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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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Objectives

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

Methods

Study population

GLADEL 2.0 is an observational cohort from 10 LA 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 first annual visits were included. The outcome variable was any serious infection during the first year of follow up that led to hospitalization.

Study assessments

Baseline demographics and clinical manifestations, disease activity (SLEDAI-2k), 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. Receiver operator characteristics (ROC) analysis was used to define the area under the curve (AUC) for SLESIS-R. The cut-off point with the best validity parameters (sensitivity and specificity) was identified.

Results

Patient characteristics

Of the 1016 patients who completed one-year follow-up, 208 (20.4%) had serious infections. Patients with serious infections were older, predominantly male, and had a longer disease duration **(Table 1)**. This group had more frequent general, cardiac, pulmonary, hematological and gastrointestinal involvement at baseline and had a higher SDI and higher proportion of previous hospitalization.

Factors associated with serious infection

Univariate and multivariate analyses **(Table 2)** show variables associated with serious infection: disease duration, pulmonary and gastrointestinal involvements, and baseline glucocorticoid use.

Validation of SLESIS-R

The AUC for the score was 0.922 (0.903-0.940) **(Figure 1)**. A score of 7 was chosen as the optimal cut-off point, demonstrating a sensitivity of 87% and specificity of 83%.

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)	**<0.001**
Rituximab	38 (4.5)	29 (4.4)	9 (4.8)	0.205
Belimumab	19 (2.2)	14 (2.1)	5 (2.6)	0.809

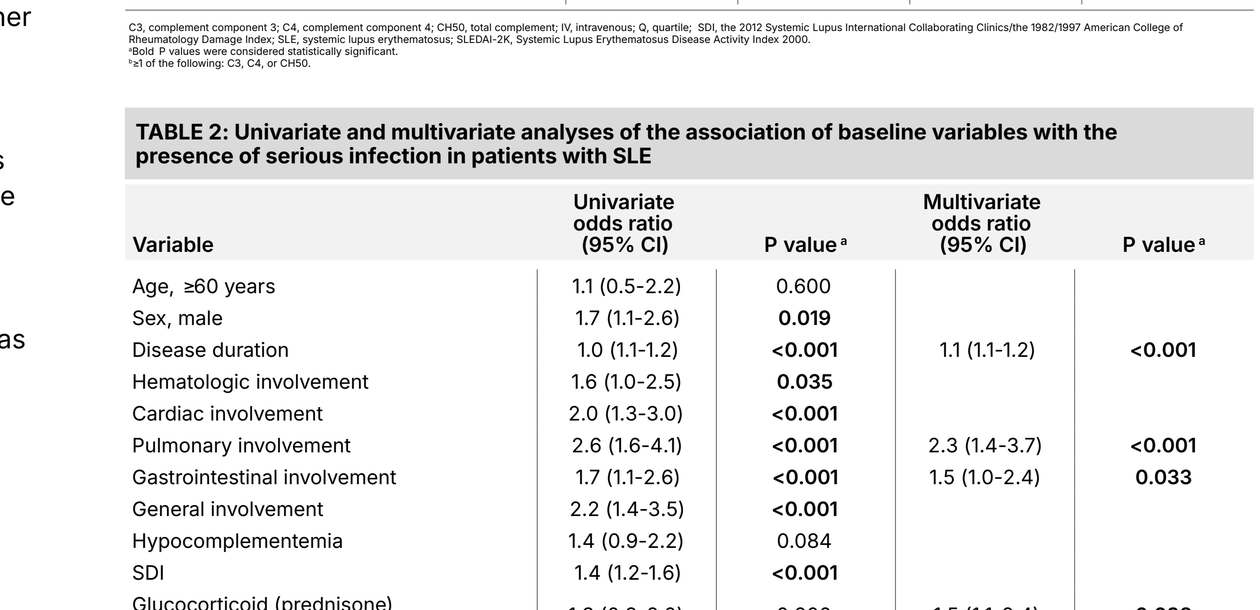
C3, complement component 3; C4, complement component 4; CH50, total complement; IV, intravenous; Q, quartile; SDI, the 2012 Systemic Lupus International Collaborating Clinics/the 1982/1997 American College of Rheumatology Damage Index; SLE, systemic lupus erythematosus; SLEDAI-2K, Systemic Lupus Erythematosus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

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)	**<0.001**	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.

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.

Conclusion

Almost a third of patients had serious infections during the first year of follow-up. The score performed well in predicting serious infections, similar to the original score.

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