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PAPER

Validity and reliability of the Lupus QoL index in Turkish systemic lupus erythematosus patients

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Background: Systemic lupus erythematosus (SLE) patients have seriously impaired quality of life (QoL). In addition to activity and damage indices used in the past, tools to evaluate QoL in SLE have been developed in recent years. In this study, we test the validity of the Turkish version of the Lupus-QoL (LupusQoL-TR) score, and investigate its association with clinical findings and activity indices. **Methods:** A total of 132 patients diagnosed with SLE according to ACR 1997 criteria were included. The clinical and demographic features, and biochemical data were retrieved from hospital records. SLE Disease Activity Index (SLEDAI) and damage score (SLICC-ACR) were determined at the time of administration of Lupus-QoL questionnaire. The Lupus-QoL includes 34 questions divided into eight domains. We reevaluated the LupusQoL-TR and pretested its understandability. SLE patients were concomitantly administered the LupusQoL-TR and generic SF-36. Internal consistency, test-retest reliability, convergent and discriminant validity were calculated. **Results:** The mean age of our SLE patients was 37.9 ± 12.8 years. Internal consistency reliability ranged from 0.88 to 0.93, and test-retest reliability from 0.84 to 0.94. LupusQoL-related domains in SF-36 were correlated (from 0.66 to 0.74). Most LupusQoL-TR domains, except planning, were able to discriminate between active and inactive SLE groups. Scores in all domains of the LupusQoL-TR were found to be discriminative for patients with and without damage according to SLICC-ACR score. **Conclusion:** The LupusQoL-TR was found to be a valid patient-reported outcome measure method when evaluating QoL in Turkish SLE patients. *Lupus* (2015) **24,** 816–821.

Key words: Systemic lupus erythematosus; LupusQoL-TR; quality of life; health outcome measure; validation

Introduction

Much progress has occurred in the treatment of systemic lupus erythematosus (SLE), which is a systemic, chronic autoimmune disease.[1] In recent years, more effective use of treatment modalities and advances in medical care systems have resulted in significant improvement in the survival of SLE patients.[2,3] Survival rates in SLE patients in Turkey are similar to those in western countries.[4]

There are many ongoing studies that seek to define biochemical and genetic biomarkers associated with disease activation and organ damage and that could be used for the routine long-term follow-up of SLE patients. As a result of longer life expectancies in SLE, investigations about the influence of disease on patient-reported outcomes, like health-related quality of life (HRQoL), have gained importance.[5–7] In addition to biochemical and genetic markers, patient-reported outcomes have also become important. There are questionnaires about QoL and psychometric status in SLE; however, they may not yield similar results in different populations because of sociocultural differences. Until now, only one QoL questionnaire in Turkish was validated for SLE patients.[8]

The LupusQoL scale is a disease-specific patient-reported outcome measure validated in different languages, and it evaluates QoL in SLE patients.[5] In this study, we undertook a cross-cultural validation of the LupusQoL-TR among Turkish SLE patients.

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Materials and methods

This study was conducted in the rheumatology departments of two university hospitals in Turkey, namely Trakya University Medical Faculty in Edirne city, and Gaziantep University Medical Faculty in Gaziantep city, between March 2012 and March 2014. SLE was diagnosed according to 1997 modified American College of Rheumatology (ACR) criteria.[9] Demographic, clinical and laboratory data about the patients were obtained from hospital files. Local ethics committee approval was obtained, and all patients gave verbal and written informed consent for inclusion in the study. SLE patients with psychiatric diagnoses requiring medications, SLE patients with other autoimmune diseases, those younger than 18 years and older than 65 years were not included. Patients with fibromyalgia were included.

The LupusQoL is a specific HRQoL questionnaire: It consists of eight domains with 34 items.[5] These domains are physical health (PH), pain (PN), planning (PL), intimate relationship (IR), burden to others (BU), emotional health (EH), body image (BI) and fatigue (F). The answers were evaluated on a five-point Likert scale (0=all of the time, 1=most of the time, 2=a good bit of the time, 3=occasionally, 4=never).

The process of translation of the questionnaire included translation from English to Turkish by a team of translators who are fully bilingual in both Turkish for Turkey and English. Then, the developer gave us permission to use it in our study (LupusQoL-TR, Corporate Translations Inc, East Hartford, CT, USA). The translation was analyzed first by the authors, and it was unanimously agreed that all indices were clear and well understood. In order to avoid misunderstanding, the instrument was given as a pretest to 10 SLE patients. Interview with the patients showed that the instrument was understandable. We made no cross-cultural validation in the translation because feedback from the pretest study group did not identify any concerns.

SLE patients were administered both the LupusQoL-TR and Short Form (SF)-36, which is another generic QoL scale. SF-36 consists of eight domains (physical functioning, physical role, bodily pain, general health, vitality, social functioning, emotional role, and mental role) with 36 items, and scores range from 0 to 100 (best HRQoL).[10] Previous studies showed that the Turkish version of the SF-36 was valid and reliable.[11]

SLE disease activity was calculated in an interview with the patient by using the SLE Disease Activity Index (SLEDAI). Active SLE was defined as a SLEDAI score >4 at the time of administration of the questionnaire.[12] SLE-related damage score was determined by using the SLE damage index (Systemic Lupus International Collaborating Clinics/ACR (SLICC-ACR)).[13] SLE patients with SLICC-ACR scores >1 were those with high damage scores.

Cronbach's alpha was used to test the internal consistency of the LupusQoL-TR. Internal consistency is a measure of the correlation between answers to various questions about the same theme.[14] If Cronbach's alpha is >0.7, then a measure might be interpreted as reliable at the group level and have internal consistency.[15]

Test-retest reliability was determined to evaluate the stability of measurement by using interclass coefficient. A small group of SLE patients—composed of 20 individuals—were re-administered the LupusQoL-TR 10 days after the first interview. The 10-day interval was chosen by considering that patients' health status would not change to a significant extent within this period. Intraclass correlation coefficient was calculated, and >0.7 was considered to be acceptable.

Discriminant validity is used to distinguish patients who have different disease activities or damage. We analyzed whether the LupusQoL-TR was able to discriminate between SLE groups with different disease activities and damage scores.

In order to confirm the adequacy of samples and items, the Kaiser-Mayer-Olkin (KMO) test and Bartlett's test of sphericity were performed; the criteria for a satisfactory factor analysis to proceed were a KMO test measure of >0.5 and a Bartlett's test with a significance level of <0.05.[16] When examining the factorial structure of the LupusQoL-TR, exploratory factor analysis (EFA) was performed by using principal component analyses. The criteria used for determining retained factors were: eigenvalues more than one rule, visual examination of the scree to determine the number of eigenvalues preceding the "elbow," item loadings over 0.4 and the interpretable factor. The factors were extracted by principal axis factoring with varimax rotations and Kaiser normalization. Dimensionality was computed by using an eight-factor item-loading matrix, and it was based on a previous suggestion of an eight-factor structure supported by the original LupusQoL.

Finally, AMOS software was used to perform confirmatory factor analysis (CFA) by using

structured equation modelling with the hypothesized eight-factor structure. In this analysis, each item represented only one domain, and the domains were allowed with each other. Comparative fit index (CFI),[17] Tucker-Lewis index (TLI),[18] and the root mean square error of approximation (RMSEA)[19] were used to evaluate model fit. The fit for CFA was considered as acceptable if the CFI and TLI were >0.90, and RMSEA values were <0.05.

In order to determine construct validity, similar dimensions of the LupusQoL-TR and SF-36 were evaluated with the Pearson correlation test. The interpretation of the Pearson correlation coefficient was as follows: $r \geq 0.91$, excellent relationship; $0.90 \geq r \geq 0.71$, good relationship; $0.70 \geq r \geq 0.51$, fair relationship; $0.50 \geq r \geq 0.31$, weak relationship; $r \leq 0.30$, little or no relationship. For statistical analysis of data, SPSS version 17.0 for Windows was used. The Chi-square test was used to compare categorical data of the groups. Continuous variables were tested for normal distribution. When comparing continuous data, the unpaired *t* test was used because all data were distributed normally. A two-tailed *p* value of < 0.05 was considered significant in all analyses.

Results

We included 132 SLE patients (128 females, four males) being followed up at the rheumatology departments of Trakya University Medical Faculty, Edirne (107 patients), and Gaziantep University Medical Faculty, Gaziantep (25 patients), Turkey. The general clinical features of SLE patients are seen in Table 1.

All eligible patients agreed to be included in the study. A total of 124 patients (93.9%) answered all 34 questions (data were 100% complete). At the baseline visit, eight patients (6.1%) could not answer at least one item in the LupusQoL-TR. The frequency of missing data for the items was low (from 0% to 3.8%). The summary of responses to the LupusQoL-TR and the mean scores are seen in Table 2. We substituted the mean value for the subscale in place of missing item values. The LupusQoL-TR instrument was completed in 7.2 minutes and the SF-36 in 8.2 minutes. The floor effect ranged from 0.8% to 6.1%, and the ceiling effect ranged from 12.1% to 27.3%.

The reliability of internal consistency ranged from 0.88 to 0.93. Test-retest variability was between 0.84 and 0.94 (Table 3). When compared to equivalent domains in the SF-36, it was seen that the domains in the LupusQoL-TR had a construct validity at a greater magnitude (Table 4).

We evaluated whether the LupusQoL-TR could discriminate between SLE patients with active vs. inactive disease, and patients with high vs. low damage scores. It was observed that the LupusQoL-TR could discriminate between active vs. inactive SLE patients in all domains, except in PL. In the group with high SLICC-ACR scores, the

Table 1 General clinical characteristics of SLE patients

Female, n *(%)*	*128 (97)*
Age (mean ± SD)	37.9 ± 12.8
Disease duration (months)	71.6 ± 59.9
Photosensitivity, *n* (%)	94 (71.2)
Oral ulcer, *n* (%)	24 (18.2)
Arthritis, *n* (%)	107 (81.1)
Pleural involvement, *n* (%)	21 (15.9)
Pericarditis, *n* (%)	15 (11.4)
Hemolytic anemia, *n* (%)	15 (11.4)
Thrombocytopenia, *n* (%)	14 (10.6)
Lymphopenia, *n* (%)	71 (53.8)
Nephritis, *n* (%)	43 (32.6)
CNS involvement, *n* (%)	26 (19.7)
Anti-dsDNA, *n* (%)	63 (47.7)
Anti-Sm, *n* (%)	17 (12.9)
Anti-Ro, *n* (%)	29 (22)
Hypocomplementemia, *n* (%)	46 (34.8)
Total SLEDAI (mean ± SD)	6.2 ± 5.3
Active disease (SLEDAI>4), *n* (%)	57 (43.2)
Total SLICC-ACR (mean ± SD)	0.99 ± 1.5

SLE: systemic lupus erythematosus; CNS: central nervous system; SLEDAI: SLE disease activity index; SLICC-ACR: Systemic Lupus International Collaborating Clinics/American College of Rheumatology damage score.

Table 2 LupusQoL-TR descriptive data: missing response, mean scores, floor and ceiling effects

	Number of missing score	*Mean ± SD*	*Number of patients with minimum score (%)*	*Number of patients with maximum score (%)*
Physical health	2	62.9 ± 26.0	1 (0.8)	16 (12.1)
Pain	1	60.7 ± 30.5	6 (4.5)	29 (22.0)
Planning	1	63.5 ± 31.7	5 (3.8)	36 (27.3)
Intimate relationship	4	68.5 ± 35.0	8 (6.1)	32 (24.2)
Burden to others	0	68.1 ± 30.9	5 (3.8)	34 (25.8)
Emotional health	2	63.3 ± 30.9	6 (4.5)	22 (16.7)
Body image	5	71.6 ± 28.2	3 (2.3)	36 (27.3)
Fatigue	4	61.7 ± 30.8	4 (3.0)	24 (18.2)

LupusQoL-TR: Turkish version of Lupus Quality of Life questionnaire.

LupusQoL-TR was discriminative in all domains, except in IR and in EH. Table 5 shows the comparison of LupusQoL-TR domains in active vs. inactive patients, and in high vs. low damage score patients.

In order to confirm sample adequacy, the KMO test (0.932) and Bartlett's test of sphericity ($\chi^2 = 3727.63$, degree of freedom (df) = 561, $p < 0.001$) were used, which indicated that correlations between items were large enough. According to the EFA, eight first components explained 78.1% of the total variance (five with an eigenvalue >1). Scree plot analysis suggested a five-factor structure (eigenvalues >1.0), accounting for 70.6% of the total variance. Factor 1 accounted for 52.1% of response variance, Factor 2 for 7.2%, Factor 3 for 4.2%, Factor 4 for 3.7%, and Factor 5 for 3.3%. Rotation with eight factors resulted in items in a very similar way to the original LupusQoL rotated-factor pattern (Table 6). Three PH items (no. 6, no. 7 and no. 8) had a higher correlation with pain (Table 6).

The CFA revealed that the model fit was satisfactory as shown by the goodness of fit indices (CFI = 0.968, TLI = 0.94); however, it was not fit for RMSEA (0.232).

Table 3 The reliability of various domains in the assessment of LupusQoL

	Number of items	*Internal consistency reliability*	*Test-retest reliability*
Physical health	8 (1–8)	0.90	0.94
Pain	3 (9–11)	0.88	0.84
Planning	3 (12–14)	0.92	0.88
Intimate relationship	2 (15–16)	0.89	0.93
Burden to others	3 (17–19)	0.89	0.91
Emotional health	6 (20–25)	0.93	0.94
Body image	5 (26–30)	0.90	0.93
Fatigue	4 (31–34)	0.88	0.93

LupusQoL: Lupus Quality of Life questionnaire.

Table 4 Convergent and construct validities for similar domains in LupusQoL-TR and SF-36

LupusQoL-TR	*SF-36*	*Pearson*
Physical health	Physical function	0.74
Pain	Bodily pain	0.66
Emotional health	Mental health	0.71
Fatigue	Vitality	0.68

LupusQoL-TR: Turkish version of Lupus Quality of Life questionnaire; SF-36: Short Form 36.

Discussion

In our study, we tested the reliability and validity of the LupusQoL-TR in Turkish patients. We found that all subscales of the LupusQoL-TR had good internal consistency and test-retest reliability. Until now, there has been only one validated Turkish patient-reported outcome scale, namely the LupusPRO, which was recently reported.[8] The LupusQoL is an instrument for patient-reported outcome measures that evaluates HRQoL in SLE patients and that was originally developed in the United Kingdom. Until now, cross-cultural validation was made in the United States;[12] and the French version was validated.[7]

As is well known, disease severity and outcome in SLE show variability in patients with different ethnic origins, like in Hispanics or in African Americans.[20,21] In addition, factors like socioeconomic status and quality of medical service vary from country to country and affect the course of disease. There are very limited data about the

Table 5 The comparison of various domains in LupusQoL-TR between active and inactive SLE patients

	SLEDAI ≤4	*SLEDAI >4*	p	*SLICC-ACR >1*	*SLICC-ACR ≤1*	p
n	61	62		31	88	
Physical health	70.7 ± 23.4	57.3 ± 27.3	0.004	52.7 ± 27.5	69.3 ± 24.1	0.002
Pain	69.7 ± 27.7	53.2 ± 32.1	0.003	52.8 ± 33.3	65.6 ± 29.4	0.048
Planning	69.8 ± 30.1	59.5 ± 32.8	0.071	53.6 ± 33.1	69.7 ± 29.7	0.014
Intimate relationship	72.0 ± 30.2	59.1 ± 33.7	0.029	56.5 ± 34.2	69.5 ± 30.9	0.058
Burden to others	78.0 ± 24.7	59.7 + 34.5	0.001	55.1 ± 34.1	74.7 ± 28	0.002
Emotional health	70.3 ± 26.6	57.4 ± 34.4	0.023	56.9 ± 30.2	68.1 ± 30.4	0.08
Body image	79.6 ± 21.9	65.6 ± 31.5	0.006	61.6 ± 30.8	77.1 ± 24.9	0.007
Fatigue	69.0 ± 27.5	56.3 ± 33.6	0.026	52.7 ± 32.9	67 ± 29.1	0.027

LupusQoL-TR: Turkish version of Lupus Quality of Life questionnaire; SLE: systemic lupus erythematosus. SLE disease activity index (SLEDAI) score was available in 123 patients; and Systemic Lupus International Collaborating Clinics/American College of Rheumatology damage score (SLICC-ACR) was available in 119 patients.

Table 6 Factor loadings for the eight-factor structure LupusQoL-TR

	Rotated factor pattern							
	Fatigue	*Emotional health*	*Body image*	*Burden to others*	*Physical health*	*Bodily pain*	*Planning*	*Intimate relationship*
Item 34	0.56							
Item 32	0.42							
Item 33	0.40							
Item 31	0.31							
Item 21		0.75						
Item 22		0.74						
Item 23		0.71						
Item 20		0.69						
Item 25		0.66						
Item 24		0.61						
Item 27			0.78					
Item 30			0.77					
Item 29			0.73					
Item 26			0.71					
Item 28			0.61					
Item 18				0.90				
Item 17				0.86				
Item 19				0.48				
Item 2					0.79			
Item 4					0.70			
Item 3					0.69			
Item 1					0.68			
Item 5					0.45			
Item 6					0.21	0.25		
Item 7					0.28	0.35		
Item 8					0.21	0.72		
Item 10						0.81		
Item 9						0.66		
Item 11						0.60		
Item 12							0.43	
Item 13							0.31	
Item 14							0.32	
Item 15								0.90
Item 16								0.89

LupusQoL-TR: Turkish version of Lupus Quality of Life questionnaire.

epidemiology of SLE in Turkey. In our recently published SLE series, we observed that mortality was similar to that in western countries.[4] In order to evaluate the effect of SLE on QoL and to reveal the role of sociocultural factors, there is a requirement for a cross-culturally validated and valid scale. Our study showed that the LupusQoL-TR scale was an acceptable patient-reported outcome measure.

The LupusQoL was observed to be valid when compared with the generic QoL scale, the SF-36. It was previously shown that the LupusQoL-TR was a valid, reliable and lupus-specific tool; therefore, we do not recommend using it together with SF-36, which was shown not to correlate well with disease status in SLE.[22,23] In addition, we detected that the LupusQoL-TR showed convergent and discriminant validity similar to the original LupusQoL.

According to factor analysis in our study, structural validity was acceptable because the factor structure resulting from the EFA with eight imposed factors was very close to the structure of the original LupusQoL. In our study, item 8 of the PH component had very high loading for pain. Similarly, the original LupusQoL study[5] and two other validation studies[7,12] reported the same results about item 8. This seems to be a problem inherent in the LupusQoL rather than being associated with the process of cultural adaptation. In addition, we observed that items 6 and 7 in the PH domain also had higher loading for pain. Jolly et al.[12] stated the same problem about item 7.

The main limitation of our study is probably its cross-sectional design. Test-retest reliability was evaluated in a small group; however, responsiveness—that is, the effect of change in activity on

QoL score—was not evaluated. We should aim for detection of responsiveness to change and clinically minimal important differences during longitudinal follow-up; therefore, larger studies should be conducted. Although the floor effect was not significant, the ceiling effect was as high as 27.3% in domains like PL and BI. This percentage was lower than that reported by the French group, but it was nevertheless noteworthy. Another limitation was exclusion of patients with psychiatric diagnoses and elderly patients. These patients were excluded because we assumed that they could not have a full comprehension of all the questions. However, these selection criteria might have caused some limitations in generalizability of our results for all SLE patients.

Our results show that the LupusQoL-TR is a useful tool to assess HRQoL in Turkish SLE patients. Still, we need larger studies to see whether there is responsiveness to the LupusQoL-TR.

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Conflict of interest statement

The authors have no conflicts of interest to declare.

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