PWE-015 CLINICAL EFFICACY AND SAFETY OF ANTI-TNF THERAPY IN INFLAMMATORY BOWEL DISEASE IN THE ELDERLY

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Introduction Many patients, especially the elderly, are excluded from clinical drug trials and little real-life data exists on the safety and efficacy of anti-TNF in this comorbid and difficult to treat group. We wanted to compare the clinical efficacy and safety of anti-TNF therapy in patients over 60 years in a tertiary IBD centre in London.

Methods We interrogated our IBD biologics database from January 2009 to November 2015 and performed retrospective data analysis until end of follow up in April 2017. Data was collected on demographics, biochemistry and clinical scores. For every '≥60' patient identified we randomly selected two '<60' comparators.

Primary endpoints week 14 and week 54 steroid free clinical remission (Harvey Bradshaw Index <5 or Simple Colitis Activity index <3).

Secondary endpoint proportion of patients remaining on anti-TNF at the end of follow up

Results 29 patients (23 Crohn's, 4 ulcerative colitis, 1 IBD unclassified) started anti-TNF aged '≥60' and 58 randomly chosen <60 years were selected for analysis.

Abstract PWE-015 Table 1

	<60 years	≥60 years
	n=58	n=29
Week 14 steroid free remission	28/41 (68.3%)	8/16 (50%)
Week 54 steroid free remission	24/40 (60%)	8/15 (53.3%)
Remain on anti-TNF at end of follow up (April 2017)	38/58 (65.5%)	12/29 (41.4%) p<0.05
Reasons for stopping biologic during study period	8 primary non-response 7 secondary loss of response 1 infusion reaction 1 remission 2 infections 1 stopped attending	4 primary non-response 5 secondary loss of response 1 infusion reaction 1 remission 1 colorectal cancer 1 severe fatigue 1 peripheral neuropathy 2 stopped attending
Anti-drug antibodies during follow up	3/58 (5.2%) – 3 infliximab	4/29 (13.8%) – 3 infliximab, 1 adalimumab
Adverse events during follow up	1 new cancer 1 infusion reaction 2 infections	3 new cancers 1 ileal perforation 1 infusion reaction 2 infections

Conclusions Only a small number of '≥60' patients started anti-TNF (29 out of greater than 650). This may reflect our local population, less severe disease or that clinicians favour non anti-TNF therapies in this older group.

Overall there was similar clinical efficacy at weeks 14 and 54 of anti-TNF therapy between the 'young' and 'old' groups.

There was a statistically significantly higher discontinuation rate after 1 year of therapy in the older group (p=0.043).

There were more adverse events in the older group (7/29), including 3 new cancer diagnoses, compared with the younger group (4/58).

4 patients had detectable anti-drug antibodies in the older group despite 2 of them having therapeutic thiopurine suggesting that the elderly may have more immunogenicity than the young.

Further studies with more patients across multiple sites are required to clarify safety and efficacy of anti-TNF therapy in the elderly.

PWE-016 DERMATOLOGICAL REACTIONS ASSOCIATED WITH ANTI –TNF THERAPY IN INFLAMMATORY BOWEL DISEASE: AN12 YEARS EXPERIENCE

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Introduction Anti-TNF therapies have significantly influenced our treatment paradigms and are amongst our most effective therapies to induce and maintain remission. They are, however, not without side effects. Data on dermatological complications are limited. Our aim was to describe the incidence, management and outcome of dermatological complications of anti-TNF therapy in IBD patients at our centre.

Methods We conducted a retrospective review of 435 consecutive IBD patients treated with anti-TNF (Infliximab or Adalimumab) therapy between 2005–2017. Data was collected from electronic case records and included demographics, disease characteristics, medical history, treatment and dermatological complications.

Results Forty-four patients (10.1%) had dermatological complications. Of these, 25 were female (56.8%). Thirty four patients had Crohn's disease (CD=77.2%) and 10 had ulcerative colitis (UC=22.8%). Disease phenotype in CD was A2 (24) L3 (22) B1 (21) in respective categories whereas 7/10 UC patients had Montreal E3 disease. Mean age at diagnosis was 34.31 years (median 28,IQR 23.5) Thirty-four patients were treated with Infliximab. The most common reaction reported was a non-specific rash in 11 patients, eczema in 8 and psoriasiform reactions in 7 patients. Shingles was noted in 5 cases and 3 patients had urticaria. Seborrheic dermatitis, cellulitis, itching, acne, and skin abscesses were noted in two patients each along with one case each of Lichen planus and chicken pox.

The average time of onset of symptoms from treatment was 20 months (median 7,IQR 27).

Twenty of 34 patients treated with infliximab, continued treatment following the dermatological side effect without any further reactions,12 were switched to adalimumab of which 1 patient had a further psoriasiform reaction leading to cessation of Anti TNF therapy and initiation of ustekinumab. One patient was not given any further Anti-TNF treatment after the initial reaction and one patient was switched to ustekinumab after the reaction.

Of 10 patients on adalimumab who had dermatological side effects, all continued on therapy without any further reactions.

Conclusions The incidence of dermatological effects was 10.1% in our cohort. We did not observe a 'class effect' as

after switching to a different anti TNF the tolerability was good. Dermatological events were more common in patients with colonic CD treated with infliximab. Further studies on cumulative dermatological effects, risk factors, time to event and outcomes are underway at our institution.

PWE-017 FROM DIARRHOEA TO DIAGNOSIS: AN ANALYSIS OF FAECAL CALPROTECTIN USE IN AN IBD REFERRAL PATHWAY

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Introduction The volume of referrals to gastroenterology from primary care is steadily increasing. In order to prioritise appointments for suspected inflammatory bowel disease (IBD), a pathway for primary care assessment and referral of patients to a specialist IBD clinic was introduced in Telford and Wrekin in 2015, based on NICE guidelines. This took symptoms, baseline bloods and faecal calprotectin (FC) result into account. We reviewed the efficacy and outcome of referrals following implementation of the pathway.

Methods A retrospective analysis of all patients in Telford and Wrekin who had a FC requested between September 2015 and September 2016. Electronic data were collected contemporaneously by the pathology laboratory on patients' age, gender and FC result. Further retrospective analysis of the cohort assessed whether a referral was made, the outcome of the referral, including endoscopy findings if performed, and diagnosis. The cohort was divided into three groups based on the FC result: negative, indeterminate and positive. The number of referrals that followed the IBD pathway was recorded for each group.

Results 506 patients had FC requested over 12 months. Ages ranged from 1 to 88 years and 63% were female. 244 were referred to secondary care. The likelihood of being referred correlated with the absolute FC value (table 1).

Abstract PWE-017 Table 1

FC result	FC value	Patients referred	Patients referred (%)
Negative	<30	247	30
Negative	30–59	65	45
Indeterminate	60–149	82	56
Positive	>150	112	84

Of those referred, there were 22 IBD diagnoses (table 2), giving an FC sensitivity of 90% and specificity of 63%

Abstract PWE-017 Table 2

FC result	Patients referred	IBD diagnoses	IBD diagnoses (% of referrals)
Negative	312	2	0.6
Indeterminate	82	2	2.4
Positive	112	18	16

161 referrals (66%) did not meet the referral criteria on the IBD pathway, including 52 suspected colorectal cancer cases who met criteria for a two week wait referral, which would supersede referral to the IBD clinic

Conclusion FC remains a sensitive marker of IBD in the symptomatic population. Whilst GP's are being guided by FC result when making referrals, there remains a significant number of patients who are being referred with IBS. In over a fifth of referrals the FC is obsolete as the patient requires a two week wait colorectal cancer appointment. This has financial implications as each FC assay costs £35. Thus there is still progress to be made regarding implementation of the IBD pathway.

PWE-018 NEW GUIDANCE ON THERAPEUTIC DRUG MONITORING; POTENTIAL CLINICAL AND COST IMPLICATIONS

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Introduction Biologic drugs are effective treatments in IBD, the use of therapeutic drug monitoring (TDM) is rapidly becoming part of routine clinical practice. The American Gastroenterology Association (AGA) and the Australian Gastroenterology Association have recently published guidance recommending the use of therapeutic drug monitoring in clinical practice. Recommendations on the minimum trough level for Infliximab differ between these two guidelines. The AGA recommends a level >5 µg/ml, whilst the Australian guidance suggests >3 µg/ml. To date there are no published recommendations from ECCO or BSG. In patients with active disease and sub-therapeutic trough levels we shorten the dose interval from 8 to 4 weeks.

Aim To review the clinical and cost implications of introducing these guidelines into clinical practice at a large district general hospital

Methods We maintain a prospective IBD database and have used TDM routinely since 2014. Data on the use of TDM from 2016 to 2017 were reviewed. Age, Sex, disease type, and disease activity were reviewed. Results of drug levels in the active disease and remission group were compared and the cost implications of intensifying drug treatment to achieve recommended trough levels calculated. The costs were calculated for escalating all patients below recommended levels to dosing every 4 weeks.

Results Biosimilar Infliximab (Remsima) trough level data was available for 167 patients. Mean age=42, Range 18–81. 133 (80%) had Crohn's disease and 34 (20%) UC. 118 had inactive disease at the time of TDM, whilst 49 had active disease. Of those with inactive disease 78/118 (66%) had an Infliximab TL <3 µg/L and 104/118 (88%) had a level <5 µg/L. In patients with active disease 33/49 (67%) had a TL <3 µg/ml and 40/49 (82%) a level <5 µg/mL. Across both groups antibodies were present in 72 (43%). The annual cost for maintaining all 167 patients on biosimilar infliximab (5 mg/kg) was calculated at £521,040, (assuming a standard dose of 5 mg/kg). If all patients with a TL <3 had treatment intensified the total annual drug cost would be £9 25 080 (+77%). If all patients <5 µg/ml were intensified the annual cost rises to £1,045,200 (+100%). If only those patients with active disease and <3 µg/mL were escalated the annual cost rises to £6 41 160 (+23%) and £6 66 640 (+28%) if those <5 µg/mL were escalated.