

TRANSLATION INTO BRAZILIAN PORTUGUESE, CULTURAL ADAPTATION AND VALIDATION OF THE SYSTEMIC LUPUS ERYTHEMATOSUS QUALITY OF LIFE QUESTIONNAIRE (SLEQOL)

Freire EAM^{*,**,**}, Bruscato A^{***,****}, Leite DRC^{*}, Sousa TTS^{*}, Ciconelli RM^{**,***}

Abstract

Objectives: Translate into Brazilian Portuguese, cross cultural adaptation and assess the reliability and validity of the Systemic Lupus Erythematosus Quality of Life Questionnaire (SLEQOL).

Material and Methods: *Study population:* 107 SLE patients, answered the SLEQOL questionnaire.

Translation: into Portuguese and cross-cultural adaptation was performed in accordance with studies on questionnaire translation methodology into other languages. *Reliability:* Was analyzed using three interviews with different interviewers, two on the same day (interobserver) and the third within 14 days of the first assessment (intraobserver). *Validity:* Validity was assessed by correlating clinical and quality of life parameters with the SLEQOL. *Statistical analysis:* A descriptive analysis of the study sample. Reproducibility was assessed using an intraclass correlation coefficient (ICC). Internal consistency was assessed using Cronbach's alpha coefficient. To assess validity we used Pearson's correlation coefficient. Five percent was the level of significance adopted for all statistical tests.

Results: The SLEQOL was translated and culturally adapted. The main findings were: a 0.807 internal consistency correlation coefficient for all questions and domains. The inter and intraobserver correlation coefficients were 0.990 and 0.969 respectively. Validation showed good correlation with the SF-36 and poor correlation with lupus activity or damage indices.

Conclusions: The quality of life parameter has been

increasingly taken into account for chronic diseases. To date there are no tools to assess Quality of Life in Systemic Lupus Erythematosus (SLE) written in the Portuguese language. The questionnaire is valid and reliable for SLE patients in Brazil.

Keywords: Systemic Lupus Erythematosus; Quality of Life; Translations; Reproducibility of Results.

Introduction

Prevalence of Systemic Lupus Erythematosus (SLE) is increasing and SLE mortality is decreasing. The most important component of SLE medical care is to reduce the consequences and disabilities associated with SLE, bearing in mind both health related quality of life issues as well as longevity. The main objective of medical treatment is to reduce disabilities and deficiencies¹. The quality of life assessment is based on applying tools or questionnaires that, for the most part, were originally written in English and focus on the English speaking population. Therefore these tools must be translated before they can be applied in another language, and the assessment properties demonstrated within a specific cultural context²⁻⁶. Scales that assess quality of life measure the changes in physical, psychological and social function as a result of disease, and reflect the patient's perception of his or her health. Generic quality of life instruments are valid for measuring the quality of life of SLE patients and enable comparison across a range of rheumatic diseases. However, critics argue that such tools are not adequately understood by the patients^{1,7}. Specific quality of life scales include domains that are important for a specific disease. With respect to SLE, these domains must assess disease progress, the extent or patient organ involvement and their response to treatment⁸.

In 2005 LEONG et al. published a paper describing

*Department of Internal Medicine, Federal University of Paraíba UFPB

**Department of Internal Medicine, Federal University of São Paulo UNIFESP

***Member of the Pronuclear Project, Brazilian Rheumatology Society

****Insper Institute of Education and Research, São Paulo

the development and preliminary validation of a specific Systemic Lupus Erythematosus Quality of Life questionnaire in English (SLEQOL). This questionnaire is made up of 40 items split into six domains: physical function, occupational activity, symptoms, treatment, mood and self-image. Each domain score varies from 1 to 7, with higher scores indicating poorer quality of life. Total scores vary between a low of 40 and a high of 280. The questionnaire was applied to 275 SLE patients and demonstrated good internal consistency, a Cronbach's alpha of 0.95 and intraobserver reproducibility of 0.83. Responsiveness was tested using a global assessment scale that varies between +7 and -7, submitted to statistical calculations that assess responsiveness, demonstrating that the SLEQOL questionnaire is more sensitive to changes over time⁹ than the Short Form-36 (SF-36, a generic instrument). This questionnaire has not yet been translated into, or validated in Brazilian Portuguese. This then became the objective of our study, especially in light of the fact that there are no Portuguese language quality of life questionnaires specific for SLE.

The objective of this effort is to translate the SLEQOL into Brazilian Portuguese, culturally adapt it and check its measurement properties so that it may be applied as a quality of life assessment tool to Brazilian SLE patients.

Material and Methods

One hundred and seven SLE patients over the age of 16, who fulfill the American College of Rheumatology¹⁰ diagnostic criteria, do not present any cognitive impairment and signed the Term of Consent is accepted for this study. In order to be eligible for this study patients had to be clinically stable so as not to be submitted to any change in medication or other procedure for a period of 15 days or less, thus enabling an assessment of the questionnaire reproducibility. All of these patients were outpatient clinics randomly selected from the Rheumatology Clinic at Hospital São Paulo, UNIFESP or in the Rheumatology Clinic at Hospital Universitário, UFPB. Patients with other inflammatory diseases, fibromyalgia and hypothyroidism were excluded from the study. These diseases are excluded through clinical examination and laboratorial data. In addition to an overall assessment of the patient's health by the patient and her physician, a protocol

listing clinical and demographic characteristics was applied and disease activity measured using SLEDAI- 2K¹¹ and BILAG¹²; chronic damage was assessed using SLICC/ACR DI¹³ and Quality of Life using SF-36².

Translation and Cultural Adaptation: The methodology for translation and cultural adaptation of these questionnaire was based on previous work discussing methodology used to translate the questionnaire into other languages⁴⁻⁶.

Initial translation: the questions in the English language version of the SLEQOL questionnaire were translated into Brazilian Portuguese by two independent English language teachers, both Brazilian and both aware of the objectives of the survey. We stressed that the translation should be conceptual, rather than strictly literary. Both translations were compared by the translators themselves and by the study coordinator and, where there were differences, adjustments were made until a consensus was reached for the initial version (Version 1 in Portuguese).

Assessment of the initial translation: Version 1 in Portuguese was back translated by two different English language teachers, also Brazilian, who had not participated in the previous steps of this study. The back translation was compared to the original questionnaire in English and a committee analyzed the differences. Where necessary the statements or questions in Portuguese were rewritten until a consensus was reached, thus generating Version 2 in Portuguese.

Assessment of the Cultural Equivalence (pre-testing): The questionnaire was applied to a group of ten SLE patients randomly selected from the Rheumatology Outpatient Clinic at Hospital São Paulo. To each of the study questions we added the option "does not apply" to find questions that were not understood or that were not truly relevant to our population and therefore culturally inappropriate. Questions considered to be "not applicable" 25% or more of the time were selected and analyzed by a group of researchers trying to obtain a consensus and replace these questions with others similar in concept so as not to significantly change the structure and assessment properties of the question. These changes generated a new version (Version 3 in Portuguese) This version was replicated until no more than 15% of the patients considered any single item to be "not applicable".

Assessment of questionnaire measurement properties: Reliability was analyzed based on three

interviews as follows: Two interviews were conducted by two separate interviewers (1 and 2) on the same day (interobserver), and a third interview was conducted by interviewer 1 within no more than 14 days following the first assessment (intraobserver) with the same patients; item consistency within the questionnaire was also assessed. All of the interviews were conducted at the same time of day.

Validation: Questionnaire validation was assessed by checking the relationship between its six domains scores, with higher scores indicating poorer quality of life and total scores vary between a low of 40 and a high of 280, and the scores obtained using existing quality of life questionnaires such as SF-36 where in each of eight domains scores varies from 0 to 100, with higher scores indicating best quality of life, and other clinical parameters such as disease activity by SLEDAI 2K and BILAG scores, Overall Physician and patient Assessment and severity by SLICC/ACR damage index during the assessment.

Statistical analysis: A descriptive analysis to characterize sample demographics and clinical status. Patient responses were evaluated using averages and standard deviations. To assess intraobserver reproducibility we calculated the intraclass correlation coefficient (ICC). Internal consistency of questionnaire items was assessed using Cronbach's alpha (Cronbach 1951). Validation was assessed using Pearson's correlation coefficient between quality of life questionnaires SLEQOL and SF-36, and other disease activity and severity parameters such as SLEDAI 2K, BILAG, Overall Physician and patient Assessment and SLICC/ACR DI. Five percent was the level of significance adopted for all statistical tests.

Results

107 SLE patients were assessed. Their socioeconomic and demographic characteristics are described in Table I. In all cases we used an interviewer to apply the questionnaire, given the socio-cultural level of the study population. During the cultural equivalence phase (pre testing) we found it hard to explain the scores (1 through 7) for each question, which required a bit more time when applying the questionnaire. Given that question 6 elicited more than 15% of "do not understand" responses, for physical function we replaced "walk for 3 km" with "walk for 1 hour". In question 7 and 8 under the oc-

Table I. Clinical and socio-demographic characteristics of 107 SLE patients

Gender	
Female n (%)	99 (99.5)
Male n (%)	8 (7.5)
Age (years)	
Average, SD	36.8; 12
Minimum-Maximum	17-68
Disease duration (years)	
Average, SD	5.9; 5.6
Minimum-Maximum	0.8-45
Race (%)	
White	46 (43)
Non white	61 (57)
Education (years of schooling)	
Average, SD	6.7; 3
Minimum - Maximum	3-16
Income (US Dollars)	
Average, SD	120; 80
Minimum-Maximum	60-220

cupational activity domain we switched "performance" and "interference" with "domestic chores or work outside the home" and "hampered career or education". In question 28 under mood we replaced "self consciousness" with "feels different from other people" and in question 34, under self image, we replaced "low self esteem" with "felt inferior to others". Once changed, the questions were considered to be appropriate or culturally equivalent by more than 95% of the patients and by the panel of experts that supported this project. The average time to apply the questionnaire was 10 minutes. Table II has the average value for each of the SLEQOL questionnaire components. The worst scores were in the "self image" and "occupational activity" domains and the best were in "treatment" and "mood" domains. In terms of the correlation coefficients, the internal consistency coefficient was 0.807 on average for all questions and domains; interobserver correlation was 0.990 and intraobserver correlation 0.969 (Table III).

A total of 107 patients filled out the clinical protocol to assess validation. We correlated the questionnaire with the clinical and Quality of Life measurements already validated and in common use. By convention correlations may be positive or negative. According with Leong and colleagues we considered very strong correlations those with $r >$

Table II. Values obtained for the SLEQOL questionnaire and domains applied to 107 SLE patients

	Minimum	Maximum	Average	SD
SLEQOL				
Domains				
Total Score	42	260	116	52
Physical Function	6	40	14.5	9.9
Occupational Activity	9	57	19.7	10.6
Symptoms	8	40	17.8	8.4
Treatment	4	25	10.4	5.1
Mood	4	28	11	5.7
Self Image	9	60	22,1	12

Table III. SLEQOL internal consistency and reproducibility in 50 patients assessed using an intraclass correlation coefficient and Cronbach's alpha

Correlation coefficients	SLEQOL
Intraobserver	0.969
Interobserver	0.990
Internal Consistency	0.807 Total 0.807 by domain

p < 0.001

7, as strong those with $r = 0.4$ to 0.69 , as moderate those with $r = 0.3$ to 0.39 and as poor those with $r = 0.20$ to 0.29 , and established the level of correlation found.

Table IV shows the correlation between SLEQOL and activity, damage and quality of life indicators. There was a strong correlation between the total score of SLEQOL and SF-36 for physical and emotional issues. In terms of mood and self image domains, there was a strong correlation between SLEQOL and SF-36 for emotional issues. All other SLEQOL domains correlated poorly with the SF-36 domains.

Regarding the activity criteria, the symptoms, treatment and self image domains of SLEQOL showed moderate correlation with disease activity measured using SLEDAI 2K, which was not the case with BILAG.

The overall health assessment by a physician showed strong correlation with the overall SLEQOL score, but within the domains correlation was poor. The patient's global health assessment showed strong correlation with the total SLEQOL

score as well as with the activities and self image domains.

Chronic damage showed strong correlation with total SLEQOL score, but moderate and poor with the domains.

Discussion

Patient perception of their health and quality of life, as well as the impact of the disease and treatment on their life is being broadly recognized as a topic of research in clinical and epidemiological studies. However, most of the tools used to assess quality of life in these patients can only be found in English.

Experts agree that translating these tools to another language must not only be accurate, but that it is also important to test the psychometric measurements in a specific cultural context. Each society has its own sets of beliefs, attitudes, habits, behaviors and social values. These give people a sense of identity, how they should behave and consequently what they should and should not do. These rules or concepts reflect and distinguish the culture of a given country. When we proposed to translate a questionnaire, it should be presented in simple language that is easy to understand and remain equivalent in terms of the cultural concepts². The differences in terms of culture and lifestyle make it difficult to find exact equivalents for a number of terms, which is why the translation must be carefully done and thoroughly tested in the new environment¹⁴.

The SLEOQL was developed by Leong et al.⁹ in English. I reported the problems our patients had in understanding the questionnaire in a personal communication with the author, primarily due to

Table IV. Assessment of the correlation between SLEQOL, including its domains and SF-36. SLEDAI, overall Physician Assessment, overall Patient Assessment, BILAG and SLICC/ACR DI in 107 SLE patients

SF-36	SLEQOL						
	Total Score	Physical Function	Activities	Symptoms	Treatment	Mood	Self Image
Physical Functioning	0.008	0.166	0.188	- 0.264**	- 0.202*	0.12	0.16
Role Physical	- 0.573***	-0.222*	0.077	0.125	0.035	0.05	0.04
Bodily Pain	0.145	0.026	0.123	- 0.232**	- 0.275**	0.14	0.08
General Health	0.141	0.022	0.109	0.153	0.153	0.08	0.11
Vitality	0.120	0.128	0.104	- 0.221*	0.158	0.058	0.071
Social functioning	- 0.240**	0.012	0.076	0.171	0.164	0.094	0.090
Role Emotional	- 0.450***	- 0.270*	0.005	0.152	- 0.210*	- 0.531***	- 0.780***
Mental Health	0.125	0.018	0.160	- 0.225*	- 0.250*	- 0.271**	0.130
SLEDAI 2K	0.001	0.110	0.190	0.361*	0.385*	0.231*	0.380*
Overall Physician Assessment	- 0.480***	- 0.240**	- 0.281*	- 0.230*	0.150	0.181	- 0.270*
Overall Patient Assessment	- 0.482***	- 0.290*	- 0.430***	- 0.291*	- 0.261*	- 0.382*	- 0.401*
BILAG	0.250*	0.120	0.181	0.241*	0.010	0.183	0.170
SLICC/ACR DI	0.412*	0.340*	0.310*	0.030	0.221*	0.190	0.210*

* P < 0.05; **P < 0.01; ***P < 0.001

the socio-intellectual level of our patients compared to those in Singapore. We had the author's support in all phases of the translation and cultural adaptation of the questionnaire.

Leong et al. (2005) achieved similar results to ours in terms of the highest scores in the "occupational activity" and "self image" domains. This is likely due to the fact that active SLE is an incapacitating disease that also changes the patient's appearance, in addition to the side-effects of treatment with steroids and immune suppressants. The better results in the Treatment and Mood domains may reflect a component of patient adaptation to the disease.

Every assessment instrument should be reproducible over time – in other words, it should produce equal or very close results in two or more instances with the same patients, evidently assuming no change in clinical status. Test-retest reproducibility has been demonstrated. The internal consistency of the Portuguese language of the SLEQOL, assessed by the correlation between the various questions proved to be adequate, with a coefficient of 0.8. This is an important observation as some of the questions were altered. In the translation and cultural adaptation to Chinese, the SLEQOL items in English could be precisely translated into Chi-

nese, so the translation proceeded smoothly. Once translated, the SLEQOL-C was applied to 638 patients with no problem in terms of understanding the questions¹⁵.

The fact that during the validation process the questionnaire correlated only moderately with disease activity and damage is consistent with other publications¹⁶. This suggests the possibility that activity and damage do not directly interfere in quality of life, as in the patient's overall health assessment the correlations were better than with these indicators were already established, or it could be that they truly do not capture this facet of the disease. A possible explanation might be adaptation to chronic disease or the type of personality influencing the subjective perception of overall quality of life¹⁷.

Gladman (2006) reported that, during the past two decades a number of tools have been developed to assess SLE activity and damage, however quality of life has been assessed using a generic tool. Recently SF-36 has been shown not to be very sensitive to changes¹⁸, which is why its use in clinical trials has been questioned. The author goes on to state that specific tools to assess quality of life in SLE patients are necessary, such as the SLEQOL that has been well tested in terms of its measure-

ment properties, and encourages that it be applied and validated with other populations¹⁹.

In conclusion, we have translated, culturally adapted, checked the reliability and validated the SLEQOL using international methodology and demonstrated that the questionnaire is valid and reproducible. Studies are already underway to demonstrate this instrument's sensitivity to change.

Correspondence to

Eutília Freire

AV. Cabo Branco 3524/501-B

Cabo Branco – João Pessoa

58045-010 - Paraíba – Brazil

E-mail: eutilia@terra.com.br

References

1. Testa MA, Simonson DC. Assessment of quality-of-life outcomes. *N Engl J Med* 1996;334: 835-840.
2. Ciconelli R, Ferraz M, et al. Tradução para língua portuguesa e validação do questionário genérico de avaliação de qualidade de vida SF-36 (Brasil SF-36). *Rev Bras Reumatol* 1999;39:143-150.
3. Mathias SD, Fifer SK, et al. Rapid translation of quality of life measures for international clinical trials: avoiding errors in the minimalist approach. *Qual Life Res* 1994;3: 403-412.
4. Guillemin F. Cross-cultural adaptation and validation of health status measures. *Scand J Rheumatol* 1995;24: 61-63.
5. Guillemin F, Bombardier C, et al. Cross-cultural adaptation of health-related quality of life measures: literature review and proposed guidelines. *J Clin Epidemiol* 1993;46:1417-1432.
6. Beaton DE, Bombardier C, et al. Guidelines for the process of cross-cultural adaptation of self-report measures. *Spine* 2000;25: 3186-3191.
7. Dobkin PL, Da Costa D, et al. Quality of life in systemic lupus erythematosus patients during more and less active disease states: differential contributors to mental and physical health. *Arthritis Care Res* 1999;12:401-410.
8. Murawski MM, Miederhoff PA. On the generalizability of statistical expressions of health related quality of life instrument responsiveness: a data synthesis. *Qual Life Res* 1998;7:11-22.
9. Leong KP, Kong KO, et al. Development and preliminary validation of a systemic lupus erythematosus-specific quality-of-life instrument (SLEQOL). *Rheumatology (Oxford)* 2005;44: 1267-1276.
10. Tan EM, Cohen AS, et al. The 1982 revised criteria for the classification of systemic lupus erythematosus. *Arthritis Rheum* 1982; 25:1271-1277.
11. Gladman DD, Ibanez D, et al. Systemic lupus erythematosus disease activity index 2000. *J Rheumatol* 2002;29: 288-291.
12. Isenberg DA, Rahman A, et al. BILAG 2004. Development and initial validation of an updated version of the British Isles Lupus Assessment Group's disease activity index for patients with systemic lupus erythematosus. *Rheumatology (Oxford)* 2005.
13. Gladman DD, Urowitz MB, et al. The reliability of the Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index in patients with systemic lupus erythematosus. *Arthritis Rheum* 1997; 40: 809-813.
14. Ferraz MB, Oliveira LM, et al. Crosscultural reliability of the physical ability dimension of the health assessment questionnaire. *J Rheumatol* 1990;17: 813-817.
15. Kong KO, Ho HJ, et al. Cross-cultural adaptation of Systemic Lupus Erythematosus Quality of Life Questionnaire into Chinese. *Arthritis Rheum* 2007;57:980-985.
16. Freire EA, Maia IO, et al. Damage index assessment and quality of life in systemic lupus erythematosus patients (with long-term disease) in Northeastern Brazil. *Clin Rheumatol* 2007;26: 423-428.
17. Snoek FJ, Pouwer F, et al. Diabetes related emotional distress in Dutch and US diabetic patients: cross cultural validity of the problem areas in diabetes scale. *Diabetes Care* 2000; 23:305-309.
18. Panopalis P, Petri M, et al. The systemic lupus erythematosus tri-nation study: longitudinal changes in physical and mental well-being. *Rheumatology (Oxford)* 2005;44: 751-755.
19. Gladman DD. A novel, disease-specific quality-of-life instrument for patients with SLE. *Nat Clin Pract Rheumatol* 2006;2:132-133.