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Evaluation of the LFA-REAL clinician-reported outcome (ClinRO) and patient-reported outcome (PRO): data from the Peruvian Almenara Lupus Cohort

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ABSTRACT

Objective The Lupus Foundation of America Rapid Evaluation of Activity in Lupus (LFA-REAL) clinician-reported outcome (ClinRO) and the LFA-REAL patient-reported outcome (PRO) were developed in order to capture manifestations of SLE from the perspective of both the clinician and the patient. The aim of this study is to compare the LFA-REAL ClinRO and PRO with other lupus disease activity measures.

Methods A cross-sectional analysis of patients from a single-centre cohort was performed using Spearman's correlation. Disease activity measures included were LFA-REAL ClinRO (range 0–1400), LFA-REAL PRO (range 0–1200), Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K), clinical SLEDAI-2K and Physician Global Assessment (PGA, range 0–100).

Results Two hundred and twenty-seven patients with SLE were studied. The mean age was 46.3 (SD: 13.8); 212 (93.4%) were female. The mean (SD) LFA-REAL ClinRO was 25.4 (34.7), LFA-REAL PRO was 241.1 (187.6), PGA was 11.9 (15.4), SLEDAI-2K was 2.3 (3.3) and clinical SLEDAI-2K was 1.6 (2.9). The LFA-REAL ClinRO correlated with PGA (r=0.758, p<0.001), SLEDAI-2K (r=0.608, p<0.001) and clinical SLEDAI-2K (r=0.697, p<0.001); the LFA-REAL PRO correlated modestly with PGA (r=0.160, p=0.016), SLEDAI-2K (r=0.121, p=0.069), clinical SLEDAI-2K (r=0.143, p=0.031) and LFA-REAL ClinRO (r=0.161, p=0.015).

Conclusions The LFA-REAL ClinRO and the LFA-REAL PRO had good and weak correlations, respectively, with several physician-based disease activity measures in a cross-sectional study, suggesting their potential usefulness in establishing disease severity. Longitudinal studies will be required to determine their value in monitoring patients with SLE.

INTRODUCTION

SLE is a complex autoimmune disease with protean manifestations. Although instruments have been developed to measure disease activity, each has some limitations. For example, the Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) and its variants do not include all possible manifestations of disease activity and do not allow for severity grading. The British Isles Lupus Assessment Group Index (BILAG) includes a comprehensive list of clinical manifestations and does include grading of improvement or worsening; however, it is complex, requires special training and takes time to complete properly, which may not always be practical in the clinical setting.[1] The Physician Global Assessment (PGA) is commonly used because it covers every manifestation considered by the physician as being part of disease activity; in fact, it is included as an element in the definition of remission and low disease activity.[2 3] When PGA is done by lupus experts, it has an excellent inter-rater reliability, and its correlation with Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) is stronger if it is done with knowledge of laboratory tests.[4] One limitation of PGA is that the global score includes and weights several disease manifestations at once, which may limit its ability to detect change in individual organ systems and may vary depending on how physicians consider each organ weight.[5]

The Lupus Foundation of America (LFA) Rapid Evaluation of Activity in Lupus (REAL) clinician-reported outcome (ClinRO) proposes to solve some of these limitations. This new index includes nine organ domains; the idea behind this scale is to keep it as simple as PGA and SLEDAI, while enabling scoring of all clinical manifestations and allow for severity scoring like BILAG. Since it records

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the evaluation of each manifestation separately, it should have better reliability than PGA.[6]

Additionally, disease activity gauged using patient-reported outcome instruments has shown poor correlation with disease activity measured by physicians.[7 8] It is unclear whether this is due to patients disagreeing with clinicians about the degree of severity of a given symptom or whether the patients are focusing on different aspects of disease than the clinicians. To improve understanding of how patients evaluate the same manifestations that the clinicians are scoring, the LFA-REAL patient-reported outcome (PRO) proposes seven domains (skin, joints, muscle pain, fatigue, fever, hair loss and body symptoms).[9] The most common features, skin and joints, are assessed in a manner that allows direct comparison with clinicians' scores.

This study was designed to perform the initial validation of LFA-REAL ClinRO and LFA-REAL PRO in an established Latin American lupus cohort.

METHODS

The Almenara Lupus Cohort has been previously described.[10] In short, this cohort was started in January 2012 at the Rheumatology Department of Hospital Guillermo Almenara Irigoyen in Lima, Peru. Patients who signed the informed consent were followed every 6 months. Evaluations included an interview, medical records review, physical examination and laboratory tests. For this study visits between November 2018 and July 2019 were included.

SLE was defined using the 1997 revised American College of Rheumatology criteria.[11] Disease activity was assessed with SLEDAI-2K,[12] LFA-REAL ClinRO,[6] the Spanish version of LFA-REAL PRO[9] and PGA (0–100 mm).

The LFA-REAL ClinRO (online supplemental file 2) includes nine domains: mucocutaneous, musculoskeletal, cardiorespiratory, neuropsychiatric, renal, haematological, constitutional, vasculitis and others. Mucocutaneous includes one global scale and three subdomains (rash, alopecia and mucosal ulcers), and musculoskeletal includes one global scale and two subdomains (arthralgia/arthritis and myalgia/myositis). For the other seven domains, the manifestation is usually a single finding and is recorded under the original domain scale. In the rare event that there are two or more manifestations in any of these domains, the extra finding is recorded and scored using one of the 'other' scales. Similarly, if there is a manifestation in organs that are not specified, one of the 'other' scales is labelled and used. This keeps the instrument quite simple but allows flexibility for comprehensive scoring of all findings determined to be due to SLE. For each manifestation a Visual Analogue Scale (VAS) from 0 to 100 mm is used, with anchors separating mild, moderate and severe disease. Several applications are possible. Individual organs or symptoms can be reported and analysed. Additionally, two possible summary results can be reported. The first one includes only individual manifestations and does not include the global measurement of mucocutaneous and musculoskeletal involvement; it ranges from 0 to 1400. The alternative option is to include only the global domains and not the individual manifestations; it ranges from 0 to 1100.

The LFA-REAL PRO (online supplemental file 3) includes seven domains: rash, arthritis, myalgia, fatigue, fever, alopecia and body symptoms (which include chest pain, shortness of breath, swelling in legs and other). The arthritis domain includes three subdomains (joint pain, joint swelling and joint stiffness). After scoring each of these separately, the patient is asked to put them together and score global arthritis. This simple, stepwise process trains the patient to consider arthritis the same way that a clinician does. Furthermore, if the patient's report is inconsistent with that of the clinician, it can be determined which aspect of the arthritis is the basis for the discrepancy. For each manifestation, a VAS (0–100 mm) is used. Two possible summary results are reported: the first one includes every VAS with the exception of overall arthritis and it ranges from 0 to 1200, and the second one includes overall arthritis but excludes the three subdomains and it ranges from 0 to 1000.

Patient and public involvement

The Almenara Lupus Cohort used focus groups, interviews and questionnaires to determine patients' priorities and preferences, including which outcomes are relevant to them, and if there are any problems with the instruments used or the length of the visits. Patients are involved in the recruitment to the study, as they inform their relatives and friends about the cohort, and invite them to participate in the educational activities; if these contacts have SLE, they are invited into the cohort if they are affiliated with the Peruvian social security system. The results of our studies are reported to our patients during our different educational activities.

Statistical analyses

Correlations between summary reports and SLEDAI-2K and PGA were examined using Spearman's r; additionally, the correlation between the corresponding domains of the LFA-REAL PRO and the LFA-REAL ClinRO was evaluated. In order to evaluate the validity of the renal domain (LFA-REAL ClinRO) and swelling in legs (LFA-REAL PRO), correlations with proteinuria and serum albumin were examined. Furthermore, the correlation between the corresponding domains of the LFA-REAL ClinRO and SLEDAI-2K was evaluated in those domains affected in at least 10 patients, and as the correlation between the measures could be affected by the degree of disease activity, patients were divided into three groups: SLEDAI-2K=0, SLEDAI-2K between 1 and 4, and SLEDAI-2K >4. Correlations between summary reports, SLEDAI-2K and PGA were examined in each subgroup.

A p value (two-sided) <0.05 was considered significant in all analyses. All statistical analyses were performed using SPSS V.21.0.

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RESULTS

Two hundred and twenty-seven patients were included; 212 (93.4%) were female, a mean age of 46.3 (SD 13.8) years and disease duration of 11.6 (7.3) years. Disease characteristics are depicted in table 1.

As shown in table 2, both approaches to the summary scaling of the LFA-REAL ClinRO had good correlation with PGA, SLEDAI-2K and clinical SLEDAI-2K. Both approaches to summary scaling of the LFA-REAL PRO correlated somewhat with clinician outcome measures, with the strongest correlation being with PGA.

When individual components of the LFA-REAL ClinRO and the LFA-REAL PRO were evaluated, no correlation was found between mucocutaneous involvement ClinRO and PRO global or subdomain scores. Arthritis assessed by the clinician using the LFA-REAL ClinRO did correlate with the articular components of the LFA-REAL PRO, including overall arthritis (r=0.271, p<0.001) and the sum of the subdomains (r=0.289, p<0.001). The myalgia/myositis subdomains of the LFA-REAL ClinRO and PRO were not correlated.

Cardiorespiratory involvement scored by clinicians (LFA-REAL ClinRO) correlated with patients' report of fatigue (r=0.163, p=0.014), chest pain (r=0.240, p<0.001) and shortness of breath (r=0.289, p<0.001) using the LFA-REAL PRO.

Renal involvement scored on the LFA-REAL ClinRO correlated with proteinuria (r=0.738, p<0.001) and negatively with serum albumin (r=−0.250, p<0.001). Swelling in legs (scored by patients using the LFA-REAL PRO) correlated negatively with serum albumin (r=−0.197, p=0.003), but did not correlate with proteinuria or renal involvement scored by clinicians using the LFA-REAL ClinRO. Correlations of the domains of the LFA-REAL ClinRO and the LFA-REAL PRO are depicted in online supplemental table 1.

In the analyses per domain, only mucocutaneous, musculoskeletal, renal and haematological domains (defined according to SLEDAI-2K) were affected in at least 10 patients. In all cases there was good correlation between SLEDAI-2K and LFA-REAL ClinRO domains (between 0.645 and 0.821). These data are depicted in online supplemental table 2.

Finally, 107 patients had a SLEDAI-2K=0, 86 SLEDAI-2K between 1 and 4, and 34 SLEDAI >4. The LFA-REAL ClinRO correlated with PGA, SLEDAI-2K and clinical SLEDAI-2K in all the categories evaluated. However, the LFA-REAL PRO did not correlate with the physician-based measures in in most of the categories, the exception being one summary score and the PGA in those patients with a SLEDAI-2K =0. These analyses are depicted in online supplemental tables 3 and 4.

Table 1 Characteristics of patients with SLE

Variable	
Female gender, n (%)	212 (93.4)
Age, years, mean (SD)	46.3 (13.8)
Educational level, years, mean (SD)	13.3 (3.1)
Socioeconomic level, n (%)	
Low	27 (11.9)
Medium	69 (30.4)
High	131 (57.7)
Disease duration, years, mean (SD)	11.6 (7.3)
Clinical SLEDAI-2K, mean (SD)	1.6 (2.9)
SLEDAI-2K, mean (SD)	2.3 (3.3)
PGA, mean (SD)	11.9 (15.4)
SDI, mean (SD)	1.2 (1.5)
LFA-REAL ClinRO 0–1400, mean (SD)	25.4 (34.7)
LFA-REAL ClinRO 0–1100, mean (SD)	23.3 (30.8)
LFA-REAL PRO 0–1200, mean (SD)	241.1 (187.6)
LFA-REAL PRO 0–1000, mean (SD)	190.3 (151.2)
LFA-REAL ClinRO domains	
Mucocutaneous global 0–100, mean (SD)	2.23 (8.56)
Rash 0–100, mean (SD)	1.74 (7.73)
Alopecia 0–100, mean (SD)	1.22 (7.53)
Ulcers 0–100, mean (SD)	0.00 (0.00)
Musculoskeletal global 0–100, mean (SD)	6.41 (14.30)
Arthralgia/arthritis 0–100, mean (SD)	6.82 (14.69)
Myalgia/myositis 0–100, mean (SD)	0.99 (6.33)
Cardiorespiratory 0–100, mean (SD)	0.95 (6.90)
Neuropsychiatric 0–100, mean (SD)	2.03 (9.62)
Renal 0–100, mean (SD)	7.88 (16.46)
Haematological 0–100, mean (SD)	2.01 (8.28)
Constitutional 0–100, mean (SD)	1.20 (6.69)
Vasculitis 0–100, mean (SD)	0.33 (3.48)
LFA-REAL PRO domains	
Rash 0–100, mean (SD)	19.62 (24.83)
Overall arthritis 0–100, mean (SD)	27.09 (26.54)
Joint pain 0–100, mean (SD)	31.48 (26.45)
Joint swelling 0–100, mean (SD)	21.50 (24.52)
Joint stiffness 0–100, mean (SD)	24.88 (26.52)
Muscle pain or aches 0–100, mean (SD)	32.97 (26.73)
Fatigue 0–100, mean (SD)	34.08 (26.38)
Fever 0–100, mean (SD)	9.53 (19.02)
Hair loss 0–100, mean (SD)	25.46 (26.87)
Chest pain 0–100, mean (SD)	13.66 (22.76)
Shortness of breath 0–100, mean (SD)	10.45 (21.04)
Swelling in legs 0–100, mean (SD)	14.37 (25.00)

ClinRO, clinician-reported outcome; LFA-REAL, Lupus Foundation of America Rapid Evaluation of Activity in Lupus; PGA, Physician Global Assessment; PRO, patient-reported outcome; SDI, Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index; SLEDAI-2K, Systemic Lupus Erythematosus Disease Activity Index 2000.

DISCUSSION

The LFA-REAL system has been proposed in order to better understand how physicians and patients ascertain disease activity and find areas where they might be

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Table 2 (A) Correlation between LFA-REAL ClinRO and PGA, clinical SLEDAI-2K and SLEDAI-2K, and (B) correlation between LFA-REAL PRO and PGA, clinical SLEDAI-2K, SLEDAI-2K and LFA-REAL ClinRO

(A)	LFA-REAL ClinRO 0–1400 r	*p* value	LFA-REAL ClinRO 0–1100 r	*p* value
PGA	0.758	<0.001	0.763	<0.001
SLEDAI-2K	0.608	<0.001	0.61	<0.001
Clinical SLEDAI-2K	0.697	<0.001	0.695	<0.001
(B)	**LFA-REAL PRO, 0–1200 r**	***p* value**	**LFA-REAL PRO 0–1000 r**	***p* value**
PGA	0.160	0.016	0.174	0.009
SLEDAI-2K	0.121	0.069	0.135	0.043
Clinical SLEDAI-2K	0.143	0.031	0.144	0.030
LFA-REAL ClinRO 0–1400	0.161	0.015	0.157	0.018
LFA-REAL ClinRO 0–1100	0.150	0.024	0.146	0.028

ClinRO, clinician reported outcome; LFA-REAL, : Lupus Foundation of America Rapid Evaluation of Activity in Lupus; PGA, physician global assessment; PRO, patient reported outcome; SLEDAI-2K, systemic lupus erythematosus disease activity index 2000.

brought together to obtain the opinion of each when assessing the same manifestation. In this study, both summary reports of the LFA-REAL ClinRO correlated well with SLEDAI-2K, clinical SLEDAI-2K and PGA, without a significant difference between them. Both summary reports of the LFA-REAL PRO correlated, although weakly, with physician-based disease activity measurements, mainly with LFA-REAL ClinRO, PGA and clinical SLEDAI-2K, with similar correlations for both summary reports and stronger correlations for certain items such as arthritis and swelling in legs, which may be a good surrogate for nephrotic syndrome.

The correlation between LFA-REAL ClinRO, SLEDAI-2K, clinical SLEDAI-2K and PGA produced similar results when performed by clinicians and only slightly lower than the correlation between these scores as assessed by clinical investigators.[6 13 14]

When compared with SLEDAI, the LFA-REAL ClinRO has the advantage of capturing different levels of disease severity within one symptom, while the SLEDAI does not. In order to capture improvement, a modification of SLEDAI has been proposed: the SLEDAI-2K Responder Index 50, which records an improvement of at least 50% in any given item as a reduction of 50% in the points due to the corresponding manifestation. However, this is not a sensitive measure of change since if the improvement is, for example, 40%, it is recorded as no improvement.[15]

The correlation between LFA-REAL ClinRO and PGA, SLEDAI-2K and clinical SLEDAI-2K was better than previously reported between the Systemic Lupus Activity Measure Revised (SLAM-R) and PGA (r=0.566) or SLEDAI-2K (r=0.560).[16] In other reports, using SLEDAI (and its derivatives), SLAM, Lupus Activity Index (LAI), BILAG and/or the European Consensus Lupus Activity Measure (ECLAM), a correlation between these indices and PGA (SLEDAI r=0.12–0.79, SLAM r=0.42, LAI r=0.30–0.64, BILAG r=0.28–0.43 and ECLAM r=0.32) was similar or slightly lower than the correlations we found between the LFA-REAL ClinRO and PGA, SLEDAI-2K and clinical SLEDAI-2K.[8 17–19] However, in a study by Liang *et al*,[20] the correlation between PGA and several disease activity measures, including BILAG, SLEDAI and SLAM, was slightly better (r=0.757–0.963). The correlation between LFA-REAL ClinRO and PGA, SLEDAI-2K and clinical SLEDAI-2K was similar independently of the degree of disease activity. Additionally, when the corresponding domains of SLEDAI-2K and LFA-REAL ClinRO were evaluated, the correlation was similar than with the global scores. Taken together, these results suggest that the LFA-REAL ClinRO may be an accurate and practical measure of SLE disease activity for use in clinical and research settings.

Some previous reports either did not find a correlation between disease activity ascertained by the patients (using global VAS) and the physician (using VAS, SLAM, SLEDAI or its variants, BILAG, LAI and ECLAM), or found weak correlations.[7 8 21–23] This could be due to the fact that patient global assessment integrates multiple aspects of disease into a global score, giving more weight to aspects of patients' illness than their clinicians may consider less important; this is certainly influenced by patients' health-related quality of life.[21 22] Assessment of specific symptoms using the LFA-REAL, along with an itemised evaluation of PROs, could shed some light on this important discrepancy. Nevertheless, the LFA-REAL PRO global score correlated only weakly with the physician-based disease activity measures, and this association was not present when patients were divided according to the degree of disease activity, with the exception of one summary score and PGA in those with SLEDAI-2K=0, reinforcing the importance of including patients' perception of disease activity and the notion that patients and physicians may

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assess disease activity differently,[21] even when evaluating the same symptoms, but when disease activity is very low their perception could be more similar. However, it is important to point out that this lack of association could be influenced by sample size. Another factor associated with a larger discordance between the patient and the physician in other chronic diseases is educational level,[24 25] and for this reason the LFA-REAL PRO should be validated in different populations.

When the individual components of the LFA-REAL ClinRO and PRO were examined, we found that the arthritis domains correlated well, suggesting that an arthritis-specific endpoint might be a useful outcome for trials wishing to include input from both patients and clinicians. Similarly, fatigue, chest pain and shortness of breath from the LFA-REAL PRO correlated with the cardiorespiratory domain from the LFA-REAL ClinRO, and swelling in legs correlated negatively with albumin level. In the validation study of the Systemic Lupus Activity Questionnaire (SLAQ), arthritis and cardiorespiratory domains correlated between SLAQ and SLAM, and good correlation was obtained in mucocutaneous and neuropsychiatric manifestations; however, renal involvement, one of the most worrisome lupus manifestations, was not included in that index.[26] Furthermore, the correlation between SLAQ and disease activity measured by the physician (SLEDAI, BILAG or SLAM) is affected by the presence of non-inflammatory symptoms (the higher the frequency, the lower the correlation).[23]

Limitations of our study include the fact that it was conducted in patients from a single-centre cohort. Additionally, we cannot rule out that sociodemographic characteristics impacted the application of the index. Second, due to relatively low prevalence of some clinical manifestations, it will take larger and longer studies to evaluate them in a more comprehensive manner.

This study did, however, involve a large number of patients. Other strengths of this report are that it is the first study comparing the LFA-REAL PRO with clinician-scored disease activity measures and is the first study evaluating the LFA-REAL outside the USA. We conclude that the LFA-REAL ClinRO and PRO appear to be potentially useful for evaluating disease activity in patients with SLE from both the clinician's and the patient's perspectives. Longitudinal evaluation of these instruments in ethnically and clinically diverse cohorts is needed to determine their impact on the evaluation of patients' progress over time and their overall prognosis.

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