

and babies, with a peculiar focus on maternal-fetal safety issues. APGAR scores at 1 min (APGAR1) and 5 min (APGAR5) from delivery were recorded.

Results: We observed 6 pregnancies from 6 mothers (4 of European, 1 Asian and 1 Latin-American ethnicity). Patient mean age at conception was 336±131 months; disease duration, 62±27 months; pre-conceptual exposure, 46±9 weeks; the (estimated) post-conceptual exposure 7±2 weeks. No major gestational complications were reported. One mother consulted the Emergency Department for a syncopal episode, but after a routine evaluation and an observation of 6 hours, was discharged; her pregnancy was otherwise unremarkable. Four girls (mean weight: 3170±200 g) and 2 boys (mean weight: 3460±60) were born. Mean gestational age was 38±2 weeks; 3 vaginal deliveries (1 oxytocine-induced for scarce dilation) and 3 caesarean sections were observed. The APGAR scores were above 8, excepting for an APGAR1 of 6 (born with caesarean section), then turned on 10 at APGAR5. Results are summarised on table 1. DAPSA, for the whole population, was under 4 (remission) at conception, and remained stable after delivery.

Abstract THU0319 – Table 1

| Observed pregnancies | 6 | | | | | |
|-------------------------------------|---------|----|----|----------|----|----|
| Gestational age (weeks+days) | 38±2 | | | | | |
| Sex | M (4) | | | F (2) | | |
| Birth weight (g) | 3460±60 | | | 3170±200 | | |
| APGAR | | | | | | |
| 1 minute | 6 | 10 | 9 | 9 | 8 | 10 |
| 5 minute | 10 | 10 | 10 | 10 | 10 | 10 |
| Delivery modality | | | | | | |
| Vaginal spontaneous | | 1 | | 1 | | 1 |
| Vaginal induced | | | | | 1 | |
| Caesarean section | 1 | | 1 | | | 1 |
| Complications | - | - | - | - | - | ED |
| Malformations | - | - | - | - | - | - |
| Growth restrictions (SGA, IUGR) | - | - | - | - | - | - |
| Maternal age at conception (months) | 336±131 | | | | | |
| PsA duration at conception (months) | 62±27 | | | | | |
| PsA activity at conception (DAPSA) | <4 | <4 | <4 | <4 | <4 | <4 |
| Pre-conceptual exposure (weeks) | 46±9 | | | | | |
| Post-conceptual exposure (weeks) | 7±2 | | | | | |
| PsA activity postpartum (DAPSA) | <4 | <4 | <4 | <4 | <4 | <4 |

APGAR, Appearance-Pulse-Grinace-Activity-Respiratory Score; SGA, Small for Gestational Age; IUGR, Intra-Uterine Growth Restriction; PsA, Psoriatic arthritis; DAPSA, Disease Activity in Psoriatic Arthritis; ED, Emergency Department (access).

Conclusions: The present study, despite the limited number of observations, represents the first report on pre-conceptual exposure to SEC. The available data, due to the lack of controlled studies, place the drug's use on FDA "B" category. Of note, SEC failed to cause teratogenicity, when administered throughout the whole pregnancy in a study conducted on primates (*Cynomolgus* monkeys). The limited knowledge on human beings suggests, nevertheless, not to administer SEC during pregnancy, unless a clear benefit overwhelm the potential risk. SEC, in conclusion, seems to have an acceptable safety profile, even when accidentally taken in the very first pregnancy phase. Reporting the cases of pregnancy exposures, as recommended by the ongoing Producer's policy, is the only way that would allow to confirm, or reject, this statement. A long-term follow-up of the mother and the offspring health, similarly, is needed.

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THU0320 A SHORT, EASILY READABLE, ONLY 3-ITEM TOOL – BRISTOL RHEUMATOID ARTHRITIS FATIGUE SCALE (BRAFF) – IS VALID IN PATIENTS WITH PSORIATIC ARTHRITIS

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Background: Fatigue in Psoriatic arthritis is very little studied. Recently, an instrument, the Functional Assessment of Chronic Illness Therapy (FACIT), has been validated in PsA, which is a relatively long, 13-item, instrument. An alternative instrument, the Bristol Rheumatoid Arthritis Fatigue Numerical Rating Scales (BRAFF-NRS), is an easily readable, much shorter, 3-item tool. The BRAFF-NRS

has been studied and validated in rheumatoid arthritis population; however, this has not been validated in patients with PsA.

Objectives: The purpose of this study was firstly to determine the internal consistency, test-retest reliability, criterion validity of the BRAFF-NRS in patients with PsA. Secondly, we also examined the potential clinical associations of worse fatigue in patients with established PsA.

Methods: Two independent cohorts fulfilling CASPAR criteria were enrolled.

STUDY PHASE 1: BRAFF-NRS SCALE VALIDATION COHORT (n=70)

A consecutive cohort of 70 PsA patients completed the 3-item BRAFF-NRS scale and 13 items of the FACIT-F scale, alongside laboratory testing and disease activity assessments. Moreover, all these patients completed BRAFF-NRS questionnaires twice, one day apart. Internal consistency was measured by Cronbach's alpha; test-retest reliability by the intra class correlation coefficient (ICC); and validity by the correlation of the BRAFF-NRS results with validated FACIT-F measures.

STUDY PHASE-2: IDENTIFYING THE POTENTIAL CLINICAL ASSOCIATIONS OF FATIGUE BY USING BRAFF-NRS (n=283)

Following informed consent, patients underwent a detailed skin and rheumatologic assessment including disease activity measures, and whether patient has achieved minimal disease activity (MDA). Moreover, we measured comorbidity using the Charlson Comorbidity Index (CCI). The factors predicting worse fatigue as measured by the BRAFF-NRS score were determined using univariate and multivariate linear regression analysis.

Results: **STUDY PHASE 1: BRAFF-NRS SCALE VALIDATION COHORT (n=70):** 67 patients had the complete assessments [mean age 52±9 years, 54% female, mean PsA duration of 5±3 years]. The internal consistency of the 3 items BRAFF-NRS questionnaire as measured by Cronbach's alpha was 0.92. Test-retest reliability as measured by the intraclass correlation coefficient between the first and repeat questionnaires was 0.98. The BRAFF-NRS scores were compared with the FACIT fatigue scores. There was an excellent correlation between the BRAFF-NRS and FACIT fatigue ($r=-0.83$ ($p<0.001$)).

STUDY PHASE-2: IDENTIFYING THE POTENTIAL CLINICAL ASSOCIATIONS OF FATIGUE BY USING BRAFF-NRS (n=283)

On multiple linear regression analysis, the model predicted the significant association of low education status ($p=0.03$), number of deformed joints ($p=0.01$), not achieving MDA ($p<0.001$), higher CCI scores and worse HAQ ($p<0.001$) with worse fatigue scores.

Conclusions: BRAFF-NRS provides a reliable, reproducible and valid instrument of measuring fatigue in PsA. Fatigue is associated with low education status, higher number of deformed joints and comorbidities, not achieving remission and worse functional index. This short assessment tool can be especially valuable in the context of a busy clinic, and also in large epidemiological studies when other core domains warrant assessment.

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THU0321 ACUTE PHASE MARKERS IN PSORIATIC ARTHRITIS IDENTIFY PATIENTS WITH A MORE SEVERE PHENOTYPE

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Background: CRP and ESR are the most commonly and probably the most studied inflammatory markers among patients with inflammatory arthritis. In contrast to rheumatoid arthritis, however, these markers are raised in less than 50% of people with psoriatic arthritis (PsA). Little is known about the long term significance of elevated inflammatory markers during the course of PsA disease.

Objectives: In a well characterised PsA cohort with a long term follow up, we examined the association of CRP and ESR over the disease course with demographics, clinical and radiographic features, patient reported outcome measures and the number of comorbid conditions.

Methods: A cohort of 283 PsA patients all meeting CASPAR criteria and attending rheumatology clinics were evaluated. All underwent detailed skin and rheumatologic assessments, along with cardiovascular risk factor evaluation. Moreover, we documented the presence/absence of comorbidities using the Charlson Comorbidity Index (CCI). All of these patients had CRP and ESR laboratory values assessed along with the other routine laboratory parameters during the disease course. For each patient, we documented CRP and ESR values at 3 different time points: firstly, at the time of the initial diagnosis; secondly, the highest value of CRP and ESR recorded during the disease course; and thirdly at the time of full assessment for this study. Cumulative inflammation over time was