POS0746

THE ARTHRITIS COMPONENT OF THE SLEDAI SHOULD ONLY BE SCORED IF THERE IS JOINT SWELLING

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Background: SLE disease activity tools do not optimally define disease activity and response. The SLEDAI arthritis item is common, and sufficient to define SRI response. Lupus patients with arthralgia often have no swelling. Glossary definitions of arthritis in different versions of the SLEDAI have included: swelling, swelling between visits, effusion, tenderness, warmth and erythema. MSK ultrasound in SLE can identify synovitis without swelling, ultrasound synovitis is associated with worse symptoms and serology, predicts response to therapy, and is more responsive to therapy than clinical variables.

Objectives: To validate different glossary definitions for SLEDAI arthritis using musculoskeletal ultrasound.

Methods: We analysed baseline data from a multicentre longitudinal study. Physicians scored SLEDAI-2K in 133 patients with joint pain that was considered inflammatory, but not necessarily swelling. Stable immunosuppressants and prednisolone ≤ 5 mg were permitted. If the arthritis criterion was scored, we asked physicians to report which glossary features drove their decision. Musculoskeletal ultrasound of hands and wrists was performed on the same day, blinded to clinical findings. We defined abnormal grey-scale in joints as 1 joint with GS ≥ 2 , and in tendons as ≥ 1 tendon with GS ≥ 1 , and abnormal power Doppler as ≥ 1 joint or tendon with PD ≥ 1 .

Results: 78/133 patients had arthritis scored on SLEDAI-2K. In 21/78, swelling was not a reason for that decision. These 21 patients had either tenderness (16/21), swelling reported between visits (4/21) or both of these (1/21). No patient was scored for warmth, erythema or effusion alone. Comparison of SLEDAI definitions and ultrasound is shown in Table 1. Of 57 patients with SLEDAI arthritis scored due to swelling, 90% had an abnormal ultrasound. The positive predictive value was 89% (95% CI 79 – 94). Of 21 patients with SLEDAI arthritis scored without swelling, 48% had an abnormal ultrasound. The positive predictive value was 48% (95% CI 31 – 67). There was no substantive difference in clinical and serological variables comparing patients with SLEDAI arthritis without swelling and patients without SLEDAI arthritis. In contrast, patients with SLEDAI arthritis with swelling had worse ESR ($p=0.0003$), Physician MSK disease activity VAS ($p<0.001$) and patient EMS VAS ($p=0.0019$) and IgG ($p=0.0625$) compared to the other two groups.

Conclusion: Although ultrasound proven synovitis in the absence of swelling is not uncommon, it is not reliably identified using other signs or symptoms. The arthritis item of the SLEDAI was likely to be associated with ultrasound synovitis if scored because of swelling, but not if scored because of tenderness or swelling between visits. Our results support raising the threshold criteria for arthritis so that it should only be scored when there is joint swelling. Previous clinical trial datasets could be re-analysed excluding SLEDAI arthritis scores not confirmed by a swollen joint count greater than one.

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POS0747

MAPPING THE NATIONWIDE CLINICAL PROFILE AND PATTERNS OF CARE OF SLE IN BRAZIL – FINDINGS FROM THE MACUNAÍMA STUDY

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Background: Systemic lupus erythematosus (SLE) is an autoimmune disease with wide clinical variability. Brazil has vast regional diversity, both from an ethnic and socio-cultural point of view.

Objectives: To map the clinical profile of SLE in Brazil and explore how this distribution is associated with regional disparities.

Methods: This cross-sectional study (GSK Study 207353) evaluated 300 Brazilian patients ≥ 18 years old with SLE (American College of Rheumatology [ACR] criteria, 1997) who had been under SLE care for ≥ 1 year. Five SLE reference teaching facilities were selected, one in each of the following Brazilian regions: North (NO), Northeast (NE), Midwest (CO), Southeast (SE), and South (SU). Each region included 60 patients. Clinical and demographic characteristics, and patterns of care were measured through questionnaires completed by physicians or nurses. The SLE Disease Activity Index (SLEDAI) score described disease activity and the Systemic Lupus International Collaborating Clinics/ACR Damage Index (SDI) described damage accrual. To assess the potential association between regional disparities and clinical outcomes, a hospitalisation profile was described. A bootstrapping approach of logistic regression was used to explore potential factors associated with hospitalisation.

Results: Overall, 92.3% of patients were female, with a mean (standard deviation; SD) age of 41.8 (12.7) years and a mean (SD) disease duration of 11.8 (7.9) years. Overall, 161 (53.7%) patients were of Latino origin; in the NO this proportion was 88%. White patients predominated in the SU (58.3%); and black patients in the SE (31.7%). The mean (SD) number of years of schooling was 11.3 (4.6), and was highest in the NO (14.2 [3.6]) and lowest in the SU (9.0 [4.0]; $p<0.001$). With regard to the distribution of the SLE clinical profile according to ACR criteria, arthritis was found in 221 patients and predominated in all regions (mean 73.7%), with a lower prevalence in the CO (40%; $p<0.001$; Figure 1A). The mean (SD) SLEDAI score was 4.33 (5.39) at the time of interview. The main contributing factors to disease activity, according to SLEDAI, were complement consumption (18%), arthritis (15.3%), and alopecia (15%). The SDI scale was scored for cataracts (15%), proteinuria (8.7%), and thrombosis (7.3%). Among the associated comorbidities, hypertension was predominant in the NO (35%; $p=0.001$). Smoking predominated in the SU (23%; $p<0.001$); obesity (27%; $p=0.059$) and dyslipidemia (35%; $p=0.023$), in the SE. Regarding patterns of care (Figure 1B), antimalarials were most frequently prescribed in the SE (88.3%) and the SU (91.7%). Corticosteroids prevailed in the NO (96.7%). The mean (SD) time between home and care facility was 4.5 (12.6) hours. Patients in the NO reported the longest transport time to reach the care facility (11.5 [25.4] hours; $p<0.001$). The hospitalisation rate during the study period was 21.3% across all regions, with no statistical difference between centres ($p=0.651$). Reasons for

SLEDAI-2K at baseline	Ultrasound Abnormalities at Baseline				Test statistics for any ultrasound abnormality				
	GS joints	PD joints	GS tendons	PD tendons	Any abnormality	Sensitivity	Specificity	PPV	NPV
	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)
All patients (n=133)	77/133 (58)	33/133 (25)	36/133 (27)	27/106 (20)	83/133 (62)	-	-	-	-
MSK SLEDAI = No (n=55)	20/55 (36)	2/55 (4)	9/55 (16)	3/55 (6)	22/55 (40)	-	-	-	-
MSK SLEDAI = Yes (n=78)	57/78 (73)	31/78 (40)	27/78 (35)	24/78 (31)	61/78 (78)	73 (62, 82) ^b	66 (51, 78) ^b	78 (70, 84) ^b	60 (49, 69) ^b
-Due to swelling (n=57)	48/57 (84)	28/57 (49)	21/57 (37)	19/57 (33)	51/57 (90)	61 (50, 71) ^c	88 (75, 95) ^c	89 (79, 94) ^c	57 (50, 64) ^c
-Without swelling (n=21) ^a	9/21 (43)	3/21 (14)	6/21 (29)	5/21 (24)	10/21 (48)	31 (16, 50) ^d	75 (60, 87) ^d	48 (31, 67) ^d	60 (45, 68) ^d

hospitalisation included disease activity (36 [12%]), infection (19 [6.3%]), surgery (10 [3.3%]), and management of clinical morbidities (6 [2.0%]). Hospitalisation was associated with ethnicity ($p < 0.016$), occupational status ($p < 0.001$), age ($p = 0.02$), and the use of hydroxychloroquine (HCQ) or chloroquine (CQ; $p < 0.001$).

Conclusion: This nationwide study highlights ethnic, social, and patterns-of-care disparities among Brazilian patients with SLE. The modelling shows evidence that such disparities contribute to the divergent clinical spectrum observed in Brazil.

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Figure 1. Distribution of the A) Brazilian SLE clinical profile according to the ACR Classification Criteria and B) Brazilian prescriptive profile for SLE treatment according to the use of immunosuppressive drugs, biological agents, and corticosteroids during the study (12 months)

ANA, antinuclear antibody

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EASY-BILAG: A NEW TOOL FOR FASTER AND MORE ACCURATE RECORDING OF BILAG-2004 DISEASE ACTIVITY IN SLE

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Background: BILAG-2004 index is an important disease activity instrument for SLE which is widely used in clinical trials and in treatment commissioning. It is more comprehensive and responsive than SLEDAI. However, BILAG-2004 may be difficult or time-consuming to complete during routine clinic visits. To derive the eventual scores from A (highly active) to E (no current or prior disease involvement) for each of the 9 organ domains, the current BILAG-2004 relies on a separate index form, glossary and scoring algorithm.

Objectives: The Easy-BILAG project aimed to develop and validate a simplified tool for scoring the original BILAG-2004 index more rapidly and accurately in routine clinical care.

Methods: Data from the UK BILAG-Biologics Registry (BILAG-BR) were used to measure the frequency with which the 97 BILAG-2004 clinical items occurred in a population with active SLE. These data and a series of prototypes were used to draft a new tool for simplified scoring of the BILAG-2004 index - the "Easy-BILAG". After preliminary testing, a validation study was conducted to test accuracy, speed and usability of Easy-BILAG compared to the standard BILAG-2004 template. Rheumatologists and specialty trainees from centres around the UK were invited to score BILAG-2004 disease activity in a timed workbook of 10 exemplar case vignettes, using either Easy-BILAG or standard BILAG-2004 reference documents. The case vignettes tested clinicians in scoring both frequent and uncommon SLE manifestations as well as longitudinal scoring of items in flare and remission. All workbooks contained an overview and detailed instructions on BILAG-2004.

Results: Among 2395 submissions to BILAG-BR the 6 most frequently scored clinical items were each present in more than 20% of records; arthralgia (72%), mild skin eruption (47%), moderate arthritis (38%), mild mucosal ulceration (34%), mild alopecia (34%), pleurisy / pericarditis (22%). Twenty-five items were active in less than 1% of assessments. Easy-BILAG was therefore designed to enhance the visibility of the most frequently scored items and capture all clinical items scoring >5% in a rapid single-page assessment. All remaining, less common items, are scored, only when necessary, on a second page. Easy-BILAG incorporates an abridged glossary definition immediately adjacent to clinical each item. A new colour-blindness compatible, colour-coding system directs clinicians instantly to the overall A-E score for each domain.

In the validation exercise, clinicians were asked to identify active disease and assign BILAG-2004 scores, from A-E, for all 9 organ domains in a workbook of 10 case vignettes. Twenty clinicians, with a range of prior experience, have so far participated. Among clinicians working with the standard BILAG-2004 reference documents ($n = 11$), scoring 10 case vignettes took 90 +/- 9 minutes (mean +/- SEM) to complete. Clinicians using Easy-BILAG ($n = 9$) completed the exercise significantly faster at 66 +/- 8 minutes ($p = 0.05$). Crucially, Easy-BILAG yielded significantly higher percentage accuracy (mean +/- SEM) at 95.3 +/- 0.8 % across all domains, as compared with 81.8 +/- 6.2 % achieved by clinicians using standard BILAG-2004 documentation ($p = 0.05$). The difference was most apparent when specifically comparing accuracy across domains where the case exercises registered active disease. Here, Easy-BILAG showed no decline in accuracy at 94.9 +/- 1.0 % compared 75.7 +/- 5.3% achieved with standard BILAG-2004 documents ($p = 0.005$). In a usability survey, all (9/9) clinicians testing the Easy-BILAG template rated it as intuitive and simple to navigate.

Conclusion: Easy-BILAG facilitates more rapid and accurate scoring of BILAG-2004 and provides a format which is amenable to use in routine clinical practice. Following completion of validation, it will be made widely available to clinicians.

The figure shows a sample of the Easy-BILAG template. It includes a key for the A-E score (A: 0, B: 1, C: 2, D: 3, E: 4) and a table for scoring items. The table has columns for ITEM, ABBREVIATED GLOSSARY, and a scoring grid with rows for Not Present, Improving, Same, Worse, and New. The items are categorized by organ domain: Skin eruption, Mucosal ulceration, Alopecia, Digital infarct / nodular vasculitis, Periorbital erythema/chilblains, Other features, Arthritis, Pleurisy / Pericarditis, and Interstitial alveolitis/pneumonitis. The scoring grid uses a color-coded system (yellow, green, red, blue) to indicate the score for each item.

Figure 1. Illustration of the Easy-BILAG template shows format, colour scheme and method of scoring highest prevalence items mucocutaneous and musculoskeletal domain.

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