SWITCHING TO SUBCUTANEOUS VEDOLIZUMAB IN INFLAMMATORY BOWEL DISEASE DURING COVID-19 PANDEMIC – COUNTY DURHAM EXPERIENCE

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Introduction The COVID-19 pandemic resulted in the need for significant adaptations to an intravenous biologics infusion service. Patients were reluctant to come to a Biologics Infusion Unit in an acute hospital due to the fear of exposure to SARS-CoV-2 virus and also due to the UK governmental advice on strict isolation and shielding. Based on the VISIBLE-1 and -2 Study data, we decided to switch our IBD patients from IV Vedolizumab to SC vedolizumab in a phased manner. We report on our experience and short term outcomes.

Methods During the COVID-19 pandemic, we decided to switch patients with Ulcerative colitis and Crohn’s disease from IV Vedolizumab to Subcutaneous Vedolizumab in a phased manner. In the first phase (July – Sep 2020) all patients with Ulcerative colitis (UC) in clinical remission of their disease beyond 16 weeks of Vedolizumab treatment were invited to switch. In phase 2 (October – Dec 2020) additional UC and Crohn’s Disease (CD) patients on maintenance were switched and in Phase 3, new patients with UC and CD entering the Vedolizumab treatment programme were included for IV induction followed by SC maintenance. 6 month outcomes were assessed for clinical response, faecal calprotectin, and for short term patient experience.

Results A total of 31 patients were switched in the 6 month period of COVID-19 adaptation. 19 patients had UC (13 pancolitis, 6 distal colitis) and 12 patients had CD (1 Crohn’s colitis, 5 ileocolonic, 5 small bowel and 1 complex). Over the 6-month period, 1 patient flared on SC Vedo and switched back to escalated IV, 1 developed abnormal LFTs and switched out of class. All remaining patients were doing well, and had mean SCAI score of 0, HBI score of 1. Mean FCF in UC patients was 197 μg/g (range 25-561), and in CD patients was 248 μg/g (range 213-283). Patient experience indicated that all patients on SC Vedo felt that they were safer during the pandemic.

Conclusion A COVID-19 adaptation of managed switching of patients with ulcerative colitis and Crohn’s disease from IV to SC Vedolizumab is safe and does not result in any adverse outcomes. Long term data on maintenance of remission and endoscopic healing is awaited.

PO-28 EFFICACY OF SUBCUTANEOUS INFlixIMAB IN PERIANAL CROHN’S DISEASE

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Background A new subcutaneous (SC) formulation of infliximab has recently been approved for the management of inflammatory bowel diseases (IBD). In the registration clinical trial, the efficacy of SC IFX was comparable to intravenous (IV) IFX (1) but specific data regarding the efficacy of SC IFX in perianal Crohn’s disease (pCD) is lacking. We aimed to investigate the efficacy of SC IFX in patients with pCD who were switched from IV IFX.

Methods We conducted a single centre observational, retrospective study of pCD patients who were maintained on IV IFX and switched to SC IFX. Elective switching was at the discretion of the treating physician. In patients with active pCD at treatment initiation, the success of SC IFX was defined by clinical success at 6 months assessed by the physician’s judgment without additional medical or surgical treatment for pCD. In patients with inactive pCD, the pCD recurrence-free survival was calculated. Treatment persistence rates were calculated at the end of 6 months. Safety and adverse events of interest were recorded. Data was analysed using SPSS for Windows with p<0.05 being significant.

Results We included 18 patients with a mean age of 36 (SD 12) and a M:F ratio of 5:4. Eleven (61%) patients were on concomitant thiopurines with a mean 6-thioguanine level of 258 (SD 153). The majority (n=13, 72%) had an inter-sphincteric fistula, 1 patient had a supra-sphincteric fistula (5.6%) and 2 patients (11.1%) each had trans-sphincteric and extra-sphincteric fistulae respectively. None of the patients had active, draining fistulae at the time of switching and 1 patient had an examination under anaesthesia (EUA) in the 6 weeks prior to switch. The mean IFX level at baseline was 9.9 μg/ml (SD 4.1). Two patients (11.1%) had recurrence of symptoms after switching to SC IFX and required further antibiotic therapy and EUA. These two patients also switched back to IV IFX after a median of 2.25 months. The mean IFX levels at 3 and 6 months after switch were 15.6 μg/ml (SD 0.2) and 15.5 μg/ml (SD 1.4) respectively (P<0.01). The treatment

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Abstracts

 SWITCHING BETWEEN INFLIXIMAB BIOSIMILARS: EXPERIENCE FROM TWO INFLAMMATORY BOWEL DISEASE CENTRES

1. Switching from originator to biosimilar infliximab (IFX) in patients with inflammatory bowel disease (IBD) is safe, effective, and common practice in the UK. Less is known about switching between biosimilars. Four biosimilar IFX brands are available in the UK, and their outcomes of a program to switch from biosimilar (Remsima®; Gilead Sciences, Inc., Foster City, USA; Gilead Sciences, Inc., Copenhagen, Denmark; University of California San Diego, La Jolla, USA; Kitisato Institute Hospital, Kitisato University, Japan) to ‘best value’ IFX (Zessly®; GP1111) in a multicentre real-life IBD cohort.

 Methods A quality improvement approach was used to assess the impact on patient acceptability, infusion reactions and quantity of ‘best value’ IFX administered over a 6 month period. All patients on treatment with biosimilar IFX for management of Crohn’s disease or ulcerative colitis were eligible to switch. Patients received written information and had the opportunity to ask questions before the switch. Infusion rates were not adjusted for the first dose of ‘best value’ infliximab. Details of infusion reactions, requests to switch back and treatment discontinuations due to loss of response (LOR) were collected prospectively. The number of vials used of each biosimilar IFX were collected retrospectively as a measure of the efficiency of the switch programme.

 Results 289 patients were eligible for the switch; all patients (100%) consented and received at least one dose of ‘best value’ IFX. One infusion reaction was reported (0.3%) which was successfully treated following standard infusion reaction procedure, and subsequent doses of IFX were not given. One patient (0.3%) switched back to the previous biosimilar IFX due to loss of efficacy and 17 (6%) stopped treatment due to LOR. ‘Best value’ IFX accounted for over 90% of total IFX use after 6 months.

 Conclusions Switching between infliximab biosimilars was acceptable to patients and was associated with a low rate of infusion reactions. The proportion of patients who discontinued treatment due to LOR over a 6 month period was consistent with the historical norm. Larger than previously published evaluations, this short-term evaluation adds to the literature that switching between biosimilar IFX is safe and appears effective.

REFERENCES

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CORTICOSTEROID-FREE REMISSION OF ULCERATIVE COLITIS WITH FILGOTINIB MAINTENANCE THERAPY: POST-HOC ANALYSIS OF THE SELECTION STUDY

1. Janus kinase 1 inhibitor. FIL for the treatment of moderately to severely active ulcerative colitis (UC) was evaluated in the phase 2b/3 randomised, double-blind, placebo (PBO)-controlled SELECTION study (NCT02914522). The aim of this post hoc analysis was to assess the CS-sparing effects of FIL in the SELECTION study.

 Methods Patients (18–75 years old) with moderately to severely active UC were randomised (2:2:1) to receive FIL 100 mg (n = 564), FIL 200 mg (n = 507) or PBO (n = 280) once daily orally for up to 11 weeks (induction study). At week 11, FIL induction responders were randomised 2:1 to continue their induction FIL dose or to receive PBO (maintenance study). CS use was kept stable up to week 14, at which point mandatory CS tapering occurred. CS could be resumed; however, if the baseline CS dose was exceeded this was considered treatment failure. In this post hoc analysis, CS-free remission was defined as remission at week 58 (endoscopic subscore ≤ 1, rectal bleeding subscore = 0 and ≥ 1-point decrease in stool frequency subscore to achieve 0 or 1) without systemic or localized CS use that was indicated for UC in the previous 1, 3, 6 or 8 months.

 Results Baseline characteristics of patients in the maintenance study were similar across treatment groups. Of the 92 patients receiving CS at maintenance baseline (week 11; maintenance week 0) who received FIL 200 mg during the maintenance study, 25 (27%) were in remission at week 58 and had been continuously CS-free for at least the previous 6 months. In patients taking CS at maintenance baseline who had continued CS-use post baseline, lower median prednisone dosing was observed with FIL 200 mg than with PBO throughout the maintenance study (maximum difference at week 34 [maintenance week 23]: 5.0 mg vs 13.8 mg). In SELECTION, a total of 199 patients received FIL 200 mg in the maintenance study, of whom 74 (37.2%) were in remission at week 58; of these 74 patients, 69 (93.2%) were continuously CS-free for at least the previous 6 months.

 Conclusions In this post hoc analysis of SELECTION maintenance study data, FIL 200 mg was effective in reducing and eliminating CS use through to week 58. The vast majority of patients taking FIL 200 mg who were in remission at week 58 had not taken CS in the previous 6 months.