AB0509

CLINICAL EQUIVALENCCE OF GENERIC AND BRAND TOFACITINIB IN REAL-WORLD: A PROSPECTIVE LONGITUDINAL COHORT STUDY IN RHEUMATOID ARTHRITIS PATIENTS

Keywords: Real-world evidence, Rheumatoid arthritis

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Background: The efficacy and safety of Xeljanz® have also been confirmed in RA patients. Varieties of generic tofacitinib have been developed in different countries. However, there is no study comparing the efficacy and safety between generic and brand-name tofacitinib yet.

Objectives: In the current study, we compared the efficacy, safety, and cost-effectiveness between a Chinese generic tofacitinib Kelejia® and the brand-name tofacitinib Xeljanz® in RA patients from a prospective real-world cohort.

Methods: RA patients receiving tofacitinib, either generic (Kelejia®, generic group) or branded (Xeljanz®, branded group) were enrolled. All the patients were followed up until the discontinuation of tofacitinib or last visit. Primary outcome was simplified disease activity index (SDAI) defined remission rate at month 6. Secondary outcomes included the rates of remission and low disease activity (LDA) defined by other composite scores; EULAR response rate and ultrasonic synovitis scores at months 1, 3, 6 and 12. Cost-effectiveness was investigated. Propensity score-based inverse probability of treatment weighting (IPTW) was adopted to reduce selection bias.

Results: 204 patients were enrolled, with 59 in generic group and 145 in branded group. The SDAI defined remission was achieved in 41.1% and 39.2% patients in generic and branded group at month 6, respectively (p=0.854). The rates of remission and LDA achievement, the changes of clinical disease activity scores, power doppler (PD) and gray scale (GS) synovitis scores at months 1, 3, 6, 12 and 18 from baseline were all comparable between two groups. Similar proportions of patients in two groups achieved moderate/good response. Rates of drug retention (78.0% vs 77.2%, p=0.911) and adverse effect (5.1% vs. 4.8%, p=1.000) in different parts of the world, its important to perform a cost-effective analysis with moderate-to-severe rheumatoid arthritis who have inadequate response or intolerance to conventional synthetic disease-modifying antirheumatic drugs (csDMARDs-IR).

Conclusion: Generic tofacitinib (Kelejia®) showed equivalent clinical efficacy and safety, and better cost-effectiveness comparing with its originator (Xeljanz®). Kelejia® can be an alternative to brand-name Tofacitinib.

REFERENCES:


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AB0510

COST-EFFECTIVE ANALYSIS OF GENERIC TARGETED SYNTHETIC DISEASE-MODIFYING ANTI-RHEUMATIC DRUG - TOFACITINIB IN RHEUMATOID ARTHRITIS (TIRA CEA STUDY)

Keywords: Rheumatoid arthritis, Targeted synthetic drugs

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Background: With the introduction of generic version of tsDMARD tofacitinib in different parts of the world, its important to perform a cost-effective analysis of introducing generic tofacitinib to the current treatment sequence for patients with moderate-to-severe rheumatoid arthritis who have inadequate response or intolerance to conventional synthetic disease-modifying antirheumatic drugs (csDMARDs-IR).

Objectives: Perform pharmacoeconomic analysis of introducing generic tofacitinib into the current treatment sequence for patients with moderate-to-severe rheumatoid arthritis who are csDMARDs-IR.

Methods: A prospective, observational study was conducted in 55 consecutive RA Indian patients (Table 1) meeting 2010 Rheumatoid Arthritis Classification Criteria with active disease and an inadequate response or intolerance to conventional disease-modifying antirheumatic drugs randomized to receive tofacitinib 5mg bd as an add on therapy. All study patients attended the rheumatology OPD with 3 months follow-up. Average cost effectiveness analysis was done by taking HAQ-DI score as a measure of effectiveness. Total cost estimation included cost of the treatment, monitoring cost and adverse effect management.

Table 1. Demographic, clinical and biochemical characteristics of 55 Rheumatoid Arthritis patients

| Age (years) | 54.93 ± 8.92 |
| BMI (kg/m²) | 24.52 ± 4.58 |
| Disease Duration (yrs) | 14.11 ± 6.96 |

Graph 1.

REFERENCE:


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Disclosure of Interests: None Declared.

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