Research Article

The Journal of Autoimmunity

The sensitivity of the SLICC 2012 and EULAR / ACR 2019 categorization criteria was compared in a Colombian population with systemic lupus erythematosus.

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Received Date : May 22, 2024
Accepted Date : May 23, 2024
Published Date : June 23, 2024

ABSTRACT

Background : Goal: An autoimmune illness affecting several systems, systemic lupus erythematosus (SLE) has a broad spectrum of clinical symptoms. A Latin American population of Amerindian heritage has not been shown to meet the most recent classification standards, EULAR/ACR 2019. This study's goal is to contrast the sensitivity of the Classification criteria for EULAR/ACR 2019 and SLICC 2012 in a cohort of SLE patients with the aforementioned ancestry.

Techniques : It was a cross-sectional study. Information was gathered by looking at the medical records of individuals who fit the requirements for inclusion. The McNemar test was used to determine and compare the overall sensitivity of the criteria.

Findings : Two referral facilities' total of 146 patient medical records were comprised. The sensitivity of the EULAR/ACR and SLICC 2012 criteria did not differ between the groups (84.9% against 85.6% p = 0.79), nor did they differ when the groups were compared according to the length of the disease (91.0% versus 92.5% p = 0.70), 10 years or more (76.7% vs 76.7% p = 1), and between 5 and 10 years (82.8% versus 82.8% p = 1). In contrast, individuals with a disease duration of less than five years were shown to be more accurately classified using the SLICC 2012 criteria (92.5% versus 76.4%, p = 0.024).

Conclusions : In the population under investigation, there are no statistically significant variations between the EULAR/ACR and SLICC 2012 criteria. There were no differences observed when comparing the group with less than 5 years of disease duration to those with 10 years or more using the SLICC 2012 criteria. These results were also obtained when analyzing them based on age at diagnosis and length of disease.

Keywords : Systemic lupus erythematosus, Prevalence, Criteria, European league against rheumatism (EULAR), American College of rheumatology (ACR), Systemic lupus international collaborating, clinics ,American College of rheumatology (SLICC)

INTRODUCTION

An autoimmune condition known as systemic lupus erythematosus (SLE) is often multisystemic. On the other hand, it occasionally just involves one organ. Women are primarily affected, with a peak onset occurring before the age of of 45 and an incidence that, while it is twice as high among Hispanics, varies from 72.8 to 102 cases per 100,000 persons annually in North America. According to calculations, the prevalence in Colombia is 0.05%, or 91.9/100,000 persons, with a female to male ratio of 7.9:1 and a peak occurrence between the ages of 45 and 49 [1–5]. Any organ or system may be moderately or severely compromised by the clinical appearance, which can vary [6]. In the past, classification standards with a sensitivity and specificity of, say, the 1982 American College of Rheumatology (ACR) 96% of them have been utilized, and they were developed by nine specialists from the American Rheumatism Association (ARA) [7]. Considering the significant variability in cutaneous lupus and the potential for individuals to be categorized as New criteria have to be created for SLE as there were just mucocutaneous symptoms and no renal histopathology [7].

Next, criteria were set for the Systemic Lupus International Collaborating Clinics (SLICC) 2012 [8]. They added new items, such as low complement, direct positive Cobbs test in the absence of hemolysis, and clinical and immunological criteria, while adhering to the fundamental concept of the ACR 1982 criteria. Moreover, renal histology in conjunction with anti-double-stranded DNA antibodies (ds-antiDNA) or

antinuclear antibodies (ANA) was acknowledged as a valid categorization.was taken out. Acute confusional condition, transverse myelitis, cranial or peripheral neuropathy, and mononeuritis multiplex were among the few contributions from the neurological domain [8]. The delicate nature 97% was attained by these criteria, which was better than the ACR 82 even though the 84% specificity was degraded [9].

New classification criteria were discovered in 2019 that preserved the specificity of ACR 1997 [10] while increasing its sensitivity. Following validation, the criteria yielded sensitivity of 96.1% and specificity of 93.4%, exceeding ACR 1997's results of 82.8% and 93.4%, respectively. These criteria were modified in three fundamental ways. Antinuclear antibodies (ANAs), the first modification, were added as a prerequisite for admission. Giving the criteria some weight was the second, and applying them only in the absence of a more plausible explanation was the third [7, 8]. Notably,

Just 73 of the 696 SLE patients that were included in the study to create new criteria were Hispanic, a group that is associated with a worse prognosis and a higher incidence of renal involvement [11].

Studies contrasting these new standards with the previous ones have been conducted, as was to be expected. Dahlstrom's [12] publication is among the initial ones. It draws a comparison between the 2012 and current SLICC criteria, concluding that their sensitivity and specificity are comparable. Results from a different research with 293 SLE patients [13] were comparable. Regarding the lack of distinctions between ACR 1997, SLICC 2012, and European League Against Rheumatism (EULAR)/ACR 2019. It is to be mentioned that there have additionally pediatric population studies, like the one conducted by Batu et al. [14], examined the three criteria used in the prior study and reported 94.8%, 89.7%, and 88.5% for specificity and 68.7%, 95.4%, and 91.6% for sensitivity. They came to the conclusion that in this group, SLICC and ACR 1997 outperform EULAR/ACR 2019 in terms of sensitivity and specificity. The revised criteria were evaluated in comparison to ACR 1997 and SLICC 2012 by the Latin American Lupus Study Group (GLADEL) [15]. When comparing the sensitivity determined for EULAR/ACR 2019 to the ACR 1997 criteria, which was considered the benchmark, came in at 91.3%. Furthermore, it was found that patients may be identified at earlier phases of the illness by employing the current standards. Nevertheless, no research that has been published in Colombia has discovered anything like this. A handful have been conducted on populations that comprise individuals with polyautoimmunity or Amerindian ancestry. This is significant because, in the context of the autoimmune tautology, the two conditions—ancestry and polyautoimmunity—are crucial [16, 17].

In this study, a Latin American sample with Amerindian heritage from two referral centers in Bogota, Colombia, is used to examine the sensitivity of the SLE EULAR/ACR 2019 and SLICC 2012 classification criteria.

TECHNIQUES

Design of the study and data gathering

It was a cross-sectional study. Information was gathered from the review in order of patients' medical records who were assessed at two referral centers between 2016 and 2019 and who were anonymously documented in an electronic collection style. Age, sociodemographic information, length of illness, age of onset, polyautoimmunity presence or absence, comorbidities, therapies, immune profile, and any other factors pertaining to the two sets of criteria (2019 and 2012) were among the variables gathered.

Population under study

All patients who satisfied the following inclusion criteria had their medical records independently reviewed by two investigators: a) the treating physician's diagnosis of systemic lupus erythematosus using International Classification of Diseases-10 codes, which range from M329, N040 to N084, from N178 to N189 and N19X noted in the inpatient and outpatient clinical histories; b) accessibility of all clinical history data, encompassing the different clinical and paraclinical factors to support both sets of requirements. Patients who were younger than eighteen or who exclusively had drug-induced or cutaneous lupus were not included.

This work was approved by the ethics committees for research on human subjects (HSJ-FUCS/CEISH Act number 576), the research ethics committees of the participating centers (Ethics Committee on research with human beings of the Fundacion Hospital Infantil Universitario de San Jose Act number 70), and guarantees the confidentiality of the participants' data. These committees also adhere to the principles of the Declaration of Helsinki. The privacy of the personal data was maintained. mous, and during the database building and analysis, a unique code was created for every subject.

Analytical statistics

The Excel ® software was used to export the data from the digital format to a database, and STATA version 15 ® was then used for analysis. Based on the EULAR/ACR 2019 and SLICC 2012 criteria, the frequency of SLE was determined by counting the number of patients who satisfied the classification requirements. Measures of central tendency and dispersion were used for the quantitative variables, while absolute and relative frequencies were used for the qualitative variables, in a descriptive study of the variables of interest. The interquartile range and median were used to

summarize the age variable. The Shapiro Wilk test was used to determine whether the data were normal.Fisher's exact test was employed to assess the disparity in amounts. The criteria's total sensitivity was determined and contrasted with one another using the McNemar examination. Using a $p < 0.05$, the level of statistical significance was determined.

OUTCOMES

One hundred forty-six SLE patients from two reference centers in Bogotá, Colombia were involved. The cohort's median age was 36 (interquartile range: 26–51), with women accounting for the majority of cases (82.8%) and those with disease durations of less than five years (46.2%). In terms of treatment, 87.6% and 98.6% of the patients got corticosteroids and antimalarial drugs, respectively. Ninety-five patients (92.4%) had positive ANA results; homogeneous was the most often reported pattern, followed by granular. recurring themes or Five patients had unreported dilutions in their medical histories. Out of them, only one satisfied the SLICC 2012 requirements; the remaining ones didn't fit any of the sets of requirements. Furthermore, it was discovered that 6 individuals had negative ANAS, 5 met None of them satisfied the EULAR/ACR 2019 requirements (an entrance criterion), nor the SLICC 2012 requirements. Smoking and hypertension are two comorbidities that stick out. 94 (85.4%) and 99 (90%) of the patients supplied by Hospital San Jose from the outpatient area met the SLICC 2012 requirements. 25 patients (69%) and 31 patients (86.1%) who were included from the hospitalization area of the Fundaci´ on Hospital Infantil Universitario de San Jos´e matched the EULAR/ACR 2019 criteria and the SLICC 2012 criteria, respectively. Of the whole Ninety-four percent of the population under study satisfied at least one of the 2012 SLICC criteria, 125 (85.6%) met the EULAR/ACR 2019 criteria, and 124 (84.9%) met the SLE qualifying criteria. Among the 125 patients who satisfied the 2012 SLICC criteria, four of them did so without fulfilling any further requirements since they had biopsy-verified lupus nephritis and positive ANAS, one of whom also had additional positive Anti-double stranded DNA (Anti-dsDNA). Table 1 displays the demographic details of the population under investigation. Tables 2 and 3 4.

This study showed that the SLICC 2012 and EULAR/ACR 2019 criteria do not differ statistically significantly in a a collection of patients (both hospital and outpatient) that reflect a real-life clinical practice in the Colombian community. There were no differences observed when comparing them based on the age at diagnosis or the length of the condition, with the exception of the group with a duration of less than five years, who were compared to those with a duration of more than ten years, using the SLICC 2012 criteria. Pons-Estel of the Latin American Lupus Study Group (GLADEL) [15] conducted one of the most representative studies conducted in Latin America, comparing the EULAR/ACR 2019 criteria and the ACR 97 in a cohort consisting of Caucasians.

DISCUSSION

This study showed that the SLICC 2012 and EULAR/ACR 2019 criteria do not differ statistically significantly in a collection of patients (both hospital and outpatient) that reflect a real-life clinical practice in the Colombian community. There were no differences observed when comparing them based on the age at diagnosis or the length of the condition, with the exception of the group with a duration of less than five years, who were compared to those with a duration of more than ten years, using the SLICC 2012 criteria. Pons-Estel of the Latin American Lupus Study Group (GLADEL) [15] conducted one of the most representative studies conducted in Latin America, comparing the EULAR/ACR 2019 criteria and the ACR 97 in a cohort consisting of Caucasians and Mestizos ruled the majority. More women with a little lower mean age than in our group (29.8 vs. 36 years) participated, as is usual in autoimmune illnesses in general and our study in particular. The level of sensitivity discovered for The new criterion was 91.3%, which is higher than the 84.9% sensitivity seen in our investigation. The LUMINA (Lupus in Minorities: Nature Vs. Nurture) cohort [18], which also includes Spanish-American patients, has some intriguing findings. These were consistent with the GLADEL group, which is a subgroup of patients with more severe disease that fulfill EULAR/ACR 2019 criteria. Furthermore, a small number of the study's patients fulfilled the primary goal of being classified as early as possible at the time the criteria were created. An further study on Latin America It demonstrated that the ACR97 criteria are less sensitive than the SLICC 2012 criteria [19].

Compared to the EULAR/ACR 2019 criteria, which only demonstrated a trend, the SLICC 2012 was more effective in categorizing individuals with a less than 5-year history of SLE. These results are in line with a research by Ines et al. [20], which found that the SLICC 2012 was a more sensitive classifier of patients than the ACR 97 criteria ($p < 0.0001$). ACR 97, SLICC 2012, and EULAR/ACR 2019 criteria were compared in a retrospective observational analysis conducted by Adamichou et al. [21] in patients with early disease (48 months). The investigation showed that the first two were more responsive to the demographic being studied than ACR 97. Also comparing was Lobo Prat [22].Results were similar to those of studies by Vrancianu and were published in EULAR/ACR 2019 and SLICC 2012, without mentioning variations in sensitivity with regard to patients with lengthy disease duration [23].and Garcia Duarte [24]. The Johnson et al. [25] study had

patients of Hispanic descent and produced findings that are in opposition to ours because,In their opinion, the sensitivity of the EULAR/ACR 2019 criteria was superior for patients with early illness. Some have even gone so far as to record that an SLE score of less than 5 with more than 20 points years length is linked to increased immunosuppression, decreased likelihood of remission, and increased disease activity [26].

Compared to adult-onset lupus, childhood-onset lupus is more aggressive, resulting in higher disease activity, increased immunosuppressive medication use, and accumulated damage that raises morbidity and mortality [27].

The same classification standards have been applied to this population group over time due to the lack of precise criteria, despite these significant variances. Aljaberi [27], for instance, concludes that while the specificity of the ACR 97 is higher, the EULAR/ACR 2019 criteria are more sensitive. is comparable. The 2012 SLICC has also been demonstrated to be more sensitive than ACR 97 [28], as supported by a study conducted in Colombia with 110 pediatric patients. But there was less specificity discovered [29]. There were no variations in the two criteria's sensitivity for the grouping of these individuals Despite this, a study conducted in Brazil by Rodríguez Fonseca et al. [30] shows that the SLICC 2012 outperforms ACR 97 and EULAR/ACR 2019. They did, however, note that if the youth population is categorized using 13 points rather than 10 as was first suggested, the 2019 criteria's performance in that demographic can be enhanced. There are no differences between the three criteria according to other recent research (EULAR/ACR 2019). ACR 97) and SLICC 2012) [31]. But this is in contradiction to information released by Levinsky et al. [28], who showed that the EULAR/ACR 2019 had better sensitivity with In regard to the SLICC 2012 in a group of young people with SLE.

Five of the six participants in the current study who had negative ANA results satisfied the requirements. Nevertheless, there were no differences between the two sets as a result of this knowledge. This demonstrates the significant variability of the illness and gives rise to the idea of seronegative SLE, which was initially defined in 1970. In this case, patients exhibited systemic clinical manifestations of the illness even in the absence of antinuclear antibodies, and as a result, the diagnosis was always made based on the treating physician's assessment rather than just the criteria. As time went on, the actions of this population will be assessed using cohorts from Latin America [32–34].

A sizable portion (39%) of the current group had polyautoimmunity. This is consistent with research on autoimmune thyroiditis, Sj¨, which has reported a prevalence of up to 41%.

The two most often linked illnesses have been antiphospholipid antibody syndrome and ogren's syndrome. Because they result in more severe symptoms, this has had a detrimental effect on the disease's progression [35, 36]. Patients with additional concurrent autoimmune disorders were not included at the time the criteria were defined. We are encouraged to keep assessing the criteria's performance in this group within the Latin American population by our findings as well as those previously documented in the literature [37]. Per our analysis, cooperative compromise was the most prevalent in both sets of criteria, followed by mucocutaneous for EULAR/ACR 2019 and hematological for SLICC 2012. In both groups, the same proportion of renal involvement occurred. These findings show a favorable correlation with the published by Lobo Prat, wherein the existence of lupus kidney disease and arthritis were found to be significantly correlated with meeting the criterion [22]. Additionally, the present criteria have been assessed in certain research as a potential prognostic tool. According to Carneiro et al.'s study results, high scores under the current criteria are linked to a high index of organ damage, particularly kidney damage [38]. A score higher than 19 indicates a two-year risk of hospitalization, according to another study [39].

There are several restrictions on our investigation. Initially, without gold standard, the treating rheumatologist's assessment was used to make the diagnosis. Secondly, certain data from medical records was absent, which hindered the acquisition of clinical or immunological variables. This could be the reason why the criterion's sensitivity is lower in our cohort—which represents patients in real life—than that the validation study computed. As a result, there are not many patients with antiphospholipid antibodies, direct Coombs, CH50 measurement, or syphilis serology.

Finding or comparing specificity was not the goal of this investigation; this could be accomplished more effectively using the ACR 1997 criteria [8]. Similarly, no composite score was used to assess the level of activity or cumulative damage in our population as has conducted in various populations. This may account for the variations observed when the two groups—those with a 5-year and those with a 10-year disease duration—were compared using the classification criteria of the SLICC 2012. Still, the The damage described above was not quantified in this investigation.

In conclusion, there is no difference in the sensitivity of the EULAR/ACR 2019 and SLICC 2012 criteria in our sample when they are assessed based on age group or diagnosis date. Classification criteria are tools that aim to standardize the patients included in clinical trials, but they are also commonly employed as a diagnostic tool in clinical practice. But given the statistics from the GLADEL, it's probable that they're being used inappropriately, particularly among Colombians.

group, early renal involvement is more common in individuals from Latin America [11]. Our study is significant since it

is the first of its sort in our nation. Additionally, we believe that comparable research should be conducted with a wider population sample in order to acquire instruments that would enable the safe use of the criteria in actual clinical practice.

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