AB0591

SLE RES PONDER INDEX (SRI) UNDERESTIMATES CLINICAL RESPONSE IN MUSCULOSKELETAL SYSTEMIC LUPUS ERYTHEMATOSUS

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Background: Musculoskeletal (MSK) manifestations are common in SLE. Many recent clinical trials were negative or had small benefits vs. placebo. SRI is a common primary endpoint but has not been independently validated. Ultrasound is an objective measure of synovitis validated in inflammatory arthritis.

Objectives: To compare the responsiveness of clinical outcome measures with ultrasound in MSK-SLE.

Methods: 20 SLE patients meeting SLICC 2012 criteria with inflammatory MSK symptoms were studied with clinical assessment (BILAG2004, SLEDAI-2K over 30 days, patient and physician VAS, symptomatic, tender and swollen joint counts in 28 joints) and MSK ultrasound (grey scale and power Doppler scores, number of abnormal joints) at 0, 2, and 4 weeks after 120 mg IM depomedrone. Change in each variable was measured using Wilcoxon matched pairs and effect sizes($r=Z/\sqrt{2N}$) compared using Cohen (1988) criteria. Changes were compared for SRI-4 responders and non-responders.

Results: All patients were ANA positive, CCP negative and female. At baseline, 15/20 had clinical synovitis. The others had either ultrasound synovitis (GS in 18/20, PD in 17/20) or >60 min EMS. 19/20 patients scored 4 points on SLEDAI for musculoskeletal involvement, BILAG scores were A in 7/20, B in 8/20, and C in 5/20. MSK-SLEDAI score improved in 9/20 at 4 weeks, MSK-BILAG improved in 16/20. For changes, see table 1.

Abstract AB0591 – Table 1

		No. pairs	P	Z	Effect Size r	Cohen Criteria
Week 0 – Week 2	PhysVAS	16	0.001	−3.409	−0.603	Large
	GS Score	16	0.002	−3.13	−0.571	Large
	US Joints	16	0.011	−3.160	−0.559	Large
	PD Score	16	0.002	−3.099	−0.548	Large
	SymJC	10	0.047	−1.988	−0.445	Medium
	Pt VAS	16	0.016	−2.409	−0.426	Medium
	SJC	16	0.059	−1.889	−0.334	Medium
Week 0 – Week 4	TJC	15	0.274	−1.093	−0.200	Small
	PhysVAS	20	<0.001	−3.388	−0.593	Large
	MSK BILAG	20	0.008	−3.643	−0.576	Large
	PD Score	20	<0.001	−3.627	−0.573	Large
	US Joints	20	0.001	−3.627	−0.573	Large
	GS Score	20	<0.001	−3.503	−0.554	Large
	MSK-SLEDAI	20	0.003	−3.000	−0.474	Medium
	TJC	20	0.007	−2.683	−0.424	Medium
	SymJC	14	0.010	−2.576	−0.487	Medium
	SJC	20	0.007	−2.425	−0.383	Medium
	PtVAS	20	0.020	−2.331	−0.369	Medium

19 patients with MSK-SLEDAI=4 at baseline were grouped into SRI-4 responders (n=9) and non-responders (n=10). There were large effect sizes for improvement in TJC and SJC in responders ($r=-0.505$ and -0.492 respectively) and medium effect sizes in non-responders (-0.365 and -0.331). For ultrasound, large effect sizes for improvements in both grey scale and power Doppler were observed in both responders ($r=-0.517$ and -0.564) and non-responders ($r=-0.629$ and -0.596).

Conclusions: In MSK-SLE, ultrasound was the variable most consistently sensitive to change. All commonly used clinical variables significantly improved by week 4 but there was variation in responsiveness between them. BILAG-2004 and physician VAS had similar responsiveness to ultrasound. SRI-4 underestimated response, with substantial objective improvements in synovitis in SRI-4 non-responders. Developing organ-specific outcome measures may improve the ability to measure treatment effects in SLE clinical trials.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.2919

AB0592

IMPAIRMENT IN HAND STRENGTH, DEXTERITY AND ACTIVITIES OF DAILY LIVING PERFORMANCE IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS: RESULTS OF A CROSS-SECTIONAL STUDY

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Background: Systemic lupus erythematosus (SLE) is a prototypic autoimmune disease affecting multiple systems. To date a small number of studies have assessed the hand function and performance of daily activities in SLE¹.

Objectives: To examine the grip and pinch hand strength, the dexterity, and the performance of Activities of Daily Living (ADL) in SLE patients compared with healthy controls.

Methods: 197 SLE patients (48,03±12,76, 88,3% female) and 100 healthy controls (47,87±12,77, 86% female), matched by age and gender, were enrolled in the study. Both groups were assessed by hand grip and pinch grip strength, dexterity and ADL performance tests. Hand grip strength was measured by Jamar dynamometer, and pinch grip strength by pinch gauge, in both hands. Dexterity was measured by purdue pegboard test. Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire and Health Assessment Questionnaire (HAQ) were used in order to determine the difficulties in ADLs.

Results: Hand grip strength, both lateral and jaws pinch grip strength, and dexterity, were significantly impaired ($p<0.001$) in both hands of SLE patients compared to healthy subjects (table 1). DASH questionnaire (19.78±20.93 vs 2.43±2.9, $p<0.001$) and Health Assessment Questionnaire score (HAQ) (0.41±0.52 vs 0.03±0.52, $p<0.001$) were also significantly different between SLE patients and healthy controls.

Abstract AB0592 – Table 1

	Right Hand			Left Hand		
	Patient group	Control group	P value	Patient group	Control group	P value
Grip Strength	25.59 ±9.12	30.89 ±9.00	<0.001	24.54 ±9.80	29.56 ±9.21	<0.001
Tip to tip Pinch Strength	3.94±2.03	4.25±1.66	0.194	3.45±1.73	4.11±1.55	0.002
Lateral Pinch Strength	6.03±2.12	7.24±1.85	<0.001	5.52±1.98	6.66±1.93	<0.001
Jaws Pinch Strength	4.68±1.99	5.86±1.93	<0.001	4.37±1.94	5.62±1.80	<0.001
Purdue Score	13.09 ±2.58	14.28 ±2.58	<0.001	12.42 ±2.16	13.10 ±2.30	<0.001

All values are presented as mean ±SD

Conclusions: These findings demonstrate that SLE patients have lower grip, pinch strength and dexterity and more difficulties in ADL performance. These findings underline the need to develop specific hand therapy programs for SLE patients.

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Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.6422

AB0593

PREDICTORS OF FATIGUE AND SEVERE FATIGUE IN A LARGE MULTICENTER INTERNATIONAL COHORT OF PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS: THE FATILUP STUDY

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Background: Fatigue is an important issue in systemic lupus and has a major impact on quality of life of the patients. Data are controversial about the factors associated with this complex symptom.¹

Objectives: To identify the factors associated with fatigue and severe fatigue in patients with systemic lupus erythematosus (SLE) in a large cohort using a multivariate model to precise the importance of each parameter in this multidimensional symptom.

Methods: We used the LBBR data base, a German French data base of SLE patients. All patients fulfilled the 1997 ACR criteria for SLE. The Fatigue Scale for Motor and Cognitive Functions (FSMC) was used to assess fatigue and severe fatigue. The depression and anxiety were measured with Hospital Anxiety and Depression Scale (HADS). Tests were performed at sampling.

Results: A total of 570 patients were included (89.1% female). The median age was 42 years (QR25–75: 34–52). The median value of the SELENA-SLEDAI was 2 (QR25–75: 0–4) and 136 patients had a SELENA-SLEDAI score >6. Fatigue was reported by 386 patients (67.7%) including severe fatigue by 209 (36.7%). In univariate analysis among the individual components of the SLEDAI arthritis (p=0.003) and oral ulcers (p=0.002) were associated with severe fatigue. In multivariate analysis fatigue was strongly associated with anxiety (OR: 4.49 [95%CI: 2.60–7.77], p<0.0001) and depression (OR: 4.72 [95%CI: 1.39–16.05, p=0.01]. It was also associated with age at sampling (OR: 1.01 [95%CI: 1.00–1.03, p=0.03] per 1 year increase), SLEDAI (OR: 1.05 [95%CI: 1.00–1.12, p=0.043] per 1 SLEDAI point increase) and glucocorticoids treatment (OR: 1.54 [95%CI: 1.00–2.38, p=0.04]). It was not associated with physical activity. Severe fatigue was strongly associated with depression (OR:6.87 [95%CI: 3.12–15.11], p<0.0001) and anxiety (OR: 3.80 [95%CI: 2.46–5.87], p<0.0001) but not with SLEDAI or physical activity.

Conclusions: Fatigue is a common symptom in SLE patients and is strongly associated with anxiety and depression. While remission remains an important therapeutic target, these manifestations should also be taken care of with psychological counselling and pharmacological intervention, when needed.

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Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.2188

AB0594

PREVALENCE OF FRAGILITY FRACTURES IN WOMEN WITH SLE, THEIR CONNEXION WITH THE COURSE OF THE DISEASE AND THE NATURE OF PHARMACOTHERAPY

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Background: Patients with rheumatic diseases are known to have the risk of osteoporosis and fragility fractures, which is significantly higher than in the healthy population. Recent studies demonstrate that age, sex, postmenopausal status, inactivity, glucocorticoid use, nutrition etc. play an important role in the reduction of bone mineral density (BMD) in systemic lupus erythematosus (SLE) patients. The role of the disease severity and the activity of the inflammatory process in the reduction BMD and the incidence of fractures in SLE patients is discursive.

Objectives: The aim of the study was to determine the frequency of osteoporosis and fragility fractures in the Ukrainian SLE patients and to establish their connexion with the course of the disease.

Methods: The main study group involved 91 women with a diagnosis of SLE according to the American College of Rheumatology criteria. The disease activity was determined using the SLE Disease Activity Index (SLEDAI), and organ damage was measured using the Systemic Lupus International Collaborating Clinics American College of Rheumatology (SLICC/ACR) Damage Index. In all patients the cumulative dose of glucocorticoids was calculated. Serum CRP and IL-6 levels were determined by immunoassay. BMD at the lumbar spine (L1–L4) and femoral neck were measured using dual-energy X-ray absorptiometry. For premenopausal SLE patients BMD by Z-score <2.0 SD was defined as «below expected range for age». For postmenopausal women osteoporosis was defined by T-scores ≤ -2.5 SD, and osteopenia – between -1.0 and -2.5 SD. To determine fractures female SLE patients were examined with x-ray.

Results: In premenopausal SLE patients the abnormal BMD of the lumbar spine was found in 9.8%, at the level of the femoral neck it was in 11.1%, in postmenopausal SLE patients – 18.4 and 13.6%, respectively. In the control group there was any premenopausal woman with low bone mass at both sites, whereas among postmenopausal individuals, these were 12.5 and 6.2%, respectively. Osteoporotic fractures were detected in 13 (14.2%) SLE patients, of which 30.7% had hip fractures and 69.3% had vertebral fractures. The reduction of bone strength and fractures were associated with a high damage index. In particular, in persons with fractures it equaled to 4.85±0.65 points, and in persons without fractures – 3.09±0.22 points. A similar tendency was detected by the disease activity SLEDAI. Glucocorticoid use also had a negative effect on the bone strength in patients with SLE. Thus, in women with fractures, the cumulative dose of glucocorticoids defined 60.9±6.63 g, and was by 37.1% higher than in patients without fractures.

Conclusions: In patients with SLE the prevalence of low BMD and fragility fractures is high. Progressive loss of the BMD and the occurrence of osteoporotic fractures are closely associated with the severity of organ damage and glucocorticoid use.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.3355

AB0595

ANTIPHOSPHOLIPID SYNDROME (HUGHES SYNDROME) IS A DISEASE WITH PROTEAN FACES: MULTIDISCIPLINARY APPROACHES ON SERBIAN COHORT OF APS PATIENTS

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Background: Antiphospholipid syndrome (APS) is a systemic autoimmune disease characterised by thrombophilic state and circulating antiphospholipid antibodies (aPL) including anti beta2-GPI.

Objectives: Since then it became one of the most systemic conditions. In the last three and half decades, a variety of clinical manifestations involving almost all organs and tissues (cardiac, pulmonary, neurological, renal, cutaneous, hematologic, gastrointestinal, ocular, skeletal and endocrinology), have been described associated with antiphospholipid antibodies (aPL).

Methods: Our study comprises a total of 608 patients: 420 primary APS (PAPS) patients and 188 SLE patients with secondary APS (SAPS). aPL analysis included detection of aCL, aβ2GPI, and LA.

Results: Thrombosis was diagnosed in 46.5% patients, with higher prevalence in PAPS compared to SAPS patients: 51.2% and 38.3%, respectively, p=0.045. Pseudo-infective endocarditis was observed in 12.8% secondary APS patients and 3.1% in primary APS patients (p=0.004). 30% of the patients with high levels of aCL IgG antibodies had valve thickening and dysfunction, as compared to 4.1% without valve abnormalities (p=0.002). Presence of β2GPI IgG was significantly related to stroke, and overall β2GPI (IgG and IgM) positivity was significantly related to TIA in SAPS patients. Valvular manifestations were significantly related to TIA in both groups of patients and were independent risk factors for TIA in PAPS (OR 3.790 CI 1.597–8.998 p=0.003; table 2). In PAPS, epilepsy correlated with β2GPI-IgM, migraine with aCL-IgM, thrombocytopenia with aCL-IgM, aCL-IgG, anti β2GPI-IgG and LA. Livedo reticularis was more prominent in PAPS with high levels of aCL-IgG. Skin ulcerations were more prevalent in aCL-IgM positive SAPS patients and epilepsy more frequently had high levels of anti β2GPI-IgG in SAPS.

Conclusions: In this cross-section analysis of a large cohort of APS patients we analysed that APS patients can be presented with a wide variety of thrombotic