

of 15.2±9.5 years. bDMARD therapy was used for a mean time period of 3.2±2.5 years. Eighty three percent of patients were treated in combination therapy and 80% of patients were seropositive (CCP and/or RF). Both groups did not differ significantly on baseline clinical characteristics (see Table), with 2 exceptions: patients who received Anti-TNF therapies were treated more frequently as first line therapy (75.2% vs 53.2%, $p < 0.001$) and received in a higher proportion combined therapy (90.9% vs 75.0%, $p < 0.001$). A total of 59% of patient achieved remission at the last visit. Three year remission rates were slightly higher but not significant in patients treated with non-anti TNF therapies vs anti-TNF therapies (59.6% vs 53.3%, $p = NS$). We did not find significant differences in remission rates according serological status.

Conclusions: In real-life setting, a meaningful proportion of RA patients achieved remission on the last visit. Patients treated with anti-TNF and non-anti TNF therapies had similar baseline characteristics and after a mean time period of treatment of 3 years, achieved similar remission rates.

Disclosure of Interest: None declared

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AB0405 SAFETY OF RITUXIMAB THERAPY IN AUTOIMMUNE DISEASES: SYSTEMATIC REVIEW AND META-ANALYSIS

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Background: Treatment with rituximab (RTX), a chimeric CD20 monoclonal antibody, has demonstrated efficacy for patients with several autoimmune diseases. There is a growing concern, however, safety evidence of RTX is still lacking.

Objectives: We conducted to evaluate the safety of rituximab (RTX) for autoimmune diseases.

Methods: A literature review was performed based on the randomized clinical trials (RCTs) that assessed adverse events by comparing RTX and placebo or no treatment for autoimmune diseases. The same add-on treatment for both arms were allowed. Study selection and data extraction were independently conducted in duplicate. Meta-analyses were performed for each outcome separately using fixed model and generic inverse variance method.

Results: In the primary analysis, 16 eligible RCTs, with a total of 4147 patients for five autoimmune diseases ($n=8$: rheumatoid arthritis, $n=3$: Sjogren syndrome, $n=1$: systemic lupus erythematosus, multiple sclerosis, ulcerative colitis, Graves orbitopathy, immune thrombocytopenia) were analyzed. The incidence of infusion related reactions and the human antichimeric antibody (HACA) were higher in RTX group than placebo/no treatment group (OR 1.49, 95% CI 1.25–1.77 and OR 2.25, 95% CI 1.35–3.76, respectively). However, there were no significant differences the odds of total adverse events, serious adverse events, withdrawal for adverse events, infections, serious infections, malignancy, and all-cause death between two groups.

Conclusions: Our meta-analysis revealed that RTX was not associated with an increased risk of adverse events except for infusion related reactions and the incidence of HACA compared with placebo.

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AB0406 STABLE EFFICACY AND SAFETY AFTER SWITCHING FROM TOCILIZUMAB INTRAVENOUS TO SUBCUTANEOUS IN RHEUMATOID ARTHRITIS: RESULTS OF A COHORT OF 200 PATIENTS

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Background: Intravenous tocilizumab has been used since 2009 in Europe for the treatment of active rheumatoid arthritis. Since 2015, a subcutaneous formulation is available. The switch from a monthly, intravenous, with dose adjusted for bodyweight treatment to a weekly, subcutaneous, fixed dose, leads to various questions about efficacy and toxicity.

Objectives: The objectives were to evaluate the efficacy maintenance (maintenance rate and DAS28 variation), the safety, the dose variation after the switch and the characteristics of patients switching to the subcutaneous form respect to those following with the intravenous tocilizumab.

Methods: Multicenter and retrospective study was performed from a cohort of 203 patients undergoing intravenous tocilizumab from the rheumatology unit of 7 university hospitals between September 2015 and May 2016. Assessment has been done on the records, effectiveness was assessed using the DAS28, adverse events and reasons for staying on IV form were reported.

Results: On the 203 records analyzed, 3 were secondarily excluded. Of the 200 patients, 77 have switched for the subcutaneous form. Mean age of the 200 patients was 58 years (+/- 13.3) with 155 women (78%) and the mean duration of rheumatoid arthritis was 14 years (+/- 10.4). 72% of patients received a standard intravenous dose (8mg/kg/month) at baseline.

At the first visit after the prescription of the subcutaneous treatment, 58 patients on 65 (89%) maintained the treatment. The mean DAS28 was 1.53 (+/-1.00) at baseline and 1.19 (+/-0.78) at T1 (45 patients). Three patients received a reduced subcutaneous dose of 162mg/2 weeks following a reduced IV dose (<8 mg/kg/month) and maintained the subcutaneous treatment.

About safety, there was no new case of neutropenia <1000/mm³. One severe adverse effect occurred (gastro intestinal perforation).

Regarding the dose variation, for the 77 patients switching, the mean difference between intravenous and subcutaneous dose was +29mg/week (+/-35mg) with the subcutaneous tocilizumab.

Reasons for staying on IV form were essentially: the subcutaneous tocilizumab was not proposed in 55% of the cases and 17% of patients refused the subcutaneous form.

Conclusions: 89% of patients maintained the subcutaneous treatment after 4 months; efficacy was maintained in patients who received a reduced subcutaneous dose. Despite the higher dose after the switch (+29mg/week), there was no new case of neutropenia.

Disclosure of Interest: None declared

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AB0407 COMPARATIVE EFFECTIVENESS OF TOCILIZUMAB (TCZ) MONOTHERAPY WITH TUMOR NECROSIS FACTOR INHIBITORS (TNFi) IN COMBINATION WITH VARYING DOSES OF METHOTREXATE (MTX) IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: Clinical studies have shown that the efficacy of TCZ monotherapy (TCZ mono) is superior to that of TNFi monotherapy and comparable to that of TCZ in combination with MTX.

Objectives: To compare the effectiveness of TCZ mono vs TNFi plus varying doses of MTX in patients with rheumatoid arthritis (RA) and prior exposure to TNFi in routine clinical practice.

Methods: Eligible participants were TCZ-naïve patients from the Corrona RA registry who had prior exposure to ≥ 1 TNFi, initiated TCZ mono or a TNFi + MTX between 2010 and 2016 and had a 6-month follow-up visit. The primary outcome was mean change from baseline in Clinical Disease Activity Index (CDAI) at 6 months. Secondary outcomes included achievement of low disease activity (LDA; CDAI ≤ 10) at 6 months. Patients initiating a TNFi + MTX were grouped by MTX dose (≤ 10 mg; > 10 to ≤ 15 mg; > 15 to ≤ 20 mg; > 20 mg); outcomes in each group were compared with those initiating TCZ mono using trimmed populations, excluding patients outside the propensity score (PS) distribution overlap (not on common support). The PS included age, sex, race, body mass index, smoking status, work status, disease duration, concomitant prednisone use/dose, prior biologic use, American College of Rheumatology functional class and baseline modified Health Assessment Questionnaire, CDAI and patient pain scores. As a sensitivity analysis, stratified-matched populations were created (stratified by 1 vs ≥ 2 prior biologics, then matched on PS). Linear and logistic regression models were estimated in the trimmed populations, adjusting for the same covariates as in the PS.

Results: Baseline demographics were generally comparable between the TNFi + MTX groups and their matched TCZ mono groups. Overall, the mean age was 54 to 59 years, and the mean disease duration was 10.5 to 15 years. A higher proportion of patients initiating TCZ mono had received ≥ 3 prior biologics compared with those initiating TNFi + MTX. Patients initiating TCZ mono had significantly longer mean disease duration than those initiating TNFi + MTX > 15 to ≤ 20 mg (13.0 vs 10.5 years) or TNFi + MTX > 20 mg (12.3 vs 9.3 years) and a higher mean baseline CDAI than those initiating TNFi + MTX ≤ 10 mg (28.1 vs 25.4). Patients in all groups had improvement in CDAI scores at 6 months. In adjusted models, improvement in CDAI and the likelihood of achieving LDA were similar between the TCZ mono group and all TNFi + MTX groups (Table). Similar results were observed in the PS-matched cohorts.

Conclusions: TCZ mono was as effective as TNFi + MTX, regardless of MTX dose, for improving disease activity in patients with prior TNFi exposure. These data suggest that TCZ mono is an effective treatment option for patients with RA who cannot tolerate or prefer not to use MTX.

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