

FR0093 IMPACT OF INTERLEUKIN 6 RECEPTOR INHIBITOR ON N-TERMINAL PRO-BRAIN NATRIURETIC PEPTIDE IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: To investigate the impact of interleukin 6 receptor inhibitor - tocilizumab (TCZ) on NT-proBNP level changes in patients with rheumatoid arthritis (RA) during a 12- month (m) follow-up period.

Methods: The investigation enrolled 31 patients (pts) (20women/5men) with the lack of efficacy/resistance and/or intolerance of basic anti-inflammatory drugs (DMARDs); median age was 54[45; 61] years, median disease duration 10[6;16]m [DAS28 6,25;1,7,1]; SDAI 35[20;5;5,1]; CDAI 30[0;2;0,2]; serum positivity for rheumatoid factor (RF)(100%); anti-cyclic citrulline peptide antibodies (ACCP)/84%. The study did not include RA pts with congestive heart failure. High incidence of traditional risk factors was found in RA pts: arterial hypertension in 75%, dyslipidemia in 61%, smoking - 17%, overweight - 61%, family history of cardiovascular diseases - 36%, hypothyromina - 68%. Coronary artery disease was diagnosed in 11% RA pts. Lack of efficacy of 3 or more DMARDs was found in 46% of pts, intolerance to previous therapy with DMARDs - in 54% pts. These patients were administered TCZ8mg/kg every 4 weeks: 39% were receiving TCZ monotherapy, and 61% - TCZ in combination with methotrexate [20;18,25;mg/week]. Serum levels of NT-proBNP were measured using electrochemiluminescence method Elecsys proBNP II (Roche Diagnostics, Switzerland).

Results: Significant positive changes in major disease activity clinical and laboratory parameters were found in RA pts after 12 m of TCZ infusion: 54% of pts achieved remission (DAS28<3,2) and 46% of pts managed to decrease activity to low level (DAS28<3,2) with accompanying improve- ment in DAS28, levels of ESR, C-reactive protein (CRP), and RF (table 1).

TCZ therapy resulted in decrease of median NT-proBNP levels from 75,8[43,0;100,7] to 37,8[25,7;85,5]pg/ml (p<0,01), while rate of elevated (>100pg/ml) NT-proBNP levels did not change (13%). DAS28<2,6 was achieved in 54% of pts, DAS28<3,2 was achieved in 71% of pts.

Conclusion: Obtained preliminary results show that 12m of TCZ therapy resulted in decreased RA activity and lower levels of NT-proBNP on both regimens - mono- or combination (TCZ+ MT) therapy.

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FR0094 LONG TERM DRUG SURVIVAL FOR BIOSIMILAR SB4 ETANERCEPT IN RHEUMATOID ARTHRITIS, PSORIATIC ARTHRITIS AND AXIAL SPONDYLOARTHROPATHY PATIENTS WITH A NON-MEDICAL SWITCH FROM ETANERCEPT REFERENCE DRUG

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Background: In the new millennium biologic therapies e.g. tumor necrosis factor inhibitors (TNFf) have played a major role improving clinical outcomes in rheumatoid arthritis (RA), psoriatic arthritis (PsA) and axial spondylarthropathies. A major limitation in many countries for prescribing these drugs has been the high drug costs. The patent period for several of these TNF inhibitors, etanercept and adalimumab has ended and as a consequence biosimilar TNF inhibitors are now reaching the market. This has a cost saving potential for payers. In Norway, encouraged by the health authorities, non-medical switch from biologic originator drugs with biosimilar drugs available, including etanercept. To the best of our knowledge no longer than one year real life experienced real life evidence data for non-medical switch from originator etanercept to biosimilar etanercept SB4 exist (ref.1).

Objectives: To explore three-year drug survival for biosimilar SB4-etanercept in RA, PsA and ax-SpA patients with a non-medical switch from etanercept originator to SB4.

Methods: At the participating outpatient clinics patients with RA, PsA and ax-SpA are monitored using a clinical computer system, as standard clinical care. Demographic, clinical and treatment data were retrieved from the computer system for patients who started treatment with biosimilar etanercept SB4 between January 2016 and January 2019. Kaplan-Meier survival curves were used to explore drug survival. Survival differences between groups were tested using Breslow statistics.

Results: At the participating outpatient clinics since 2016 a total of 474 RA, 249 PsA and 320 ax-SpA patients had a non-medical switch from etanercept originator to biosimilar etanercept SB4. In RA, PsA and ax-SpA patients the percentage of women was 68.2%, 42.6% and 30.3%, the percentage of current smokers 17.0%, 12.8% and 19.6%, mean (SD) age was 63.0 (13.1), 58.2 (11.3), 53.1 (12.1) years and disease duration 16.8 (9.3), 16.1 (5.7), 17.7 (11.8) years, respectively. In RA 80.0% were anti-CCP positive and in PsA and ax-SpA 34.4% and 90.8% were
CHANGES IN B CELL PROFILE AS INDICATOR OF RESPONSE TO TNFI TREATMENT IN PATIENTS WITH RHEUMATOID ARTHRITIS

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OBJECTIVE: To analyse the change of peripheral blood mononuclear cells (PBMC) profile after 6 months (m) of treatment with TNFi in order to find cellular indicators of response.

METHODS: Prospective bi-center pilot study including 100 RA patients receiving TNFi therapy. PBMC were isolated from patients at baseline and 6m of treatment, and were analysed by flow-cytometry. Clinical activity at baseline and 6m of TNFi treatment was assessed by DAS28. Clinical remission (DAS28<2.6) after 6m of treatment was considered as optimal response. The association between clinical remission and the percentage of change (Δ, 6m-0m) within each PBMC subset was analysed through univariate logistic regression model (odds ratio; 95% CI; β; p-value). All the analyses were adjusted by sex, age, disease duration, concomitant-methotrexate, seropositivity (ACPA and/or Rheumatoid factor) and baseline-DAS28.

RESULTS: Demographic characteristics before starting TNFi therapy are shown in Table 1. After 6m of TNFi treatment, 40% patients achieved clinical remission. Decreased percentage of B cells (ACD19+) was found after 6m of TNFi treatment in optimal responders, while suboptimal responders did not show changes with the baseline (OR: 0.78; 95% CI: 0.63-0.97; β: -0.25; p: 0.027) (Figure 1). This effect was essentially owing to a reduction of naïve B cells (OR: 0.76; 95% IC: 0.62-0.94; β: -0.27; p: 0.011) (Figure 1). No significant association was found between the other PBMC subsets (monocytes, NK cells, CD4+ T cells and CD8+ T cells) and clinical remission (Figure 1).

CONCLUSION: Our long term real life data show that the majority of patients with a non-medical switch from originator etanercept to biosimilar etanercept SB4 remained on the drug. No significant difference in drug survival was seen between RA, PsA and axSpa patients. Men however had a significantly longer drug survival than women (2.5 (2.4-2.6) vs 2.2 (2.1-2.3), p=0.001).

REFERENCE: