PTH-132 HIGH RATES OF CLINICAL RESPONSE ARE MAINTAINED AFTER SWITCHING FROM ORIGINATOR TO BIOSIMILAR INFLIXIMAB

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Introduction Biosimilar infliximab (BI) has been widely adopted in to clinical practice since launch in 2015. Switching patients with Inflammatory Bowel Disease (IBD) from originator infliximab (OI) to BI was endorsed by the BSG and ECCO despite a lack of data on the long-term implications of this strategy. Infliximab discontinuation (ID) occurs in 20–40% patients per annum. It is unclear whether switching to BI affects ID rates. This study assessed long-term outcomes after a managed BI switch programme.

Methods Individuals with Crohn's disease (CD) and Ulcerative Colitis (UC) who were changed from OI to BI in a switch programme in Dec 2016 were reviewed via electronic patient records. Demographics and pre-switch disease characteristics were recorded. Pre-switch medications and laboratory data were collected. Changes to BI dose/frequency at switch and during follow-up were recorded along with other changes to IBD medications. Post-switch durability of clinical response was evaluated. Rates of IBD related steroid use, hospitalisation and surgery were gathered. Incidence of adverse events was determined. Potential pre-switch indicators of future ID were explored.

Results 76 individuals considered to be clinically responding to OI were entered in to the BI switch programme. 2 patients had OI stopped prior to 1st dose BI based on clinical assessment and Therapeutic Drug Monitoring (TDM) results. 74 people were switched from OI to BI.

Abstract PTH-132 Table 1

Characteristic	Number
Median age	42 (range 21-71)
Male	50
Female	24
Smoker	9
CD	58
UC	15
IBD unclassified	1
Disease duration	
<5 years	25
>5 years	49
>10 years	19
>20 years	10

At time of switch 38 (51%) were prescribed an immunomodulator. 52/74 (70%) were on 5 mg/kg 8 weekly treatment, the rest on higher doses. 48/74 had a pre-switch FC, 32 (67%) FC<250. 61/70 (87%), 69/73 (95%) and 65/73 (89%) had normal CRP, albumin and haemoglobin respectively <3 months prior to switch.

2 years post switch, 54/74 (73%) remained on BI with sustained clinical response. ID was observed in 20 (27%); 11 (55%) now on another biologic, 8 (40%) biologic free. 33/54 remaining on BI had treatment escalation at time of or subsequent to switch.

There was 1 non-treatment/IBD related death. 1 infusion reaction adverse event was observed. There were 6 IBD related surgeries, 4 unplanned hospital admissions and 12 required steroids for IBD flare. Evaluation of data identified no pre-switch factors associated with ID.

Conclusions Over 2 years of follow-up clinical response was maintained in the majority of individuals following BI switch. Rates of ID were lower than historically reported in non-switched patient cohorts. BI switching appears to be a safe and effective intervention.

PTH-133 THERAPEUTIC DRUG MONITORING SUPPORTS CLINICAL DECISION MAKING WHEN EMPLOYED BEFORE AND AFTER BIOSIMILAR INFLIXIMAB SWITCHING

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Introduction Therapeutic drug and antibody monitoring (TDM) of infliximab (IFX) is used with increasing regularity as a tool to optimize outcomes in inflammatory bowel disease (IBD). Trough levels (TL) of 2–8 mcg/ml are recommended during maintenance IFX treatment. The introduction of biosimilar infliximab (BI) in 2015 lead to widespread switching of patients from originator infliximab (OI) to BI. The value of TDM when switching to BI has not been defined. This study aimed to assess the impact of TDM testing before and after a managed switch to BI.

Methods Individuals with IBD treated with OI and demonstrating a satisfactory response to treatment, were entered in to BI switch programme in Dec 2016. Pre-switch information was provided to patients, virtual or face to face clinical assessment was undertaken and it was recommended that all patients had pre-switch TDM performed. After switching patients returned to routine clinical care. Further TDM was performed at clinician discretion with recommendation to follow published TDM testing guidance.¹ Virtual review of all patients was undertaken 2 years post-switch. Demographics, pre and post switch TDM data, OI and BI dosing regimens and other IBD related medications were recorded along with clinical outcome data. Comparative analysis of pre-switch and most contemporary TDM results was performed.

Results 76 individuals considered to be clinically responding to OI were entered in to the BI switch programme. 70/76 (92%) had TDM at < 3 months pre-switch. OI was discontinued prior to switch in 2 patients. 74 people were switched from OI to BI. 52/74 (70%) were on 5 mg/kg 8 weekly OI pre-switch, 38 (51%) were on immunomodulators.

Of 69/74 with pre-switch TDM, 32/69 (46%) had subtherapeutic TLs (<2 mcg/ml). Median pre-switch TL was 2.2 mcg/ml (IQR 1.1–3.4 mcg/ml). Pre-switch TL review lead to 37/74 (50%) receiving an increased dose of BI at switch. In total 47/74 had ≥1 dose escalation at the time of or subsequent to switch.

58/74 (78%) had TDM testing in the 2 years after switch (median no. tests 2; range 1 – 5) at which point 54/74 (73%) remained on BI with sustained clinical response. 49 out of 54 still on BI had both pre and post switch TDM with results demonstrating a statistically significant increase in mean TLs (2.1 vs 6.3 mcg/ml; p<0.001); only 6% had persisting subtherapeutic TLs.