52-WEEK EFFICACY AND SAFETY OF BARISITINIB PLUS METHOTREXATE VERSUS METHOTREXATE MONOTHERAPY IN PATIENTS WITH RHEUMATOID ARTHRITIS: A REAL-WORLD COHORT STUDY

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Abstract:

Background:
While Methotrexate (MTX) remains the first-line treatment for rheumatoid arthritis (RA), inadequate response is common. Barisitinib, a Januskinase inhibitor, has shown efficacy when used in combination with MTX in controlled trials. However, real-world data from smaller cohorts remain limited.

Objective:
To evaluate the 52-week clinical efficacy and safety of Barisitinib + MTX compared to MTX monotherapy in a real-world cohort of RA patients.

Methods:
A prospective observational study was conducted on 35 patients with moderate-to-severe RA. Patients were divided into two groups: 18 received Barisitinib (2-4 mg monthly) plus MTX (10–20 mg/week), and 17 received MTX monotherapy. Clinical outcomes at 52 weeks included ACR20/50/70 response rates, DAS28-CRP, HAQ-DI, and pain visual analog scale (VAS). Safety outcomes included adverse events (AEs), serious infections, and treatment discontinuation.

Results:
At 52 weeks, the combination group showed superior outcomes. ACR20/50/70 responses were achieved in 72%, 50%, and 28% of patients, respectively, compared to 35%, 18%, and 6% in the MTX monotherapy group. Mean DAS28-CRP decreased by 2.4 in the combination group versus 1.1 in the monotherapy group. HAQ-DI improvement ≥0.25 occurred in 67% vs 35% of patients, and pain VAS scores decreased by a mean of 38 mm vs 20 mm. Mild-to-moderate AEs occurred in 6 patients (33%) on combination therapy and 3 patients (18%) on MTX alone. One serious infection occurred in the combination group. No deaths or malignancies were reported. Discontinuation rates were low in both groups.

Conclusion:
In this 35-patient real-world cohort, Barisitinib plus MTX provided greater clinical and functional improvement over 52 weeks compared to MTX alone, with an acceptable safety profile. These findings support the use of combination therapy in MTX-inadequate responders in everyday clinical settings.

Keywords: Rheumatoid Arthritis, Barisitinib, Methotrexate, Real-World Data, ACR Response, DAS28, HAQ-DI, Safety, Biologics

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