

sub-group of responders (n = 70) were sent the same mailing 6 weeks later for test-retest. The fatigue scales used were: the Inflammatory Bowel Disease Fatigue (IBD-F), the Multidimensional Fatigue Inventory (MFI) and the Multidimensional Assessment Fatigue (MAF). Internal consistency was measured by Cronbach's alpha and test-retest reliability by the intra-class correlation coefficient (ICC).

Results 465 (77%) questionnaires were completed for the test and 69% for retest. All three scales are highly correlated (p < 0.001). Test-retest suggests good agreement for all scales' total scores with ICC values of 0.74 and 0.83 (IBD-F Section 1 and 2), 0.74 (MAF) and 0.65–0.84 (MFI). Age, gender, bowel condition, anxiety, depression and IBDQ scores were significantly associated with level of fatigue (p < 0.001) for all three fatigue scales. Older patients had lower fatigue scores, females had higher scores than males, colitis patients had significantly lower scores than Crohn's patients, patients with a higher level of anxiety and depression had higher fatigue scores and better IBDQ was associated with lower fatigue scores.

Conclusion All three tested fatigue scales were found to be valid and reliable measures of IBD fatigue. Factors such as age, gender, bowel condition, quality of life, anxiety and depression are significantly associated with fatigue and should all be taken into account in the process of care delivery to people with IBD and fatigue.

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PTH-089 EXPERIENCE OF LIVING WITH FATIGUE AS REPORTED BY PEOPLE DIAGNOSED WITH INFLAMMATORY BOWEL DISEASE – A PHENOMENOLOGICAL STUDY

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Introduction Fatigue is one of the main symptoms of inflammatory bowel disease (IBD), however, little is known about specific areas of life affected by fatigue, its pattern over time or how people with IBD manage it.¹ This study aimed to address this shortfall in evidence.

Method Descriptive phenomenology with face-to-face in-depth interviews. Twenty participants diagnosed with IBD and reporting fatigue were purposively selected. Interviews were audio-recorded, transcribed verbatim and analysed using Moustakas' method,² which involves seven steps and analyses data at two levels: i) textural level – which generates a description of the phenomenon, ii) structural level – which describes underpinning factors and their relationships with fatigue.

Results Participants found fatigue difficult to describe and used different terms, metaphors and similes to describe their experience. The terms fatigue, tiredness and exhaustion were used interchangeably. Fatigue was described as 'heaviness of the body and fuzziness of the brain' with a constantly fluctuating pattern and severity. The invisible and fluctuating nature of fatigue makes it difficult for patients to describe to others.

Fatigue was perceived to impact on all aspects of daily functioning. Participants spoke of being trapped in an unreliable body, which made them feel angry, frustrated, isolated and depressed, and lead to loss of self-confidence and identity.

Physical, psychological, cognitive and situational factors were perceived to contribute to fatigue. Different methods to manage fatigue were attempted by participants (e.g., sleep and rest, pacing, energy preservation, exercise, stress reduction, help seeking), but few were used systematically, possibly resulting in their apparent limited effectiveness.

Conclusion Fatigue is a complex symptom (both multi-causal and multidimensional) and reduces quality of patients' lives. Patients need to be informed that fatigue is part of IBD, and they need advice on how to manage it, encouragement to report it and to seek help when needed. An algorithm for assessment and management of fatigue could provide a more structured approach to the care of people reporting this troublesome symptom.

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PTH-090 LABORATORY EXPERIENCE OF ANTI-TNF DRUG MONITORING IN ROUTINE PRACTICE – PERSPECTIVE FROM THE FIRST UK CENTRE

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Introduction Therapeutic drug monitoring (TDM) of Infliximab (IFX) and Adalimumab (ADAL) has been in use in our centre since 2012. Here we present the TDM experience of our laboratory service at Viapath, St Thomas' Hospital.

Method Anti-TNF requests received between June 2012 and January 2015 were reviewed. All assays were performed using LISA-TRACKER Duo kits automated on eRobot (Theradiag,

France). These assays measure free drug and anti-drug antibody (ADAb) and therefore inhibition studies were performed on samples with detectable drug levels (>1 ug/ml) and positive ADAb. Results were classified according to drug levels (DL) and ADAb status.

Results The laboratory analysed 2424 (17% internal) samples for IFX (Median DL 3.8 ug/mL, IQR 1.2–6.3) and 1335 (21% internal) samples for ADAL (Median DL 5.2 ug/mL, IQR 3.4–7.3) from IBD patients. Prevalence of detectable antibodies was higher in IFX (10%) than ADAL (4.1%) samples. External requests originated from >90 different hospitals. Number of requests received for both assays doubled from 2013 to 2014 with batch frequency consequently decreasing from fortnightly to weekly.

Abstract PTH-090 Table 1

	Therapeutic DL (>2 ug/mL)	Intermediate DL (1.0–2.0 ug/mL)	Subtherapeutic DL (<1 ug/mL)
Infliximab	1614 (67%)	249 (10%)	561 (23%)
Anti-Infliximab antibody positive (>10 ng/mL)	0	0	245 (44%)
	Therapeutic DL (>5 ug/mL)		Subtherapeutic DL (<5 ug/mL)
Adalimumab	691 (52%)		644 (48%)
Anti-Adalimumab antibody positive (>10 ng/mL)	0		53 (8%)

40 patients had IFX >1 ug/ml and were antibody positive. 16 of these patients were confirmed to have switched to ADAL due to loss of response to IFX therapy. Detectable DL observed in these cases was due to cross reactivity of ADAL with the IFX assay. 11 patients had false positive drug levels and 4 patients had borderline antibodies due to non specific binding. 1 patient had sample collected around infusion.

4 patients had subtherapeutic ADAL (1.1–1.4 ug/ml) and were antibody positive. 1 of these patients was confirmed to have switched to IFX due to loss of response to ADAL therapy. Detectable DL observed in this case was due to cross reactivity of IFX with the ADAL assay. 3 patients had false positive results for ADAL.

From the data, it was evident that some centres monitored patients with serial measurements and made subsequent changes to therapy. 63 patients (IFX) and 52 patients (ADAL) had an average of 7 and 3 repeat measurements taken respectively.

Conclusion Anti-TNF testing has been embedded in several IBD centres as a way of optimising therapy however variation in TDM practices was observed highlighting the need for national guidance. Significant increase in test requesting suggests assay based treatment strategies combined with clinical assessment is now an accepted practice in IBD.

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PTH-091 MEASUREMENT OF TNF-ALPHA DRUG LEVELS AND FREE VERSUS TOTAL ANTI-DRUG ANTIBODIES USING THREE COMMERCIALY AVAILABLE ASSAYS

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Introduction Commercial assays are now available for therapeutic drug monitoring (TDM) of anti-TNF drugs and antibodies (ADAb). Utility of free versus total ADAb assays remains debatable, further complicated by lack of assay standardisation. Here we report analytical comparison of 3 commercially available assays for Infliximab (IFX) and Adalimumab (ADAL) drug levels (DL) and ADAb.

Method Prospective evaluation of IFX and ADAL DL and ADAb was performed using our local LISA-TRACKER (LT) assay automated on e-Robot in IBD patients. Samples were also analysed by Immundiagnostik (IM, Germany) and Promonitor (PM, Spain) ELISA automated on Grifols Triturus. LT and PM utilises a specific bridging ELISA to quantitatively measure free-ADAb whereas IM utilises a dissociation step to enable detection of total-ADAb generating semi-quantitative results. IFX assays measure free drug but differ in microtitre plate coating and secondary detection reagents. Data was analysed using Passing Bablok and bias plots. LT and PM kits were provided at no cost.

Results

Summary of DL comparisons shown below:

Abstract PTH-091 Table 1

Infliximab range: 1.30 – 16.70 ug/mL	Immundiagnostik (n = 76)		Promonitor (n = 63)	
	Passing Bablok	Bias	Passing Bablok	Bias
Lisa-Tracker	IM=1.24–0.38	8.00%	PM=1.16LT – 0.43	–1.71%
Immundiagnostik			IM= 0.94PM-0.15	–4.82%
Adalimumab range: 0.2–19.9 ug/mL	(n = 78)		(n = 58)	
Lisa-Tracker	IM=1.73LT-0.06	79.60%	PM=1.47LT+1.25	74.00%
Immundiagnostik			IM=0.84PM+1.27	–0.30%

Samples analysed in different batches showed different kit biases against each other for IFX. Batch 1 showed that LT assay had 43.9% positive bias against ID kit whereas batch 2 demonstrated –26% negative bias. Both LT and ID kits used had different lot numbers. This change in bias was not observed in ADAL assays which showed consistent and systematic bias. PM kit showed concentration dependent bias changes within the same assay.

4 patients tested (n = 79) IFX ADAb positive with undetectable DL with one exception where total/free ADAb was negative using ID and PM assays. A further 17 patients tested total ADAb positive using IM with detectable DL (0.5–9.2 ug/mL). 1 patient tested ADAL ADAb positive using LT, PM and ID assays however ID and PM assays produced positive results on a further 4 specimens, all with ADAL DL >5 ug/mL.

Conclusion Although commercial assays are now available, our data highlights the need for assay standardisation. Free ADAb