(0-100 mm) on the same day of the clinical evaluation. To analyse the discrepancy between PGA and PhGA, the [PGA-PhGA] variable was calculated, considering as discordant a difference ≥ 25 mm as previously proposed (2) All the subjects completed the following questionnaires: Health Assessment Questionnaire (HAQ), SF36 Health Survey, State-Trait Anxiety Inventory (STAI-Y1/Y2), Self-rating Depression Scale (SDS Zung) and Insomnia Severity Index. Statistical analysis was performed to compare concordant and discordant groups.

Results: The study included 106 patients, (93 women, 13 men) with a median age of 48 (41-58) and a median SLE duration 227 months (124-330). At the last evaluation median SLEDAI was 0 (0-2) and median SLICC was 1 (0-1). According to Zen definitions of remission, 51 patients (48%) and 20 (19%) also fulfilled the criteria of clinical remission off corticosteroids and complete remission respectively. Nevertheless, in 24 patients (22,7%) [PGA-PhGA]≥25. Patients in the discordant group were older (median 58 years, IQR 49-62 vs 46, IQR 39-57; p=0,0043) and less frequently achieved the definition of clinical remission off corticosteroids (n=4, 16,7% vs n=47, 57,3%,p<0.001;OR6,7; CI95%2.1-21) than concordant. No differences were found in gender, SLE duration, serology, disease activity or damage and other treatment. Data about differences in PROs between two groups are reported in Table 1: discordant patients had a worse performance in all the PROs included. At multivariate analysis SF-36 Physical Component Summary (PCS) resulted associated with [PGA-PhGA] ≥25 (p=<0,0001).

Table 1. Data are expressed as median and interquartile range (IQR) and compared using Mann-Whitney test.

	TOTAL N=106 (%)	CONCORDANT GROUP (PGA-PhGA) <25 N=82 (%)	DISCORDANT GROUP (PGA-PhGA) ≥25 N=24 (%)	P value
VAS-pain [0-100],	10 (0-30)	10 (0-20)	50 (40-60)	< 0.001
SF-36 Physical Component Summary (PCS)	50 (37,5-53)	51 (44-54)	30 (27,5-39)	< 0.001
SF-36 Mental Component Summary (PCS)	48 (38-55)	51 (40-55)	40 (36-48,5)	0,015
STAI-Y1 [20-80]	35 (30-47)	33 (28,3-45,5)	42 (36,5-49,5)	0,013
STAI-Y2 [20-80]	37 (30-46)	35 (29-43,3)	42 (36-46)	0,021
Test di Zung [20-80]	34,5 (29-43)	33 (27-43)	39 (35,5-44,5)	0,008
Insomnia severity index [0-28]	6 (2-12)	4 (1-9)	9 (6,8-14,3)	<0,0001
HAQ	0 (0-0,1)	0 (0-0)	0,38 (0-0,6)	< 0.001

Conclusion: In our study we found that, even in patients considered in remission, in more than 20% of patients there is a considerable discordance between the global disease assessment reported by patients and their physicians. Patients that had a higher PGA also presented worse score at PROs. Our data seems to confirm that potential causes for discordance could be more related to the presence of non-inflammatory processes, depression, or anxiety than clinical manifestations or damage related to SLE.

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POS0118 SMALL FIBER NEUROPATHY EVALUATION IN SYSTEMIC LUPUS ERYTHEMATOSUS PATIENTS: A SINGLE CENTER STUDY.

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Background: Neuropsychiatric involvement represents one of the most relevant Systemic Lupus Erythematosus (SLE) manifestations and it is characterized by a protean spectrum of clinical disorders. Among them, small fiber neuropathy (SFN) could represent a relevant reason for chronic pain and somatosensorial dysfunctions, even if not included in ACR 1999 nomenclature yet.

Objectives: In the present study we aimed at evaluating the prevalence of SFN among SLE patients with neuropathic pain and identifying significant associations with clinical and laboratory disease features.

Methods: Consecutive SLE patients (according to ACR 1987 criteria), were screened for neuropathic pain through a specific questionnaire (DN4). Subjects were enrolled to the full protocol in the presence of bilateral limb pain and one of the following: hypoesthesia to touch or prick; pain caused or increased by brushing; tingling, numbness and itching; electric shocks, painful cold or burning pain. We excluded SLE patients with other possible explanation for SFN including diabetes, Sjogren's syndrome and kidney impairment (eGFR <30 ml/m). For each patient the following data were collected: demographics, medical history, treatments, disease activity (SLEDAI-2K) chronic damage (SLICC *damage index)*, clinical and laboratory data, including complement level and the main autoantibodies. Each patient enrolled underwent different tools specific for neuropathic pain (such as SFN-SIQ and NPSI), nerve conduction study, quantitative sensory testing (QST) and skin biopsy performed at proximal thigh and distal leg. SFN was diagnosed when intraepidermal nerve fiber density (IENFD) reduction was associated with at least one thermal detection threshold abnormality at QST. A concomitant fibromyalgia (FM) was evaluated by different tools including FIRST, FibroDetect and ACR 2016 criteria.

Results: Among the 114 recruitable subjects, 58 were excluded because of confounding factors and 25 declined the study. Therefore we enrolled 31 patients (M/F 3/28, median age 50.0 years, IQR 21.0; median disease duration 132.0 months, IQR 197.0; median SLEDAI-2k 0, IQR 4 and median SDI 1, IQR 1.2). FM was identified in 81.8% of subjects according to ACR criteria. SFN was diagnosed in 35.5% of patients; among them, in 81.8% a non-length dependent distribution was recognized while in 18.2% a length-dependent pattern and the large fiber dysfunction were found. SFN was associated with anti-Sm (p=0.03), Raynaud's phenomenon (p<0.01), low complement levels (p=0.04) and SLEDAI-2k≥4 (p=0.04). Neurovegetative symptoms and pain intensity correlated with distal (p<0.001) and slightly with proximal IENFD reduction (p=0.02 and p=0.04). No significant association was found between FM and SFN or IENFD.

Conclusion: The present study suggests that SFN is a common finding in SLE and it should be considered in patient with neuropathic pain, somatosensorial and neurovegetative dysfunctions, especially in subjects with low complement levels, high disease activity and Raynaud's phenomenon.

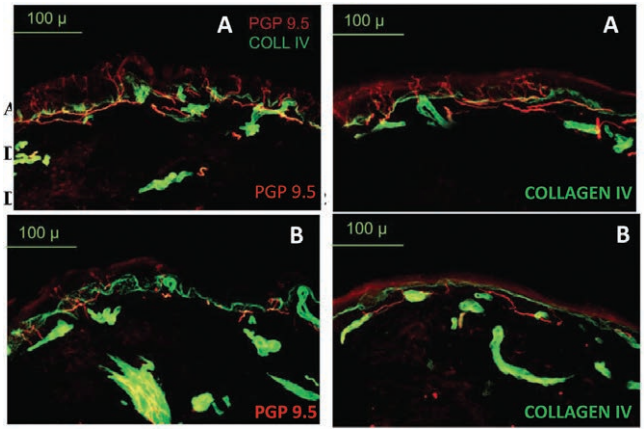

Figure 1. A: SLE patient with normal IENFD. B: SLE patient with low IENFD, consistent with SFN.

Disclosure of Interests: None declared

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POS0119 SLE-DAS REMISSION AND LOW DISEASE ACTIVITY STATES ARE ASSOCIATED WITH IMPROVED HEALTH-RELATED QUALITY OF LIFE AND FATIGUE: POST-HOC ANALYSIS OF THE BLISS-52 AND BLISS-76 PHASE III TRIALS.

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Background: Accurate and practical outcome measures for clinical trials in systemic lupus erythematosus (SLE) are lacking. The SLE Disease Activity Score (SLE-DAS) is a recently validated 17-item instrument, with high accuracy and sensitivity to changes in SLE disease activity. The SLE-DAS definitions of remission and low disease activity (LDA) were newly validated against disease activity physician-applied measures in the clinical setting [1, 2]. Criterion validity of

SLE-DAS for Patient Reported Outcomes, namely health-related quality of life (HR-QoL) and fatigue needs to be assessed.
Objectives: To evaluate if the attainment of SLE-DAS remission and LDA states is associated with improvements in HR-QoL and fatigue.
Methods: Post-hoc analysis of the merged study population in the BLISS-52 and -76 trials (NCT00424476; NCT00410384) of intravenous belimumab versus placebo for moderate to severe SLE disease activity. We analysed the Functional Assessment of Chronic Illness Therapy (FACIT) and 36-Item Short Form Survey (SF-36) trial data. Fulfillment of SLE-DAS remission (defined as absence of all SLE-DAS clinical items and prednisone ≤5mg/day) and LDA (defined as SLE-DAS≤2.48 and prednisone ≤7.5mg/day) definitions were retrospectively assessed from the individual participants' data. Mean changes from study baseline to week 52 in FACIT and SF-36 physical component summary (PCS) and mental component summary (MCS) and domain scores were compared between patients attaining at week 52 the SLE-DAS remission *vs* non-remission and the SLE-DAS LDA *vs* non-LDA using multivariate regression analysis adjusted for baseline scores.
Results: A total of 1684 SLE patients were included. Few patients were in SLE-DAS remission (0.5%) and LDA (0.8%) at study entry. At week 52, 12.5% patients attained SLE-DAS remission and 17.5% attained SLE-DAS LDA. Mean improvements in SF-36 PCS and MCS scores were greater in patients that attained SLE-DAS remission *vs* non-remission (5.4 *vs* 3.4, and 4.6 *vs* 2.7, respectively; multivariate p<0.005 for both) and SLE-DAS LDA *vs* non-LDA (5.0 *vs* 3.4 and 4.6 *vs* 2.6, respectively; multivariate p<0.005 for both), at week 52 (Figure 1). Similarly, improvements in all individual domain scores were greater in SLE-DAS remission *vs* non-remission patients (all multivariate p<0.005) and SLE-DAS LDA *vs* non-LDA patients (all multivariate p<0.005) (Figure 1). Importantly, improvements in the summary scores and in all the individual domain scores largely exceeded the minimum clinically important differences (MCIDs) of 2.5 and 5 points, respectively, in those patients attaining SLE-DAS remission or LDA.

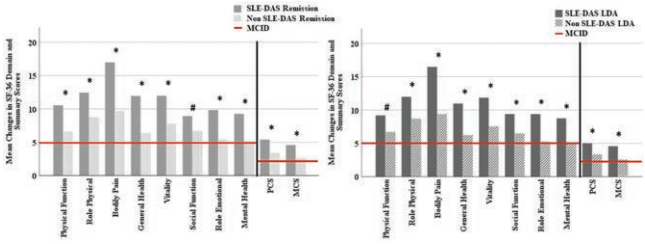

Figure 1. Mean changes in SF-36 domains and summary scores from baseline to week 52. #p<0.005; *p<0.001; MICD, Minimum Clinically Important Difference; MCS, Mental Component Summary; PCS, Physical Component Summary; SF-36, Medical Outcomes Survey Short Form; SLE-DAS, Systemic Lupus Erythematosus Disease Activity Score.

Additionally, mean improvements in FACIT scores were higher in SLE-DAS remission than non-remission (6.3 *vs* 3.6, multivariate p<0.001) and in SLE-DAS LDA than non-LDA (5.9 *vs* 3.6, multivariate p<0.001), and exceeded the MCID of 4 points.
Conclusion: Attainment of SLE-DAS remission and LDA is associated with meaningful improvement in HR-QoL and fatigue.
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POS0120 NEUROLOGICAL INVOLVEMENT IN A MONOCENTRIC COHORT OF PATIENTS WITH SERONEGATIVE ANTIPHOSPHOLIPID SYNDROME

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Background: The nervous system is affected in a relevant number of patients with antiphospholipid syndrome (APS), being responsible for high morbidity and mortality rates. The identification of neurological manifestations is crucial since those symptoms may benefit from anticoagulation treatment. Noteworthy, the prevalence and the characteristics of neurological manifestations in the subset of patients with "seronegative APS" (SN-APS) still need to be investigated.
Objectives: The aim of this study was to assess the neurological involvement in patients with SN-APS. Secondly, association between non-conventional antiphospholipid antibodies (aPL) and clinical characteristics were investigated.
Methods: We included all consecutive patients referred to the Lupus Clinic and to the Stroke Unit of our Hospital, presenting clinical features consistent with a diagnosis of APS despite the evidence of persistently negative tests for anti-cardiolipin antibodies (aCL), anti-β2 glycoprotein I, and lupus anticoagulant. Patients with an identified cause of thrombosis and/or pregnancy morbidity were excluded. Patients' sera were analyzed for the detection of aCL using thin layer chromatography (TLC), while ELISA test was used to detect antibodies directed against the anti-vimentin/cardiolipin complex (aVim/CL).
Results: From January 2015 to October 2019, 40 patients with SN-APS and neurological involvement were enrolled. Clinical and demographic characteristics are reported in Table 1. Thirty-three patients (82.5%) resulted positive for at least one non-conventional test (62.5% positive on two occasions) while 17.5% were negative. The occurrence of aCL by TLC immunostaining was 33/40 (82.5%), while a Vim/CL were found in 10/40 (25%). Double positivity for aCL by TLC-immunostaining and aVim/CL was observed in 8/40 patients (20%). Patients who tested positive for non-conventional aPL on two occasions had a five-fold increased risk of developing venous thrombosis (LR 5.24; p=0.022). The positivity for aCL by TLC immunostaining determined an augmented risk of sinus vein thrombosis (LR 5.49; p=0.019) while positivity for aVim/CL raised the likelihood of epilepsy (LR 4.133; p=0.042). Almost all (16/18, 88%) patients with ischemic stroke resulted positive at least one test, 15 tested positive for aCL by TLC-immunostaining and 3 for aVim/CL. In this subset of patients, the positivity for non-conventional aPL on two occasions determined an increased risk of venous thrombosis (LR 8.905; p=0.003) and recurrent stroke (LR 6.321; p=0.012). In particular, those who tested positive for aVim/CL were at higher risk of developing recurrent stroke (LR 6.659; p=0.01).

Table 1.

Characteristics	Patients N= 40 (%)
Female/Male	35/5
Mean age in years (S.D.)	48 (12.5)
Thrombosis	34 (85)
Arterial	23 (57.5)
Venous	17 (42.5)
Recurrent	13 (32.5)
Pregnancy morbidity	12 (34.3)
Recurrent miscarriage	11 (31.4)
Foetal deaths	2 (5.7)
Premature births	2 (5.7)
Thrombosis + Pregnancy morbidity	6 (17.1)
Neurological manifestations	
Stroke	18 (45)
Recurrent stroke	7 (17.5)
Transient ischemic attack	4 (10)
Venous sinus thrombosis	5 (12.5)
Headache	18 (45)
Epilepsy	7 (17.5)
Transverse myelitis	2 (5)
Other manifestations	
Livedo reticularis	5 (12.5)
Low platelets	3 (7.5)

Conclusion: The nervous system is one of the most frequently affected in APS, however only few data exist about prevalence, characteristics and outcome of its involvement in SN-APS patients. In this work, using TLC immunostaining and ELISA for aVim/CL, we identified non-conventional aPL antibodies in 62,5% SN-APS patients. This subset of patients presented a wide spectrum of neurological manifestations, with frequencies and features that resemble those observed in APS patients. Furthermore, we demonstrated the association between non-conventional aPL and neurological manifestations, such as sinus vein thrombosis, recurrent stroke and epilepsy. In conclusion, testing for non-conventional aPL antibodies may contribute to the evaluation of the stratification of risk for neurological manifestations in SN-APS.
Disclosure of Interests: None declared
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