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

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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 purpose of the study was to assess the clinical tolerability and effectiveness of tofacitinib in a real-life setting.

Methods: Consecutive patients between June 2013 and April 2017 with RA were included if they fulfilled the American College of Rheumatology/EULAR 2010 criteria. Inclusion was based on a prospectively designed analysis of retrospective data. Patients were initiated on tofacitinib 5 mg bid. The primary objective was to analyse safety of tofacitinib in a real-life cohort. Safety was assessed by the reasons to stop tofacitinib and the reasons for dosing reduction. The secondary outcome was to analyse 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 (n=5), myalgia (n=2), remission (n=2), headache, cough, blue toe syndrome, interstitial lung disease, hemoglobin, and creatinine.

Conclusions: GCs could be reduced or withdrawn without deterioration with appropriate increased MTX.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

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AB0499

EVALUATION OF THE EFFECTIVENESS OF METAXODINE 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 pyroglyptic 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 patients with RA treated with MTX. The study included 64 patients with the mean age of 51.3 years (28–73); among them 8 patients were treated with biologics (4 patients with adalimumab, 4 patients with etanercept). The study group was compared with a control group consisting of 16 healthy volunteers.

Results: Among the 64 patients, 11 patients (17.2%) showed an increase in ALT and AST. In 9 patients (14%), both parameters were increased. The mean increase was 1.6-fold for both AST and ALT. In 5 patients (7.8%), both AST and ALT were more than 3 times the upper limit of normality. In those patients, MTDX was administered with a median dosage of 3.72 mg. In these patients, AST and ALT decreased by a median of 2.77 and 2.07, respectively. In the control group, no changes were observed. The differences were statistically significant (p<0.05).

Conclusions: Metadoxine may be a valuable option in a treat target approach. Our data justify an early use of tofacitinib in the therapeutic strategy.

Disclosure of Interest: None declared

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AB0498

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

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Background: Use of short- term glucocorticoids (GCs) along with methotrexate (MTX) have 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 impaired disease control by optimising MTX dose in RA patients with stable medication in real-world clinical practice setting.

Methods: 70 patients with RA who regularly visit our outpatient clinic for ≥1 year were enrolled. Clinical characters, disease activity, and medications at present and 1 year before were retrospectively collected. Therapeutic strategy was to increase MTX with reducing prednisolone (PSL) based on patient’s consent. Initiating bDMARDs was allowed in case of uncontrolled disease. Wilcoxon test and chi-square test were used for statistics.

Results: Clinical characters (median [IQR]) were: age 62 [51.6], yrs; female 69%; disease duration 6.8 [3.4, 13.7] yrs. Rate of MTX was elevated from 57% to 62%, and dose (mean ±SD) 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±3.1 to 0.8±1.8 mg/w (p<0.0004) for all patients. bDMARDs were used for 16 patients, and newly initiated for 2 patients. Although not significant, median CDAI, SDAI, and DAS28 were suppressed from 5.7 to 3.8, 6.2 to 3.9, and 2.92 to 2.77, and remission rate were increased from 24% to 39%, 27% to 41%, and 36% to 41%, respectively.

ABSTRACT AB0498 – Table 1

| %MTX | 57% | 67% | 0.2226 |
|------|-----|-----|--------|
| MTX (mg/w) for users | 9.8±3.2 | 11.6±3.7 | p<0.0001 |
| %PSL | 56% | 26% | 0.0003 |
| PSL (mg/w) for all patients | 2.0±3.1 | 0.8±1.8 | 0.0004 |
| CDAI remission | 24% | 39% | 0.0687 |
| SDAI remission | 27% | 41% | 0.075 |
| DAS28 remission | 36% | 41% | 0.4874 |

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