Original article

Design and validation of LupusCol, an instrument for the evaluation of health-related quality of life in Colombian adult patients with systemic lupus erythematosus

Gerardo Quintana López1,2,3, Gerardo Muñetón López1, Paola Coral-Alvarado2,3, Paul Méndez Patarroyo2,3, José Molina4, Philippe Chalem5 and Jorge Díaz6

Abstract

Objective. The aim of this study was to design and validate LupusCol, an instrument for the evaluation of health-related quality of life (HRQoL) in Colombian adult patients with SLE.

Methods. Items and domains of the initial instrument were defined. Preliminary tests were made with the participation of patients. Validity and reliability tests of the administration method were conducted. Usability tests were applied to the version obtained in the previous phases to complete the validation process.

Results. Following preliminary tests, six items and one domain were excluded and two new items were added to the instrument, producing a form with 44 questions and 7 domains, which was submitted for validity and reliability tests. Factor analysis excluded three items, obtaining a Pearson’s correlation (PC) for the criteria validity of $0.48$; a Cronbach’s $\alpha$ coefficient for internal consistency of $0.96$; an intraclass correlation coefficient (ICC) for personal test-retest-telephone of $0.96$ and an ICC personal test-retest-personal of $0.96$. For interrater concordance a PC of $0.8$, an ICC of $0.77$ and a Lin’s coefficient of $0.86$ were found. Sensitivity to change was demonstrated through analysis of variance, obtaining significant indicators about the scale, demonstrating the instrument’s ability to detect changes in HRQoL.

Conclusion. The design and validation process was completed successfully. The scale has significant values for validity, reliability and sensitivity to change in the studied population.

Key words: health-related quality of life, systemic lupus erythematosus, scales development and validation, factor analysis, health status.

Introduction

SLE is a chronic autoimmune disease that targets several tissues in the body through key pathways in the immune system with serious consequences for patients’ life and health [1, 2]. Over the past five decades the mortality of SLE has decreased, focusing attention on other aspects of the disease [3, 4]. The grade of irreversible lesions, disease activity, adverse events to treatment, cost-effectiveness analysis and health-related quality of life (HRQoL) are some of the main outcomes of care in the study of SLE that should be evaluated in accordance with the OMERACT Group [5].

Assessing the state of the disease by activity measurement and accumulated damage are essential in the clinical review of a patient, and we have adequate tools to do this [6–8]. However, we do not have an instrument...
for the measurement of quality of life in Colombia that guarantees an objective and reliable assessment.

The importance of measuring quality of life is that it allows patients to be more involved in their treatment, improves communication with the treating physician, aids in decision-making and provides benefits that go beyond the control of clinical and pathophysiological concepts, which, although important to health professionals, are not always paramount in patients' lives.

There are measurement scales designed to be used in different diseases, with specific scales for certain diseases, to assess HRQoL. Of the general scales, the most used is the 36-item Short Form Health Survey (SF-36), which was designed and validated to assess aspects of diseases that might impair quality of life [9, 10]. It can be used to compare results between various diseases or with normal controls; however, being a general scale, it misses some items that may be relevant in patients with lupus, such as sleep disorders, body image disturbance, and fine motor impairment. This decreases the sensitivity of the instrument and thus the best approach would be to develop disease-specific instruments.

Currently there are three specific scales for SLE: the SLE symptom checklist (SSC) [11], the SLE-specific quality of life instrument (SLEQOL) [12] and the LupusQoL [13]. Because these scales were designed in another language, they require a translation and validation study in Colombia for their use. There are also some shortcomings in their designs. Thus the best strategy to evaluate quality of life in Colombian patients is through the development of a new scale with input from experts and suggestions from Colombian patients.

The aim of this study was to design and validate a questionnaire for the assessment of HRQoL in Colombian adult SLE patients, allowing this important concept to be included in clinical practice and research studies on the effectiveness and cost utility of treatment.

Methods

Creation of the questionnaire

The initial version of the instrument was created by a group of rheumatologists who defined the respective domains and items that make up the questionnaire according to the recommendations of OMERACT for assessing quality of life, taking into account the domains required for the measurement. This initial version was presented to a group of five expert rheumatologists, who agreed on a final version to begin preliminary testing.

Preliminary testing

The version obtained in the creation phase of the questionnaire was applied by five rheumatologists to 50 patients. The questionnaire was applied as a personal interview or in a self-reporting form.

At this stage tests were done related to the items, and to the scale's utility. The tests relating to the items evaluated the degree of understanding, the ambiguity of the questions, frequency of response and response range restriction. Tests regarding usefulness evaluated the time needed for training of survey administrators, the presentation format and the ease of rating scale scores.

Following the application of questionnaires, meetings with patients were held and patients submitted their suggestions and comments. These suggestions were studied by the rheumatologists' group and an agreed version of the questionnaire was entered into validity and reliability testing. Due to the validation process, and in order to avoid any difficulty in self-filling of the questionnaire, it was decided that data collection would be performed via personal interview for validity and reliability testing.

Validity testing

An evaluation of appearance validity, construct validity, criterion validity and sensitivity to change was performed. The data used were the results of the survey conducted by personal interviews of 230 patients. The number of interviews used to perform factor analysis was determined according to Streiner [14], who suggests that for each item in the scale at least five data items must be used; in the case of our form with 44 variables, we should use at least 220.

Appearance validity was performed by looking at the pertinence of the items to evaluate quality of life in SLE according to the experts' group. Construct validity first determined that the items in the survey were of a factorial structure with the following parameters found using SPSS 15.0 (IBM, Armonk, NY, USA): (i) study of significance levels and determinant in the correlation matrix, (ii) partial correlations and uniqueness in the anti-image correlation matrix and (iii) the Kayse, Mayer and Olkin (KMO) measure of sample adequacy and Bartlett's test of sphericity. Following this, factor analysis was performed for data reduction using the factor analysis function. The version of the form obtained from the factor analysis was used in subsequent studies.

Criterion validity demonstrated concurrent validity for the personal and telephone interviews. It was performed by calculating Pearson's coefficient between the results of our survey and those obtained from application of the SF-36 questionnaire for quality of life, culturally adapted for Colombia [15].

Sensitivity to change was evaluated by performing a comparison of the HRQoL instrument results at two time points in a group of patients with increased lupus activity according to the SLEDAI lupus activity scale [16] and, following the start of treatment start, when a decrease in disease activity was determined in the same group of patients. Tests were performed by two different evaluators. Results were evaluated by analysis of variance (ANOVA) using Stata 10.0 statistical analysis software (StataCorp, College Station, TX, USA).

Reliability testing

The reliability tests included internal consistency by Cronbach's $\alpha$ coefficient, application method reliability by the intraclass correlation coefficient (ICC),
test-retest intrarater reliability by the ICC and test-retest interrater reliability by calculation of the ICC, Pearson’s correlation (PC) and Lin’s concordance correlation. Sample size was determined by Donner and Eliasziw’s formula [17] in accordance with the tables of Walter et al. [18]. Sample size was calculated for test-retest intrarater and interrater reliability testing with \( \tau = 0.05, \beta = 0.20, p_0 = 0.8 \) and \( p_1 = 0.9 \). Intrarater testing was applied 1 week apart and interrater testing 2–4 days apart to avoid bias from response recall by patients. The interrater evaluation was applied between medical staff and patients.

Utility testing
Application time, the need for training the personnel applying the survey, the form by which the survey was presented and the methodology and time needed to calculate the score obtained by the scale were again evaluated. This project was approved by the Medical Ethics Committee of Fundación Instituto de Reumatología e Inmunología. All patients included in this study, including those in the preliminary test phase, gave their informed consent.

Results
Creation of the questionnaire
An initial questionnaire containing 48 items and 8 domains was created for measuring quality of life in patients with SLE (mental functioning, emotional functioning, pain, physical limitation, personal maintenance, interpersonal relationships, self-image perception, social acceptance). The initial proposal was submitted to a group of five expert rheumatologists. They found that all the items and domains were relevant, thus the questionnaire was not modified for the initiation of preliminary testing.

Preliminary testing
The survey was applied to 50 patients and items and utility-related aspects were evaluated. Regarding the items, the survey was easy to understand (clear questions) for most patients (88%), but was considered too large with repeated items about physical activity by 33% of patients. All considered it relevant for investigating aspects related to quality of life, but 22% suggested adding anger and rage to the emotional domain, 22% suggested adding loneliness and lack of support, 11% suggested adding discrimination and 11% thought that although most items evaluate physical activity, none referred to limitations due to sun exposure. Eleven per cent of patients thought that item 47 should be more specific and 44% suggested that response options should be only always, often or never. Twenty-two per cent thought the periodicity should be 8 weeks, while 11% suggested 1 or 2 weeks.

Suggestions were discussed among patients and the expert group and a new version of the questionnaire containing seven domains with 44 items was agreed upon. Six items were excluded that were part of a domain that was excluded and two new items were included for the emotional health domain. It was decided to preserve the five-option range of responses because these allow a more specific definition about the factor being evaluated, and 56% of patients agreed. The excluded items were those belonging to the my image perception domain:

(i) I cannot be independent and I am a burden to others.
(ii) I worry others due to the status of my disease.
(iii) I’m not interested in sex any more.
(iv) My physical appearance does not make me happy.
(v) Because of my physical appearance, I feel uncomfortable in social activities.
(vi) My physical appearance makes me feel less attractive.

New items were the following: ‘Over the last 4 weeks, SLE has made me feel

(i) Rage or anger.
(ii) Abandoned or alone.

Regarding utility, the survey was performed by personal interview and self-report. The average time to complete the survey was 5.22 min; the time for the interview was 8 min. There is no training required by the evaluator, and the score is easily calculated by summing the points in each item. The points in each item are obtained by assigning a number to each option of the response: never = 1, occasionally = 2, often = 3, mostly = 4, always = 5. Because data were missing in the self-filled forms, it was decided to perform validation and reliability tests by personal and telephone interviews.

Validity testing
For appearance validity, the expert rheumatologists agreed that all items included in the form assessed HROqOL in patients with SLE. For construct validity, before factor analysis, tests were performed to demonstrate that the items of the scales belonged to a factorial structure and that the factor analysis was the appropriate method of analysis for data reduction. All significance levels for all items were <0.01, with the exceptions of items 28–30, which presented significance levels of 0.01–0.2. This tells us that the correlation between the variables is significantly different from zero. The determinant found in the correlation matrix was 1.54E-017, which tells us that the variables have a linear correlation. Regarding partial correlations, 90% of the values were found very close to 0, the remaining 10% were >0.15.

All onenesses were close to 1, and we concluded that the variables have a very small percentage of variance. For the measurement of adequacy, the KMO measure was 0.923 and Bartlett’s sphericity was 6290.681 with a significance level <0.001. The results of the KMO and Bartlett’s test show that the variables included in the analysis have a factorial structure and that the
recommended method for performing data reduction is factor analysis.

In the factor analysis, extraction of factors was performed by the principal axis factoring method and the number of factors was determined by Kaiser’s theory by selecting all factors with eigenvalues > 1. Commonalities obtained and the number of factors in the percentage of the explained variance are shown in Tables 1 and 2.

Eight factors are obtained with eigenvalues > 1, and all commonalities are > 0.3. We reviewed the screen graphic plot (Fig. 1) and only three factors showed a significant slope. The extraction was performed again, this time extracting only three factors. The results are shown in Table 3. According to Table 3, all commonalities > 0.3 were obtained with the exception of variables 28–30, which were excluded. The extraction of the three factors was performed again without the three mentioned

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variables and all commonalities >0.3 were obtained. With commonalities >0.3, the rotation of the factorial solution is performed by direct oblimin, obtaining the saturations observed in Table 4. By grouping items according to their factor loadings the final solution is

**Factor 1 (physical functioning):** 10, 11, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34

**Factor 2 (interpersonal social relationships functioning):** 35, 36, 37, 38, 39, 40, 41, 42, 43, 44

**Factor 3 (psychological affection):** 1, 2, 3, 4, 5, 6, 7, 8, 9, 12

**Criterion validity**

The PC coefficient was −0.48, which means that the relation is negative, thus by increasing the value of one
variable, the value of the other is reduced. Since with a higher score in our instrument, quality of life is impaired, and with higher SF-36 score quality of life is improved, the PC coefficient should be negative, which means that a patient with a good quality of life will have a higher SF-36 score and a lower score with our instrument.

Reliability testing

**Internal consistency**

Internal consistency assessment for the internal version of the questionnaire obtained following the factorial analysis was performed calculating the Cronbach’s $\alpha$, which was 0.96. This result tells us that our scale is very homogeneous and the items are adequately related.

**Reliability of the application method**

The ICC was 0.955, which tells us that the questionnaire is suitable to be evaluated in person or by telephone.

**Reliability of test-retest intrarater concordance**

The ICC for our intrarater concordance was 0.96, which indicates that the concordance is very good and changes between assessments of the same evaluator.
will not be affected by factors outside those being measured.

Reliability of interrater concordance
The obtained PC coefficient was 0.876, a high score, meaning that the test is stable and can be applied by different evaluators (physicians, patients, etc.). The Lin’s coefficient is 0.865, in accordance with the above interpretation. Graphics related to these estimates are shown in Fig. 2, showing limits of agreement between evaluators of between 38 and -30, a relatively small range considering that the maximum score is 220.

Sensitivity to change
The scale was evaluated twice with 20 patients, first with patients with a SLEDAI score >8 with <2 days on treatment and the second 2–4 weeks after treatment when a significant reduction in the SLEDAI score (<7) was determined. Each evaluation was performed by two different clinicians. Using ANOVA, the effect of the change in disease activity on quality of life before and after treatment was evaluated. Because of the other variability source, i.e. the two observers, the two measures were repeated: evaluation before and after treatment and by both evaluators.

These data show that the difference between the evaluations is significant, which can be interpreted as the scale having good sensitivity to change (F was high at 261.55 and the P-value was significant). As in repeated measures, there was another possible variability source, i.e. both observers (F was low at 0.06 and the P-value was non-significant). But the results show that it is not a source of variability and any difference in individuals detected is more from the change (treatment) than the observers.

Utility testing
The time to conduct the interview was estimated at between 7 and 8 min. The personnel conducting the survey did not require previous training and the formula for determining the scale score is a simple sum. Patients do not require any specific knowledge before the interview. The final version of the questionnaire is available as supplementary material at Rheumatology Online.

Discussion
In this study we set out to design and validate a questionnaire capable of assessing the HRQoL in Colombian patients with SLE to include this concept in clinical monitoring of our patients and in studies evaluating the effectiveness and cost-utility of treatment. We have described the process used to perform the validation of the scale according to the standardized method recommended in the Colombian guidelines for health measurement scale validation [19]. Very good results were obtained from the performed tests, thus demonstrating that the evaluation of quality of life in Colombian patients with SLE using LupusCol is valid and reliable.

The results of the factorial analysis grouped the items of our scale into three factors; however, it is important to note that at the time the questionnaire was created the OMERACT [5] group recommendations were taken into account and the factors addressed included mental functioning, emotional functioning, pain, physical limitation, personal maintenance, interpersonal relationships, self-image and social acceptance. The results of the validity testing were adequate, finding a good correlation with the version of the SF-36 questionnaire culturally adapted for Colombia [15].

Reliability of in-person and telephone test-retest and interrater tests highlights the possibility of performing in-person or telephone interviews and using different evaluators without the risk of modifying results. This is very important, since the possibility of evaluating quality of life by phone and not during a visit represents an advantage for the patient and the treating physician.
In the literature we have found other health measurement scales specific for SLE. The LupusQoL [13] and SLEQoL [12] were designed by rheumatologists and patients, and have completed an adequate validation process. The authors in these studies agree with our position that the best way of approaching quality of life evaluations in SLE is to do it through a specific instrument, as there is a risk of missing important items using general instruments. We think that these instruments are adequate for quality of life measurements and they could be translated and validated for individual populations. However, we have demonstrated the superiority of an assessment questionnaire created including the opinions of our patients. The instrument may be used in any Latin American population; however, sociocultural validation is necessary depending on the country.

In conclusion, we consider that the design and validation of the instrument were adequate and the scale has acceptable validity, reliability and sensitivity to change at the time of being evaluated in the present population. We hope to include evaluation of quality of life in the treatment of all Colombian SLE patients, as well as in research and clinical evaluation studies. Patients’ perception of their health status is a new field that requires continued research and the availability of an adequate instrument for the measurement of quality of life.

**Rheumatology key messages**

- Measuring health-related quality of life (HRQoL) in SLE allows patients to be more involved in their treatment.
- Physicians should explore HRQoL as an emerging field of interest in comprehensive SLE management.
- Colombian patients with SLE now have a validated questionnaire capable of assessing their HRQoL.

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**Supplementary data**

Supplementary data are available at *Rheumatology* Online.

**References**


