Table: Scores, differences, SDD and ICC for hospital and home PROs.

	Hospital, mean (SD)	Home, mean (SD)	Difference, mean (95% CI)*	SDD	ICC (95% CI)
Rheumatoid arthritis (RA)					
HAQ (0-3)	0.580 (0.499)	0.619 (0.531)	-0.040 (-0.283, 0.204)	0.244	0.984 (0.962, 0.994)
VAS pain, mm	25.5 (24.2)	24.2 (23.8)	1.3 (-15.3, 17.7)	16.4	0.969 (0.927, 0.987)
VAS fatigue, mm	35.6 (30.4)	33.1 (30.3)	2.4 (-15.8, 20.7)	18.2	0.975 (0.942, 0.990)
VAS global, mm	34.0 (29.8)	34.8 (30.7)	-0.81 (-18.3, 15.4)	16.1	0.982 (0.955, 0.993)
Spondyloarthritis (AS)					
HAQ (0-3)	0.356 (0.307)	0.319 (0.276)	0.038 (-0.215, 0.290)	0.253	0.947 (0.868, 0.979)
VAS pain, mm	25.2 (22.6)	23.5 (21.6)	1.7 (-10.6, 14.0)	12.3	0.979 (0.948, 0.992)
VAS fatigue, mm	33.8 (23.8)	32.4 (23.7)	1.4 (-11.6, 14.4)	13.0	0.980 (0.951, 0.992)
VAS global, mm	30.9 (25.9)	30.3 (28.2)	0.6 (-7.3, 18.4)	17.8	0.972 (0.930, 0.989)
BASDAI, mm	26.0 (20.7)	24.4 (21.1)	1.6 (-8.6, 11.8)	10.2	0.983 (0.959, 0.993)
BASFI, mm	27.8 (22.7)	25.9 (23.8)	1.9** (-6.4, 10.2)	8.3	0.990 (0.974, 0.996)

*Spearman's rho>0.9 for all items

**p<0.05 (Wilcoxon rank sum test for difference between hospital and home scores)

results comparable to results obtained from the existing touch-screen solution and were preferred by the patients.

References:

[1] Scheffe et al. (2010).

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THU0663 SERUM GALECTIN-3 BINDING PROTEIN IS A NOVEL PREDICTOR OF VENOUS THROMBOEMBOLISM IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)

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Background: SLE patients have a marked increased risk of venous (VTE) and arterial (AT) thrombosis, which is not fully explained by traditional risk factors or the presence of anti-phospholipid antibodies. Thrombosis is a major cause of damage accrual, morbidity, and mortality in SLE. A better understanding of the pathogenesis and development of new biomarkers to identify patients at risk are needed. Recent studies link leptin and tumor necrosis factor-like weak inducer of apoptosis (TWEAK) to subclinical atherosclerosis and galectin-3-binding protein (G3BP) to type I interferon activation and a pro-thrombotic environment.

Objectives: To explore G3BP, interferon gamma-induced protein 10 (IP-10), soluble CD163 (sCD163), TWEAK, and leptin serum levels as predictors of venous and arterial thrombotic events, damage accrual, and all-cause mortality during long-term follow-up in a large cohort of Swedish SLE patients.

Methods: Baseline clinical and paracrine data including disease activity and damage scores (SLICC) were available from 167 SLE patients. VTE (deep vein thrombosis and/or pulmonary embolism) and AT (myocardial infarction and/or cerebrovascular incident) data were available with a median follow-up period of six years. Baseline serum G3BP, IP-10, sCD163, TWEAK, and leptin were quantified using ELISA. Univariate and multivariate analyses were conducted to assess associations between the serum biomarkers and the occurrence of VTE/AT, damage accrual, and death.

Results: In the follow-up period 11 (7%) VTE and 12 (7%) AT events occurred. SLICC-scores increased in 79 (47%) patients, and 19 (11%) patients died. In the univariate Cox regression analysis G3BP levels were significantly associated with an increased risk of VTE (hazard ratio (HR) 1.10, 95% confidence interval (CI): 1.01–1.2, $P=0.03$). This persisted in the multivariate cox regression analyses when adjusting for age, gender, diabetes, antiphospholipid syndrome, and treatment with warfarin (HR 1.16, 95% CI: 1.04–1.31, $P=0.01$). None of the other serum biomarkers were associated with AT and VTE. No significant associations were observed between the biomarkers and changes in SLICC-scores or all-cause mortality.

Conclusions: Our study identifies serum G3BP as a novel independent predictor of VTE in SLE. This may improve our understanding of VTE pathogenesis in SLE and aid future VTE risk stratification and prophylaxis. Further studies are needed to translate this into clinical practice.

Disclosure of Interest: None declared

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THU0664 TRANSLATION, CULTURAL ADAPTATION AND VALIDATION OF THE SYSTEMIC LUPUS ACTIVITY QUESTIONNAIRE (SLAQ) IN A COHORT OF ITALIAN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)

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Background: Evaluation of disease activity is one of the most important assessments in SLE; several instruments have been developed based on clinical and laboratory information recorded by the physician. Patient-administered questionnaires provide useful information with significant time and cost saving. Indeed, patient-reported outcomes are gaining a central role as outcome measures. SLAQ is a patient-reported instrument for the assessment of disease activity in SLE. It consists of three scores: Patient Global Assessment question (PGA) about presence and severity of lupus activity over the past month, questions on 24 symptoms (SLAQscore) and a single Numerical Rating Scale (NRS) for disease activity (0–10).

Objectives: The aim of the study was to translate and to validate the SLAQ in Italian.

Methods: The process of translation and cultural adaptation followed published guidelines (1). The final version of the questionnaire (SLAQit) was pretested in a group of 35 SLE patients to assess acceptability, comprehension and feasibility. The validity of the SLAQit was evaluated by its administering to consecutive SLE patients attending the outpatient's clinic or the inpatients wards. Internal consistency between the three components of the score was evaluated by Chronbach's alpha; the external validity was tested toward validated activity indices (SLEDAI and ECLAM) scored by a physician blinded to the SLAQ results. In a subgroup of 30 patients the questionnaire was administered twice at 2 weeks' interval to assess its reliability.

Results: 137 patients were enrolled (92% female, mean age 43.1 years, mean disease duration 15.3 years). At enrollment, the median SLEDAI score was 2 (range 1–18) and 45% of patients had at least one organ damage (median 2, 1–8). The pilot test provided a good acceptability (99.9% of response rate) and feasibility (mean of 4.6±2.3 minutes to be completed, 1–10); moreover, the 100% of patients declared to comprehend the scope of the SLAQ and 67.5% declared no content comprehension problems. Internal consistency was very good between (NRS vs PGA vs SLAQscore ($\alpha=0.79$). NRS and PGA showed a linear correlation with both ECLAM and SLEDAI scores ($\rho=0.24$, $p=0.004$ and $\rho=0.45$, $p<0.001$ respectively), while the correlation with the SLAQscore didn't reach the statistical significance. SLAQit showed a very high reliability by comparing the test-retest results ($\alpha>0.8$ for NRS, PGA and SLAQscore). SLAQit scores resulted directly related to the patients age ($p=0.002$) and the SLICC score ($p=0.003$) while no correlation with disease duration was observed.

Conclusions: SLAQit demonstrated to be acceptable, comprehensible and feasible in our routine clinical setting; it also showed good internal consistency; correlation with physician's driven instruments is weaker and the SLAQit was influenced by epidemiological and disease-related factors (i.e. damage), thus confirming that the disease perception from the patient's perspective can be different from physicians and influenced by several factors. The SLAQit can be considered a useful screening tool for the first assessment of the disease activity before the standard visit.

References:

[1] Guillemin F, et al. Journal of Clinical Epidemiology 1993; 46: 1417–1432.

Disclosure of Interest: None declared

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THU0665 CAN ONE GIVE UP BASDAI IN FAVOR OF ASDAS IN MONITORING SPONDYLOARTHRITIS PATIENTS ON BIOLOGICS?

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Background: Disease activity in SpA is widely evaluated through BASDAI or ASDAS with no proven superiority between the two, in spite the more objective evaluation of ASDAS through the inflammatory markers.

Objectives: The aim of this study was to evaluate the clinical quality and discriminating power between the above indices when subdividing patients with anti-TNF therapy according to their disease status indicated by BASDAI, ASDAS or PtGA.

Methods: This prospective, observational study included 100 patients with definite SpA on biological therapy. Demographic, clinical and laboratory data was collected. Statistical analysis was performed with SPSS 20.0.

Results: When used as an external criterion PtGA showed that 12% of patients had active disease with a PtGA of over 5 while 88% were classified as low disease activity. Mean ASDAS-CRP and ASDAS-ESR in the active group were 3.39 and 3.24. Mean BASDAI score in the high activity group according to PtGA was 5.66. We showed that both ASDAS scores had good discriminating capacities, with similar values when using the SMD (2.0034 [95% CI 1.29–2.71]). Based on PtGA, BASDAI outperformed ASDAS scores with a SMD of 3.3391 [95% CI 2.5334–4.1447]. ROC curves of the disease activity scores by using the PtGA ≥ 5

as variable of high disease activity state showed the following: for ASDAS-CRP, ASDAS-ESR and BASDAI the AUCs (area under curve) were 0.89 (P=0.05; 95% CI 0.80–0.99), 0.88 (P<0.001; 95% CI 0.77–0.99), and 0.99 (P=0.009; 95% CI 0.97–1.00). For CRP and ESR the AUCs were 0.81 and 0.79. This shows the high accuracy of the three scores in assessing SpA activity, but with a lower fidelity of the inflammatory markers alone. When dividing patients according to BASDAI score, 14% showed a more active disease than the rest of 86% who had low disease activity. Mean ASDAS-CRP scores in the first group was 3.31. When correlating disease activity scores for the entire study group we observed that BASDAI correlated to both ASDAS scores ($r=0.65$ and 0.71 , $P<0.001$) and that PtGA showed a stronger correlation to BASDAI ($r=0.912$, $P<0.01$) than ASDAS and to acute phase reactants.

Conclusions: This study shows that disease activity scores have good discriminatory powers. BASDAI surpassed ASDAS scores when relating to the PtGA. According to Van der Heijde et al. (1), the only situation in which BASDAI can outperform ASDAS is when assessing the PASS (patient acceptable symptom state). However, ASDAS-CRP had better discriminatory power than ASDAS-ESR or acute phase reactants. This demonstrates that ASDAS-CRP is a more objective evaluation that can better differentiate patients with high or low disease activity.

References:

- [1] D van der Heijde, ASDAS, a highly discriminatory ASAS-endorsed disease activity score in patients with ankylosing spondylitis, *Ann. Rheum. Dis.*, vol. 68, Dec 2009.

Disclosure of Interest: None declared

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THU0666 PATIENT GLOBAL ASSESSMENT IS MORE SENSITIVE TO CHANGE THAN HEALTH-RELATED QUALITY OF LIFE INSTRUMENTS IN EARLY AXIAL SPONDYLOARTHRITIS OVER 3 YEARS: DATA FROM THE DESIR COHORT

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Background: Several questionnaires assess similar constructs of global patient-reported state or Health-Related Quality of Life (HRQoL).

Objectives: To evaluate sensitivity to change (ie, discriminance) of several questionnaires in early axial spondyloarthritis (axSpA) over 3 years of follow up: the SF36, axial spondyloarthritis quality of life (ASQoL), axial spondyloarthritis health assessment questionnaire (AS-HAQ) and patient global assessment (PGA).

Methods: DESIR is an ongoing prospective, multicenter, longitudinal, observational French cohort (1). Patients had inflammatory back pain of more than 3 months and less than 3 years suggestive of axSpA. For our analysis, only patients with no missing data for MCS and PCS SF36 values during the first 3 years were included. A global construct of patient global state was assessed by the SF36 questionnaire and its 2 subscales (scored 0–100 with higher scores indicating better status): the physical composite score (PCS) and the mental composite score (MCS), ASQoL, a disease-specific HRQoL scale, PGA and AS-HAQ. ASDAS-CRP was used as comparator. Each outcome was assessed at baseline, 6 months, 12 months, 24 months and 36 months. Standardized mean differences (SMD) were calculated using Cohen's effect size with confidence intervals, between each time point for each outcome. A SMD <0.5 is usually considered small, between 0.5 and 0.8 moderate and >0.8 as important.

Results: In all, 442 patients were analyzed: at baseline, mean age was 34.2±8.6 years; mean disease duration was 18.6±10.7 months; 239 (54%) were females, 274 (62%) had HLAB27 and 124 (28%) had radiological sacroiliitis. At baseline, patients were not in an optimal state; improvement was clear up to month 6 then minimal (at the group level): Table. Sensitivity to change was greatest for PGA, then ASQoL whereas AS-HAQ, MCS and PCS appeared the least discriminant measure (Table).

Conclusions: PGA was more sensitive to change than HRQoL measures in early

axSpA. ASDAS appeared also sensitive to change. Changes in all the measures were very small at the group level after 6 months of follow-up indicating the concepts conveyed may be as much patient- as disease-related.

References:

- [1] Dougados M. et al. Clinical presentation of patients suffering from recent onset chronic inflammatory back pain suggestive of spondyloarthritis: The DESIR cohort. *Joint Bone Spine*. 2015;82(5):345–51.

Disclosure of Interest: None declared

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THU0667 A QUALITATIVE AND QUANTITATIVE COMPARISON OF SYNOVIAL BIOPSY TECHNIQUES DURING CLINICAL TRIALS OF INFLAMMATORY ARTHRITIS

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Background: Synovial tissue is an attractive area of research for biomarkers of disease outcome in RA. Currently acquisition of synovial tissue using an arthroscopic approach in clinical trials is recommended though two US-guided techniques have been described, a portal and forceps (P&F) approach and an adaptation using a quick core needle (NB). However before US-guided biopsy techniques are widely adopted into clinical trials validation of performance against arthroscopy is required.

Objectives: To evaluate whether there were significant differences in synovial sampling quality and quantity between arthroscopic, US-P&F and US-NB procedures within the context of clinical trials.

Methods: This was a multicentre retrospective analysis of inflammatory arthritis patients recruited to clinical trials utilizing US-guided NB (Barts Health NHS Trust), US-guided P&F (ICRSS Policlinico San Matteo and University Hospital Birmingham) and arthroscopic biopsy (Repatriation General Hospital).

Paraffin embedded synovial sections from each procedure underwent H&E staining and sections examined for intact cell lining layer (graded sections). Biopsy procedures were segregated into large (knee) and small joint procedures (wrist/MCP) for analysis. Proportion of samples yielding graded tissue per procedure was recorded. Using CellSens Dimensions software the mean area of synovial tissue obtained per procedure was determined. In addition the degree of synovitis was assessed using semi-quantitative scoring (0–9).

Results: 78 patient procedures were evaluated, 22 on small joints (11 US-NB, 11 US P&F) and 56 on large joints (11 US-NB, 35 US-P&F, 10 arthroscopic). 47 patients had RA, 11 undifferentiated arthritis and 10 psoriatic arthritis. Arthroscopic sampling resulted in a significantly higher area of tissue retrieved per procedure than US P&F or US-NB. There were no significant differences in proportion of graded samples per procedure suggesting quality of synovial tissue was preserved between techniques. Finally no significant differences in degree of histological synovitis were demonstrated between sampling techniques.

Conclusions: The results suggest that US-guided biopsy provides a reliable method for sampling synovial tissue of comparable quality to that obtained from arthroscopy. However when sampling large joints arthroscopic techniques, and when sampling small joints US-P&F yield a significantly higher quantity, though not quality, of tissue per procedure than US-NB. These results may influence choice of biopsy technique when designing clinical trial protocols in inflammatory arthritis.

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Abstract THU0666 – Table 1. Sensitivity to change (SMD (95% CI)) of different outcomes in early axSpA over 3 years

	Baseline value (mean ± SD)	SMD between baseline and M6 [95% confidence interval (CI)]	SMD between M6 and M12 [95% CI]	SMD between M12 and M24 [95% CI]	SMD between M24 and M36 [95% CI]
PCS	40.5±9.2	0.27 [-0.41; 0.14]	0.02 [-0.11; 0.15]	0.02 [-0.11; 0.16]	-0.02 [-0.15; 0.11]
MCS	40.4±11.0	-0.26 [-0.39; -0.13]	0.02 [-0.11; 0.16]	-0.08 [-0.21; 0.05]	0.00 [-0.13; 0.13]
PGA	6.1±2.2	0.69 [0.56; 0.83]	0.09 [-0.04; 0.22]	0.06 [-0.07; 0.19]	0.05 [-0.08; 0.18]
ASQoL	9.1±5	0.36 [0.22; 0.49]	-0.01 [-0.14; 0.12]	0.02 [-0.12; 0.15]	0.00 [-0.14; 0.13]
AS-HAQ	0.63±0.5	0.24 [0.11; 0.38]	-0.04 [-0.17; 0.09]	0.02 [-0.11; 0.15]	0.00 [-0.13; 0.13]
ASDAS-CRP	2.6±0.98	0.52 [0.38; 0.65]	-0.03 [-0.17; 0.10]	0.06 [-0.08; 0.20]	0.10 [-0.04; 0.24]

Abstract THU0667 – Table 1

Mean (SD)	Small joint biopsies			Large joint biopsies		
	US –NB (n=11)	US P&F (n=11)	P value	US-NB (n=11)	US P&F (n=35)	Arthroscopic (n=10)
Joint biopsied	7 wrist 5 MCP	1 wrist 10 MCP		10 knee	32 knee 3 ankle	10 knee
% graded samples per procedure	82.3 (22.4)	91 (10)	0.34	89.8 (17.5)	83.23 (19)	97 (11)
Mean area of tissue (mm ²) per procedure	3.19 (1.75)	7.95 (4.91)	<0.005*	4.66 (3.19)	8.8 (8.17)	17.64 (7.56)
Synovitis score	4.9 (3.2)	NA	NA	3.8 (2.6)	4.53 (2.26)	4.5 (1.71)

0.08
<0.0001*