Effectiveness, Tolerability, and Safety of Tofacitinib in Rheumatoid Arthritis: A Retrospective Analysis of Real-World Data from the St. Gallen and Aarau Cohorts

Ruediger B Mueller, Caroline Hasler, Florian Popp, Frederik Mattow, Mirsada Durmisi, Alexander Souza, Paul Hasler, Andrea Rubbert-Roth, Hendrik Schulze-Koops & Johannes Von Kempis

Tofacitinib is an oral JAK inhibitor indicated for the treatment of rheumatoid arthritis (RA). The efficacy and safety of tofacitinib have been shown in several randomized clinical trials. The study presented here aimed to assess the clinical tolerability and effectiveness of tofacitinib among RA patients in real life. Consecutive patients between January 2015 and April 2017 with RA who fulfilled the American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) 2010 criteria were included in a prospectively designed analysis of retrospective data. Patients were initiated on tofacitinib 5 mg bid. The primary objective was to analyze the safety of tofacitinib in a real-life cohort. Safety was assessed by the reasons to stop tofacitinib during follow up and changes of liver enzymes, hemoglobin, and creatinine. The secondary outcome was to analyze the frequency of and time to achieve low disease activity (LDA) and remission as defined by 28 joint count disease activity score (DAS28). A total of 144 patients were treated with tofacitinib. A total of 84.9% of patients were pre-exposed to at least one biological agent. The average DAS28 at the initiation of tofacitinib was 4.43. A total of 50.0% of patients were positive for rheumatoid factor and 49.0% for ACPA. The mean follow up was 1.22 years (range 10d-3.7a) after initiation of tofacitinib treatment. A total of 94 (64.4%) patients remained on tofacitinib during follow-up. The average time to stop tofacitinib was 190.0 days. Reasons to stop tofacitinib were: insufficient response (n = 23), gastrointestinal symptoms (n = 18), infection (n = 5), myalgia (n = 2), remission (n = 2), headache (n = 2), cough, blue finger syndrome, intolerance, heartburn, psoriasis, and increased liver enzymes (all n = 1). Increased alanine amino transferase (ALAT) or aspartate amino transferase (ASAT) > 2× upper limit of normal (ULN) were detected in 3.3% and 4.4% of patients, respectively. Hemoglobin decrease of >10% was detected in 15.1% of the patients and decreased lymphocytes <500/μL in 3.4%. An increase of creatinine >20% was detected in 9.4% of patients. A total of 62.9% and 50.0% of the patients achieved low disease activity (LDA) or remission after a median of 319 and 645 days, respectively. These rates were significantly higher in patients naïve to biologic agents as compared to
patients pre-exposed to biologics (LDA: naïve 100% 92 d, pre-exposed 57.0% 434 d, p ≤ 0.001; remission: naïve 86.7% 132 d, pre-exposed 44.1%, 692 d, p = 0.001). Tofacitinib is a safe and effective treatment option for patients with RA. Tofacitinib may induce high rates of LDA and remission in patients with active disease, even after the use of one or more biologics, though the rate appeared higher in patients naïve to biologics. Tofacitinib may be a valuable option in a treat-to-target approach. Our data demonstrate that Janus kinase (JAK) inhibitors are safe and efficacious in real life patients.

type: journal paper(review (English))
date of publishing: 26-09-2019
journal title: J Clin Med (8/10)
ISSN print: 2077-0383