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(AOSD); all were exposed to a biologic agent: 16 Etanercept (ETA), 7 Adalimumab (ADA), 4 Infliximab (IFX), 1 Certolizumab (CTZ), 5 Rituximab (RTX), 1 Anakinra (ANK). Median age was 34 yrs (range 24-50). All patients treated with TNFi and ANK withdrew therapy in early pregnancy (<10 weeks gestational age). 2 RA patients had 2 pregnancies each, during ETA treatment. A RA woman became pregnant 4 times during RTX therapy. 10 patients were also on csDMARDs therapy at the time of conceptions: 7 Hydroxycloroquine (HCQ),1 HCQ + Sulphasalazine (SSZ), 1 Cyclosporine A (CYA), which was continued, and 1 with Methotrexate which was immediately withdrawn. 1 RA patient started SSZ from the 24th week. 15 patients (7 RA, 2 PsA, 2 AS, 2 uSpA, 1 DM) started or increased oral and/or intra-articular steroids because of disease flare. A control group of 45 pregnancies observed in 42 patients not exposed to biologics was selected="selected" (19 RA, 12 uSpA, 3 Juvenile Idiopatic Arthritis (JIA), 5 PsA, 1 AS, 1 DM, 1 AOSD), median age 35 (range 22-42). 18 patients were treated with csDMARDs during pregnancy (8 HCQ; 4 SSZ; 2 CYA+HCQ; 4 SSZ+HCQ). No other drugs were taken at the time of conception, apart from low dose of steroids in 24 cases; in 1 case intra-articular steroids were given because of disease flare.

Pregnancy outcomes are summarized in tab.1: therapeutic abortions were performed for an extrauterine pregnancy occurred twice in the patient with RA who became pregnant 4 times during RTX treatment, after the 5th and the 6th retreatment. After the 4th retreatment she had an early spontaneous abortion. Previously, she delivered 2 healthy children after exposure to ETA and 3 treatment cycles of RTX. No serious perinatal complication occurred, excluding very preterm baby delivery at 28th weeks, who needed neonatal intensive care. No congenital malformations were observed. Klinefelter syndrome was diagnosed in 1 case.

Tab. 1: Pregnancy outcomes of women with RD exposed to biological (<u>BE</u>) compared with pregnant women with RD non-exposed to biological agent (NE).

	BE group (34)	NE group (45)	p
Live births	29 (85,3%)	43 (95,5%)	ns
Spontaneous abortion	2 (5,9%)	2 (4,4%)	ns
Therapeutic abortion	2 (5,9%)	0	ns
Voluntary interruption of pregnancy	1 (2.9%)	0	ns
Pre-term delivery	5 (14,7%)	6 (13,3%)	ns
Preterm rupture of membrane	3 (8,8%)	4 (8,9%)	ns
Intra-uterine growth restriction	1 (2.9%)	1 (2,2%)	ns
Average birth weight	2875 g (720-4234)	3140 (1880-4200)	ns
Low birth weight (<2500 g)	6 (17,6%)	5 (11,1%)	ns

Conclusions: In our case series no significant differences did occur in pregnancy outcome between BE and NE group, according to the most recent data published in literature. Additional data from larger numbers of pregnacy exposed to biological agents are required.

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## SAT0157 MYCOBACTERIUM TUBERCULOSIS SPECIFIC RESPONSES FROM CD8+ AND CD4+ T CELLS IN PATIENTS WITH LATENT AND ACTIVE FORM OF TUBERCULOSIS

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Background: Testing the presence of latent or active tuberculosis using IGRA tests is necessary part of the diagnostic screening at risk individuals. QuantiFERON-TB Gold Plus (QFT-Plus) is a test for cell-mediated immune (CMI) responses to peptide antigens that simulate mycobacterial proteins. Peptide antigens in TB1 tube elicit CMI responses from CD4+ T-helper lymphocytes, in TB2 tube from CD8+ T-cytotoxic lymphocytes. Test is based on the ability of effector T lymphocytes to produce the cytokine interferon gamma (IFN-v)

Objectives: To compare and evaluate levels of IFN-γ produced by CD4+ and CD8+ cells in TB1 and TB2 tubes.

Methods: It was studied 33 subjects with latent form of tuberculosis (LTBI) and 33 subjects with active TB. QFT-Plus was used to detect in vitro responses to peptide antigens associated with Mycobacterium tuberculosis infection (ELISA, QIAGEN). Results were obtained by calculation of INF- $\gamma$  levels in Mitogen, TB antigen (TB1, TB2) and Negative control tubes using QFT analysis software.

Results: QFT-Plus positive results were observed in both groups of people. Increased levels of IFN- $\gamma$  produced by CD4+ cells (TB1) has been detected in 21 subjects with LTBI (63,64%) and in all 33 subjects with active TB (100,0%). Increased levels of IFN-y produced by CD8+ cells (TB2) has been detected in 27 people with LTBI (81,82%) and in all 33 people with active TB (100,0%). Joint increase levels of IFN- $\gamma$  in the tubes TB1 and TB2 was observed in 16 individuals with LTBI (48,48%) and in all 33 individuals with active TB (100,0%). In the group of patients with a negative QFT-Plus it was not observed increased levels of IFN in tubes TB1 and TB2.

Conclusions: Our findings confirm specific CD4+ and CD8+ T cell response to mycobacterial protein antigens in individuals with LTBI and also in active TB subjects, in which INF- $\gamma$  was frequently found. The immunological response represented by CD4+ and CD8+ T cells was not detected in subjects with QFT-Plus negative.

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## SAT0158 EFFICACY OF SWITCHING FROM ETANERCEPT TO ADALIMUMAB IN RHEUMATOID ARTHRITIS AND PSORIATIC ARTHRITIS PATIENTS WHO EXPERIENCED A FIRST-LINE **BIOLOGIC THERAPY FAILURE: THE FEARLESS STUDY**

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Background: The strategy for the choice of the second biologic agent after the failure of the first TNF inhibitor (TNFi) is still an unclear aspect in the treatment of both rheumatoid arthritis (RA) and psoriatic arthritis (PsA). Switching between structurally different TNFis (from etanercept [ETN] to monoclonal antibody [mAb] or vice versa) has been proposed as a more effective procedure than switching among different mAbs, but to date no study has been specifically focused on exploring this topic

Objectives: To evaluate the comparative 2-year retention rate and the 12-month efficacy of adalimumab (ADA) as second biologic agent in etanercept (ETN) non-responder RA and PsA patients in a multicentre retrospective study.

Methods: All RA and PsA patients from 11 Italian Rheumatology Units treated with ADA after a first-course ETN failure and with at least 12-month follow-up were retrospectively collected in a multicentre registry. Data analysis was limited to the period from January 2002 to May 2016. Two-year ADA retention rate was calculated by Kaplan-Meier method. 12-month ADA response was defined as achievement of disease activity score 28 calculated by using erythrosedimentation (DAS28-ESR) <2.6 (remission) or >2.6 and <3.2 (low disease activity, LDA). Sub-analyses according to reason for ETN discontinuation and concomitant methotrexate in RA and PsA patients have been performed.

Results: The study population (219 patients) included 117 RA (female 85.5%, mean [± standard deviation, SD] age 53.2±13.5 years, mean [±SD] disease duration 10.1±7.7; positive rheumatoid factor 70.2%; positive anti-citrullinated peptide antibodies [ACPA] 59.6%; mean [±SD] baseline DAS28-ESR 4.97±1.3; MTX users 64.9%) and 102 PsA (female 63.7%; mean [±SD] age 51.7±10.6; mean [±SD] disease duration 7.1±5.1; mean [±SD] baseline DAS28-ESR 4.4±1.1; MTX users 50%). The 2-year retention rate was 48.2% in RA and 56.5% in PsA patients, irrespective of reason for ETN discontinuation. Similarly, concomitant MTX was not associated with an increased drug survival in both RA (p=0.09) and PsA (p=0.969) subgroup. 12-month clinical remission and LDA were achieved respectively in 27.3% and 23.9% RA patients, and 27.4% and 23.5% PsA patients. Conclusions: In our large real-life cohort, the use of ADA in primary and secondary ETN failures was highly effective in both RA and PsA patients, with more than 50% of ADA treated patients achieving remission or LDA. Reasons for ETN discontinuation were not associated with different ADA clinical response, as well as concomitant MTX.

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## SAT0159 IMPACT OF PARTICIPATION IN THE ADALIMUMAB PATIENT SUPPORT PROGRAM ON FUNCTIONAL AND CLINICAL **OUTCOMES AMONG PATIENTS WITH RHEUMATOID** ARTHRITIS: PASSION STUDY

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Background: Patients (pt) with Rheumatoid arthritis (RA) who are treated with adalimumab (ADA) are offered a Patient Support Program (PSP) with variety of services. To date, no prospective study has been conducted to analyze the acceptance and the impact of these PSPs on treatment effectiveness and pt

Objectives: The purpose of this study was to examine the effectiveness of ADA on rheumatoid arthritis (RA) treatment course in the context of PSP participation. Methods: PASSION (NCT01383421) was a 78-week (wk) post-marketing observational study of pts with RA receiving ADA in routine clinical care. Pts from the EU, Israel, Mexico, Puerto Rico, and Australia with an insufficient response to ≥1 disease-modifying antirheumatic drug (DMARD) newly initiating ADA (1 prior