FRI0387

DISEASE COURSE AND OUTCOMES DURING PREGNANCY IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS: COMPARISON BETWEEN TNFI USERS AND NAIVE PATIENTS

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Background: Axial Spondyloarthritis (AxSpA) can be active during pregnancy, especially in those patients who discontinued TNFi at the beginning of pregnancy. The severity of flare during pregnancy can influence the gestational outcome and the attitude of the physician towards treatment.

Objectives: To describe: 1)the disease course of AxSpA during pregnancies in patients who never used TNFi (bio-naïve) and those who were TNFi users; 2)the severity of flares; 3)the impact of resuming TNFi in patients who experienced a flare during pregnancy (on both maternal disease control and gestational outcome).

Methods: Retrospective analysis of 18 prospectively-followed pregnancies from 2010 to 2018 in 15 patients with AxSpA. Two pregnancies ended in miscarriage, so they weren't considered for the analysis of flares during pregnancy. Active disease was defined as ASDAS-CRP >2.1. Flare was defined as an increase of ASDAS-CRP greater than 0.6 with CRP elevation and one of the followings: introduction or increase above 5mg/day of prednisone, introduction of cDMARD or bDMARD.

Results: At preconception visit, 2 patients were on treatment only with steroids, 1 with sulfasalazine and steroids and 9 with bDMARDs (5 etanercept, 2 adalimumab, 2 golimumab; 2 with steroids). At conception, 3 patients presented active disease. TNFi was stopped at positive pregnancy test in 7 pregnancies; 1 patient continued TNFi over pregnancy.

Twelve out of 16 (75%) patients had at least one disease flare (4, 10 and 3 during 1st, 2nd and 3rd trimester respectively). Among pregnancies with flare, medication resumed during pregnancy were steroids (7, 58%), cDMARDs (1 salazopyrine and 1 cyclosporine A, 17%) and bDMARDs (4 etanercept and 1 certolizumab, 42%). Six patients (38%) had a flare in postpartum period. Table 1 shows the comparison between pregnancies with and without flares during pregnancy.

By comparing the pregnancies of patients with and without history of TNFi use (table 2), we have registered 8 flares (8/11, 73%) in the first group and 4 flare (4/5, 80%) in the second one. In the group of TNFi users, medications resumed during pregnancy were steroids in 5/11 (46%) and bDMARDs in 5/11 (46%), whereas in the group TNFi naïve only in 1 pregnancy steroids was resumed and no bDMARDs were started. Mean ASDAS-CRP was higher in the group of TNF user.

For what concerned gestational outcome, we did not observe any SGA, pre-eclampsia and eclampsia. Two pregnancies ended with miscarriage and 2 with preterm birth (at 36 and 34 gestational weeks). Two patients had PROM and 1 pPROM (this patient refused to resume TNFi during pregnancy and her flare was treated with medium doses of prednisone).

Conclusion: Three out of 4 AxSpA patients with severe disease phenotype and history of TNFi use prior to pregnancy experienced a disease flare after TNFi discontinuation at conception. Conversely, AxSpA patients with mild disease phenotype had a similar rate of flare during pregnancy but less severe and without the need for chronic treatment during pregnancy. When resumed during pregnancy TNFi was able to control disease activity and to favor a good gestational outcome. In preconception counselling the continuation of TNFi during pregnancy should be discussed with the patients.

Disclosure of Interests: Francesca Crisafulli: None declared, Laura Andreoli: None declared, Maria Chiara Gerardi: None declared, Antia García Fernández: None declared, Cecilia Nalli: None declared, Matteo Filippini: None declared, Roberto Gorla: None declared, Marco Taglietti: None declared, Micaela Fredi: None declared, Maria Grazia Lazzaroni: None declared, Andrea Lojaco: None declared, Sonia Zatti: None declared, Franco Franceschini: None declared, Angela Tincani Consultant for: UCB, Pfizer, Abbvie, BMS, Sanofi, Roche, GSK, AlphaSigma, Lilly, Janssen, Cellgene, Novartis

DOI: 10.1136/annrheumdis-2019-eular.7705

Table 1: clinical features, medication and disease activity in pregnancies with flare vs pregnancies without flares

	FLARE YES (12)	FLARE NO (4)
CLINICAL FEATURES		
Mean age at conception, years (SD)	33 (5.12)	32.7 (6.7)
Mean Disease duration, months (SD)	74.8 (52)	93 (122.1)
Peripheral arthritis, n (%)	4 (33)	2 (50)
Enthesitis, n (%)	3 (25)	2 (50)
Dactylitis, n (%)	1 (8)	0 (0)
Psoriasis, n (%)	3 (25)	1 (25)
IBD, (%)	2 (17)	1 (25)
Uveitis, n(%)	1 (8)	0 (0)
MEDICATION		
History of TNFi, n (%)	8 (67)	3 (75)
History of TNFi >1, n (%)	2 (17)	2 (50)
TNFi at preconception visit, n (%)	6 (50)	2 (50)
TNFi stopped at pregnancy test+, n (%)	3 (25)	1 (25)
cDMARDs history, n (%)	9 (75)	3 (75)
cDMARDs >1, n (%)	2 (17)	1 (25)
DISEASE ACTIVITY		
ASDAS-CRP >2.1 at preconception visit, n (%)	2 (17)	1 (25)
Elevated CRP at preconception visit, n (%)	0 (0)	1 (25)
ASDAS-CRP >2.1 during 1 st trimester, n (%)	4 (33)	0 (0)
Elevated CRP during 1 st trimester, n (%)	3 (25)	1 (4)

Table 2: flare, medications at preconception visits and medications initiated during pregnancy in pregnancies of patients with history of TNFi use or not.

	TNFi users	TNFi naïve
FLARE AND ASDAS-CRP		
Flare during pregnancy *	8/11 (73%)	4/5 (80%)
Flare in post partum period	5/12 (42%)	1/6 (17%)
ASDAS-CRP 1 st TRIMESTER (mean)	2.04 (SD 1.23)	0.82 (SD 0.39)
ASDAS-CRP 2 nd TRIMESTER (mean)	2.54 (SD 1.31)	1.55 (SD 0.82)
ASDAS-CRP 3 rd TRIMESTER (mean)	1.56 (SD 0.64)	1.02 (SD 0.99)
ASDAS-CRP post partum (mean)	2.46 (SD 0.73)	1.53 (SD 1.34)
MEDICATION AT PRECONCEPTIONAL VISIT		
TNFi	6/12 (55%)	0/6 (0)
Prednisone	2/12 (18%)	1/6 (17%)
cDMARDs	0/12 (0)	2/6 (33%)
MEDICATION RESUMED DURING PREGNANCY *		
TNFi	5/11 (46%)	0/5 (0)
Prednisone	5/11 (46%)	1/5 (20%)
cDMARDs	1/11 (9%)	1/5 (20%)

*two pregnancies ended in miscarriage were not considered

FRI0388

SECUKINUMAB IMPROVES HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH ANKYLOSING SPONDYLITIS, IRRESPECTIVE OF TIME SINCE FIRST DIAGNOSIS: POOLED RESULTS FROM THE SECUKINUMAB PHASE 3 TRIAL PROGRAM

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Background: Ankylosing spondylitis (AS) is a chronic rheumatic condition that has a negative impact on health-related quality of life (HRQoL). Secukinumab (SEC), a fully human anti-IL-17A monoclonal antibody, has been shown to effectively control AS symptoms and improve HRQoL.

Objectives: To evaluate the impact of SEC on HRQoL, assessed by the Short Form-36 Health Survey (SF-36), in pts with active AS stratified by time since first diagnosis (<2 or ≥2 yrs).

Methods: Pts were randomized to placebo (PBO) or SEC in MEASURE 1 (10 mg/kg intravenously followed by 150 or 75 mg SC), MEASURE 2 (150 or 75 mg SC) and MEASURE 4 (150 mg SC with/without SC loading). At Wk 16 or Wk 24, depending on ASAS 20 response, pts on PBO were re-randomized to SEC. Mixed-models for repeated measures were used to evaluate changes in SF-36 from baseline (BL) to Wk 16; observed data are presented at Wk 52. The proportion of pts reporting improvements meeting/exceeding the minimal clinically important differences (MCID) for SF-36 physical (PCS responders) and mental component summary (MCS responders), and individual SF-36 domains was also