FRI0130

CERTOLIZUMAB PEGOL EXPOSURE DURING PREGNANCY IN WOMEN WITH RHEUMATOID ARTHRITIS: EVALUATION OF THE LONG-TERM NEWBORN OUTCOMES

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Background: Increased TNF alpha (TNF α) levels have been associated to pregnancy complications such as intra-uterine growth retardation and fetal loss. Even if pregnancy has classically been considered as having a positive impact on RA, disease flares potentially leading to poor obstetrical outcomes are not uncommon, raising the challenge of RA management in the early stages of pregnancy. Among TNF α inhibitors indicated for rheumatoid arthritis (RA), the use of certolizumab pegol (CTZ) has been reported as safe during pregnancy. As such, CTZ is allowed during pregnancy as provided by the factory-issued product's sheet.

Objectives: To assess the CTZ use safety during RA pregnancies, including maternal-fetal outcomes.

Methods: We retrospectively evaluated twelve women with RA, fulfilling the 2010 ACR/EULAR criteria, who had been exposed to CTZ throughout pregnancy. All women had signed an informed consent prior to treatment initiation.

Results: All cases were free from any potentially teratogenic drug, stopped at least 6 months before conceiving. Due to the underlying disease activity, and thanks to the approval for CTZ to be continued throughout the whole pregnancy, we carried on the treatment. Mean maternal age at conception was 31.6 $\pm$ 4.0 months; mean disease duration dated of 51 $\pm$ 26 months. All patients were on low-dose daily oral prednisone ranging from 2.5 to 5 mg; four subjects were on sulfasalazine 500 mg TID and four others on hydroxychloroquine 200 mg TID. We observed 12 singleton pregnancies; 8/12 mothers were primiparous. Mean gestational duration was 37 $\pm$ 3 weeks and mean birth weight 3.037 $\pm$ 0.58 grams. No stillbirths or fetal deaths were recorded. Five patients experienced elective caesarean section, while the others had vaginal delivery (four labour were induced by intravenous oxytocin; no dystocic births were reported). Mean APGAR scores after 1, 5 and 10 min from delivery were, respectively, 8 $\pm$ 2; 8 $\pm$ 1 and 9 $\pm$ 1. No obstetric, perinatal or neonatal complications were observed. Eight/12 newborns were breastfed. After a 12 months observational gap, all babies were healthy and the development index above the 75th percentile. All children underwent the Italian scheduled vaccine program, without complications. Their antibody vaccine response is nowadays being investigated by our Research team.

Conclusions: The data from our case series confirm the safety of CTZ administration during pregnancy in women with RA, regarding both the mothers and the offspring. No infection rate increase, neither major maternal-fetal issue were reported. The higher caesarean section rate in our patients, in comparison to the average of northern Italy (20%), could have a iatrogenic explanation, as suggested by the fact that all had been scheduled ahead of time. Similarly, the relative low rate of breastfeeding could be justified by the lack of information given to mothers. Further large data collection and perspective, controlled studies are needed to confirm this statement.

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Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.4632

FRI0131

POTENTIAL FACTORS ASSOCIATED WITH LONG-TERM CONTINUATION OF ETANERCEPT

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Background: With the advent of biologic agents, it has become possible to prevent progression of symptoms and joint destruction in rheumatoid arthritis (RA). However, less than half of patients achieve remission. The patient subgroup that benefits from a specific biologic agent remains unclear. Etanercept has been repeatedly reported to have a high long-term continuation rate, and can also be tapered once the therapeutic goal has been achieved. Identification of a patient

subgroup that benefits from long-term use of etanercept would not only benefit the patients but would also reduce healthcare costs.

Objectives: The purpose of this study was to evaluate the characteristics of patients who benefited from long-term use of etanercept and patients who discontinued the drug due to loss of efficacy using our hospital records, and evaluated factors that may predict the difference in efficacy.

Methods: We compared RA patients who continued etanercept treatment for at least 3 years, without interruption for 3 months or longer for reasons other than remission, including patients who switched from other biologics (continuation group), and patients who discontinued treatment within 3 years of treatment initiation due to loss of efficacy (discontinuation group). All patients were treated at our hospital before October 31, 2017. Multiple regression analysis was used to determine factors that may predict long-term etanercept efficacy, using 10 patient background characteristics, including age at initiation of etanercept and DAS28ESR, as explanatory variables.

Results: At the time of evaluation, the 3 year continuation rate of etanercept by the Kaplan-Meier method was 49.7%. Reasons for discontinuation included adverse events (33.3%), loss of efficacy (50%), and patient preference (17.3%). The continuation group comprised 87 cases, including 5 cases where etanercept was discontinued due to remission. Initial dose was 50 mg, and relative dose intensity was 0.78 (95% confidence interval 0.66–0.89). The discontinuation group included 51 cases. Regarding patient characteristics at the time of etanercept initiation, age (continuation group 60.1 vs. discontinuation group 66.7, $p=0.019$), number of previously used biologics (continuation group 1.24 vs. discontinuation group 1.45, $p=0.016$), and disease duration (continuation group 110.2 months vs. discontinuation group 74.2 months, $p=0.035$) were statistically significant with $\alpha=0.05$, suggesting potential utility in predicting long-term response. In contrast, combination therapy with methotrexate ($p=0.259$), rheumatoid factor, or anti-cyclic citrullinated peptide antibody positivity ($p=0.086$), and DAS28ESR ($p=0.056$) were not statistically significant.

Conclusions: Although this was a retrospective study, the results showed that young RA patients who have previously used few biologics, with long disease duration, may be more likely to benefit long-term from etanercept without loss of efficacy.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.2394

FRI0132

FACTORS INFLUENCING SATISFACTION IN PATIENTS WITH RHEUMATOID ARTHRITIS TREATED WITH TOLICIZUMAB

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Background: Biologics are effective for improving disease activity in patients with rheumatoid arthritis (RA). However, improved disease activity of RA alone does not always lead to high patient satisfaction.

Objectives: We evaluate which factors among items of disease activity and health status are correlated with improvement of patient satisfaction in patients with RA treated with biological agent.

Methods: Patients with RA who were planning to be treated with tocilizumab (TCZ) were enrolled in this study. Satisfaction, disease activity, and health status were assessed at week 0 and week 24 of TCZ therapy. Disease activity was evaluated using SJC, TJC, PGA, EGA and CDAL. Pain was also assessed using Visual Analogue Scale (VAS). Satisfaction and health status were assessed using the patient satisfaction score and the 5 components of the Arthritis Impact Measurement Scale 2 (AIMS-2).

Multiple linear regression analysis was used to assess the correlation between changes in satisfaction, disease activity and health status adjusted for CDAL at week 0. Also, Wilcoxon signed rank test was used to evaluate effect of TCZ on satisfaction, disease activity, and health status.

Results: Nineteen patients (male/female: 4/15) were evaluated. Patients' data at baseline were as follows: mean of age (51.3), disease duration (7.6 years), SJC (12.2), TJC (9.6), PGA (47.9 mm), EGA (51.4 mm), CRP (2.9 mg/dl) and CDAL (10.2), respectively. SJC, TJC, PGA, CDAL and RA-pain showed a statistically significant decrease at week 24 compared to the baseline ($p<0.001$, for each of all items). Out of the 5 components of AIMS-2, "physical", "symptom", "role" and "affect" improved statistically significantly at week 24 compared to the baseline ($p<0.0001$, $p=0.0179$, $p<0.0005$, $p=0.0056$, respectively), while there was no statistically significant improvement for "social interaction". Patient satisfaction was also statistically significantly higher compared to the baseline ($p=0.00038$).

After adjusting for CDAL at week 0, the change in satisfaction from week 0 to week 24 showed statistically significant correlation with changes in PGA and pain-VAS (all p -values <0.05), but not with changes in TJC, SJC EGA. Regarding