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Short communication

ICHOM-aligned outcomes in patients with rheumatoid arthritis receiving biologic therapy: initial experience from a pilot observational study

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Introduction

In routine management of patients with rheumatoid arthritis (RA) treatment effectiveness is commonly assessed using clinical and laboratory indicators of disease activity. However, important aspects of health status, including pain, fatigue, physical functioning and quality of life, are not always systematically evaluated in daily practice (De Mits et al, 2016;). Patient-reported outcomes (PROs) provide direct insight into the patient's perception of disease burden and treatment impact through validated patient-reported outcome measures (PROMs) (Oude Voshaar et al., 2019). This challenge is particularly relevant in North Macedonia, where fragmented health data systems and the lack of standardized outcome measurement have been identified as important barriers to the implementation of value-based healthcare and systematic evaluation of treatment outcomes (Grozdanova et al., 2025).

The ICHOM Standard Set for Inflammatory Arthritis provides a comprehensive framework for standardized outcome measurement by integrating clinical outcomes, patient-reported outcomes, treatment-related adverse events and patient characteristics. Such an approach enables a more holistic evaluation of treatment effectiveness than conventional disease activity measures alone. (Oude Voshaar et al., 2019).

The aim of this study was to establish and describe an ICHOM-aligned outcome dataset, characterize the clinical, patient-reported, and safety outcomes collected, and report the initial experience of standardized outcome measurement among patients with RA receiving biologic therapy at the University Clinic for Rheumatology, Skopje, North Macedonia.

Materials and methods

An ongoing pilot observational study, initiated in March 2026, is being conducted at the University Clinic for Rheumatology, Skopje, North Macedonia, among patients with RA receiving biologic therapy. The study was designed by a multidisciplinary team consisting of rheumatologists and pharmacists and is based on selected clinical and patient-reported outcome measures from the ICHOM Standard Set for Inflammatory Arthritis. Adult patients diagnosed with RA (ICD-10 codes M05.9, M06.0, and M08) and receiving biologic disease-modifying

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antirheumatic drugs (bDMARDs) are consecutively enrolled during routine outpatient follow-up visits. All participants provided written informed consent prior to inclusion in the study.

Results and discussion

The collected ICHOM-aligned dataset incorporated the key domains recommended by the ICHOM Standard Set for Inflammatory Arthritis, including demographic and clinical characteristics, disease activity measures, patient-reported outcomes, and treatment-related adverse events. Clinical variables comprised age, sex, disease duration, smoking status, body mass index, list of comorbidities, concomitant medications, and biologic therapy.

The study included 80 patients with rheumatoid arthritis receiving biologic therapy. Participants were predominantly female (86.2%), younger than 65 years (81.2%), and had seropositive disease (86.2%). The median disease duration was 12 years, indicating a cohort with longstanding rheumatoid arthritis. Tocilizumab (42.5%) and rituximab (27.5%) were the most commonly prescribed biologic agents, followed by adalimumab (11.2%), etanercept (8.8%), golimumab (5.0%), infliximab (3.8%), and secukinumab (1.2%).

In addition to baseline clinical characteristics, longitudinal disease activity data, including DAS28-ESR, Clinical Disease Activity Index (CDAI) and Simplified Disease Activity Index (SDAI) scores recorded up to the predefined data cut-off date, were collected and incorporated into the ICHOM-aligned outcome dataset. We selected four PROMs questionnaires based on the ICHOM Standard Set for Inflammatory Arthritis: VAS Pain to assess pain intensity, PROMIS Fatigue to evaluate fatigue severity, HAQ-DI to measure functional disability and physical functioning, and EQ-5D-5L to assess health-related quality of life. These assessments were administered during routine follow-up visits, alongside standard clinical evaluation. Simultaneous collection of PROMs and clinical data enabled subsequent comparison of PROMs with disease activity and other clinical characteristics. An important advantage of the ICHOM-aligned dataset was the inclusion of treatment-related adverse events alongside clinical and PROMs, enabling a more comprehensive assessment of treatment outcomes. In our cohort, several clinically relevant adverse events were identified, including urticarial, bronchospasm, photosensitivity and hematological adverse events all of which were documented according to the ICHOM framework. Initial experience demonstrated high acceptance of the ICHOM-based data collection process among clinicians and strong patient engagement with PROM completion.

Conclusion

To our knowledge, this study represents the first implementation of an ICHOM-aligned outcome dataset in patients with rheumatoid arthritis receiving biologic therapy in North Macedonia. The dataset integrates clinical, patient-reported, and safety outcomes, providing a standardized framework for comprehensive outcome assessment. The structured collection of health data was perceived as a valuable approach for capturing patient-centered outcomes alongside conventional measures of disease activity. Ongoing follow-up will enable longitudinal evaluation of treatment effectiveness and support the development of a real-world outcomes registry aligned with value-based healthcare principles.

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