Cultural Adaptation and Validation of the Chinese Version of the Systemic Lupus Erythematosus Activity Questionnaire in a Cohort of Chinese Patients with Lupus

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Abstract

Objectives:

To examine the responsiveness, reliability, and validity of Chinese version of Systemic Lupus Erythematosus Questionnaire (SLAQ).

Methods:

A cross-sectional observational study was designed for this research. The principal attributes evaluated were linguistic and cultural adaption, reliability, and validity.

Standardized response means and acceptability were calculated to estimate the responsiveness of the SLAQ. Cronbach's alpha was used to evaluate its reliability. The Spearman correlation coefficient was used to assess the criterion validity by calculating the association with measurement of other lupus disease activity.

Results

The response rate for the pilot study was 99.9%. The mean time to complete the questionnaire was 6.7 ± 2.8 min. The Chinese version of SLAQ had good reliability, with a Cronbach's alpha of 0.857. Cronbach's alpha for the test-retest reliability was 0.878. For validity, the SLAQ was correlated with SLAM, SLEDAI-2000 and SLEDAI-no lab. The correlation was good at 0.832, 0.506 and 0.668 respectively.

Conclusion:

The Chinese version of the SLAQ questionnaire has adequate responsiveness, reliability, and validity in our cohort, and it is a helpful and meaningful tool for assessing disease activity in lupus patients without laboratory results.

Significance & Innovation

- Systemic Lupus Erythematosus Questionnaire (SLAQ) is recommended measure of patient self-assessed scale without laboratory results.
- There is no Chinese version of SLAQ which could help lupus patients assess the disease activity.
- This study confirmed test-retest reliability, criterion validity and responsiveness of Chinese version of SLAQ.

Introduction

Assessing disease activities in patients with lupus is an important part of their disease management. Lupus flares can contribute to organ damage and even death [1]. Clinical symptoms and laboratory results are typically collected by physicians to evaluate disease activity using assessment tools.

BACKGROUND

The Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) is a commonly used scale for evaluating disease activity. The SLEDAI is a cumulative index used by physicians and other professional healthcare providers across 21 different disease descriptors. Medical history, physical examination, and laboratory data must be collected to be scored in hospitals, which is time-consuming and costly. Some clinical features, such as fatigue, fever, and weight loss, are common and disabling symptoms affecting lupus patients. These symptoms, causing decreased functioning capacity, negatively influence health-related quality of life [2].

The Systemic Lupus Erythematosus Activity Questionnaire (SLAQ) is a patient-reported instrument based on patients' subjective complaints in the absence of laboratory results for assessing disease activity. The SLAQ was developed based on the Systemic Lupus Activity Measure (SLAM) as a more economical way of following and tracking large groups of SLE patients who may be at a distance from a center in epidemiologic studies. This scale has three parts, including a single patient assessment (PGA) regarding the presence and severity of lupus flares, a list of 24 questions related to lupus symptoms (symptom score), and a single question regarding the numerical rating scale (NRS) for global disease activity.

Scoring on the PGA ranged from 0 to 3 and asked about the presence and severity of lupus activity during the past three months. There are 24 questions related to different lupus symptoms, including constitutional, mucocutaneous, articular, respiratory, gastrointestinal, neuropsychiatric, and gastrointestinal manifestations. Among these 24 questions, there was no rating severity for symptoms, and positive answers were accounted for. The NRS is a single numerical scale for patients' global disease activity during the previous three months. The NRS score ranges from 0 to 10, indicating a scale of no activity to high activity.

The prevalence range of lupus is 30-60 per 100,000 persons. The 10-year survival rate was over 70%. The SLAQ is the only patient reported instrument for assessing patients' disease activities without laboratory results. However, there is no Chinese version for SLE patient in China.

The purpose of this study is to translate the SLAQ into Chinese and verify its reliability and validity in a large cohort.

Participants And Methods

Study Design

A cross-sectional observational study was designed for this research. The principal attributes evaluated were linguistic and cultural adaption, reliability, and validity.

Method

Setting and sample

The study population included patients with systemic lupus erythematosus (SLE) who were 18 years or older and were seen by the rheumatology department of a teaching hospital in Shanghai, China. All eligible subjects had SLE (according to the revised American College of Rheumatology [ACR] criteria for SLE) [3] and provided informed consent to participate in this study. Dementia, neurological deficit, or linguistic barriers that could significantly compromise the understanding of the questionnaire were included in the exclusion criteria [4].

Variables

All participants were provided with SLAQ, SLEDAI, SLAM, and a demographic questionnaire to collect data on the following variables: sex, age, disease duration, educational level, marital status, and fertility status. SLEDAI was administered to demonstrate criterion validity and was assessed by rheumatologists who were blinded to the SLAQ results. 1) the SLAQ score contains 24 symptoms, and patients were asked to choose a response from among mild, moderate, severe, and no symptoms. All items were weighted and aggregated based on Karlson et al [5] and ranged from 0 to 44. 2) PGA is related to the presence and severity of lupus activity during the past three months (range 0-3). 3) The NRS is a numerical rating scale for global disease activity (range 0-10).

Analysis

Translation and pilot study

Translation process

The translation and cultural adaptation process followed international guidelines.

1. Two native Chinese speakers each translated the original scale into Chinese and obtained two versions of the scale; the two translations were then reconciled into a single Chinese version. The two translators are bilingual and bicultural professional translators.
2. Another experienced English-speaking translator who was blinded to this study and to the English version of the original scale translated the Chinese version back into English. The English-speaking translator is a bilingual and bicultural professional healthcare provider.
3. A manager approved a harmonized translation through discussion with the three translators.
4. Comparing the original English version with the harmonized translation, a professional multidisciplinary committee that formed the research team approved the Chinese version, and all translators reviewed and finalized the translation.

Cognitive debriefing and pilot study

Following the recommended guidelines, the Chinese version of the SLAQ was evaluated in a pilot study with 35 SLE patients with different demographic characteristics (age, gender, education level, and place of residence), which indicated a need for minor linguistic corrections. Cognitive debriefing interviews were

conducted. Moreover, in the face-to-face interviews, the participants were encouraged to verbalize anything they thought about. The retrospective probing was held to ask the participants further questions based on their feedback. Both the think-aloud and retrospective probing processes can facilitate better observation of any difficulties in understanding, recalling, and answering. Finally, an expert review committee including six Chinese experts, who are rheumatology doctors and advanced practice nurses, reviewed the final Chinese version of the SLAQ.

Validation

Each patient provided written informed consent.

Inclusion criterion

Rheumatology ward inpatients enrolled in the study met the diagnosis of the 1997 American College of Rheumatology (ACR) criteria for lupus between June and August 2019 in a teaching hospital. All patients were 18 years or older.

Exclusion criteria

The patients had no neurological deficits, dementia, or linguistic barriers.

Statistical analysis

For the descriptive analysis, the categorical variables were reported as proportions, and continuous values were expressed as mean and standard deviation as appropriate.

Cronbach's alpha was used to test the internal consistency of the SLAQ. A Cronbach's alpha of > 0.7 was considered internally consistent and reliable at the group level.

Criterion validity was tested using the validated activity index (SLEDAI-2000 and SLAM) scored by a physician who was blinded to the SLAQ results. Spearman's rank correlations were used, and the level of statistical significance was defined as 5% ($p < 0.05$).

There were 35 patients in a subgroup testing the reliability and agreement for the test-retest validity assessment, which was two weeks after the first assessment.

For the test-retest validity assessment, 35 patients from the study were enrolled in a subgroup and administered the questionnaire again two weeks after their first questionnaire was completed.

Ethics

The study was reviewed and approved by the institutional review board (IRB). All the participants signed an informed consent approved by the IRB.

Results

Cohort description

A total of 245 patients participated in our study, which included the 35 patients in the pilot study and the remaining 245 patients in the validation cohort. The epidemiological and descriptive characteristics of the pilot study and the entire study are reported in **Table 1**. There were no significant differences between the pilot study and the entire study.

Table 1-Demographic and clinical data of the pilot sample and of the entire cohort

	Pilot Study (N=35)	Entire Study (N=245)
Female n (%)	34 (97.1%)	233 (95.1)
Age (mean±SD)	35.8±12.5	37.2±13.0
Disease duration (mean±SD)	4.71±4.7	8.36±7.2
Education Background n (%)		
None	2 (5.7)	1 (0.4%)
Elementary School	0	19 (7.8)
Junior School	5 (14.4)	21 (8.6)
Senior School	7 (20)	39 (15.9)
Bachelor	20 (57.1)	157 (64.1)
Higher Learning Institute	1(2.9)	8(3.3)
Marital Status n(%)		
Single	8 (22.9)	70(28.6%)
Married	27 (77.1)	173 (70.6%)
Widowed	0	2(0.8%)
Fertile Status n (%)		
Infertile	14 (40)	116 (47.3%)
Fertile	21 (60)	129 (52.7%)
Disease Activity (SLEDAI)		
(mean±SD)	3.93±2.2	6.56±6.16

Feasibility

The response rate of the pilot study was 99.9%, indicating a good level of acceptance of the questionnaire. The mean time to complete the questionnaire was 6.7±2.8 min. All patients understood the scope of the Chinese version of the SLAQ with no comprehension problems.

Internal consistency

The SLAQ demonstrated excellent internal consistency with a Cronbach's alpha of 0.857. The Cronbach's alpha of the SLAQ symptom items was 0.802. The test-retest reliabilities of the SLAQ and SLAQ symptoms were 0.878 and 0.799, respectively, which also indicated good reliability.

Criterion validation

The correlation coefficients among SLAM, SLEDAI, SLEDAI-no lab, SLAQ, PGA, and NRS are shown in **Table 2**. The correlations were good to moderate between SLAM($p=0.832$), which was assessed by a physician, and SLAQ, which were self-assessed by patients. The correlation between SLAQ and SLEDAI and SLEDAI-nolab was good, at 0.506 and 0.668, respectively.

Table 2-Correlation between the instructions

Items	SLAQ	PGA	NRS	SLEDAI	SLAM	SLEDAI-no lab	P value
	Correlation Coefficient Sig. [two-tailed]						
SLAQ	1.000	.570**	.647**	.506**	.832**	.668**	0.00
PGA	.570**	1.000	.698**	.548**	.406**	.513**	0.00
NRS	.647**	.698**	1.000	.517**	.525**	.508**	0.00
SLEDAI	.506**	.548**	.517**	1.000	.426**	.605**	0.00
SLAM	.832**	.406**	.525**	.426**	1.000	.539**	0.00
SLEDAI-no lab	.668**	.513**	.508**	.605**	.539**	1.000	0.00
N	175	175	175	175	175	175	0.00

** . At level 0.01 (two-tailed), the correlation was significant

Discussion

This study translated and validated the SLAQ questionnaire into Chinese, providing a useful tool for the self-assessment and evaluation of the symptoms and disease activity of lupus patients without the use of laboratory results. We report moderate to good correlation between SLAQ, SLAM, and SLEDAI, which included patients' and physicians' assessments of disease activity. The feasibility, reliability, and validity of the Chinese version of the SLAQ were evaluated in this study.

Following the process of translation and transcultural adaptation, the final Chinese version of the SLAQ was tested in a sample of 245 patients with lupus. Its feasibility was good in routine clinical practice. All patients completed the questionnaire in less than ten minutes, with a mean time of less than seven minutes. All patients completed the questionnaire before visiting their physician. Every patient declared their understanding of the scope and content comprehension of the questionnaire.

The reliability of the Chinese version of the SLAQ questionnaire was good, and its internal consistency and test-retest reliability demonstrated excellent results.

The validation of the questionnaire also showed good results, while the SLAQ score, symptom score, NRS, and PGA all showed a moderate correlation with SLAM. When we reviewed the patients' responses, we observed that the higher the PGA and NRS scores reported, the more positive symptoms the patient reported and the higher the SLAM scores that the physicians provided were. The results may suggest that there is agreement regarding the judgment of disease activity between patients' and physicians' assessments.

The SLAQ questionnaire, as a validated and patient-reported disease activity measurement, would be very helpful in clinical practice. Patients cannot assess their disease condition accurately, and the SLAQ helps them evaluate themselves objectively. To optimize the clinical evaluation, the disease activity evaluated by patients contributes information that improves physicians' rating of the impact of the disease [6].

Conclusion

In conclusion, it was demonstrated that the Chinese version of the SLAQ had adequate responsiveness, reliability, and validity in our cohort, and it is a helpful and meaningful tool for self-assessing disease activity in lupus patients. Although further studies are needed to explore the intersection, the SLAQ is a promising tool for studying lupus outside a clinical setting.

Limitations

Further studies should explore the comparison of the SLAQ to other measurements assessed by physicians. Patients would have a better idea of when they should go to the clinic.

Declarations

Ethical Approval and Consent to participate

The study was reviewed and approved by the institutional review board (IRB). All the participants signed an informed consent approved by the IRB.

Consent for publication

The authors have obtained the informed consent of the patients and/or subjects mentioned in the article. The author for correspondence is in possession of this document.

Availability of supporting data

All data generated or analyzed during this study are included in this published article.

Competing interests

Authors have no conflict of interests to declare.

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Authors' contributions

PL and ZC conducted the data analysis, led the interpretation of findings, and drafted the manuscript. PL and XH conceived and designed the study. PL, XH, HY and ZC participated in study design, interpretation of findings, revision and final approval of the manuscript. PL, XH and HY acquired the data, participated in interpretation of findings, revision and final approval of the manuscript.

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