Effectiveness, Tolerability, and Safety of Subcutaneous Methotrexate in Early Rheumatoid Arthritis: A Retrospective Analysis of Real-World Data From The St. Gallen Cohort

Ruediger B. Mueller, MD,1 Johannes von Kempis, MD,1 Sarah Haile,2 and Michael H. Schiff, MD2

1Division of Rheumatology, Immunology and Rehabilitation, Kantonsspital St. Gallen, St. Gallen, Switzerland; 2Division of Biostatistics, Institute for Social and Preventive Medicine, University of Zurich, Zurich, Switzerland; 3University of Colorado, Denver, CO, USA

BACKGROUND
Methotrexate (MTX) has been the cornerstone of treatment for rheumatoid arthritis (RA) for more than 30 years and has the highest 5-year retention rate of all disease-modifying antirheumatic drugs (DMARDs) at approximately 70%. Several studies have examined the clinical benefit of switching from oral to subcutaneous (SC) MTX; however, fewer studies have assessed the clinical efficacy and safety of SC MTX in MTX-naive patients. In addition, the real-world use of SC MTX in MTX-naive patients has not yet been explored.

OBJECTIVE:
To assess the efficacy, tolerability, and safety of SC MTX in MTX-naive patients with RA under real-world clinical circumstances

METHODS
• Longitudinal, prospective, retrospective chart review
• Therapeutic decisions were made at the discretion of the treating clinician

Table 2: Inclusion/Exclusion Criteria

Inclusion
Exclusion
Primary and point: Longitudinal disease activity as measured by DAS28 (Disease Activity Score including 28 joints); LDAS = low disease activity; MTX = methotrexate.

Primary and point: All MTX-only MTX-biol

Primary and point: All patients with RA who did not require the addition of biologics (MTX-biol). LDAS, low disease activity state; MTX, methotrexate.

SAFETY:
• Most frequent adverse events leading to cessation of MTX were gastrointestinal distress and lack of efficacy
• Seven severe infections were observed (Table 4)

From the time to starting SC MTX through follow-up, 14 patients in the MTX-only group and 13 in the MTX-biol group required the addition of biologics (MTX-biol). The time to addition of first biologic (C) for patients with RA who did not require the addition of biologics (MTX-only, solid line) or those who required the addition of biologics (MTX-biol, dashed line).

Figure 4. Average weekly doses of SC MTX and daily doses of prednisolone.

Average weekly doses of (A) SC MTX, and average daily doses of prednisolone, for all patients, patients treated with only SC MTX (MTX-only), and patients requiring the addition of biologics (MTX-biol). MTX-only vs MTX-biol (Student's T-Test, P<0.05).

Table 3. Reasons for Stopping SC MTX

Table 4. Serious Adverse Events

All (n=70) n (%)

MTX-only (n=37) n (%)

MTX-biol (n=33) n (%)

MTX-only vs MTX-biol

Allergic reaction 1 (1.4)
Aphthosis 1 (1.4)
Hair loss 1 (1.4)
Infectious event 1 (1.4)
Infection 1 (1.4)
Increase of liver enzymes 1 (1.4)
Intestinal obstruction 1 (1.4)
Pneumonia 1 (1.4)
Progression of rheumatoid nodules 1 (1.4)
Restoration of treatment 1 (1.4)
Ruptured aneurysm 1 (1.4)
Carcinoid syndrome 1 (1.4)
Benign prostatic hypertrophy 1 (1.4)
Therapeutic interruptions 1 (1.4)
Coronary heart disease 1 (1.4)
Rheumatoid factor 1 (1.4)
Pregnant or lactating 1 (1.4)
Hospitalization for pulmonary symptoms 1 (1.4)

References

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