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BRIEF REPORT

Classification of Systemic Lupus Erythematosus: Systemic Lupus International Collaborating Clinics Versus American College of Rheumatology Criteria. A Comparative Study of 2,055 Patients From a Real-Life, International Systemic Lupus Erythematosus Cohort

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Objective. **The new Systemic Lupus International Collaborating Clinics (SLICC) 2012 classification criteria aimed to improve the performance of systemic lupus erythematosus (SLE) classification over the American College of Rheumatology (ACR) 1997 criteria. However, the SLICC 2012 criteria need further external validation. Our objective was to compare the sensitivity for SLE classification between the ACR 1997 and the SLICC 2012 criteria sets in a real-life, multicenter, international SLE population.**

Methods. **We conducted a cross-sectional observational study of patients with a clinical diagnosis of SLE followed at the participating rheumatology centers and registered in the Portuguese and Spanish national registries. The sensitivity of the 2 classification sets was compared using McNemar's test. The sensitivity of ACR 1997 and SLICC 2012 was further examined in 5 subgroups, defined according to disease duration.**

Results. **We included 2,055 SLE patients (female 91.4%, white 93.5%, mean ± SD age at disease onset 33.1 ± 14.4 years, mean ± SD age at SLE diagnosis 35.3 ± 14.7 years, and mean ± SD age at the time of the study 47.4 ± 14.6 years) from 17 centers. The sensitivity for SLE classification was higher with the SLICC 2012 than with the ACR 1997 (93.2% versus 85.6%; $P < 0.0001$). Of 296 patients not fulfilling the ACR 1997, 62.8% could be classified with the SLICC 2012. The subgroup of patients with ≤5 years since disease onset presented the largest difference in sensitivity between the SLICC 2012 and the ACR 1997 (89.3% versus 76.0%; $P < 0.0001$); this difference diminished with longer disease duration, and it was no longer significant for patients with >20 years of disease duration.**

Conclusion. **The SLICC 2012 criteria were more sensitive than the ACR 1997 criteria in real-life clinical practice in SLE. The SLICC 2012 criteria may allow patients to be classified as having SLE earlier in the disease course.**

Introduction

Systemic lupus erythematosus (SLE) poses great challenges to diagnosis and classification, due to its extremely heterogeneous multisystemic manifestations (1). Classification criteria are of utmost importance to ensure a consistent case definition for clinical research and randomized

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Significance & Innovations

- The Systemic Lupus International Collaborating Clinics (SLICC) 2012 criteria were more sensitive than the American College of Rheumatology (ACR) 1997 criteria in real-life systemic lupus erythematosus (SLE) clinical practice.
- The SLICC 2012 may allow patients to be classified as having SLE earlier in the disease course.
- Most clinically diagnosed SLE patients not satisfying the ACR 1997 criteria fulfilled the SLICC 2012 set.

clinical trials. The SLE classification criteria set most commonly used is the one established by the American College of Rheumatology (ACR) in 1982 and updated in 1997 (ACR 1997) (2,3). Despite the fact that the ACR 1997 performed well, problems with these criteria are recognized, in particular a limited sensitivity against the "gold-standard" of SLE expert clinical diagnosis (4). Other major concerns with the ACR 1997 include the inability to classify patients with only biopsy-proven lupus nephritis, the redundancy of photosensitivity with skin rashes, not considering several clinically relevant integument and nervous system lupus manifestations, as well as important immunologic tests, namely complement fractions and anti–β2-glycoprotein I. Consequently, patients included in clinical trials and other clinical research studies with SLE defined according to the ACR 1997 criteria may not be representative of the real spectrum of the disease. To address these problems, the Systemic Lupus International Collaborating Clinics (SLICC) research group recently proposed a new classification criteria set (SLICC 2012) (5). Sensitivity of the ACR 1997 and of the SLICC 2012 for clinically diagnosed SLE as "gold-standard" was 83% and 97%, respectively, in the original validation set of patient scenarios (5). Inversely, specificity was reduced from 96% with the ACR 1997 to 84% with the SLICC 2012 (5). Taken together, the SLICC 2012 criteria resulted in fewer misclassifications of SLE compared to the ACR 1997.

However, it is not known if the SLICC 2012 sustains an increased sensitivity for SLE compared to the ACR 1997, if applied to a more heterogeneous real-life SLE population. The primary aim of this study is to compare the sensitivity for SLE clinical diagnosis of the ACR 1997 and SLICC 2012 classification criteria sets in a real-life, multicenter international SLE population.

Patients and methods

Study population. We aimed to include all patients with a clinical diagnosis of SLE followed at the participating hospital-based rheumatology departments. Data collection was performed through the national Portuguese or Spanish registries (Reuma.pt and RELESSER, respectively) (6,7). The clinical diagnoses of SLE were established by an attending rheumatologist experienced in SLE and did not require the fulfillment of the SLE classification criteria. However, RELESSER excluded from registration patients with $\leq$2 criteria from the ACR 1997 set (3). Patients signed a written informed consent to participate in the study. At study closure, at least 70% of all the patients with a clinical diagnosis of SLE identifiable in the administrative or clinical databases of each participating center were included (7). The inclusion period was from October 27, 2011 to June 30, 2013.

Study design and data collection. This was a cross-sectional observational study. Coprimary end points were the proportion of patients cumulatively fulfilling each of the SLE classification criteria sets (ACR 1997 and/or SLICC 2012) at the time of this study.

Variables assessed for each participant included sex, ethnicity, age at onset of SLE (defined as age at first clinical manifestation attributable to SLE, as established by the attending rheumatologist), age at SLE clinical diagnosis (defined as age at SLE diagnosis, regardless of classification criteria but implying that the attending rheumatologist starts intent-to-treat care for SLE), age at enrollment in this study, SLE duration since disease onset and from diagnosis, medication, and cumulative fulfillment of each SLE criterion included in the ACR 1997 and SLICC 2012 sets. Data for each variable were obtained from direct patient evaluation and from review of hospital records. The patients' data were recorded in the respective

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Table 1. Characteristics of the SLE study population*

Characteristic	Value
SLE patients, no.	2,055
Participating centers, no.	17
Ethnicity, % white European	93.5
Female sex, %	91.4
Age at study entry, mean ± SD years	47.4 ± 14.6
Age at SLE onset, mean ± SD years	33.1 ± 14.4
Age at SLE diagnosis, mean ± SD years	35.3 ± 14.7
SLE duration since diagnosis, median (IQR) years	10.3 (12.0)
SLE duration since onset, median (IQR) years	12.1 (12.3)

* SLE = systemic lupus erythematosus; IQR = interquartile range.

national registry. Anonymized data from the participants were extracted from the registries and collected in an Excel spreadsheet.

Both registries guarantee confidentiality of the participants' data and comply with the applicable national laws for data protection. This project adheres to the principles of the Declaration of Helsinki and obtained approval by the participating centers' research ethics committees.

Statistical analyses. For each patient, we scored as a dichotomous variable the fulfillment of the ACR 1997 and of the SLICC 2012 classification criteria sets. The sensitivity for SLE classification of each set was calculated. We compared the proportion of cases in the study population fulfilling the ACR 1997 and SLICC 2012 criteria using McNemar's test.

The sensitivity of each criterion from the ACR 1997 and SLICC 2012 sets for SLE was calculated. To examine the sensitivity of the 2 sets according to disease duration, we categorized the study population into 5 subgroups from disease onset to enrollment in this study (up to 5 years, >5 to ≤10, >10 to ≤15, >15 to ≤20, and >20 years). For each subgroup, the sensitivity of the ACR 1997 and SLICC 2012 classification criteria was compared applying McNemar's test. We applied a chi-square or Fisher's exact test (as appropriate) to test for differences in sensitivity of each classification criteria set across categories of SLE duration and also to compare medication across subgroups. The statistical level of significance considered for all tests was less than or equal to 0.05. Analyses were done using SPSS Statistics, version 19.0 (IBM).

Results

We included 2,055 patients with a clinical diagnosis of SLE, followed at 17 hospital-based rheumatology clinics (12 Portuguese and 5 Spanish). Four centers (2 in Portugal and 2 in Spain) included from 200 to 351 patients, and 5 centers included <50 patients each. Characteristics of the study population are presented in Tables 1 and 2. A significantly higher proportion of these patients fulfilled the SLICC 2012 classification criteria than the ACR 1997 set (93.2% versus 85.6%; $P < 0.0001$). In this study, 94.6% of the patients satisfied at least 1 of these SLE classification criteria sets and 92.3% were treated with antimalarials and/or immunosuppressants during followup. There was no significant difference in the proportion of patients treated with antimalarials comparing the subgroup fulfilling the ACR 1997 and those fulfilling only the SLICC 2012.

Applying the SLICC 2012 criteria resulted in the addition of 186 SLE cases as compared to the ACR 1997 set. Isolated biopsy-proven lupus nephritis with positive antinuclear or anti–double-stranded DNA antibodies

Table 2. Sensitivity of each SLICC 2012 and ACR 1997 criterion for SLE in the study population*

Criteria set	Sensitivity, %
SLICC 2012	
Acute cutaneous lupus	67.4
Chronic cutaneous lupus	12.9
Oral or nasal ulcers	35.4
Non-scarring alopecia	28.8
Synovitis	72.5
Serositis	23.0
Renal	29.4
Neurologic	8.6
Hemolytic anemia	11.1
Leukopenia (<4,000 cells/mm^3) or lymphopenia (<1,000 cells/mm^3)	47.1
Thrombocytopenia (<100,000 cells/mm^3)	19.2
ANA	98.9
Anti-dsDNA	74.3
Anti-Sm	15.2
Antiphospholipid antibodies	35.2
Low complement	71.0
Direct Coombs' test	13.9
ACR 1997	
Malar rash	44.2
Discoid rash	10.3
Oral or nasal ulcers	35.4
Photosensitivity	50.0
Arthritis	72.5
Serositis	23.0
Renal	29.4
Neurologic	6.1
Hematologic	67.0
Hemolytic anemia	11.1
Leukopenia (<4,000 cells/mm^3)	41.8
Lymphopenia (<1,500 cells/mm^3)	47.7
Thrombocytopenia (<100,000 cells/mm^3)	19.2
Immunologic abnormalities	82.1
Anti-dsDNA	74.3
Anti-Sm	15.2
Anti-phospholipid antibodies	31.3
ANA	98.9

* SLICC = Systemic Lupus International Collaborating Clinics; ACR = American College of Rheumatology; SLE = systemic lupus erythematosus; ANA = antinuclear antibody; Anti-dsDNA = anti–double-stranded DNA.

Table 3. Comparison of classification set performance according to categories of SLE duration*

SLE duration since onset	Sensitivity of ACR 1997 criteria, %	Sensitivity of SLICC 2012 criteria, %	Difference in sensitivity	*P*
Any duration	85.6	93.2	7.6	< 0.0001
≤5 years	76.0	89.3	13.3	< 0.0001
>5 to ≤10 years	82.0	90.3	8.3	< 0.0001
>10 to ≤15 years	87.7	94.9	7.2	< 0.0001
>15 to ≤20 years	91.9	98.2	6.3	< 0.0001
>20 years	94.3	96.9	2.6	0.0963

* SLE = systemic lupus erythematosus; ACR = American College of Rheumatology; SLICC = Systemic Lupus International Collaborating Clinics.

accounted for 10 of such cases. Conversely, 1.6% of patients (n = 29) fulfilling the ACR 1997 failed to be classified with the SLICC 2012 criteria as follows: in 18 cases because of photosensitive malar rash scored as just 1 criterion in SLICC 2012, in 3 cases due to loss of the lymphopenia criterion because of the lower cutoff (1,000 cells/mm^3) with the SLICC 2012; in 4 additional cases because of both of the aforementioned issues, and yet another 4 cases failed the immunologic criterion.

The proportion of missing data for each criterion from the ACR 1997 and SLICC 2012 sets was <4%, except for the direct Coombs' test, which was not available in 36.3% of cases. The SLICC 2012 acute cutaneous lupus criterion was fulfilled by 67.4% of patients, whereas 62.9% scored the ACR 1997 malar rash and/or the photosensitivity criteria ($P < 0.0001$). A higher proportion of patients scored the SLICC 2012 chronic cutaneous lupus criterion compared to the ACR 1997 discoid rash criterion ($P < 0.0001$). More patients scored for the neurologic criterion with the SLICC 2012 compared to the ACR 1997 ($P < 0.0001$). Beyond antinuclear antibody positivity, significantly more patients scored at least 1 of the other immunologic abnormalities in the SLICC 2012 compared to the ones included in the ACR 1997 criterion (89.6% and 82.1%, respectively; $P < 0.0001$). This difference was mostly due to the inclusion of low complement levels in the SLICC 2012. The sensitivity of the individual SLICC 2012 and ACR 1997 criteria for SLE classification in the study population is presented in Table 2.

The sensitivity for SLE classification increased with longer disease duration, for both criteria sets ($P < 0.0001$). The subgroup of patients with ≤5 years of disease duration presented the largest gain in sensitivity of SLICC 2012 set compared to ACR 1997 (89.3% versus 76.0%; $P < 0.0001$); this difference diminished as disease duration increased, and it was no longer significant for the subgroup with >20 years of disease duration (Table 3).

Discussion

Our study confirms that the SLICC 2012 criteria are more sensitive than the ACR 1997 criteria in a large group of patients representing real-life clinical practice in SLE and therefore provides a further external validation of the SLICC classification criteria. Furthermore, our results suggest that the SLICC 2012 may allow an SLE classification earlier in the disease course.

For the original derivation and validation work, SLE patients and control subjects with a relevant non-SLE diagnosis were selected from highly specialized lupus clinics, and the "gold standard" SLE clinical diagnosis was established by an expert committee reviewing abstracted patient scenarios (5). In our study we aimed to include a multicenter representative sample of the real-life SLE population participating in interventional and observational studies in Spain and Portugal (7–9). The large population included in this study is also likely to be representative of the general population of SLE patients, as most individuals with a clinical suspicion of SLE regardless of disease severity are likely to be referred to the participating centers in these countries.

Possibly the most controversial change brought by the SLICC 2012 is ending the "double counting" of photosensitive malar rash as 2 criteria, as allowed with the ACR 1997 (10,11). In fact, we found this to be the most frequent cause for losing SLE classification by the SLICC 2012 when achieved by the ACR 1997. Nonetheless, in our study this caused a loss of classification with SLICC 2012 in a very small proportion of patients. In a study in the LUpus in MInorities, NAture versus nurture (LUMINA) cohort, the proportion of SLE patients not classified with SLICC 2012 criteria while satisfying the ACR 1997 criteria due to this issue was larger (11). However, it must be noted that fulfilling the ACR 1997 criteria was a precondition to be included in the LUMINA cohort. Furthermore, data for additional cutaneous features, as well as other clinical and immunologic manifestations newly included in SLICC 2012, had not been obtained in those patients in a systematic manner. These are likely sources of bias limiting the interpretation of those results. In our study, data regarding the clinical and immunologic parameters newly included in the SLICC 2012 were obtained purposely, with a very low

proportion of missing data; the Coombs' test was the only exception.

The arthritis criterion was substantially redefined from the ACR 1997. In the SLICC 2012 it has an exclusively clinical definition and may be established even without detection of joint swelling. This definition requires a substantial expertise in rheumatologic evaluation to correctly differentiate lupus arthritis from other conditions, such as fibromyalgia. In this study all patients were evaluated by rheumatologists, and the proportion fulfilling the ACR 1997 and SLICC 2012 arthritis definition was the same.

The increased scope of clinical and immunologic manifestations included in SLICC 2012 may allow fulfillment of SLE classification earlier in the disease course. In our study, the subgroup analysis supports this possibility, as the improvement in sensitivity of the SLICC 2012 over the ACR 1997 was greater in those patients with shorter disease duration. On the contrary, a study in the LUMINA and Grupo Latino Americano de Estudio del Lupus Eritematoso (GLADEL) cohorts showed that the proportion of patients fulfilling the ACR 1997 earlier in the disease course was larger than for the SLICC 2012. However, as noted, this study had no data on several clinical and immunologic manifestations newly included in SLICC 2012 (11).

Our study has some limitations. It included mostly white European patients recruited from adult rheumatology clinical settings, and this does not guarantee comparable performance of classification criteria in other ethnic groups or for pediatric cases (11,12). Another limitation is the exclusion of patients fulfilling ≤2 ACR 1997 criteria from entering the Spanish registry. This study was not designed to determine which set of criteria allows an earlier SLE classification; an observational longitudinal study of an inception cohort of patients suspected of having lupus and related disorders will be better suited for that. Finally, we did not aim to compare specificity of these classification criteria; the original SLICC 2012 derivation and validation work and subsequent studies suggest that specificity may be better with the ACR 1997 (5,11,12).

The SLICC 2012 criteria greatly contribute to reducing the frequent issue of "incomplete lupus" cases not fulfilling the classification criteria. However, the SLICC 2012 were not tested for purposes of diagnosis. Development of diagnostic criteria for SLE to use in the clinical practice remains an important unmet need (10,13).

The use of the SLICC 2012 criteria in interventional and observational studies will allow the inclusion of a larger proportion of patients with a clinical diagnosis of SLE. The possibility of simultaneously applying the ACR 1997 does not seem justifiable; that would add unnecessary complication as almost all patients fulfilling the ACR 1997 will also be positively classified with SLICC 2012. For studies where the specificity of SLE classification is a dominant issue, the ACR 1997 may be considered.

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AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be submitted for publication. Dr. Inês had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Acquisition of data. Inês, Silva, Galindo, Lopez Longo, Terroso, Romão, Rua-Figueroa, Santos, Pego-Reigosa, Nero, Cerqueira, Duarte, Cunha-Miranda, Bernardes, Gonçalves, Mouriño Rodriguez, Araújo, Raposo, Barcelos, Couto, Abreu, Otón-Sánchez, Macieira, Ramos, Branco, da Silva, Canhão, Calvo-Alen.

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