Abstract PO.4.75 Table 1 Proportions of patients who had arthritis and rash by SLEDAI-2K or BILAG-2004 musculoskeletal and mucocutaneous grades A or B at baseline and improved in joint and skin symptoms at week 24

	Placebo	BIIB059 450 mg
Pts with both arthritis and rash at baseline (SLEDAI-2K), n*	52	61
Pts with no arthritis at Week 24, n (%)	13 (25.0)	31 (50.8)
Pts with no rash at Week 24, n (%)	6 (11.5)	18 (29.5)
Pts with neither arthritis nor rash at Week 24, n (%)	5 (9.6)	14 (23.0)
LS mean, % (SE)	9.6 (4.3)	25.2 (6.4)
LS mean difference, % (95% CI)†		15.6 (1.4, 29.8)
OR (95% CI)†		2.8 (0.9, 8.3)
P-value†		0.071
Pts with BILAG-2004 Grade A or B in both musculoskeletal and mucocutaneous organ domains at baseline, n*	44	54
Pts who improved from baseline Grade A or B in musculoskeletal domain at Week 24, n (%)	22 (50.0)	38 (70.4)
Pts who improved from baseline Grade A or B in mucocutaneous domain at Week 24, n (%)	16 (36.4)	29 (53.7)
Pts who improved from baseline in both musculoskeletal and mucocutaneous scores at Week 24, n (%)	15 (34.1)	27 (50.0)
LS mean, % (SE)	27.8 (8.4)	52.9 (8.8)
LS mean difference, % (95% CI)†		25.1 (5.0, 45.2)
OR (95% CI)†		2.6 (1.0, 6.3)
P-value†		0.043

*Analyses were based on generalised linear regression adjusted for treatment, baseline corticosteroid usage level, region and baseline SLEDAI-2K score (for SLEDAI data) or baseline BILAG (for BILAG data) using a logit link function
†BIIB059 versus placebo
BILAG-2004, British Isles Lupus Assessment Group 2004 index; CI, confidence interval; LS, least squares; OR, odds ratio; Pts, patients; SE, standard error; SLEDAI-2K, Systemic Lupus Erythematosus Disease Activity Index 2000

greater with BIIB059 than placebo, as were the proportions with improvements in the BILAG-2004 musculoskeletal and mucocutaneous domains (Table 1). Mean changes in total joint count and CLASI-A score from baseline were numerically greater with BIIB059 than placebo in the respective subpopulations.

Conclusions Among patients with active SLE in both joints and skin, those receiving BIIB059 had greater improvements versus placebo in both manifestations. These data support the potential benefit of BIIB059 treatment for joint and skin manifestations in SLE.

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PO.4.77 AGREEMENT BETWEEN LLDAS AND EXPERT ASSESSMENT IN IDENTIFYING SLE PATIENTS WITH LDA: STUDY ON A REAL-WORLD COHORT OF CAUCASIAN PATIENTS

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Purpose Both lupus low disease activity state (LLDAS) and remission have been proven to be good and achievable targets in the management of SLE. Nevertheless, considerable overlap between LLDAS and remission exists: an average of 80% of patients in LLDAS also meet the definition of remission in different cohorts worldwide, raising the question whether LLDAS definition is too close to definition of remission. Our aim was to evaluate the performance of LLDAS in identifying patients in LDA, defined according to gold standard, which is physician judgement.

Methods We prospectively collected data of SLE patients attending our outpatient clinic from October 2021 to January

Abstract PO.4.77 Table 1

	Expert LDA (%)	LLDAS/no rem (%)	Expert LDA/rem (%)	LLDAS* (%)
N° of patients	45 (21.7)	29 (14)	173 (84)	154 (74)
Articular manifestations	19 (40.4)	17 (58.6)	19 (10.3)	17 (11)
Cutaneous manifestations	9 (19.1)	5 (17.2)	9 (5.1)	5 (3.2)
Renal manifestations	7 (14.9)	-	7 (4)	-
Hematological manifestations **low WBC** **low PLT**	8 (17): • 6 (12.7) • 2 (4.2)	7 (24.1) • 5 (17.2) • 2 (6.9)	8 (4.5) • 6 (3.4) • 2 (1.1)	7 (4.5) • 5 (3.2) • 2 (1.3)
Serositis	2 (4.2)	-	2 (1.1)	-
No clinical activity (cSLEDAI=0)	-	-	128 (73.2)	125 (80.6)
Serological activity	27 (61.7) positive serology: • 11 (23.4) dsDNA only • 6 (12.7) C3/C4 only • 10 (25.5) both 18 (38.3) none	17 (58.6) positive serology • 10 (34.5) dsDNA only • 3 (10.3) C3/C4 only • 4 (13.7) both 12 (41.4) none	94 (54.9) positive serology: • 29 (16.6) dsDNA only • 30 (17.1) C3/C4 only • 35 (21.1) both 79 (45.1) none	85 (54.8) positive serology 28 (18) dsDNA only 27 (17.4) C3/C4 only 30 (19.3) both 69 (45.1) none
PDN daily dose	3.48±5.1 (median 2.5, IQR 0-5) • **PDN=0:** 5 (10.6) • **PDN≤5:** 41 (87.2) • **PDN 5-7.5:** 1 (2.1) • **PDN ≥7.5:** 1 (2.1)	3.56±1.91 (median 3.75, IQR 2.5-5.0) • **PDN=0:** 2 (6.9) • **PDN≤5:** 26 (89.6) • **PDN 5-7.5:** 1 (3.5) • **PDN ≥7.5:** 0	2.1±2.6 (median 0, IQR 0-5) • **PDN=0:** 90 (51.4) • **PDN≤5:** 83 (47.4) • **PDN 5-7.5:** 1 (0.56) • **PDN ≥7.5:** 1 (6.6)	1.7±2.3 (median 0, IQR 0-3.75) • **PDN=0:** 88 (57.1) • **PDN≤5:** 65 (42.2) • **PDN 5-7.5:** 1 (0.7) • **PDN ≥7.5:** 0
PGA>1	0	0	0	0

cSLEDAI: clinical Systemic Lupus Erythematosus Disease Activity Index, LDA: Low Disease Activity, LLDAS: Lupus Low Disease Activity State, PDN: prednisone or prednisone equivalent dose, PGA: Physician Global Assessment, PLT: platelets, Rem: DORIS Remission, WBC: white blood cells

2022. Each patient received a complete clinical evaluation and review of recent laboratory tests by a rheumatologist expert in SLE, who classified patients in the following states: remission, LDA, active disease. Each category was mutually exclusive. The definitions of LLDAS and remission were also applied. LLDAS was defined, according to Franklyn et al., as SLEDAI-2k≤4 without major organ activity (including renal, cardiac and fever), no new disease activity, PGA≤1 (0–3), stable immunosuppressive therapy and prednisone equivalent dose up to 7.5 mg/day. Remission was defined according to the DORIS definition as clinical SLEDAI-2k=0 and PGA <0.5 in patients treated with standard immunosuppressive therapy and a prednisone equivalent dose ≤5 mg/die. In addition, patients fulfilling the definition of LLDAS but not that of remission (LLDAS/no remission) were identified. Cohen's kappa coefficient was used to assess the agreement between expert definition of LDA and LLDAS.

Results During the follow-up we enrolled 207 patients with SLE (mean±SD age 46±12.9 years, mean±SD disease duration 9±6 years, 84.5% female). Among them, 154 (74.4%) were in LLDAS, of which 29 (14%) were in LLDAS/no remission, meaning an overlap between LLDAS and remission consisting of 125 (81.2%) patients. According to expert opinion, LDA was observed in 45 (21.7%) and remission in 128 (61.8%) patients. The agreement between expert opinion and LLDAS in discriminating active patients from LDA+remission was overall good (Cohen's k 0.67). However, definition of LLDAS failed to discriminate patient in LDA from patients in remission as identified by the experts (Cohen's k -0,02). We also analyzed the agreement after removing patients in remission from the pool of LLDAS (LLDAS/no remission): the agreement between expert definition of LDA and LLDAS/no remission markedly improved (Cohen's k 0,68). Notably, 9 out of 16 patients were in LDA according to the expert opinion but not to LLDAS due to minimal renal and serosal involvement.

Conclusions Our analysis shows that LLDAS is effective in discriminating patients with active diseases from those in LDA/remission. However, the great majority of patients in LLDAS are in remission and some patients with LDA are not identified by LLDAS. Thus, LLDAS should be implemented to capture all patients in LDA and to discriminate patients in LDA from those in remission.

PO.4.78 VALIDATION ANALYSIS OF THE PHYSICIAN GLOBAL ASSESSMENT (PGA) SCALE IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS INCLUDED IN RELESSER-PROS REGISTRY

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Objective There is currently no agreement on which scale should be used to evaluate SLE disease activity. The aim of this study was to analyze the construct and criterion validity of the physician global assessment (PGA), from 0 to 10, in the Spanish population, analyzing the correlation with SLEDAI and its ability to predict damage in order to promote its more widespread use.

Methods An observational, longitudinal and prospective design was performed. 1821 patients from the RELESSER-PROS registry and data from 5 annual consecutive visits were tested. Activity was analyzed using: PGA from 0 to 10 transformed to AM-PGA (mean-adjusted PGA), AM-SLEDAI (mean-adjusted SLEDAI); damage: SLICC/ACR Damage Index (SDI)) and health-related quality of life (QoL): EuroQoL 5D y Lupus Impact Tracker (LIT). The correlation between indices and their ability to predict damage progression (defined as any increase of 1 unit in SDI from baseline) and QoL was calculated. Pearson's or Spearman's correlation coefficients were calculated for each variable in comparison.

Results The correlation between PGA and SLEDAI was higher for lower PGA values and there was a correlation between AM-PGA and AM-SLEDAI, ranging 0.4 and 0.5. AM-SLEDAI explains a percentage of PGA variation that rises to 27.11% when introducing the number of domains affected by SLEDAI, in non-parametric model. AMS and AMP values are discrepant, especially for patients with low AMS and high AMP values and differs significantly in 3 domains: serological, neuropsychiatric, and renal. Excluding patients from the model, who were marked as discrepant, a significant linear relationship between AMS and AMP, around 0.5 shown up. Regarding damage, the correlation between AM-PGA, AM-SLEDAI and SLICC/ACR explained 13% of SDI variance. SLEDAI accounts for a higher percentage of SDI variance than PGA (10.18% vs. 5.65% in smoothed model), but both do it independently. Analysis the discrepant and non-discrepant patients showed a fairly discrete linear relationship, less than 3%, between the AMS and AMP with the LIT and the EQ5D6 for the non-discrepant patients, but this relationship was not found in discrepant patients.

Conclusion The correlation between PGA and SLEDAI is low and both should be used together. PGA could improve the assessment of disease activity and its use adds the possibility to improve damage prediction.

PO.4.79 NAILFOLD CAPILLARY CHANGES IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOUS

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Purpose This study aims to investigate nailfold capillary (NF) changes in patients with Systemic Lupus Erythematous (SLE), and its association with disease activities, autoantibodies, clinical symptoms.

Methods 52 patients were enrolled (7 m and 45 f), between 2015 and 2022, and underwent to NF. Alterations in capillary morphology, diameter, architecture and density were analyzed. CSURI index was calculated. Clinical symptoms and autoantibodies were reported. Disease activity was evaluated by SLE disease index (SLEDAI).

Results 46% of the enrolled patients showed non-specific pattern, 6% early scleroderma pattern (EAP), 18% like-