

biological (51%), articular (38%), haematological (24%) and glandular (22%). Low DAS was reported in 4480 (56%) patients, moderate DAS in 2483 (31%) and high DAS in 1098 (14%) patients. The mean baseline ESSDAI was higher the younger the patient was ( $p < 0.001$ ), higher in White patients (6.9 vs 5.1,  $p < 0.001$ ), males (8.4 vs 6.2,  $p < 0.001$ ), those with positive ocular (6.7 vs 4.9,  $p < 0.001$ ) or oral (6.8 vs 6.2,  $p = 0.016$ ) tests, and those with ANA (6.9 vs 4.5,  $p < 0.001$ ), RF (7.5 vs 5.8,  $p < 0.001$ ) and anti-Ro/La antibodies (7.2 vs 4.4,  $p < 0.001$ ). Logistic regression identified as independent variables White ethnicity (OR 3.07), abnormal ocular tests (OR 2.14), ANA (OR 1.67) and Ro/La autoantibodies (OR 2.78).

**Conclusions:** This is the largest series of patients with primary SS in whom the ESSDAI score has been evaluated. Primary SS is undeniably a systemic disease even at the time of diagnosis, with nearly 80% of patients showing an ESSDAI score  $> 0$ .

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**THU0682 POPGEN-OSSA: DEVELOPMENT OF AN ORGAN SPECIFIC SELF ASSESSMENT (OSSA) FOR INTERDISCIPLINARY DOCUMENTATION OF PATIENT REPORTED CLINICAL OUTCOMES**

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**Background:** Patient reported outcome measures are comprised of either sets of questionnaires or patient global assessment based on visual analogue scale (VAS). These patient-reported outcome measures lack accuracy and/or clinical feasibility when comparing heterogeneous patient groups with different diseases, or when characterizing patients with systemic disease involving different organ systems.

**Objectives:** Developing a clinical feasible patient-reported outcome measure based VAS assessment of different organ systems.

**Methods:** Patients were asked to rate their health status in a 10cm VAS (0–100%) concerning their global health as well as of different organ systems, namely heart, lung, muscle and joints, gastro-intestinal, metabolic, uro-genital, skin, neuro-psychiatric, eyes and ears. All VA-scales were “anchored”. Patients were advised to rate their health status below 75% if they felt “medical action is needed”, they should rate the health status  $< 50\%$  in case of a “strong need for medical action” and  $< 25\%$  in case of a “medical emergency”.

336 patients from different outpatient clinics (cardiologic, pneumologic, gastro-intestinal, nephrologic, neurologic, dermatologic, rheumatologic, ophthalmologic and obesity outpatient clinic) as well as patients from internal emergency clinics and a general practitioner clinic were evaluated. Both, patients and the attending physicians completed the Popgen-OSSA. In addition the attending physician was asked to document ranking of the 5 most important diagnoses of the patient.

Statistical analysis was carried out using non-parametric testing. Furthermore, to predict main diagnoses based on patients' as well as physician's OSSA state-of-the-art machine learning tools, namely support vector machines (SVMs), were applied. To assess model performance multi-class AUC (area under the ROC curve) according to Hand and Till (2001) was estimated based on repeated cross validation (10 folds, 5 repeats), optimizing the SVM's hyperparameters using grid search.

**Results:** The test showed a good reproducibility. With a mean percentage of  $74 \pm 0.98$  SE and  $66 \pm 1.17$  SE, respectively, the physicians OSSA rating was significantly higher than the rating of the patients ( $p_{\text{Wilcoxon}} < 0.001$ ). Models predicting main diagnoses were constructed and estimated to perform with multi-class AUCs of 63.5% and 73.4% based on patient's and physician's OSSA, respectively.

**Conclusions:** In this preliminary trial with low sample size the Popgen-OSSA showed a good reproducibility and allowed a correct allocation of the patient's clinical problem to involved organ system by SVM analysis with multi-class AUC of up to 73.4%. These data merit further investigation and development of the Popgen-OSSA on larger patient cohorts.

**References:**

[1] David J. Hand and Robert J. Till (2001). A Simple Generalisation of the Area Under the ROC Curve for Multiple Class Classification Problems. *Machine Learning* 45(2), p. 171–186. DOI: 10.1023/A:1010920819831.

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**THU0683 RAPID DETERMINATION OF THE INFLAMMATION MARKER CALPROTECTIN IN SERUM FROM PATIENTS WITH INFLAMMATORY ARTHRITIS AT THE POINT OF CARE**

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**Background:** A Treat-to-Target (T2T) strategy for inflammatory arthritis, targeting remission or minimal disease activity, is the recommended treatment approach by EULAR and ACR. This strategy relies on “tight monitoring” which necessitates regular clinical examination and measuring acute-phase reactants such as C-reactive protein. Calprotectin (MRP8/14; S100A8/A9), a relatively novel inflammation and disease activity marker in the arthritis field, exhibits several features which fit the “theranostic needs” for accurate therapy monitoring. Those features include discrimination between responders and non-responders [1], detection of subclinical disease activity [2] and prediction of relapse or radiographic progression [3]. The classical method to determine calprotectin in serum (sCAL) is ELISA which is used in service or central laboratories. A rapid and simple determination of sCAL at the point of care is a substantial step forward in supporting clinicians to deliver an efficient T2T strategy. Here, we report on the validation of a quantitative, rapid test which can measure sCAL within 15 minutes.

**Objectives:** (1) To demonstrate the performance evaluation of a quantitative lateral flow assay combined with a dedicated test reading device for a rapid quantification of calprotectin in serum; and (2) to compare results to a well-established laboratory reference method using patient samples.

**Methods:** The Quantum Blue<sup>®</sup> sCAL sandwich lateral flow immunoassay uses two highly specific monoclonal antibodies immobilized on the test membrane and on the gold label. 10 $\mu$ L of serum was diluted in 90 $\mu$ L of chase buffer, 60 $\mu$ L of this mixture was applied onto the lateral flow test cassette, which was incubated for 12 minutes at ambient temperature and then measured with the BÜHLMANN Quantum Blue<sup>®</sup> Reader. Performance evaluation (sensitivity, linearity, high-dose hook effect, interferences) was carried out according to CLSI guidelines. A method comparison based on 178 serum samples from RA and PsA patients was performed against the BÜHLMANN sCAL (MRP8/14) reference ELISA.

**Results:** The linearity study over the complete measuring range together with the observed limit of quantification (LoQ) of  $< 0.5$   $\mu$ g/mL allowed a quantitative measurement in the clinically relevant range from 0.5 to 10.0  $\mu$ g/mL calprotectin. No high dose hook effect was observed up to a concentration of 200  $\mu$ g/mL. Moreover, no interferences were detected with triglycerides (37mmol/L), conjugated bilirubin (342 $\mu$ mol/L), unconjugated bilirubin (342 $\mu$ mol/L), and hemoglobin (200mg/dL). The Quantum Blue<sup>®</sup> sCAL lateral flow assay showed an excellent linear correlation ( $r = 0.94$ , slope = 1.05) to the BÜHLMANN sCAL (MRP8/14) reference ELISA. There was a negligible bias of -3.1% by Bland-Altman difference plot between the sCAL lateral flow assay and ELISA.

**Conclusions:** Rapid quantification of serum calprotectin using the Quantum Blue<sup>®</sup> sCAL assay represents a fast and reliable method for the determination of inflammation and the disease activity of a patient with inflammatory arthritis at the point of care. This rapid test shows excellent agreement to a corresponding laboratory reference method.

**References:**

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[2] Inciarte-Mundo J. *Arthritis Res Ther* (2016);18:160.

[3] Hurnakova J. *Arthritis Res Ther* (2015);17:252.

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**THU0684 WORK IMPACT IN AXIAL SPONDYLOARTHRITIS: THE AS-WIS QUESTIONNAIRE PREDICTS THE RISK OF WORK IMPACT: A LONGITUDINAL STUDY OF 101 PATIENTS**

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**Background:** Axial spondyloarthritis (axSpA) mainly affects the working-age subject and can have a moderate (short-term sick leave) or significant (long-term sick leave, disability status, unemployment) work impact.

**Objectives:** To evaluate the value of a simple and short (2 minutes) questionnaire, the AS-Work instability scale (AS-WIS) to predict the work impact of axSpA after 1–2 years.

**Methods:** Longitudinal study in 3 centers in Paris, France. Patients with axSpA according to the rheumatologist and the ASAS criteria were included. Patients were asked twice (1 to 2 year interval) to answer questionnaires evaluating: disease activity, demographic characteristics, impact on work (short-term and long-term sick leave, disability, unemployment), and the ASWIS questionnaire (1): a 20 item, simple screening tool for Work Instability (the consequences of a mis-match between an individual's functional ability and their work tasks). The risk of disability is assessed as low if the score is  $< 11$ , medium between 11–18 and high  $> 18$ . Only patients who answered both questionnaires were included for analyses. Statistical analyses included descriptive analyses and univariate/ multivariate

analyses to search for baseline factors of work impact at 1–2 years (including a medium/high ASWIS score, gender, age, schooling level, BASDAI, BASFI).

**Results:** Among the 188 patients who answered the first questionnaire, 144 were currently working and were asked to answer the second questionnaire. A total of 101 patients answered both questionnaires. Mean age at inclusion was 45 (SD 9) years, 52% were male, disease duration was 14 (SD 8) years and 62% had an education level equivalent to more than high school. The BASDAI and the BASFI were respectively 34 (SD 21) and 23 (SD 23). At baseline, median ASWIS was 10, a low-risk score was found in 55 patients (54%), and a medium/high risk score in 46 (46%).

1–2 years later, 37 patients (36%) had work impact: 25 patients (25%) a short-term sick leave, and 12 patients (12%) a significant work impact (long-term disability or unemployment due to Ax-SpA).

Among patients with a low ASWIS score at baseline (n=55), only 13 (24%) had a work impact (including only 2 with a significant impact). Among patients with a medium/high ASWIS score (n=46), 24 (52%) had a work impact (including 10 patients of a significant impact).

In univariate analysis, baseline factors associated with work impact (moderate or significant) were a medium/high ASWIS score, a high BASFI and a shorter disease duration. In multivariate analysis, medium/high ASWIS (odds ratio, OR 2.71 (1.04–7.22)) and a lower disease duration (0.94 (0.89–0.99)) were independent predictive factors of work impact.

**Conclusions:** In patients with axSpA, a medium/high ASWIS score was followed by a work impact in 50% of cases within 2 years in this well-controlled population. This short questionnaire can be helpful to screen for future difficulties at work, whatever the stage of disease.

#### References:

[1] Gilworth G, et al. Reducing work disability in ankylosing spondylitis: development of a work instability scale for AS. *BMC Musculoskeletal Disorders* 2009 Jun 16;10:68.

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### THU0685 ASAS HEALTH INDEX FOR PATIENTS WITH SPONDYLOARTHRITIS: TRANSLATION INTO PORTUGUESE, VALIDATION, AND RELIABILITY

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**Background:** The Assessment of SpondyloArthritis international Society Health Index (ASAS HI), is a unidimensional questionnaire, that includes 17 items, measuring functioning and health in patients with spondyloarthritis (SpA) (1). At the beginning of this project, only an English version of the instrument existed.

**Objectives:** The aim of this study was to conduct the cross-cultural adaptation of the ASAS-HI into European Portuguese language and investigate its reliability and validity in a sample of Portuguese patients with SpA.

**Methods:** The ASAS-HI has a range from 0 (best health state) to 17 (worst health state). The questionnaire was first translated and then back translated following published guidelines. Patients fulfilling ASAS classification criteria for either axial (axSpA) or peripheral SpA (pSpA) were included. Reliability was assessed through internal consistency coefficient, and internal consistency was assessed using Cronbach's alpha. Construct validity was assessed through Spearman's correlation analyses between the ASAS-HI and the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Ankylosing Spondylitis Disease Activity Score-CRP (ASDAS-CRP), and the Short Form (36) Health Survey (SF-36) (physical) SF-36 (physical) for convergent validity and between the ASAS-HI and the HAD-S Anxiety/Depression, and SF-36 (mental) for divergent validity. Discriminative validity was tested comparing the ASAS-HI across ASDAS-CRP disease activity states using the Kruskal-Wallis test.

**Results:** In total, 86 patients were included: 65% male, mean (SD) age 47.1 (12.9) years, symptom duration 11.4 (11.0) years, BASDAI 3.1 (2.1), BASFI 2.2 (2.6), ASDAS-CRP 2.2 (0.8). The diagnosis of axSpA was established in 58 patients (AS =45, nr-axSpA =13) and of pSpA in 28 patients. The forward backward translation was successful and qualitative interviews raised no further comments of the patients. The total mean score of the ASAS-HI was 4.6 (3.8). The ASAS-HI showed an excellent test-retest reliability (n=72) (ICC=0.93: 95% CI=0.89;0.96, p<0.001) and a good internal consistency (Cronbach's- $\alpha$  of 0.87). According to the predefined hypothesis, the ASAS-HI correlated strongly with the BASDAI (0.76, p<0.001), SF-36 (physical) (-0.75, p<0.001), moderately well with the HAD-S Anxiety (0.41, p<0.001), and SF-36 (mental) (-0.44, p<0.001) (Table 1), and showed a good discriminatory capacity across the different levels of disease activity (p<0.001) (Table 2).

**Table 1 – Correlation between ASAS-HI at baseline and other health outcomes**

| Characteristics          | R     | P value |
|--------------------------|-------|---------|
| BASDAI (0-10)            | 0.76  | <0.001  |
| BASFI (0-10)             | 0.63  | <0.001  |
| ASDAS-CRP                | 0.64  | <0.001  |
| SF-36 (physical) (0-100) | -0.75 | <0.001  |
| SF-36 (mental) (0-100)   | -0.44 | <0.001  |
| HAD-S Anxiety            | 0.41  | <0.001  |
| HAD-S Depression         | -0.05 | 0.660   |

**Table 2 - Discriminant ability of ASAS-HI (at baseline) stratified by disease activity (mean±SD)**

|         | ASDAS-CRP      |                 |             |                 | p-value |
|---------|----------------|-----------------|-------------|-----------------|---------|
|         | Inactive (N=9) | Moderate (N=30) | High (N=32) | Very high (N=6) |         |
| ASAS-HI | 1.6 (1.5)      | 2.3 (2.0)       | 6.2 (4.1)   | 8.1 (3.3)       | <0.001  |

**Conclusions:** The findings of this study showed that the Portuguese version of the ASAS-HI is a comprehensible questionnaire that is reliable and valid. Therefore, its use can be recommended, both for clinical practice and research purposes, to assess the state of health and functioning in Portuguese SpA patients. Future research is needed to evaluate the responsiveness of the ASAS-HI in SpA patients.

#### References:

[1] Kiltz U et al. *Ann Rheum Dis*. 2015;74(5):830–5.

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### THU0686 HEART RATE VARIABILITY IN INFLAMMATORY JOINT DISEASE. A META-ANALYSIS

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**Background:** Autonomic dysfunction is an established predictor of all-cause mortality and post-myocardial infarction mortality. It has been suggested to be a pathogenic factor for the development of cardiovascular disease (CVD) in the general population, possibly acting through the impact of the autonomic nervous system on inflammation [1]. Heart rate variability (HRV) is a marker of cardiac autonomic function and is increased in many conditions including chronic widespread pain. HRV is responsive to physical exercise. Inflammatory joint diseases (IJD) are characterised by joint inflammation and symptoms include pain, functional decline and restricted movement. Patients with IJD have an increased risk of premature death due to CVD.

**Objectives:** To compare HRV between adult patients with IJD and healthy controls, using the "Preferred Reporting Items for Systematic Reviews and Meta-Analyses" (PRISMA) methodology, and to describe the associations between IJD disease activity, pain and physical activity, and HRV.

**Figure 1** Flow chart literature search

