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UP TO 5-YEAR RETENTION OF ABATACEPT IN BELGIAN PATIENTS WITH MODERATE-TO-SEVERE RA: PROSPECTIVE DATA FROM THE REAL-WORLD ACTION STUDY

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Background: With its specific mechanism of action, abatacept (ABA) has shown good efficacy, acceptable safety and is well tolerated in patients (pts) with RA in randomised clinical studies.^{1,2} In a chronic disease such as RA, the long-term efficacy and safety of treatment are crucial and require validation in a real-world setting.

Objectives: To explore long-term safety and retention in pts with RA treated with IV ABA in routine clinical practice in the Belgian cohort of the Abatacept In Routine Clinical practice (ACTION) study.

Methods: ACTION is a noninterventional, multicentre, prospective, longitudinal study of pts (aged >18 years) with established active moderate-to-severe RA, who initiated IV ABA in routine care.³ In Belgium, reimbursement criteria require failure with 2 conventional synthetic DMARDs and DAS28 (CRP) >3.7. The primary study objective was retention rate estimated using the Kaplan-Meier method.

Results: Overall, 135 Belgian pts from 16 sites (6 [4.4%] first-line biological and 129 [95.6%] second or further line) were enrolled between October 2010 and December 2012. Of these, 131 were evaluable for effectiveness analysis. Pts had a mean (SD) disease duration of 10.5 (9.7) yrs and were at high risk of disease progression: 25.4% of the evaluable pts had erosions (n/n=33/130), 71.6% were anti-cyclic citrullinated peptide positive (n/n=63/88) and 76.7% were RF positive (n/n=79/103). Overall, pts showed high disease activity at baseline according to mean (SD) DAS28 (ESR) 5.21 (1.02), DAS28 (CRP) 4.72 (1.09), CDAI 28.5 (11.1), SDAI 29.9 (11.9) and HAQ-DI score 1.23 (0.65). Patient and Physician Global Assessment of disease were mean (SD) 65.3 (20.95) and 58.02 (21.77), respectively. The overall retention rate (95% CI) was 76% (68.8, 82.5), 64% (54.8, 71.5) and 34% (22.6, 45.4) at 12, 24 and 60 mths, respectively. When temporary discontinuations (>84 days, n=24) were not included in the number of events, retention rates were 80% (72.0, 85.9), 73% (64.0, 79.4) and 51% (40.1, 61.0) at 12, 24 and 60 mths, respectively (Fig). Average DAS28 (CRP) before discontinuation and at restart was stable (3.37 [1.30] vs 3.73 [1.78], respectively [n=12]), suggesting that a temporary discontinuation of >2 consecutive ABA infusions does not seem to have a major clinical consequence. Pts who discontinued ABA due to lack of efficacy (n=37) had significantly shorter disease duration, higher CRP, higher number of prior DMARDs at baseline, mean DAS28 (CRP) of 3.61 (1.17) and DAS28 (ESR) of 4.66 (1.35) at discontinuation. Overall, ABA was generally well tolerated and no new safety signals were identified.

Abstract AB0462 – Figure 1. Treatment Retention Rate Over Time (Mths) in Study Population Evaluable for Effectiveness.

Conclusions: These real-world data demonstrate an acceptable safety profile for abatacept in Belgian pts with a stable retention rate of up to 5 years in a difficult-to-treat population. A temporary discontinuation also seems feasible.

REFERENCES:

- Westhovens R, et al. Clin Exp Rheumatol 2014;32:553–62.
- Genovese MC, et al. J Rheumatol 2012;39:1546–54.
- Nüßlein HG, et al. Clin Exp Rheumatol 2016;34:489–99.

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A REVIEW OF THE OUTCOMES OF WOMEN WITH RHEUMATOID ARTHRITIS (RA) TREATED WITH BIOLOGIC AGENTS ATTENDING THE SHEFFIELD COMBINED OBSTETRICS AND RHEUMATOLOGY CLINIC 2002 TO 2013

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Background: Women with RA have increased risk of complications including preeclampsia, low birth weight babies and Caesarean sections compared with unaffected women.¹ Higher levels of disease activity have a negative influence on birth weight.² More women are being treated with biologic agents, and there is growing evidence for their safe use in pregnancy.³

Objectives: To assess disease activity during pregnancy, and to review foetal and maternal outcomes.

Methods: Retrospective review of case notes.

Results: Between 2002 and 2013, 17 women with RA treated with biologic agents attended the combined clinic. 13 were treated with Etanercept, 2 Adalimumab, 1 Tocilizumab and 1 Rituximab. 13 were in combination with disease modifying anti-rheumatic agents (DMARDs). There were 17 pregnancies. 2 women stopped their biologic prior to conception; 14 stopped on confirmation of pregnancy. 12 women had active disease during pregnancy. All had some form of steroid treatment, 3 had a DMARD introduced, and 1 restarted Etanercept at 20 weeks.

There were 14 live births and 2 first trimester miscarriages. There was 1 elective Caesarean section, 7 spontaneous deliveries, and 5 inductions, 3 of which proceeded to Caesarean. Data is missing for 2 women. 10 babies were born at term, 3 were pre-term and data is missing for 2. 2 babies weighed less than 2500 g and 2 more than 4500 g. Data is missing for 3 babies. The low birth weight babies were also pre-term, had cardiac abnormalities and required admission to the neonatal unit. Both mothers had stopped Etanercept at confirmation of pregnancy. Both flared during pregnancy.

6 women developed complications: hypertension, diabetes, proteinuria, cervical incompetence, and hypothyroidism. 4 of these had active disease during their pregnancies. 2 babies had intrauterine growth restriction, 2 cardiac abnormalities and 1 macrosomia. All had mothers who flared during pregnancy.

Conclusions: Our group of patients is small, but the outcomes are comparable to those of women with RA. There is no discernible increase in adverse events due to biologic use. In 2014 product recommendations were to stop biologics prior to conception.⁴ Since 2016 the British Society for Rheumatology has advised that Etanercept and Adalimumab are compatible with use in the first and second trimesters. Tocilizumab and Rituximab should still be stopped prior to conception.³ Local practice has changed to reflect this guidance, and the next step in this project is to review the data from more recent pregnancies to determine whether more prolonged use of biologics improves disease control and in turn foetal and maternal outcomes.

REFERENCES:

- Lin H, et al. Increased risk of adverse pregnancy outcomes in women with rheumatoid arthritis. Annals of the Rheumatic Diseases 2010;69(4):715–7.
- de Man Y, et al. Association of higher rheumatoid arthritis disease activity during pregnancy with lower birth weight. Arthritis & Rheumatism 60:3196–3206.
- Flint J, et al. BSR and BHPR guideline on prescribing drugs in pregnancy and breastfeeding—Part I. Rheumatology. 2016;55(9):1693–1697.
- Hyrich K, et al. Biologic therapies and pregnancy: the story so far. Rheumatology 2014;53(8):1377–1385.

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