 1 unclear.

46(76.7%) TDM were performed during maintenance. 5/46 (10.9%) had subtherapeutic DLs; 3 remission, 1 moderate, 1 unclear. The remaining 40/46(86.9%) had therapeutic DLs; 16 remission, 11 mild, 10 moderate, 3 severe disease, 1 unclear.

For both sub analysis groups, no relationship between disease state and drug level was observed.

Conclusion The results from this small cohort do not suggest a relationship between serum VDZ levels and clinical outcomes. Further research in larger cohorts is needed to confirm or refute these findings.



Abstract P154 Figure 1

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P155 88000 FAECAL CALPROTECTIN MEASUREMENTS OVER 15 YEARS: INSIGHTS GAINED FROM THE EDINBURGH FAECAL CALPROTECTIN REGISTER

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Introduction Faecal calprotectin (FC) is a reliable biomarker for intestinal inflammation. Our tertiary centre has used FC a) as a screening test for distinguishing between inflammatory bowel disease (IBD) and irritable bowel syndrome (IBS) and b) for non-invasive assessment of mucosal healing and disease activity in IBD. The FC testing service was established in the Clinical Biochemistry Lab in Edinburgh in Q1 2005 and has expanded massively over time. The same FC ELISA has been used throughout. We aimed to assess the temporal use of the Edinburgh Faecal Calprotectin Register (EFCR).

Methods This was a retrospective study of data regarding all FC measurements performed between Q1 2005 until September 2019. All data was extracted from the ECFR database. FC testing was requested either as part of a screening process for gastrointestinal symptoms or as part of monitoring in patients with IBD. FC was measured using a standard enzyme-linked immunosorbent assay technique (Calpro AS, Lysaker, Norway). All assays were performed using the same protocol in the Department of Clinical Biochemistry at the Western General Hospital (Edinburgh, UK). We analysed this data for prominent trends concerning the use of the FC testing service over time. We matched this data to our rigorously validated Lothian IBD cohort (LIBDR) to assess the use of FC measurement in our current IBD population.[1]

Results In total 88365 FC measurements for 42256 patients were included in the analysis (figure 1). 19432, (22%) were performed for IBD monitoring, 25334 (28.6%) were performed to screen primary care referrals for GI symptoms. In particular the impact on opening up the testing directly to primary care doctors is clearly demonstrated from Q1 2017 onwards. The Biochemistry lab currently runs 1500 samples per month at a cost of approximately 25 GBP per assay.