THE IBD BIOSIMILAR TO BIOSIMILAR SWITCHING

INTRODUCTION

The aim of this study was to evaluate the clinical outcome of switching a cohort of IBD patients from CT-P13 to SB2 in a real-world setting, as well as explore the patient experience of having their medication switched and were analysed using thematic analysis.

RESULTS

133/158 patients approached participated in iBiSS with a mean disease duration of 9.2 years. The primary objective was clinical outcome at week 30/32. The mean mHBI and pMCS at week 0 vs week 30/32 were 3.14 vs 2.9 and 1.53 vs 1.18 (p<0.77) respectively. The IBD Control-VAS score for the whole cohort was 11.75 vs 13.19 (p=0.005) and the IBD Control-VAS was 75.24 vs 79.59 (p=0.57).

35 patients discontinued during the study (6 lost to follow-up, 12 due to adverse events, 4 withdrew consent, 13 for other reasons). There were 16 serious adverse events and no fatal adverse events.

Interviews were conducted on 26 participants. Six major themes were identified that reflected the patient experience. These included confidence through information, worry through information, trust in the clinical team, barriers to switching, motivators for switching and the fragility of their condition.

CONCLUSIONS

The data presented here suggests there is no detrimental effect on the clinical outcomes of patients switched from one biosimilar of infliximab to another which is vital information to guide clinical practice.

REFERENCE


THE IBD BIOSIMILAR TO BIOSIMILAR SWITCHING STUDY (iBiSS)

METHODS

This was a prospective, phase IV interventional study at University Hospital Southampton. Patients treated with CT-P13 (6/8 weekly regime at 5mg/kg) were approached and were switched to SB2. Demographics, disease history, validated disease activity scores (partial Mayo Score for UC and modified Harvey-Bradshaw Index for Crohn’s), patient reported outcome measures (IBD Control PROM and PRO2) and laboratory measurements (full blood count, C-reactive protein, albumin and faecal calprotectin) were collected at each visit. Semi-structured qualitative interviews were also conducted to explore the patient experience of having their medication switched and were analysed using thematic analysis.

RESULTS

133/158 patients approached participated in iBiSS with a mean disease duration of 9.2 years. The primary objective was clinical outcome at week 30/32. The mean mHBI and pMCS at week 0 vs week 30/32 were 3.14 vs 2.9 and 1.53 vs 1.18 (p<0.77) respectively. The IBD Control-VAS score for the whole cohort was 11.75 vs 13.19 (p=0.005) and the IBD Control-VAS was 75.24 vs 79.59 (p=0.57).

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CONCLUSIONS

The data presented here suggests there is no detrimental effect on the clinical outcomes of patients switched from one biosimilar of infliximab to another which is vital information to guide clinical practice.

POM-21 IMPACT OF COVID-19 ON INFlixIMAB PRESCRIBING PRACTICES IN INFLAMMATORY BOWEL DISEASE

INTRODUCTION

The COVID-19 pandemic has impacted upon many aspects of clinical practice. As previously reported, use of biologic therapeutic drug monitoring (TDM) reduced markedly immediately after the UK wide lockdown of March 2020, followed by a gradual increase in testing volume as lockdown measures were relaxed. Data from the Secure IBD registry suggested an increased risk of severe COVID with anti-TNF combination therapy (with a thiopurine) vs monotherapy. The impact of the COVID-19 pandemic on biologic prescribing practices is largely unknown. The aim of this work was to assess the early effect of the COVID-19 pandemic on Scottish infliximab prescribing practices for individuals with IBD.

METHODS

IBD specific data was extracted from the Scottish biologic TDM database between 1/10/2019 and 31/7/2020 providing 5 months of data pre and post pandemic onset. Results were included for analysis if associated dosing and immunomodulator co-prescription data were available. Changes in concomitant immunomodulator (CI) prescription, dosing regimes and TDM strategy (proactive vs reactive) were reviewed.
Tofacitinib is a pan-Janus kinase (JAK) inhibitor that is approved for the treatment of both biologic naïve and ongoing active IBD. Assessment of IDA remains inadequate. As a result, IDA amongst the IBD population in Lothian is largely static. However July 2020’s drop in CI prescribing may be an early indicator of decreased use. The small rise in non-standard dosing may be due to COVID-19 strategies employed to reduce hospital attendances and requires further review. While the nature of our data will not convey the COVID-19 impact, it highlights the need for stringent review of post-COVID-19 clinical practices, patient outcomes, and updated clinical guidance as our understanding of the COVID-19 impact on IBD develops.

**REFERENCES**


**Abstract PMO-21 Table 1**

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**PMO-22 INVESTIGATING IRON DEFICIENCY ANAEMIA IN THE INFLAMMATORY BOWEL DISEASE POPULATION IN LOTHIAN, SCOTLAND**

1Rachel Walters*, 2Ian Arnott, 3Gareth-Rhys Jones. 1University Of Edinburgh Medical School, Edinburgh, UK; 2Edinburgh IBD Unit; Western General Hospital, Edinburgh, UK; 3Centre for Inflammation Research, The Queen’s Medical Research Institute, University of Edinburgh, Edinburgh, UK. 10.1136/gutjnl-2021-BSG.161

**Introduction**

Iron deficiency anaemia (IDA) negatively impacts the quality of life of patients with Inflammatory Bowel Disease (IBD) and is commonly undertreated. Many patients with IBD do not attend secondary care and the frequency of IDA in this group is unknown. We aimed to investigate the incidence of anaemia and IDA amongst the Lothian IBD population and the frequency of IDA in this group is unknown. We aimed to investigate the incidence of anaemia and IDA amongst the Lothian IBD population comparing those known to secondary care (IFU) and those not (NIFU).

**Methods**

The Lothian IBD registry is a rigorously validated prevalent IBD cohort that has been shown to be 95.5% complete for the ~1 million population of Lothian, Scotland. Data were extracted on prevalent IBD patients for the period 01/01/15 – 31/12/18. Anaemia was defined as a reduced sex-age appropriate haemoglobin and IDA if anaemia with a corresponding ferritin <20mg/dL within 4 weeks was recorded.

Secondary Care follow-up (IFU) was defined by attendance at a secondary care outpatient appointment between 01/01/15 – 31/12/18, with those not categorised not in follow-up (NIFU).

Median age was calculated on 01/01/2017; the midpoint of the study. Data were analysed in SPSS, using Levene’s test (p>0.05) to detect equality of variance, followed by an independent sample t test (p<0.05) or Welch’s t test (p<0.05). Cohen’s d effect size was also calculated.

**Results**

Of the 7396 prevalent IBD patients, 1289 (17.43%) did not have a full blood count (FBC), equating to 19.58% of total patients IFU (632/3228) and 15.67% of total patients NIFU (657/4168).

2607 (1425 male, 1182 female) of the 6107 patients (42.69%) with at least one FBC were diagnosed with anaemia at least once in the study period. 1394 patients had Ulcerative Colitis (UC), whilst 1107 had Crohn’s Disease and 106 had another IBD sub-type. Median age was 55. 1443 (53.35%) were IFU. 1439 of the 3228 patients IFU (44.56%) had at least one episode of anaemia, compared to 1165 of the 4168 NIFU (27.95%).

1466 of the 2607 anaemic patients (56.23%) had a corresponding ferritin, with 926 (63.17%) IFU. 564 (264 male, 300 female) patients with a corresponding ferritin (38.47%) were diagnosed with IDA. 281 patients had UC, whilst 237 had CD and 46 had another IBD sub-type. Median age was 48. 424 (75.18%) were IFU. 424 of the 3228 patients IFU (13.10%) had at least one episode of IDA, compared to 140 of the 4168 NIFU (3.36%).

**Conclusions**

We report that IDA is common in the Lothian IBD population. The frequency is higher in patients IFU, although IDA is still present in those NIFU; indicative of ongoing active IBD. Assessment of IDA remains inadequate. As a result, IDA amongst the IBD population in Lothian is likely underestimated and further work should be performed to identify patients that are living with undetected IDA.

**PMO-23 TREATMENT PERSISTENCE RATES WITH TOFACITINIB IN A REAL-WORLD COHORT OF ANTI-TNF REFRACTORY ULCERATIVE COLITIS PATIENTS**

1Thomas Conley*, 2James Colclough, 3Eleanor Liu, 3Violeta Razanskaite, 1William Jakobek, 2Jimmy Limdi, 2Paul Flanagan, 3Sreedhar Subramanian. 1Liverpool University Hospitals NHS Foundation Trust, Liverpool, UK; 2Pennine Acute Hospitals NHS Trust, Manchester, BL97TD 10.1136/gutjnl-2021-BSG.162

**Introduction**

Tofacitinib is a pan-Janus kinase (JAK) inhibitor that is approved for the treatment of both biologic naïve and non-standard dosing after March 2020. This data is expanded in table 1.

**Conclusions**

Our data suggests prescribing practices remain largely static. However July 2020’s drop in CI prescribing may be an early indicator of decreased use. The small rise in non-standard dosing may be due to COVID-19 strategies employed to reduce hospital attendances and requires further review. While the nature of our data will not convey the COVID-19 impact, it highlights the need for stringent review of post-COVID-19 clinical practices, patient outcomes, and updated clinical guidance as our understanding of the COVID-19 impact on IBD develops.

**Results**

639 TDM tests fulfilled the inclusion criteria. Comparing data after March 2020 to data before March 2020; no clear change was observed in the prescribing of CI or thiopurine, or the use of proactive TDM strategies. Early indications may suggest an increase in non-standard dosing after March 2020. This data is expanded in table 1.