SAT0135 MAINTAINING REMISSION IN PATIENTS WITH ESTABLISHED RHEUMATOID ARTHRITIS WHILE TAPERING ETANERCEPT: AN INSIGHT IN THE TAPERA TRIAL

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Background: EULAR 2016 recommendations for the management of Rheumatoid Arthritis (RA) suggest to consider tapering of biological Disease-Modifying Antirheumatic Drugs (bDMARDs) in patients in sustained remission. More insight on the effect of tapering strategies is needed in daily practice.

Objectives: To investigate maintaining disease control after spacing dosages of etanercept 50mg from weekly to every other week (EOW) in a pragmatic randomized controlled trial (RCT).

Methods: Patients with RA who were in remission according to the disease activity score 28 (DAS28) remission criteria for at least 6 months and treated with etanercept 50mg weekly for at least a year were included in the one-year non-blinded multicentre TapERA (Tapering Etanercept in RA) RCT (EudraCTnumber 2012-004631-22). Patients were 1:1 randomly assigned to continue etanercept 50mg weekly or to taper to 50mg EOW. Patients who lost remission (DAS28 C-Reactive Protein (CRP) $\geq$ 2.6) received nonsteroidal anti-inflammatory drugs and if needed were re-escalated to etanercept weekly. If remission was still not reached, treatment had to be adapted, at the discretion of the treating rheumatologist. The outcomes were proportion of patients in DAS28 remission at 6 and 12 months, proportion in sustained remission and proportion regaining remission after reintroducing weekly etanercept (intention to treat analysis). Missing components of DAS28 were imputed using expectation maximization.

Results: In total, 69 patients (69.6% female) with a mean ± standard deviation (SD) age of 55.7 ± 11.3 years and a mean ± SD disease duration of 14.7 ± 8.0 years were included. The weekly and EOW group consisted of 35 and 34 patients respectively. At the month 6 visit 77.1% patients of the weekly and 76.5% of the EOW group were in remission (p=0.947) and 68.6% and 58.8% respectively maintained remission on every visit (p=0.400) (Table 1).

Three (8.6%) patients of the weekly and 11 (32.4%) of the EOW group required a treatment adaptation, which was statistically significantly different (p=0.014). There was no difference between the weekly and EOW group in the mean ± SD DAS28 CRP at the first time of losing remission in patients flaring, namely 3.1 ± 0.6 and 3.1 ± 0.5 respectively (p=0.957).

Eleven patients were re-escalated to a weekly treatment after a mean ± SD duration of 4.5 ± 3.1 months. Of these, 54.5% (6/11) regained remission after a mean ± SD duration of 4.7 ± 1.7 months. Of the 5 patients not regaining remission, 1 switched to a weekly regimen on the last trial visit, 1 required switching to another bDMARD and 3 patients had no additional treatment changes (mean ± SD DAS28 CRP at month 12: 3.4 ± 0.2). Two patients of the EOW group restarted weekly etanercept while still being in remission.

Table 1: Proportion of patients of the weekly and EOW group in remission and LDA

	Weekly group (n=35)	EOW group (n=34)	p-value
Remission at M6 n(%)	27 (77.1)	26 (76.5)	0.947
LDA at M6 n(%)	29 (82.9)	30 (88.2)	0.526
Sustained remission M6 n(%)	24 (68.6)	20 (58.8)	0.400
Sustained LDA M6 n(%)	29 (82.9)	26 (76.5)	0.510
Remission at M12 n(%)	30 (85.7)	24 (70.6)	0.128
LDA at M12 n(%)	33 (94.3)	28 (82.4)	0.122
Sustained remission M12 n(%)	21 (60.0)	15 (44.1)	0.187
Sustained LDA M12 n(%)	25 (71.4)	24 (70.6)	0.939
Patients with treatment adaptation due to efficacy loss n(%)	3 (8.6)	11 (32.4)	0.014

Treatment adaptation is defined in the weekly and EOW group as intensifying DMARD therapy and re-escalation to weekly respectively; EOW *every other week*, M *month*, LDA *low disease activity (DAS28 CRP ≤ 3.2)*

Conclusion: Approximately half of the EOW group was in sustained remission after 1 year and two thirds remained on their reassigned treatment. Furthermore, one in two patients were able to regain remission after reintroducing etanercept weekly. Therefore tapering of etanercept to EOW seems a feasible strategy in patients with RA in sustained remission, potentially leading to a beneficial cost-saving and safety profile.

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SAT0136 CONSISTENCY WITH INTERNATIONAL GUIDELINES REGARDING MOTHERS WITH RHEUMATOLOGIC DISEASES EXPOSED TO TUMOUR NECROSIS FACTOR INHIBITORS (TNFI) DURING THE ANTE- AND POSTNATAL PERIODS AND CHANGE OVER TIME

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Background: Many women with rheumatologic diseases require ongoing treatment with TNFi during pregnancy to maintain remission or low disease activity. Until recently, there has been a paucity of published evidence regarding the safe use of these medications during the ante- and postnatal periods to guide clinical practice.

Objectives: To observe compliance with current guidelines for TNFi therapy in Australian women with rheumatologic diseases during the ante- and postnatal periods and change over time.

Methods: All Australian women with rheumatologic diseases, exposed to biologics (bDMARDs) and targeted synthetic disease modifying antirheumatic drugs (tsDMARDs) during the preconception, antenatal and/or postpartum periods were eligible to participate in the Pregnancy Exposed to Biological (PEB) study. Commencing in 2015, recruitment was via invitation from patient's treating rheumatologists, community groups, and social media. Following self-referral to the study, retrospective data was collected, including rheumatologic condition and management recommendations made by health professionals.

Results: Preliminary data is available for 37 infants born to 29 mothers from Feb 2009-Dec 2018. Of these, 32 women received TNFi. We assessed 3 outcomes – TNFi continuation during pregnancy, TNFi continuation during lactation and vaccination practice in infants exposed to TNFi. Women exposed to non-TNFi bDMARDs and tsDMARDs were excluded from this abstract, as these are not recommended for use during the perinatal period (2).

Specialist Society Guidelines from the British Society of Rheumatology and the British Health Professional in Rheumatology were published in 2016 regarding the safety of TNFi during pregnancy (2). Prior to guideline publication, 67% (n=16/24) of the women in PEB ceased their TNFi pre-conception. Of those in PEB who became pregnant subsequent to guideline publication, only 25% (n=2/8) ceased TNFi pre-conception. Overall, 40.6% (n=13/32) women received a TNFi during the antenatal period consistent with guidelines, which improved from 33.3% (n=8/24) pre-publication, to 62.5% (n=5/8) post publication.

84.4% (n=27/32) women exposed to TNFi breastfed their infants. Prior to availability of evidence regarding the safety of TNFi during lactation, 79.2% (n=19/24) of infants were breastfed. After publication, 100% (n=8/8) infants exposed to TNFi were breastfed.

In total, 96.9% (n=31/32) of the infants exposed to TNFi in PEB were vaccinated. Rotavirus vaccine should have been delayed in 43.8% (n=14/32) infants, but was not. 9.4% (n=3/32) infants had live vaccines deferred until only 3 months; 3.1% (n=1/32) infants had live vaccines unnecessarily delayed. Only 3.1% (n=1/32) infants had live vaccines appropriately delayed until 7 months. Compliance with vaccination recommendations increased from 43.5% (n=10/24) pre-publication to 62.5% (n=5/8) post publication of guidelines.

Conclusion: Preliminary data from PEB suggests that there has been a shift in practice following the publication of Specialist Society Guidelines, with increasing numbers of women continuing TNFi therapy during pregnancy and the postpartum period, in keeping with current evidence. Compliance with vaccination recommendations could be improved to be more consistent with published international guidelines.