Conclusions: Despite evidence from literature suggesting that RA patients have a better treatment response switching to a non-TNFi after initial TNFi inadequate response and despite the majority of physicians in our study believing that there is a class effect with TNFis, regarding efficacy and safety, 46.5% of patients still cycled to a second TNFi rather than switched to a non-TNFi as second-line therapy.


Acknowledgements: Research sponsored by Sanofi and Regeneron Pharmaceuticals, Inc.


AUDIT OF THE CLINICAL EFFICACY AND SAFETY OF ETANERCEPT BIOSIMILAR TO ITS REFERENCE PRODUCT IN PATIENTS WITH INFLAMMATORY ARTHRITIS: EXPERIENCE FROM A DISTRICT GENERAL HOSPITAL IN THE UNITED KINGDOM

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Background: Etanercept has been widely used in rheumatology practice since NICE approval in 2000. Biologics have been pivotal treatments for inflammatory arthritis but are associated with a considerable economic burden. The expiry of patent protection has led to the introduction of biosimilar drugs at competitive prices. SB4 was the first biosimilar of etanercept approved by the European Medicines Agency. SB4 was launched in February 2016 in the UK for use in all adult indications for which reference etanercept is approved. The rheumatology team at the Dudley Group of Hospitals (DGH) negotiated with commissioners to share the cost savings of switching the cohort of patients who were on reference etanercept to SB4.

Objectives: This audit aimed to compare the clinical efficacy and safety profile of etanercept biosimilar SB4 (post switch) with its reference etanercept (pre switch).

Methods: The first 50 patients switched were sampled and followed up for 6 months. Data was collected from hospital databases and patient records (disease activity scores 6 months pre and post switch; adverse events (AE)). Inclusion criteria: all patients established on reference etanercept for more than 12 months. Exclusion criteria: patients attempting to conceive, pregnant or breast feeding women, patients on 25mg of reference etanercept or with JIA.

Results: Of the 194 patients on reference etanercept in the Dudley area, 160 (83%) were successfully switched at the time of audit. Of the first 50 patients who switched, 32 (64%) patients had rheumatoid arthritis (RA), 15 (30%) ankylosing spondylitis (AS), and 3 (6%) psoriatic arthritis (PsA). The mean age was 60 years (range 29-83 years) with equal gender distribution. Mean years on reference etanercept was 6 years (range 1-13 years). In the RA cohort: 23/72% patients were female with mean change of DAS28: +0.1 (SD:0.87). In the AS cohort,14/93% patients were male with mean change of BASDAI: -0.6 (SD:1.34). PsA: 2; patients symptoms were unchanged. 1 patient’s tender and swollen joint count decreased. At 6 months post switch, 84% patients continued etanercept biosimilar SB4. Reasons for discontinuation included: AE (n=4), inefficacy (n=3) and new contraindication (cancer n=1).

Conclusions: Following switching to etanercept biosimilar SB4, no clinically significant change in DAS28 or BASDAI were observed during the audit period. Switching from reference etanercept to SB4 has resulted in a potential yearly saving of £660,000, from which the rheumatology department has secured funding to employ an additional clinical nurse specialist and secretary. Our audit found SB4 to be as safe and effective as its reference etanercept and has demonstrated a positive experience with biosimilar switching. This is relevant given the expiry of their biologic drugs’ patent protections and further biosimilar drugs becoming available.

Disclosure of Interest: None declared


PATIENT-REPORTED OUTCOMES FOLLOWING DISCONTINUATION OF METHOTREXATE IN PATIENTS WITH RHEUMATOID ARTHRITIS TREATED WITH SUBCUTANEOUS TOCILIZUMAB: RESULTS FROM A RANDOMISED CONTROLLED TRIAL

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Background: Patients with rheumatoid arthritis (RA) often receive methotrexate (MTX) in combination with biologics; however, MTX may be discontinued due to intolerance or to reduce the medication burden once disease control is achieved. Whereas previous studies have established the efficacy of tocilizumab (TCZ) initiated as monotherapy (MONO) for the treatment of RA,1,2 patient-reported outcomes (PROs) after MTX withdrawal in patients achieving good clinical response to TCZ +MTX have not been evaluated. PROs are important measures when determining response to therapy in patients with RA with respect to health-related quality of life (HRQOL).3,4

Objectives: This study evaluated PROs between patients with RA who achieved low disease activity with TCZ +MTX and then continued or discontinued MTX in the COMP-ACT trial (NCT01855789).

Methods: US patients with RA who were inadequate responders to MTX were enrolled; initial combination therapy included MTX (≤15 mg/week orally) plus TCZ 16 mg subcutaneous either weekly (qw) or every 2 weeks (q2w). Patients who achieved DAS28-ESR<3.2 at Week 24 were randomised 1:1 to receive TCZ-MONO or continue TCZ +MTX until week 52 (double-blind). Changes in PRO scores were measured between Week 24 and Weeks 40 and 52, and included patient global assessment of disease activity (PtGA; visual analogue score [VAS], 0–100 mm), patient (VAS), Health Assessment Questionnaire Disability Index (HAQ-DI, 0–3) and Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue.

Results: Of the 296 randomised patients (TCZ +MTX, n=148; TCZ-MONO, n=148), 74.8% were women, mean age was 55.5 years, mean RA duration was 6.8 years and mean DAS28-ESR was 6.3 at baseline. At Week 24 (randomization), PRO scores were similar between the randomised treatment groups. The mean changes in PtGA, pain, HAQ-DI and FACIT-fatigue scores from Week 24 to Weeks 40 were similar between the TCZ +MTX and TCZ-MONO groups (table 1). The proportion of patients with HAQ-DI <0.5 was similar between the groups at Week 24 (randomization), and remained similar at Weeks 40 and 52.