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Short communication

Assessment of patient-reported outcomes in rheumatoid arthritis patients treated with biologic therapy

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Introduction

Rheumatoid arthritis (RA) is a chronic inflammatory disease associated with pain, functional impairment and reduced health-related quality of life. Although biologic therapies have substantially improved disease control, conventional clinical and laboratory measures do not always fully reflect the patient's experience of disease and treatment (Smolen et al., 2023). Patient-reported outcome measures (PROMs) are increasingly integrated into routine rheumatology practice, providing valuable information on pain, physical functioning, fatigue and quality of life. Their use may improve outcome assessment beyond traditional clinical indicators (Arumalla et al., 2023).

Public reporting of patient outcomes by health care providers is proposed as a mechanism that will accelerate identification and adoption of high value care, through shared learning and promoting benchmarking of outcomes that matter to patients. To facilitate standardized outcome measurement, the International Consortium for Health Outcomes Measurement (ICHOM) developed the Standard Set for Inflammatory Arthritis, which incorporates both clinical outcomes and PROMs. The present study evaluated patient-reported outcomes among RA patients receiving biologic therapy using PROMs recommended within the ICHOM framework.

Materials and methods

This pilot observational study included adult patients with rheumatoid arthritis (ICD-10 codes M05.9, M06.0 and M08) receiving biologic therapy at the University Clinic for Rheumatology, Skopje, North Macedonia. Written informed consent was obtained from all participants. Clinical and demographic data were collected from the national electronic health information system *Moj Termin* and structured according to the ICHOM Standard Set for Inflammatory Arthritis.

PROMs included Visual Analogue Scale (VAS) and Health Assessment Questionnaire (HAQ), supplemented with the Patient-Reported Outcomes Measurement Information System (PROMIS) and EuroQol five-dimension five-level questionnaire (EQ-5D-5L) to assess fatigue, physical functioning, health-related quality of life and the broader social aspects of the disease.

Data were analyzed using descriptive statistics. Continuous variables were presented as mean ± standard deviation (SD) or median (IQR), and categorical variables as percentages.

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Results and discussion

A total of 80 patients with rheumatoid arthritis receiving biologic therapy were included in the study. Most patients were younger than 65 years (81.2%), female (86.2%), and diagnosed with seropositive rheumatoid arthritis-ICD-10 code M05.9 (86.2%). The median disease duration was 12 years (mean 13.4 ± 6.6 years), indicating a population with longstanding disease. Among patients with available data, the mean body mass index (BMI) was 27.2 ± 5.7 kg/m². More than half of the patients had never smoked (52.7%), whereas 27.5% were current smokers and 17.6% were former smokers. Regarding treatment, tocilizumab was the most frequently prescribed biologic agent, used by 34 patients (42.5%), followed by rituximab in 22 patients (27.5%), adalimumab in 9 patients (11.2%), etanercept in 7 patients (8.8%), golimumab in 4 patients (5.0 %), infliximab in 3 patients (3.8%) and secukinumab in 1 patient (1.2 %). In addition, 42 patients (52.5%) received prednisolone, while hydroxychloroquine and methotrexate were used by 20 (25.0%) and 19 (23.8%) patients, respectively.

The most common comorbidities were hypertension (23.8%), osteoporosis (21.2%) and diabetes mellitus (13.8%). This finding highlights the considerable clinical complexity of patients receiving biologic therapy. Patient-reported outcome assessment revealed a substantial disease burden despite ongoing biologic therapy. The median VAS pain score was 7.0 (mean 6.2 ± 2.7), indicating persistent pain in a considerable proportion of patients. Functional status assessed using the HAQ demonstrated a median score of 1.5 (mean 1.35 ± 1.02), suggesting moderate functional impairment. The mean PROMIS Fatigue T-score was 58.0 ± 12.1, reflecting fatigue levels above those observed in the general population. Health-related quality of life assessed by EQ-5D-5L showed a mean utility score of 0.63 ± 0.34, indicating a notable reduction in perceived health status. Given that tocilizumab and rituximab were the most frequently used biologics, a descriptive comparison showed similar pain and functional impairment (VAS: 7.0 vs. 7.0; HAQ: 1.50 vs. 1.38), while rituximab-treated patients reported slightly higher fatigue (PROMIS: 60.7 vs. 57.0) and lower EQ-5D-5L scores (0.56 vs. 0.83). The observed burden of pain, fatigue, functional impairment, and reduced health-related quality of life in our cohort is consistent with previous evidence demonstrating that substantial patient-reported disease burden may persist despite biologic therapy in patients with rheumatoid arthritis (Provan et al., 2020; Pickles et al., 2022). Pain, fatigue and functional impairment may reflect both disease activity and factors such as comorbidities, sleep disturbances, and treatment-related adverse effects.

Conclusion

Systematic collection of PROMs may help identify unmet patient needs that are not fully captured by conventional clinical assessments.

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