

SYSTEMIC LUPUS ERYTHEMATOSUS SYMPTOM CHECKLIST: CROSS-CULTURAL ADAPTATION TO BRAZILIAN PORTUGUESE LANGUAGE AND RELIABILITY EVALUATION

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Abstract

Introduction: Reliable and sensitive measurements are needed to evaluate quality of life (QOL) in patients with systemic lupus erythematosus (SLE). No lupus-specific questionnaires are available in the Portuguese language.

Objectives: This study describes the translation, cultural adaptation and reliability testing of the Systemic Lupus Erythematosus Symptom Checklist questionnaire in Portuguese.

Patients and Methods: We evaluated 50 patients with SLE. A protocol was developed for translating and validating the SLE Symptom Checklist, in accordance with the proposals in publications report on the methodology for translating questionnaires into foreign languages.

Results: With regard to cross-cultural adaptation, some adaptations to people's culture had to be made without endangering the main objective of the questions in the original language. The correlation coefficients for internal consistency, intraobserver reproducibility and interobserver reproducibility were 0.874, 0.925 and 0.917, respectively.

Conclusions: This questionnaire was shown to be reliable when applied to patients with SLE. Studies are currently being carried out to demonstrate its validity and sensitivity to changes.

Keywords: Lupus; Quality of Life; Assessment; Translation

Resumo

Introdução: Medidas sensíveis e confiáveis são ne-

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cessárias para avaliar a qualidade de vida (QV) em pacientes com Lupus Eritematoso Sistêmico (LES). Não existe na língua portuguesa a disponibilidade de um questionário específico para LES.

Objetivos: Este estudo descreve a tradução, adaptação cultural e reprodutibilidade do questionário *Systemic Lupus Erythematosus Symptom Checklist* para a língua portuguesa.

Pacientes e Métodos: Foram avaliados 50 pacientes com LES. Um protocolo foi desenvolvido para a tradução e validação do SEL *Symptom Checklist* de acordo com as diretrizes metodológicas para a tradução de questionários em línguas estrangeiras proposto por Guillemin *et al.*

Resultados: Com relação a adaptação cultural do questionário, algumas alterações foram realizadas para melhor compreensão pelos pacientes sem contudo modificar o sentido da questão na língua original do questionário. Os coeficientes de correlação para consistência interna, de reprodutibilidade intraobservador e reprodutibilidade interobservador foi 0,874, 0,925 e 0,917 respectivamente.

Conclusões: Este questionário mostrou-se confiável quando aplicado a pacientes com LES. Estudos estão sendo realizados para demonstrar sua validade e sensibilidade a mudanças.

Palavras-chave: Lupus; Qualidade de Vida; Avaliação; Tradução

Introduction

Systemic lupus erythematosus (SLE) is an autoimmune disease in which autoantibodies are produced against a large variety of the body's own antigens, thereby possibly affecting multiple organs. The cause of and cure for this chronic disease are still unknown. In clinical trials, some objective parameters have been used to describe the disease activity and treatment efficacy.¹ However, some

subjective aspects of quality of life also need to be evaluated in order to establish patients' perceived health conditions and the impact of treatments administered. Practical and reliable measurements are required for evaluating the quality of life (QOL) of patients with SLE.^{1,2} Today, medical care for SLE aims mainly to reduce the disabilities that result from this disease. Thus, QOL improvements should also be assessed whenever possible within routine medical practice. Scales for evaluating QOL measure patients' functional, psychological, and social characteristics and reflect their perceptions of their health conditions and the impact of the medical intervention on their QOL.¹⁻³ With few exceptions, scales measuring QOL have been developed in English to be used in countries where this language is spoken.² Because of the rising number of multicenter studies, there is an increasing need for evaluation criteria than can be adopted in countries in which the language is not English.² For this, it is necessary either to create new measurements in the country's own language, which is quite a complex and time-consuming process, or to translate the available measurement methods. This latter option requires appropriately standardized methodology, especially because of the cultural variations between nations, in order to obtain semantic, idiomatic, experimental and conceptual equivalence. Some rules have now been established for such purposes, thus making this work easier and more standardized for all countries.²

In 2003, Grootscholten *et al.* published an English-language validation of an SLE-specific QOL questionnaire called the SLE Symptom Checklist.⁴ This measures the impact of SLE and its treatment. The questionnaire deals with the presence and impact of 38 symptoms related to this disease and/or its treatment, on a four-point scale. The final result from the questionnaire is the sum of all the impacts of these 38 items, thereby yielding a final score ranging from 0 to 152. Tests were carried out with regard to internal consistency, reproducibility and validity on 87 patients. The coefficients obtained were 0.89, 0.67 and 0.87, respectively, thus indicating that the questionnaire presented satisfactory correlation indexes.

A comparison with other QOL instruments, such as SF-36 (Medical Outcomes Study Short Form 36), visual analog scales, IRGL (Influence of Rheumatic Disease on General Health and Lifestyle) and POMS (Profile of Mood States), showed significant but moderate correlations. A responsiveness test was performed on 17 patients with lupus nephritis who

were treated with cyclophosphamide at the beginning of the disease and one year after significant shifts in its symptoms.⁴ There are no SLE-specific QOL questionnaires that have been translated into Portuguese and validated for this language. This study describes the translation, cultural adaptation and reliability testing of the Systemic Lupus Erythematosus Symptom Checklist questionnaire in Portuguese.

Patients and Methods:

Fifty patients with SLE were evaluated in accordance with the criteria established by the ACR (American College of Rheumatology), at the rheumatology clinic of Hospital São Paulo, Federal University of São Paulo (UNIFESP), and at the rheumatology clinic of the University Hospital of the Federal University of Paraíba (UFPB). The SLE patients included in this study had to be at a clinically stable stage of the disease and it was required that the treatment had not been altered with regard to medication or any other procedure over the preceding fifteen days, in order to evaluate the reliability of the questionnaire. Patients with other inflammatory rheumatic diseases, fibromyalgia or hypothyroidism were excluded from this investigation because of similarity to SLE symptoms. A protocol was developed for translating (double translation) and validating the SLE Symptom Checklist, in accordance with the rules proposed by Guillemin *et al.* report on the methodology for translating questionnaires into foreign languages.^{2,5}

Initial translation – The Lupus Checklist questionnaire was translated into Portuguese with the original authors' approval. The items were translated into Portuguese by two independent Brazilian teachers of English, who were fully aware of the aim of the present research. The translations were compared by the two translators and the study coordinator. In the event of any divergence of opinion, they modified the translation to arrive at a consensus with regard to the initial translation, and this product was called version #1 in Portuguese.

Evaluation of the initial translation – This version #1 in Portuguese was then translated into English by two other Brazilian teachers of English, who did not participate in the previous stages of the present study. The new translation was compared with the original questionnaire in English and any discrepancies found were analyzed and dis-

cussed, so as to achieve a consensus, thus creating version #2 in Portuguese.

Evaluation of Cultural Equivalence (pretest) – The questionnaire was applied to a random sample of 32 patients with SLE. The option *not applied* was added to each item of the questionnaire, to be used if the patients could not understand the question or if they dealt with it in an abnormal manner because the question was culturally inappropriate for them. Questions for which the rate of *not applied* answers was greater than 25% were picked out and analyzed by the research group. These were then replaced by another question with a similar concept, in a way that would not significantly alter the structure and properties of the evaluation. Such modifications generated version #3 in Portuguese. This version was reapplied until the *not applied* answer was selected by no more than 15% of the patients.

Questionnaire reliability – The reproducibility of version #3 of the questionnaire was analyzed by means of three interviews that were all conducted at the same time of the day, in 50 patients as follows:

- Two interviews were performed on the same day (interobserver evaluation) by two different observers, and the third interview up to 14 days after the first evaluation (intraobserver evaluation) by the same observer of the first interview.
- Statistical analysis – Descriptive statistical analysis was carried out to characterize the samples demographically and clinically. The answers given by the patients were evaluated using means and standard deviations. The intraobserver reproducibility was evaluated by calculating the intraclass correlation coefficient (ICC). Cronbach's alpha coefficient was used to evaluate the internal consistency of the items. All statistical tests were performed at a significance level of 5%.

Results

Fifty patients were evaluated with regard to clinical and sociodemographic characteristics (Table I). The translation, back translation and cultural adaptation were investigated using 32 pretest patients. Because of cultural differences, the terms used in some questions in the SLE Symptom Checklist were replaced as follows: in #4 the term 'fatigue' was replaced by 'tiredness'; in #10 the term 'shortness of breath' was replaced by 'lack of air'; in #12 two terms were used in Portuguese for 'itch':

Table I. Clinical and sociodemographic characteristics of 50 patients with systemic lupus erythematosus

Gender	
Females (%)	44 (93)
Males (%)	6 (7)
Age (years)	
Mean (SD)	34.2 (12,0)
Disease duration (years)	
Mean (SD)*	6.5 (7.4)
Race (%)	
Caucasian	17 (32)
Non-Caucasian	33 (68)
SLEDAI-2K**	
Mean (SD)*	7.2 (4.7)

*SD - standard deviation;

**SLEDAI-2K: Systemic Lupus Erythematosus Disease Activity Index - 2000

'coceira' (used in northeastern Brazil) and 'comichão' (used in southeastern and southern Brazil); in #20 the term 'spontaneous bruises' was replaced by 'purple spot on skin with being hit'; in #36 the term 'vulnerable skin' was explained to patients who could not understand this question; and in #37 the term 'disturbed memory' was replaced by 'forgetfulness'. The modifications implemented were deemed appropriate, with cultural equivalence, by more than 95% of the patients interviewed. Because of the low socioeconomic and educational levels of our patients, this questionnaire was applied by the researchers. The mean time taken to apply the questionnaire was 5 min.

The resulting scores ranged from 0 to 88 and the most frequently mentioned symptoms, with greatest impact on the patients, were: fatigue, photosensitivity, painful joints and muscle pain, as shown in Table II.

The evaluation of the internal consistency and reliability of the questionnaire, which was applied to 50 patients (Table III), showed high intraobserver and interobserver concordance (ICC = 0.87 and 0.90) and good internal consistency (Cronbach's alpha = 0.92).

Discussion

The results from the present study have confirmed the reliability of the SLE Symptom Checklist for Brazilian populations. This questionnaire deals

Table II. Frequency and impact of symptoms in the SLE Symptom Checklist on four-point scale, in 50 patients with systemic lupus erythematosus (SLE)

Symptoms	Percentage (%)	n	Impact (mean)	Standard deviation (SD)
Fatigue	91	42	2.7	0.9
Sensitivity to sunlight	61	30	2.4	0.6
painful Muscle	55	27	2.4	0.9
painful Joint	50	25	2.3	0.7
Loss of concentration	48	24	2.0	0.9
Disturbed Memory	47	22	2.0	0.7
Muscle cramps	46	20	2.0	0.6

with 38 symptoms that are relevant for health-related quality of life, according to researchers and patients. Factorial analysis did not distinguish dimensions among disease-related symptoms or therapeutics, which suggests that these domains were not clearly distinguished for patients. The specificity of this measurement method may provide valuable additional information on subjective health conditions. Thus, it may help in detecting changes in patients' wellbeing resulting from therapeutic interventions, and also in distinguishing the presence of a given symptom and whether or not it has an impact on the patient's quality of life.

The symptom frequencies observed in the present study had some similarities with the symptoms observed by Grootsoolten et al.⁴ in their original report on the creation of the SLE Symptom Checklist, except in relation to photosensitivity to solar radiation. In their study, which was carried out in Holland, this environmental factor had less impact, due probably to different climatic conditions in that European country. High sensitivity to solar radiation among lupus patients was observed

in Brazil by Vilar et al.,⁶ under the same climatic conditions as in the present study. Grootsoolten's study also reported that fatigue and muscle and joint pains had a great impact on patients. The internal consistency of the SLE Symptom Checklist was high in our population, which reflects the coherence of the questions dealing with SLE symptom problems. For stable patients, the correlation coefficients for reliability were very good, thus showing that the patients had a good level of comprehension of the final version of the questionnaire. In conclusion, the SLE Symptom Checklist is brief, easily applied and specific for SLE, which makes it useful for daily clinical

practice or clinical research. Studies are currently being conducted to investigate its validity and sensitivity in relation to changes.

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Table III. Reproducibility of the SLE Symptom Checklist in 50 patients with stable systemic lupus erythematosus (SLE)

n	Min	Max	Mean	SD (s)	Internal consistency α^a	Intraobserver correlation ^b	Interobserver correlation ^b
50	0.0	88	31	20	0.92	0.87	0.91

Min = minimum value of the SLE Symptom Checklist
Max = maximum value of the SLE Symptom Checklist
 α^a = Cronbach's alpha coefficient
^b = intraclass correlation coefficient