**AB0497**

**EFFECTIVENESS, TOLERABILITY, AND SAFETY OF TOFACITINIB IN RHEUMATOID ARTHRITIS: A RETROSPECTIVE ANALYSIS OF REAL-WORLD DATA FROM THE ST. GALLEN AND AARAU COHORT**


**Background:** Tofacitinib is an oral JAK inhibitor indicated for the treatment of RA. Efficacy and safety of tofacitinib have been shown in several randomised clinical studies. OBJECTIVES: The present study aimed to assess the clinical tolerability and effectiveness of tofacitinib among patients with RA in real life.

**Methods:** Consecutive patients between June 2013 and April 2017 with RA who fulfilled the American College of Rheumatology/EULAR 2010 criteria were analysed in a prospectively designed analysis of retrospective data. Patients were initiated on tofacitinib 5 mg bid. The primary objective was to assess safety of tofacitinib in a real life cohort. Safety was assessed by the reasons to stop tofacitinib and follow-up adverse effects of liver enzymes, haemoglobin, and platelet count.

**Efficacy:** The secondary outcome was to assess the frequency of and time to achieve low disease activity (LDA) and remission as defined by DAS28. Results: Overall, 144 patients were treated with tofacitinib. 84.9% of the patients were pre-exposed to at least one biological agent. The average DAS 28 at initiation of tofacitinib was 4.43. 50.0% were rheumatoid factor and 49.0% ACPA positive. 1.4% were pre-exposed to at least one biological agent. The average DAS 28 at initiation of tofacitinib was 4.43. 50.0% were rheumatoid factor and 49.0% ACPA positive. The mean follow up was 1.22 years (range 10 days – 3.7a) after initiation of tofacitinib treatment. 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=3), myalgia (n=2), remission (n=2), headache, cough, blue toe syndrome, intolerance, heart burn, psoriasis, and increased liver enzymes (all n=1). Increased ALT or AST >2 x ULN were detected in 3.3% and 4.4%, respectively. These elevated transaminase levels were transient in 50% and 60% of the cases, respectively. Haemoglobin 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%.

**Conclusion:** 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 use of one or more biologicals, though the rate is significantly higher in patients naïve to biological agents as compared to patients pre-exposed to biologicals (LDA: naïve 100% after median 100d, pre-exposed 57.0% after 359d; remission: naïve 86.7% after 132d, pre-exposed 44.1% after 720d).

**Disclosure of Interest:** None declared

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**AB0498**

**OPTIMISATION OF METHOTREXATE DOSE INDUCED SUCCESSFUL REDUCTION OF GLUCOCORTICOID DOSAGE WITHOUT IMPAIRED DISEASE CONTROL IN PATIENTS WITH RHEUMATOID ARTHRITIS**

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**Background:** Use of short-term glucocorticoids (GCs) along with methotrexate (MTX) has been recommended for newly onset patients with rheumatoid arthritis (RA) in EULAR recommendation 2016. However, it is not always easy to reduce or withdraw GCs due to patients’ fear of relapsed pain or fatigue. As well, some patients are negative to increase MTX dose for fear of adverse events.

**Objectives:** To clarify whether GCs could be reduced without deterioration with appropriately increased MTX. Moreover, disease control rather showed improved tendency.

**Methods:** To clarify whether GCs could be reduced without deterioration with appropriately increased MTX. Moreover, disease control rather showed improved tendency.

**Results:** 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=3), myalgia (n=2), remission (n=2), headache, cough, blue toe syndrome, intolerance, heart burn, psoriasis, and increased liver enzymes (all n=1). Increased ALT or AST >2 x ULN were detected in 3.3% and 4.4%, respectively. These elevated transaminase levels were transient in 50% and 60% of the cases, respectively. Haemoglobin 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%.

**Conclusion:** 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 use of one or more biologicals, though the rate is significantly higher in patients naïve to biological agents as compared to patients pre-exposed to biologicals (LDA: naïve 100% after median 100d, pre-exposed 57.0% after 359d; remission: naïve 86.7% after 132d, pre-exposed 44.1% after 720d).

**Disclosure of Interest:** None declared

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**AB0499**

**EVALUATION OF THE EFFECTIVENESS OF METOTREXATE IN THE HEPATIC TOXICITY DUE TO METHOTREXATE IN PATIENTS WITH RHEUMATOID ARTHRITIS**

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**Background:** Methotrexate inhibits the metabolism of purines resulting in the accumulation of adenosine; it also inhibits the activation of T cells and suppresses the expression of intercellular adhesion molecules for T cells. Side effects may show up during the treatment and among them there is hepatic toxicity, characterised by an increase of AST and ALT; such increase is usually asymptomatic but it may lead to a suspension of the treatment. Metadoxine (MTDX) is a drug which is used in order to treat both acute and chronic alcohol intoxication; it also prevents the inactivation of ATP from acetalddehyde and pyrogallic acid. MTDX also showed to improve hepatic function markers and to decrease oxidative stress leading to a protective effect against radicals.

**Objectives:** The aim of this preliminary study was to evaluate the possible effect of MTDX on hepatic function in patients affected by RA in therapy with MTX.

**Methods:** The study involved 24 patients with RA (20 women), with an mean age of 51.3 years (±14.1) and mean MTX dose of 11.6±3.7 mg/w. MTX was increased from 9.8±3.2 to 11.6±3.7 mg/w (p=0.0001) for uses only, whereas PSL was suppressed from 56% to 26%, and decreased from 2.0±1.1 to 0.8±1.8 mg/week (p=0.0004) for all patients. MTX was increased from 9.8±3.2 to 11.6±3.7 mg/w (p=0.0001) for uses only, whereas PSL was suppressed from 56% to 26%, and decreased from 2.0±1.1 to 0.8±1.8 mg/week (p=0.0004) for all patients.

**Conclusions:** GCs could be reduced or withdrawn without deterioration with appropriately increased MTX. Moreover, disease control rather showed improved tendency.

**Disclosure of Interest:** None declared

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