Targeted proteomics data from the PsA and Pso patients was subjected to univariate and multivariate analysis using a leave one out cross validation approach. The initial results revealed that the application of the PAPRICA method to the BIOCOM-Pso samples resulted in a dataset in which 88 of the 206 PAPRICA proteins could be reliably measured (CV Area < 20%; Signal to Noise ratio > 5; Library Dot Product > 0.8). This subset of the PAPRICA proteins was not able to discriminate between PsA and Pso and none of the associated peptides were significantly different between the two groups (p value < 0.05).

Conclusion: Analysis of a subset of 88 of the 206 biomarker proteins in the PAPRICA method, in patients with PsA and Pso, did not reveal peptides (proteins) that were statistically different between these two groups. Multivariate analysis generated a model that was unable to discriminate between patients with PsA and Pso. The possibility that the full PAPRICA assay may be able to discriminate between PsA and Pso will be explored, as will supplementing the PAPRICA method with additional biomarkers including proteins that may be identified in an unbiased proteome wide screen of PsA vs Pso serum samples.

Disclosure of Interests: None declared


SAT0643

FACIT-FATIGUE TO PROMIS-FATIGUE CROSS-WALKED DATA FROM MONARCH, MOBILITY AND TARGET RANDOMIZED CLINICAL TRIALS OF SARILUMAB FOR THE TREATMENT OF MODERATE-TO-SEVERE ACTIVE RHEUMATOID ARTHRITIS (RA)

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Background: Fatigue is a common symptom in RA and increasingly recognized as an important therapeutic target in disease management. Phase 3 randomized clinical trials (RCTs) have shown significant improvements in fatigue for sarilumab, based on the 13-item Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue measure. In TARGET and MOBILITY (including Week 52 CFB) and sarilumab 200mg SC Q2W vs adalimumab 40mg SC Q2W monotherapies in MONARCH. This systematic review was conducted in accordance with the Preferred Reporting Items for systematic reviews and Meta-analysis (PRISMA) statement. All articles available in English, published from June 1967 to March 1, 2018, in PubMed, EMBASE, PsycINFO, Cochrane Library and EULAR Library for Outcome Measure were screened as well as extensive hand search. Study selection and data collection were performed by four independent reviewers. All data were extracted using a standardized template designed for this review. Each outcome was characterized according to the OMERACT Filter 2.0 considering core areas (pathophysiological manifestations, life impact, death, resource use) and domains [Ref].

Objectives: To describe patient-level, cross-walked PROMIS-fatigue and MOBILITY outcomes in fatigue for sarilumab, based on the 13-item Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue measure. In TARGET and MOBILITY, Week 24 LSM CFB for cross-walked PROMIS-Fatigue scores ranged from -6.10 to -7.22 for sarilumab 150mg and -6.76 to -7.05 for sarilumab 200mg (-6.72 and -6.94 Week 52 CFB) in MOBILITY, respectively and -4.08 to -4.90 for placebo (-4.34 Week 52 CFB). △LSM was significant (p < 0.05) for sarilumab vs placebo for both doses, in both RCTs. In MONARCH, Week 24 LSM was -5.80 for adalimumab and -7.24 for sarilumab, with non-significant △LSM. T-scores on 13- and 10-item PROMIS-fatigue obtained similar results across all studies (Table).

Conclusion: Consistent with trial results shown for FACIT-Fatigue, following cross-walk to PROMIS-Fatigue and on PROMIS-Fatigue 13 and 10 T-scores, patients treated with sarilumab demonstrated statistically greater and clinically meaningful improvement in fatigue vs placebo and a trend towards greater improvement vs adalimumab. Converting FACIT-fatigue data to PROMIS-fatigue using either the patient level cross-walk or via the patient level scoring service provides a common metric for comparisons of fatigue outcomes across treatments for RA and against US clinical population reference scores.

Green boxes P < 0.05; * P < 0.001

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SAT0644

OUTCOME MEASURES IN NEUROPSYCHIATRIC SYSTEMIC LUPUS ERYTHEMATOSUS

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Background: Neuropsychiatric involvement in Systemic Lupus Erythematosus (NPSLE) is one of the most complex and severe expressions of the disease consisting of a variety of neurological and psychiatric syndromes. To date the NPSLE spectrum is lacking in validated disease activity instruments to support specific interventions. This absence of standardization for defining response to therapy is one of the most important barriers to test new therapeutic strategies or drugs in controlled clinical trials in NPSLE.

Objectives: To identify the instruments used to assess NPSLE in published studies according to the OMERACT (Outcome Measures in Rheumatology) Filter 2.0 [Ref].

Methods: This systematic review was conducted in accordance with the Preferred Reporting Items for systematic reviews and Meta-analysis (PRISMA) statement. All articles available in English, published from June 1967 to March 1, 2018, in PubMed, EMBASE, PsycINFO, Cochrane Library and EULAR Library for Outcome Measure were screened as well as extensive hand search. Study selection and data collection were performed by four independent reviewers. All data were extracted using a standardized template designed for this review. Each outcome was characterized according to the OMERACT Filter 2.0 considering core areas (pathophysiological manifestations, life impact, death, resource use) and domains [Ref].

Results: Of 2,625 abstracts, we included in the review 62 studies of which 1 randomised clinical trial (1.6%, 32 patients), 4 systematic literature reviews (6.4%, 8,024 patients), 21 cohort studies (33.8%, 2,684 patients) and 36 observational studies (58.1%, 1,534 patients), with a total of 12,274 patients. Patients were predominantly female (89.6%) with a mean±SD age of 34.9±5.8 years. The mean disease duration was 5.1±2.2 years (range 1 - 9.6). The most frequent included events were seizures (34 studies, 54.8%), cerebrovascular disease (30 studies, 48.4%), psychosis and myelopathy (29 studies, 46.8%), mood disorders (28...