

studies assessing its sensitivity to change will inform whether MVF can be used as end point of skin microvascular involvement in SS.

References:

[1] C. Tolosa-Vilella et al. *Semin Arthritis Rheum* 46(2016):200–208.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2017-eular.6582

THU0660 POLYMYALGIA RHEUMATICA TREATMENT SERUM BIOMARKERS VERSUS RHEUMATOID ARTHRITIS

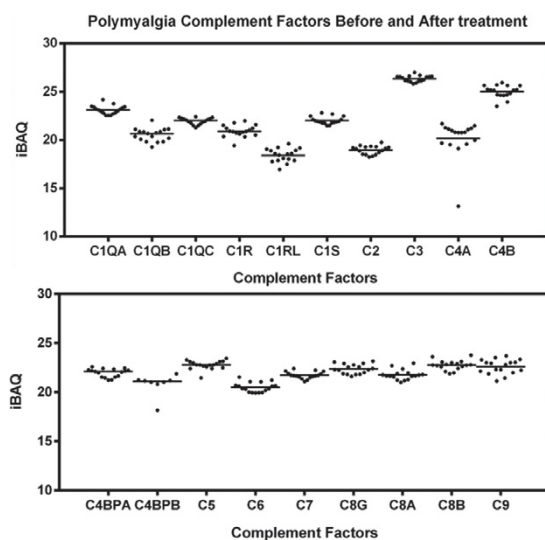
M.K. Meyer¹, M. Andersen¹, T.V. Stausbo², K.J. Elbæk², G.N. Andersen¹, A. Stensballe². ¹Department of Rheumatology, Nørmark Regional Hospital, Hjørring; ²Department of Health Science and Technology, Aalborg University, Aalborg, Denmark

Background: Polymyalgia rheumatica (PMR) is a systemic inflammatory disorder with unknown etiology and overlapping symptoms with giant cell arthritis and late-onset rheumatoid arthritis (RA). To date, no proteomics studies have been performed on PMR patients, and the number of biomarker studies remain limited.

Objectives: The primary aim of this study was to thoroughly investigate the corticosteroid treatment serum proteome of PMR with a focus on acute-phase reactions, complement system, and cytokines.

Methods: Filter-aided sample preparation for mass spectrometry, cell free DNA (cfDNA) assay, and 10plex cytokine assay were applied to PMR serum samples from the same patients before and after treatment, DMARD-naïve RA patients, and healthy controls.

Results: The core serum proteomes of the four groups were remarkably similar, and consisted of >200 proteins, which included acute-phase reactants, coagulation and complement proteins (figure), immunoglobulins, and apolipoproteins, and several more. Acute Phase Serum Amyloid A (SAA1) was differentially less abundant after PMR treatment, and CRP (after adjusting for two patients with low baseline CRP). cfDNA were more abundant in both groups of PMR compared to healthy controls. Complement factors were narrowly distributed and not affected by PMR treatment. The individual serum proteome of each PMR patient provided more than 100 differentially abundant proteins, and highlights the heterogeneity of patients.



Conclusions: We have established the core serum proteome of PMR in response to treatment, and compared it with RA and healthy controls. The results suggest a functional role of SSA1, and increased cfDNA in the pathogenesis of PMR indicates the activation of NETs.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2017-eular.5844

THU0661 CLINICAL RELEVANCE OF DETECTING ANTI-ADALIMUMAB ANTIBODIES WITH A DRUG-TOLERANT ASSAY

A. Martínez-Feito¹, L.Y. Bravo Gallego², B. Hernandez-Breijo¹, C. Plasencia¹, A. Jochems¹, M.A. Gonzalez², I. Monjo¹, D. Peiteado¹, G. Bonilla¹, P. Nozal², A. Balsa¹, D. Pascual-Salcedo¹. ¹Immuno-Rheumatology research group; ²Immunology, University Hospital la Paz, Madrid, Spain

Background: Adalimumab (Ada) has proven effective in treating rheumatoid arthritis (RA) and spondyloarthropathies (SpA), although approximately 30% of responders will present secondary clinical failure. Immunocomplex formation between antibodies to Ada (ATA) and Ada can increase drug clearance. Most of the assays to measure ATA present drug interference. Currently, different assays are available to measure total ATA (free and complexed).

Objectives: To compare the detection of ATA along Ada treatment between two

assays: one drug-sensitive and another drug-tolerant assay. Study the association of ATA with the clinical status.

Methods: This is a prospective observational study with 63 patients with rheumatic diseases under Ada treatment enrolled at Biological Therapy Unit of Hospital La Paz. Serum Ada levels were measured by ELISA and serum ATA levels by two assays: an in-house two-site (bridging) ELISA (bELISA) to detect uncomplexed ATA (free ATA) and a drug-tolerant assay developed by ImmundiagnostikÖ (Bensheim, Germany) (IDK) to measure simultaneously free and complexed ATA (total ATA). Samples were evaluated at 0, 0.2, 0.5, 1, 1.5 and 2 years after Ada initiation.

Results: Out of the 63 studied patients, 12 (19%) had RA and the rest (51, 81%) had different spondyloarthropathies (24, 38%) ankylosing spondylitis, 9 (14%) psoriatic arthritis, 14 (22%) undifferentiated spondyloarthritis and 4 (6%) spondyloarthritis associated with inflammatory bowel disease). Thirty-one patients (49%) received concomitant methotrexate (26% RA patients and 74% SpA patients), 13 (21%) received another DMARDs associated to Ada and 19 (30%) were on monotherapy. Out of the 63 patients, in 27 (43%) no ATA were detected. Thirty six patients (57%), were IDK+ and 12 patients (19%) were bELISA+ (all of them IDK+). The presence of ATA by bELISA was associated with absence of serum Ada levels. However, most (78%) samples with complexed ATA had low circulating Ada levels (1.65 mg/ml in ATA+ vs 6.25 mg/ml in ATA-, $p < 0.0001$). ATA appeared by IDK at earlier treatment stages than by bELISA, statistically different at all studied time points. In patients who dropped-out (30 patients, 48%) ATA detection was frequent and significant by both methods. Ten patients (33%) bELISA ATA+ dropped-out vs 2 patients bELISA ATA+ in those who continued treatment ($p < 0.0001$). Twenty four patients (80%) IDK ATA+ dropped-out vs 12 patients (36%) who continued treatment ($p < 0.0001$). The percentage of ATA detected by IDK was higher than by bELISA, with a tendency of more IDK ATA+ among patients with less survival (24,80% IDK positive vs 10,33% bELISA +; $p = 0.06$).

Conclusions: ATA are detected by a drug-tolerant assay at earlier stages of treatment than by bELISA. The antibodies formed early are associated with lower levels of circulating Ada, indicating higher drug clearance. This information might be useful to implement the Therapeutic Drug Monitoring. However, the detection of early complexed ATA has not demonstrated a significant advantage over the bELISA to predict treatment survival.

Acknowledgements: This work has been supported by a collaboration with Leti laboratories.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2017-eular.2864

THU0662 COMPARING ELECTRONIC COLLECTION OF PATIENT REPORTED OUTCOMES AT HOME VERSUS TOUCH-SCREENS IN THE WAITING AREA AMONG PATIENTS WITH ARTHRITIS IN CLINICAL PRACTICE: A RANDOMISED AGREEMENT STUDY WITH ONLINE RECRUITMENT USING DANBIO

A.E. Secher¹, B. Glinborg¹, H. Gudbergson², N.S. Krogh³, D.V. Jensen¹, I.J. Sørensen¹, R. Christensen², M. Skougaard², M.L. Hetland¹. ¹DANBIO registry, Glostrup; ²The Parker Institute; ³Zitelab Aps, Frederiksberg, Denmark

Background: Collection of patient-reported outcomes (PROs) is an important aspect of modern treatment strategies. Electronic capture in waiting areas by touch screens is part of routine care in the Danish DANBIO registry¹. It is not known whether this data collection can be replaced with electronic data entry from home.

Objectives: To test the feasibility of online patient recruitment via touch screens and to investigate if electronic reporting of PROs from home (ELECTOR IT-platform) is comparable to reporting completed at the hospital among patients with rheumatoid arthritis (RA) or axial spondyloarthritis (AS).

Methods: Patients with RA or AS were recruited via touch screens and randomized to one of two groups by a pre-computed list generated through DANBIO; the first group completing the PROs at home and then at the hospital-site, and vice versa for the second group. All patients completed the Health Assessment Questionnaires (HAQ), the Visual Analogue Scales (VAS) for fatigue, pain and global health and the annual visit questions. Furthermore, AS patients completed the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and the BAS Function Index (BASFI). Pearson's Chi-square test, independent samples t-test and Mann-Whitney U test were calculated. Smallest detectable differences (SDDs), 95% confidence intervals (CIs) and intra-class correlation coefficients (ICCs) were calculated. Clinicaltrials.gov identifier: NCT02818478.

Results: A total of 952 patients received invitation, 45% accepted, 127 patients were contacted by phone, and 56 (44%) gave consent to participate. 22 patients with RA and 20 patients with AS completed the trial.

All differences between scores from home vs hospital were smaller than SDD, and all were non-significant ($p < 0.05$), except for BASFI and BASDAI item 5. ICC ranged from 0.947–0.990 ($p < 0.00001$). Annual visit questions showed 96% concordance between the two methods. 50% of the patients preferred from home data entry over hospital and 10% vice versa.

Conclusions: Recruitment of patients for a randomized trial via touch screens was feasible. PROs collected from patients' own devices at home generated

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 (-17.3, 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).

Disclosure of Interest: A. E. Secher: None declared, B. Glintborg Grant/research support from: AbbVie, H. Gudbergens Speakers bureau: MSD and Pfizer, N. Krogh: None declared, D. Jensen: None declared, I. Sørensen: None declared, R. Christensen: None declared, M. Skougard: None declared, M. Hetland Grant/research support from: AbbVie, BMS, MSD, Pfizer, UCB, Biogen, Orion
DOI: 10.1136/annrheumdis-2017-eular.3726

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

A.S.R. Peretz¹, N.S. Rasmussen², N.H.H. Heegaard³, S. Jacobsen², C. Sjöwall⁴, C.T. Nielsen². ¹Centre for Rheumatology and Spine Diseases, Gentofte, Copenhagen University Hospital, Denmark., Gentofte; ²Copenhagen Lupus and Vasculitis Clinic, Centre for Rheumatology and Spine Diseases, Rigshospitalet; ³Department of Autoimmunology and Biomarkers, Statens Serum Institut, Copenhagen, Denmark; ⁴Rheumatology/AIR, Department of Clinical and Experimental Medicine, Linköping University, Linköping, Sweden

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 paraclinical 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

DOI: 10.1136/annrheumdis-2017-eular.4287

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

C. Tani¹, R. Vagelli², L. Carli², C. Stagnaro¹, F. Drago¹, V. Lorenzoni³, G. Turchetti³, M. Mosca¹. ¹Rheumatology Unit, University of Pisa, Pisa, Italy; ²Via Roma 67, Pisa, Rheumatology Unit, University of Pisa; ³Institute of Management, Scuola Superiore Sant'Anna, Pisa, Italy

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

DOI: 10.1136/annrheumdis-2017-eular.4207

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

C. Cobilinschi, D. Opris-Belinski, R. Ionescu. *Santa Maria Clinical Hospital, Bucharest, Romania*

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