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VALIDATION OF A SCORE FOR THE PREDICTION OF SERIOUS INFECTION IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS: DATA FROM A LATIN AMERICAN LUPUS COHORT

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GLADEL LATIN AMERICA SCIENCE & EDUCATION

BACKGROUND

- Patients with systemic lupus erythematosus (SLE) are at increased risk of serious infections, which are associated with morbidity and mortality[1]
- The Systemic Lupus Erythematosus Registry of the Spanish Society of Rheumatology (RELESSER) has developed and internally validated a tool for the prediction of serious infections in SLE, with a recently improved version (SLE Serious Infection Score Revised [SLESIS-R]) being an accurate and reliable instrument[2]
  - SLESIS-R includes age, previous SLE-related hospitalization, previous serious infection, and glucocorticoid dose
- This study aimed to validate the recently improved version of SLESIS-R in a multiethnic, multinational, Latin American SLE cohort

METHODS

Study population

- GLADEL 2.0 is an observational cohort from 10 Latin American countries of patients ≥18 years of age who fulfilled the 1982/1997 American College of Rheumatology (ACR) and/or the 2012 Systemic Lupus International Collaborating Clinics (SLICC) classification criteria
- Patients with sufficient data at baseline and their first annual visit were included and categorized into 2 subsets according to the presence of a serious infection during the first year of follow-up that led to hospitalization

Study assessments

- Baseline demographic and clinical manifestations, disease activity (based on Systemic Lupus Erythematosus Disease Activity Index 2000 [SLEDAI-2K]), damage accrual (based on SLICC/ACR Damage Index [SDI]), and treatments were examined

Statistical analysis and validation

- Logistic regression was used to examine the predictive effect of baseline variables on the development of serious infection in the first year of follow-up
  - *P* values <0.05 were considered statistically significant
  - All analyses were done using R v4.4.0
- A receiver operator characteristic analysis was used to validate SLESIS-R by defining the area under the curve for SLESIS-R
  - The cutoff point with the best validity parameters (ie, sensitivity and specificity) was identified

RESULTS

Patient characteristics

- Of the 1016 patients with SLE who completed 1 year of follow-up, 208 (20.5%) had serious infections
- Patients with serious infections were older, were predominantly male, and had a longer disease duration (**Table 1**)
  - This group had more frequent general, cardiac, pulmonary, hematologic, and gastrointestinal involvement at baseline and had a higher SDI score and rate of previous SLE-related hospitalization

TABLE 1: Baseline demographic and clinical characteristics of patients with SLE with and without serious infection

Parameter	Total (N = 1016)	No serious infection (n = 808)	Serious infection (n = 208)	*P* value[a]
Age, years, median (Q1-Q3)	35.3 (27.2-44.3)	34.7 (27.1-44.2)	37.0 (28.2-45.6)	0.068
Female, n (%)	910 (89.6)	733 (90.7)	177 (85.1)	**0.025**
Disease duration, years, median (Q1-Q3)	5.6 (1.6-11.7)	4.9 (1.3-10.9)	9.3 (3.0-15.2)	**<0.001**
Ethnicity, n (%)				
African Latin American	83 (8.1)	68 (8.4)	15 (7.2)	0.621
Indigenous	8 (0.7)	5 (0.6)	3 (1.4)	
Mestizo	670 (65.9)	537 (66.5)	133 (63.9)	
Other	2 (0.1)	2 (0.2)	0 (0)	
Caucasian	249 (24.5)	193 (23.9)	56 (26.9)	
Baseline clinical features, n (%)				
General involvement	783 (77.5)	602 (75.1)	181 (87.0)	**<0.001**
Cutaneous involvement	920 (90.7)	726 (90.1)	194 (93.3)	0.200
Articular involvement	844 (83.3)	671 (83.4)	173 (83.2)	1
Hematologic involvement	824 (81.4)	644 (80.1)	180 (86.5)	**0.042**
Renal involvement	610 (60.1)	479 (59.4)	131 (63.0)	0.383
Cardiac involvement	129 (12.7)	88 (10.9)	41 (19.8)	**<0.001**
Pulmonary involvement	90 (8.8)	56 (6.9)	34 (16.4)	**<0.001**
Gastrointestinal involvement	133 (13.1)	94 (11.7)	39 (18.8)	**0.009**
Neurologic involvement	13 (1.28)	11 (1.3)	2 (0.9)	1
Serosal involvement	323 (31.9)	254 (31.6)	69 (33.2)	0.724
Hypocomplementemia[b]	827 (81.4)	649 (80.3)	178 (85.6)	0.102
SLEDAI-2K score, median (Q1-Q3)	5.0 (1.0-11.0)	4.0 (1.0-10.0)	6.0 (2.0-12.0)	0.274
SDI score, median (Q1-Q3)	0 (0-1.0)	0 (0-1.0)	1.0 (0-2.0)	**<0.001**
Previous SLE-related hospitalization, n (%)	694 (68.6)	486 (60.4)	208 (100)	**<0.001**
Previous serious infection, n (%)	546 (53.7)	359 (44.4)	187 (89.9)	**<0.001**
Baseline treatments, n (%)				
Glucocorticoid use (prednisone)				0.216
≤5 mg/day	237 (33.1)	193 (34.8)	44 (27.3)	
>5 to <10 mg/day	136 (19.0)	99 (17.9)	37 (23.0)	
≥10 to <30 mg/day	194 (27.1)	146 (26.4)	48 (29.8)	
≥30 mg/day	148 (20.7)	116 (20.9)	32 (19.9)	
Antimalarials	979 (97.2)	780 (97.6)	199 (95.7)	0.198
Cyclophosphamide IV	100 (11.9)	76 (11.6)	24 (13.0)	0.094
Mycophenolate	348 (40.9)	269 (40.6)	79 (42.2)	0.074
Azathioprine	143 (16.9)	117 (17.8)	26 (14.0)	**0.0001**
Rituximab	38 (4.5)	29 (4.4)	9 (4.8)	0.205
Belimumab	19 (2.2)	14 (2.1)	5 (2.6)	0.809

C3, complement component 3; C4, complement component 4; CH50, total complement; IV, intravenous; Q, quartile; SDI, the 2012 Systemic Lupus International Collaborating Clinics/the 1982/1997 American College of Rheumatology Damage Index; SLE, systemic lupus erythematosus; SLEDAI-2K, Systemic Lupus Erythematosus Disease Activity Index 2000.
[a]Bold *P* values were considered statistically significant.
[b]≥1 of the following: C3, C4, or CH50.

Factors associated with serious infection

- Univariate and multivariate analyses show that disease duration, pulmonary and gastrointestinal involvement, and baseline glucocorticoid use were associated with the presence of serious infection in patients with SLE (**Table 2**)

TABLE 2: Univariate and multivariate analyses of the association of baseline variables with the presence of serious infection in patients with SLE

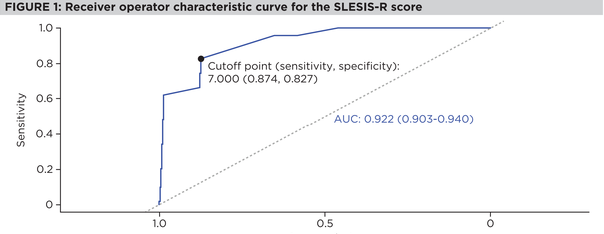
Variable	Univariate odds ratio (95% CI)	*P* value[a]	Multivariate odds ratio (95% CI)	*P* value[a]
Age, ≥60 years	1.1 (0.5-2.2)	0.600		
Sex, male	1.7 (1.1-2.6)	**0.019**		
Disease duration	1.0 (1.1-1.2)	**<0.001**	1.1 (1.1-1.2)	**<0.001**
Hematologic involvement	1.6 (1.0-2.5)	**0.035**		
Cardiac involvement	2.0 (1.3-3.0)	**<0.001**		
Pulmonary involvement	2.6 (1.6-4.1)	**<0.001**	2.3 (1.4-3.7)	**<0.001**
Gastrointestinal involvement	1.7 (1.1-2.6)	**<0.007**	1.5 (1.0-2.4)	**0.033**
General involvement	2.2 (1.4-3.5)	**<0.001**		
Hypocomplementemia	1.4 (0.9-2.2)	0.084		
SDI	1.4 (1.2-1.6)	**<0.001**		
Glucocorticoid (prednisone) ≥30 mg/day at baseline	1.3 (0.8-2.0)	0.200	1.5 (1.1-2.4)	**0.038**
Azathioprine	1.1 (0.6-1.7)	0.700		
Cyclophosphamide IV	1.1 (0.6-1.9)	0.600		

CI, confidence interval; IV, intravenous; SDI, the 2012 Systemic Lupus International Collaborating Clinics/the 1982/1997 American College of Rheumatology Damage Index; SLE, systemic lupus erythematosus.
[a]Bold *P* values were considered statistically significant.

Validation of SLESIS-R

- The area under the curve for the SLESIS-R score was 0.922 (0.903-0.940; **Figure 1**)
- A score of 7 was chosen as the optimal cutoff point, demonstrating a sensitivity of 87% and a specificity of 82%

FIGURE 1: Receiver operator characteristic curve for the SLESIS-R score



AUC, area under the curve; SLESIS-R, Systemic Lupus Erythematosus Serious Infection Score Revised.

CONCLUSIONS

- 20% of patients with SLE in the GLADEL 2.0 cohort had serious infections during the first year of follow-up
- The SLESIS-R performed well in predicting serious infections, similar to the original score

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