Effectiveness and Safety of Biosimilar Etanercept (Altebrel) in Iraqi Rheumatoid Arthritis Patients: A Prospective Observational Study

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ABSTRACT

Patients in Iraq with rheumatoid arthritis (RA) still face challenges accessing advanced biologic treatments. Biosimilars, highly similar to original biologics in efficacy and safety, have emerged as cost-effective alternatives to improve access in low- and middle-income countries. Barriers like limited availability and referral delays hinder access to appropriate biologics. Recent years have seen growing interest in real-world data on biosimilar effectiveness. The study aimed to Assess the effectiveness and safety of the biosimilar etanercept (Altebrel) in Iraqi RA patients. Thirty-five adult RA patients eligible for Altebrel treatment participated in a prospective, real-world study in Hilla, Iraq. Clinical outcomes (DAS28-ESR, ESR, TNF-α, IL-6), laboratory safety profiles, and PROMIS-HAQ assessments were recorded at baseline and after 12 weeks of treatment. The mean age of patients was 51.31 ± SD years. Significant decreases were observed in DAS28-ESR, TNF-α, and ESR IL-6 levels showed no significant decrease. All PROMIS-HAQ domains showed meaningful improvements. Physical function showed the most significant improvement (median T-score increased from 50 to 60.5; $p < 0.001$). Most adverse events were moderate, and no new safety issues emerged. PROMIS improvements in physical function and pain are modestly correlated with DAS28 decreases ($r = -0.41$ and -0.47, respectively). The study concluded that short-term treatment with Altebrel was effective and well-tolerated in RA patients. PROMIS-HAQ was valuable in capturing changes in quality of life. These data support the use of PROMIS-HAQ in routine RA assessments. Further long-term, larger sample size studies are needed to support these findings.

Keywords: Rheumatoid arthritis; biosimilar etanercept; Altebrel; DAS28; TNF-alpha; IL-6

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