of *in utero* fetus exposure during the second and third trimesters. These results support continuation of CZP treatment during pregnancy.

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OP0018 TOOL AND THRESHOLD PREDICTING A SUCCESSFUL BIOLOGICAL DMARDS TAPERING IN PATIENTS WITH RA REMISSION DETERMINATION

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Background: Tapering trials confirmed the feasibility of TNF inhibitors (TNFi) tapering for a relevant proportion of patients in remission and/or low disease activity. However, there are no consensual predictors of a good response to therapeutic spacing among patients with rheumatoid arthritis (RA) in remission.

Objectives: To determine the most predictive tool and threshold of a successful TNFi tapering.

Methods: *Population:* The Spacing of TNF-blocker injections in Rheumatoid Arthritis Study (STRASS) trial included 137 RA patients fulfilled the ACR 1987 criteria with sustained (at least 6 months) DAS28 <2.6. Patients were randomly assigned to one of the two following strategies: in the Maintain arm, patients continued to receive TNFi at the standard full regimen and in the Spacing arm, the strategy applied progressive spacing of ADA or ETN subcutaneous injections up to discontinuation at the forth step in the spacing arm. We used the data of the Spacing arm.

Analysis: The performances of several variables (DAS28, SDAI, CDAI, CRP, ACPA status, HAQ, patient/physician global assessment, and booleen remission criteria) were assessed for the prediction of successful TNFi tapering, defined as reaching at least 25% tapering of the full regimen during at least 6 months, using sensitivity and specificity for dichotomous variables, or the area under the ROC curve (AUC) and its 95% confidence interval for continuous variables. A predictive score of successful tapering was constructed using LASSO regression modeling technique to avoid overfitting (R software version 3.2.1).

Results: The main characteristic of the 64 patients of the Spacing arm were the following (mean ± SD): age 54.3±10.7 years, disease duration 8.3±5.4 years, and DAS 28 1.9±0.6.

The baseline variables were similar between patients who failed or succeeded at TNFi spacing, except for the HAQ score (0.30 in the group success and 0.89 in the failure group, p=0.01) and the CRP (2.35 mg/l versus 3.48 mg/l, respectively, p=0.02).

Baseline variables performance in predicting successful TNFi spacing: None of the tested variables was able to predict successful TNFi spacing, except the HAQ score and the CRP. A HAQ threshold $\geq$1.125 had a specificity (Spe) of 93% and an AUC: 0.713 (CI95%: 0.540–0.886). A CRP threshold $\geq$6.8 mg/l had a Spe of 0.97 and an AUC: 0.689 (CI95%: 0.547–0.831).

Composite criteria: A composite criteria able to predict successful TNFi spacing has been elaborated, including ACPA status, Boolean criteria, SDAI, CRP and HAQ. A composite score lower than 0.502 was able to predict a successful TNFi spacing: Spe: 100%; Se: 54%; AUC: 0.829 (CI95%: 0.671 - 0.986).

Conclusions: The remission maintenance in rheumatoid arthritis after TNFi spacing is possible. Our results showed that in a population of RA patients in remission with TNFi, baseline HAQ and CRP are independent predictor factors of successful tapering. We have developed a composite index able to predict successful TNFi spacing, with an AUC of 0.829 and a specificity of 100%. A validation study will be needed to confirm its ability to select patients for treatment decrease.

Disclosure of Interest: None declared

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OP0019 DMARD WITHDRAWAL IN RA PATIENTS ACHIEVING THERAPEUTIC RESPONSE WITH CERTOLIZUMAB PEGOL COMBINED WITH DMARDS: INTERIM RESULTS FROM A CANADIAN OBSERVATIONAL RANDOMIZED STUDY

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Background: The efficacy and safety of certolizumab pegol in the treatment of adult patients with moderate to severe rheumatoid arthritis (RA), when administered either in combination with methotrexate (MTX) or as monotherapy, has been previously shown in several controlled clinical trials. However, a detailed assessment of certolizumab pegol in combination with a wide range of non-biologic disease-modifying drugs (nbDMARDs) used in real-life routine clinical practice is lacking compared to switching to monotherapy after achieving a response when added to nbDMARD(s).

Objectives: The objective is to compare the effectiveness and tolerability of certolizumab pegol given as add-on to nbDMARDs, including MTX and others, or as monotherapy after achieving a DAS28(ESR) improvement of $\geq$1.2 In this descriptive interim analysis, preliminary data on the effectiveness of certolizumab pegol given in combination nbDMARDs or monotherapy, are presented.

Methods: RA patients who had certolizumab pegol added to their existing DMARD regimen due to inadequate response to their nbDMARD(s) were eligible. At 3 or 6 months, those patients who achieved a change in DAS28 of $\geq$1.2 were randomized to continue combination therapy (Combination group) or withdraw nbDMARD therapy (Monotherapy group) and be followed for 18 months. A sample size of 125 randomized patients per group was calculated to have 100 randomized (50 per group) to find a difference of 15% in response.

Results: A total of 121 patients were enrolled, of whom 79 were randomized to continue combination therapy (n=35) or withdraw nbDMARDs (n=44). No significant differences were observed between-groups in baseline age, gender (83% vs. 71% female), race (89% vs. 91% Caucasian), rheumatoid factor status (56% vs. 60% positive), or prior biologic experience (17% vs. 11%).

At 18 months, upon adjusting for baseline scores, similar improvements were observed between groups in DAS28 ESR (-2.1 vs. -2.0). Furthermore, the odds of achieving DAS28 LDA (OR [95% CI]: 0.96 [0.28–3.31]), ΔDAS28$>$1.2 (0.97 [0.29–3.26]), or both (1.00 [0.29–1.49]), were not different between the Combination and Monotherapy groups. Similarly, no differences were observed between groups at 12 months of treatment with respect to these outcomes.

Conclusions: The results of this interim analysis suggest that, among RA patients achieving a therapeutic response when on combination therapy with certolizumab pegol and nbDMARDs, nbDMARDs could be withdrawn without impact on treatment effectiveness over the next year. Additional analyses with the full number of patients will be conducted to confirm this finding.

Disclosure of Interest: None declared

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OP0020 ASSESSMENT OF 3-MONTH CHANGES IN BONE MICROSTRUCTURE UNDER ANTI-TNFα THERAPY IN PATIENTS WITH RHEUMATOID ARTHRITIS USING HR-PQCT

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Background: Bone erosions are usually thought to be irreversible and occur in the first few months of RA onset. With its resolution of up to 81 μm, HR-pQCT has emerged as valuable tool to assess bone changes in RA[(1,2)]. Although one previous study showed minimal erosive progression in patients with RA one year after TNFα inhibition therapy [(3)], no studies have investigated yet the very early bone changes after the initiation of anti-TNFα treatment.

Objectives: To investigate the early changes in bone erosion progression and bone microarchitecture in the MCP joints and wrist of RA patients using HR-pQCT, radiographs, and 3T MRI after 3 months of anti-TNFα treatment.

Methods: 26 RA patients underwent 3T MRI wrist scans and HR-pQCT scans of the MCP and wrist joints at baseline (BL) and at 3 months (3M). Radiographs were obtained at the baseline time point only. DAS28 was assessed at BL and 3M. Patients were divided into two groups: the anti-TNFα group and the MTX-only group.HR-pQCT-derived erosion volume, joint volume/width and bone microarchitectural parameters were computed using methods previously developed[(4–6)], and the joint destruction was assessed via Sharp and RAMRIS scorings using radiographs and MR images respectively.

Results: Patients in the Anti-TNFα group were slightly younger than patients in the MTX only group and had a higher initial DAS28 score,but otherwise displayed similar anthropometerics and demographics (Table).

DAS scores significantly improved in the anti-TNFα group from BL to 3M (Fig. A). 75 erosions were identified at BL by HR-pQCT. The anti-TNFα group showed a significant decrease of erosion volume from BL to 3M at MCH3 (with decreasing trend at MCH2 and wrist). The MTX-only group in contrast, displayed significant