

Is There an Advantage Over SF-36 with a Quality of Life Measure That Is Specific to Systemic Lupus Erythematosus?

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ABSTRACT. *Objective.* To assess whether the Lupus Quality of Life (LupusQoL) questionnaire contributed additional information not obtained using the Medical Outcomes Study Short-Form 36 questionnaire (SF-36) in a cohort of patients with systemic lupus erythematosus (SLE).

Methods. Forty-one patients seen at a single center were followed at monthly intervals for 12 months. The LupusQoL and the SF-36 questionnaires were coadministered monthly. Disease activity was determined by the Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) every 30 days. We determined the correlation of the 4 comparable domains of both questionnaires. For the 4 non-comparable domains of the LupusQoL we determined the correlation between each domain with the Physical Component Summary scores (PCS) and the Mental Component Summary scores (MCS) of the SF-36. The effect size (ES) and the standardized response mean (SRM) were used to compare the responsiveness of both questionnaires when a clinically significant change in disease activity occurred as determined by SLEDAI-2K.

Results. Three hundred seventy-six patient visits were recorded. There was a strong correlation between comparable domains in both questionnaires. For the 4 noncomparable domains of the LupusQoL, there was a correlation with the MCS and PCS of SF-36. The mean scores for comparable domains in both questionnaires were similar. Both questionnaires displayed responsiveness, as determined by ES and SRM among patients who flared and improved, but not among patients in remission, when compared to the previous visit.

Conclusion. LupusQoL and SF-36 were equivalent in assessing quality of life over time in this group of patients. Both questionnaires are responsive measures of quality of life in patients with SLE flares and improvement. (J Rheumatol First Release July 1 2011; doi:10.3899/jrheum.110007)

Key Indexing Terms:

QUALITY OF LIFE

LUPUSQoL
SYSTEMIC LUPUS ERYTHEMATOSUS

SF-36

RESPONSIVENESS

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Survival of patients with systemic lupus erythematosus (SLE) has improved significantly over a 36-year period and new morbidities have emerged, leading to altered patterns of outcome in this disease¹. Health-related quality of life (HRQOL) refers to the effect that a disease and its treatment have on an individual's ability to function and his or her perceived well-being in physical, mental, and social domains of life². The assessment of HRQOL has become an important outcome measure in the assessment of patients with SLE and can readily be assessed by questionnaire^{3,4}. The Outcome Measures in Rheumatology IV recommended that for both randomized clinical trials and longitudinal observational studies the outcome be assessed in terms of disease activity and damage in all organ systems involved, as well as by HRQOL (which is meaningful to patients) and adverse events⁵. HRQOL of patients with SLE seems to be significantly worse and affects all health domains at an earlier age in comparison to patients with other common chronic diseases^{6,7,8,9}.

Although several measures of HRQOL have been studied in SLE, the most commonly used and accepted measure is the

Medical Outcomes Study Short-Form 36 (SF-36), a generic measure that is applicable in a variety of conditions and chronic diseases including SLE^{2,3,6,10,11}. The Systemic Lupus International Collaborating Clinics Group (SLICC) has recommended the SF-36 as the measure of quality of life in SLE⁴. The SF-36 is a valid and reliable tool that identifies the physical, psychological, and social effect of the disease on patients with SLE^{6,11}. Studies of HRQOL have shown that the SF-36 is not sensitive to change in SLE in longitudinal studies when administered biannually or yearly^{3,12}. SF-36 scores in patients with established SLE changed little over an 8-year period. Scores are not affected by disease activity, steroids, or damage accumulation during the interval, but are affected by the presence of fibromyalgia. The only domain that showed a decline over time was physical functioning, and changes in this domain were different among ethnicities and were associated with fibromyalgia³. The SF-36 assesses the preceding 1-month period, yet patients in longitudinal studies are usually surveyed yearly or at 3–6 month intervals^{3,12}. Given the rapidly fluctuating course of the disease, the instrument may not have captured the patient's full experience with SLE throughout the entire year. On the other hand, when administered monthly and over 6 months, the SF-36 scores changed with disease activity¹³. HRQOL measures may evaluate the effect of the disease on areas that are not adequately addressed in routine clinical practice (such as functioning and sleep)¹⁴. It has been suggested that because the SF-36 is a generic instrument, it may not be sufficient to characterize the numerous dimensions in which SLE may affect a patient (i.e., infertility, physical appearance) and it lacks 1 or more domains pertinent to patients with SLE: sleep, body image, and sexual health¹⁵.

It has therefore been recommended that disease-specific questionnaires should be included in the assessment of HRQOL, as they might be more sensitive to change than generic instruments, and appropriate to evaluate specific therapeutic interventions in clinical trials¹⁶. Several SLE-specific scales have been published in the literature: the LupusQoL, the SLE Symptom Checklist (SSC), and the SLE-specific Quality of Life instrument (SLEQoL)^{15,17,18,19}. The LupusQoL was developed and validated in the United Kingdom. Items generated for this questionnaire were derived from semistructured interviews with patients with SLE. The LupusQoL has 34 items across 8 domains defined by patients as being important¹⁵. More recently, LupusQoL has been adapted and validated for the assessment of patients with SLE in the United States (LupusQoL-US) and for the Spanish-speaking population^{20,21}. Studies have focused on evaluating the validity of LupusQoL and its correlation with disease activity^{15,20}. A recent cross-sectional study has shown that HRQOL is impaired in this group of patients and more importantly, no association could be found between the 8 domains of the LupusQoL and clinical or demographic variables²². Responsiveness, which De Bruin defines as the ability of an instrument to accurately detect change when it has occurred,

needs to be determined for LupusQoL²³. Therefore, a well designed study is required to accurately detect the responsiveness of LupusQoL.

The objectives of our investigation were to determine whether the LupusQoL questionnaire contributed additional information not obtained using the SF-36 in a cohort of patients with SLE, and to evaluate the LupusQoL's responsiveness.

MATERIALS AND METHODS

Patient selection and assessment. Patients were selected from the University of Toronto Lupus Clinic. All patients met the American College of Rheumatology (ACR) classification criteria for SLE²⁴. Forty-one patients were enrolled and followed at monthly intervals for 12 months. The LupusQoL and SF-36 questionnaires were coadministered to the patients at each visit, when a complete history was performed, including demographics, physical examination, and laboratory tests^{15,25}. All surveys were administered and completed on the same day as the clinic visit.

Outcome measures. The LupusQoL contains 8 domains: physical health (8 items), emotional health (6 items), body image (5 items), pain (3 items), planning (3 items), fatigue (4 items), intimate relationships (2 items), and burden to others (3 items)¹⁵. Patients typically need < 10 min to complete the LupusQoL, and the scoring and the transformation of the scores takes about 5 min. Each question is evaluated with a 5-point Likert response format, where 0 = all of the time, 1 = most of the time, 2 = a good bit of the time, 3 = occasionally, and 4 = never. Scores for each of the 8 domains range from 0 to 100¹⁵.

SF-36. The standard version (4-week recall) of the SF-36 was used¹⁰. This self-administered SF-36 measures QOL in 8 areas of perceived health: physical functioning (10 items), role physical (4 items), bodily pain (2 items), general health (5 items), vitality (4 items), social functioning (2 items), role emotional (3 items), and mental health (5 items)¹⁰. In 6 of the 8 domains, responses are recorded on multipoint scales. Domain scores are on a scale from zero to 100. The SF-36 subscales can be further summarized into 2 component scores: the physical component summary (PCS) and the mental component summary (MCS). Both of these are standardized so they can easily be compared to the Canadian population, that is, set to follow a normal distribution with a mean of 50 and an SD of 10. For SF-36, 0 reflects the worst QOL and 100 the best^{10,15}.

Domains common to both questionnaires (identified as comparable domains) are physical health (LupusQoL) and physical functioning (SF-36); emotional health (LupusQoL) and mental health (SF-36); pain (LupusQoL) and bodily pain (SF-36); and fatigue (LupusQoL) and vitality (SF-36)^{10,15}. The remaining domains of both questionnaires were deemed noncomparable.

Demographics, disease duration, and disease activity were determined. Disease activity was measured by the Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) 30 days, a valid measure of disease activity in SLE²⁶. The adjusted mean SLEDAI-2K (AMS) was determined for the study interval. AMS has the same units as the original SLEDAI-2K²⁷. The Systemic Lupus International Collaborating Clinics (SLICC)/ACR damage index (SDI) was evaluated at study start²⁸. Written consent was obtained from all patients and the study was approved by the Institutional Review Board at the University of Toronto, Toronto Western Hospital.

Statistical analyses. SAS software was used to analyze the data. Descriptive statistics for all the domains of LupusQoL and SF-36 were reported. We analyzed the mean score for all comparable and noncomparable domains in LupusQoL and SF-36 in 376 patient visits. We determined the correlation of the 4 comparable domains of the LupusQoL and SF-36 using the Pearson correlation coefficient. We transformed each score into z scores to compare LupusQoL to SF-36 for the 4 comparable domains. Paired t-test was used on the z transformed values. For the 4 noncomparable domains of the LupusQoL we determined the Pearson's correlation between each domain with both the

PCS and the MCS of the SF-36. All tests were 2-tailed, with a p value < 0.05 considered statistically significant.

Responsiveness measures. Two measures of responsiveness were used: effect size (ES) and standardized response mean (SRM)^{23,29,30,31}. ES is constructed as a ratio of mean change score in the relevant measure values (numerator) for patients who have “changed” to SD of baseline visit (denominator). SRM uses SD of the change score in the denominator²³. For each responsiveness measure (ES and SRM) and each pair of visits, 4 separate analyses were carried out, each using a different subset of patients: patients who improved, flared, were in remission, and were unchanged. The external criterion adopted was SLEDAI-2K 30 days, where improvement was defined as reduction in SLEDAI-2K ≥ 4 from the previous visit, flare as an increase in SLEDAI-2K ≥ 4 from the previous visit, remission as SLEDAI-2K = 0, and unchanged for the rest of the patient visits. Higher values for the responsiveness measures represent a greater degree of responsiveness. Different cutpoints, based on the judgment of the reader, have been used to define an acceptable level of responsiveness. A responsive questionnaire should yield relatively moderate to large effect (Cohen defined responsiveness as 0.2 small effect, 0.5 moderate effect, and > 0.8 large effect, or “good responsiveness”)²³. We hypothesized that both SF-36 and LupusQoL questionnaires should yield responsiveness whenever patients experience flare and improvement (this was deemed to be a “statistically meaningful change” that needs to be detected by QOL questionnaires), while among the group of patients in remission or unchanged, the values of the responsiveness measure should be as low as possible.

RESULTS

Patient demographics and disease activity. Among the 41 patients, 37 were women and 4 were men. Fifty-nine percent of the patients were white, 17% black, 7% Asian, and 17% other. The mean age at SLE diagnosis was 30.5 ± 10.3 years (median 30.9), age at study start was 45.3 ± 13.2 years (median 43.5), and disease duration at study start was 14.8 ± 10.3 years (median 12.8). The disease activity at first clinic visit and last visit were SLEDAI-2K of 2.59 ± 2.41 and 2.20 ± 2.61 , respectively. Adjusted mean SLEDAI-2K over the 12 months of the study was 2.32 ± 1.84 (median 2.22) and SDI at study start was 2.12 ± 2.48 (median 1.0). Sixty-three percent of patients were taking prednisone with a mean dose of 8.7 ± 5.8 mg, 89% were taking antimalarial drugs, and 54% were taking immunosuppressants (9 patients were taking azathio-

prine, 5 methotrexate, and 5 mycophenolate mofetil). There were a total of 376 patient visits in the interval. Forty-one were “baseline” visits, 127 visits of 376 visits in 23 patients showed remission, 14 visits in 10 patients showed flare, 11 visits in 8 patients showed improvement, and 183 visits in 34 patients were unchanged.

LupusQoL and SF-36. QOL as assessed by SF-36 and LupusQoL was low in this group of patients with SLE. The mean scores for each of the domains of the LupusQoL and SF-36 are shown in Table 1. The mean scores are < 70 in 7 domains of the SF-36 but not in social functioning (75.5 ± 27.7). The MCS and PCS scores were both < 50. Despite the fact that the mean score in LupusQoL was always higher than in SF-36 for each of the comparable domains, all standardized p values were not statistically significant (mean score in 376 patient visits: physical health/physical function, $71.0 \pm 22.6/64.0 \pm 27.7$, $p = 0.96$; emotional health/mental health, $77.0 \pm 22.6/68.1 \pm 22.3$, $p = 0.94$; pain/bodily pain $74.1 \pm 24.1/64.7 \pm 27.6$, $p = 0.84$; and fatigue/vitality $64.0 \pm 26.6/50.5 \pm 26.2$, $p = 0.83$; Table 1).

The correlation of the comparable domains of LupusQoL and SF-36 was studied. There was a strong correlation between comparable domains in LupusQoL and SF-36 in 376 patient visits (physical health and physical functioning, $r = 0.75$; emotional health and role emotional, $r = 0.62$; pain and bodily pain, $r = 0.76$; and fatigue and vitality, $r = 0.75$; all p values < 0.0001, Figure 1). For the 4 noncomparable domains of the LupusQoL, there was a correlation between each domain and 1 of the component scores of SF-36: body image and SF-36 MCS, $r = 0.61$; planning and SF-36 MCS, $r = 0.68$; intimate relationships and SF-36 PCS, $r = 0.73$; and burden to others and SF-36 MCS, $r = 0.70$ (Table 2, Figure 2).

The mean scores in both questionnaires decreased in patient visits with flare and increased with improvement compared to baseline visit (Table 3). The SRM incorporates the variation in response and is smaller when the variation in the

Table 1. Descriptive statistics for SF-36 and LupusQoL domains in 376 patient visits. There was no statistically significant difference among comparable domains of SF-36 and LupusQoL; p values were all > 0.05.

Domains	LupusQoL	Mean \pm SD	Domains	SF-36	Mean \pm SD
Physical health		71.0 ± 22.6	Comparable domains:		
Emotional health		77.0 ± 22.6	Physical functioning		64.0 ± 27.7
Pain		74.1 ± 24.1	Mental health		68.1 ± 22.3
Fatigue		64.0 ± 26.6	Bodily pain		64.7 ± 27.6
			Vitality		50.5 ± 26.2
			Noncomparable domains:		
Planning		77.4 ± 26.3	Social functioning		75.5 ± 27.7
Intimate relationships		62.6 ± 35.7	General health		54.1 ± 25.7
Burden to others		71.9 ± 26.9	Role emotional		62.6 ± 44.6
Body image		75.6 ± 25.8	Role physical		53.1 ± 45.2
			PCS		41.3 ± 11.1
			MCS		47.2 ± 12.6

SF-36: Medical Outcomes Study Short-Form 36 questionnaire; LupusQoL: Lupus Quality of Life questionnaire; PCS: physical component summary scores; MCS: mental component summary scores.

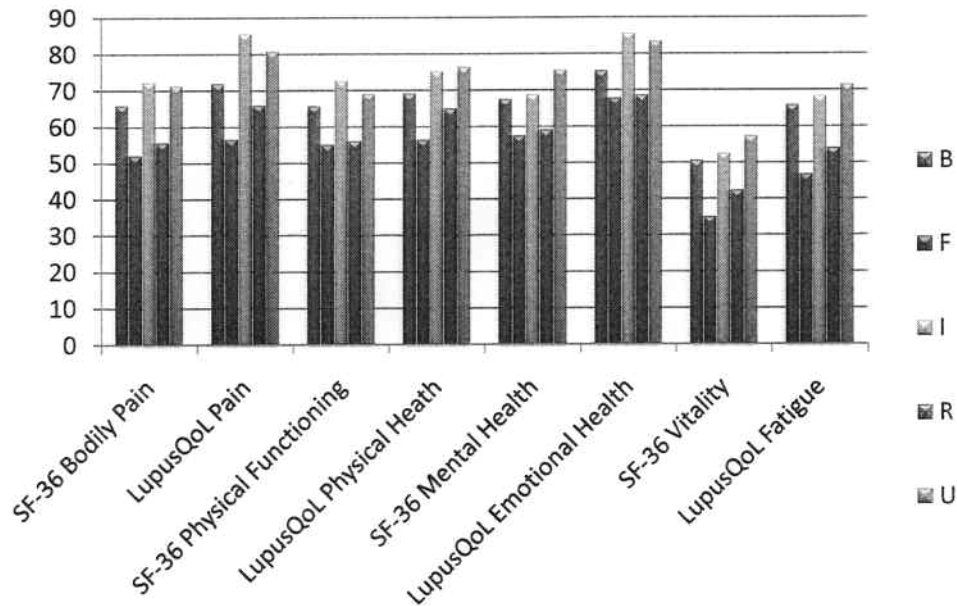


Figure 1. Mean scores of comparable domains in Medical Outcomes Study Short-Form 36 (SF-36) and the LupusQoL questionnaire in patients with clinically significant change in disease activity. B: baseline; F: flare; I: improvement; R: remission; U: unchanged.

Table 2. Correlation between noncomparable domains of LupusQoL and SF-36 (PCS and MCS) in all 376 patients visits.

Domains	SF-36: PCS		SF-36 MCS	
	r	p	r	p
Body image	0.50	< 0.0001	0.61	< 0.0001
Planning	0.59	< 0.0001	0.68	< 0.0001
Intimate relationships	0.73	< 0.0001	0.41	< 0.0001
Burden to others	0.45	< 0.0001	0.70	< 0.0001

LupusQoL: Lupus Quality of Life questionnaire; SF-36: Medical Outcomes Study Short-Form 36 questionnaire; PCS: physical component summary scores; MCS: mental component summary scores.

change is greater. The ES seems less desirable than the SRM as it relates the change score to the SD at baseline and is influenced by the heterogeneity of the population. Both questionnaires displayed responsiveness in some domains as determined by ES and SRM among patients who flared (SF-36, SRM of moderate effect of 0.64 in role physical, small effect of 0.42 in social functioning, and of 0.30 in PCS; LupusQoL, SRM of moderate effect of 0.67 in fatigue and small effect of 0.49 in burden to others). Both questionnaires also displayed responsiveness among patients who improved (SF-36, SRM moderate effect of 0.60 in MCS and small effect of 0.43 in mental health, 0.40 in general health, 0.30 in vitality, 0.30 in role physical, 0.24 in social functioning, and 0.23 in physical functioning; LupusQoL, SRM moderate effect of 0.73 in pain, 0.53 in fatigue, and 0.51 in physical health, and small effect of 0.45 in emotional health, 0.39 in body image, 0.37 in burden to others, and 0.36 in planning). But this responsiveness was

not observed among patients in remission when compared to a previous visit. If we look at ES/SRM for both improvement and flare, the scores are higher in LupusQoL compared to SF-36, but we could not find a clear distinction (Table 4 displays means and Table 5 shows the ES/SRM of the 4 groups of patients: flare, improvement, remission, and unchanged).

DISCUSSION

SLE affects patients very differently. Disease activity and damage related to SLE and its treatment are well described^{4,26,27}. However, current lifestyle and personal and family expectations are so diverse that a brief review in a clinic gives a limited perspective of the effect of a major illness such as SLE on HRQOL.

We compared the SF-36 and the LupusQoL as measures of HRQOL in SLE^{10,15}. The potential advantage of the LupusQoL is that it contains items and domains related more specifically to patients with SLE. Nevertheless, we showed that the comparable domains in both questionnaires correlated well with each other and each of the noncomparable domains of the LupusQoL correlated with at least one of the summary scales of SF-36 (PCS and MCS) in all patient visits. The correlation between LupusQoL and SF-36 at the cross-sectional level has been demonstrated in a previous study¹⁵. In our study, we have shown that LupusQoL and SF-36 were equivalent in assessing the HRQOL over time of patients with SLE. However, because SF-36 is generic, comparisons can be made with other patient groups or, through the standardized PCS and MCS, compared to the population at large. Therefore, SF-36 might be a better instrument to use.

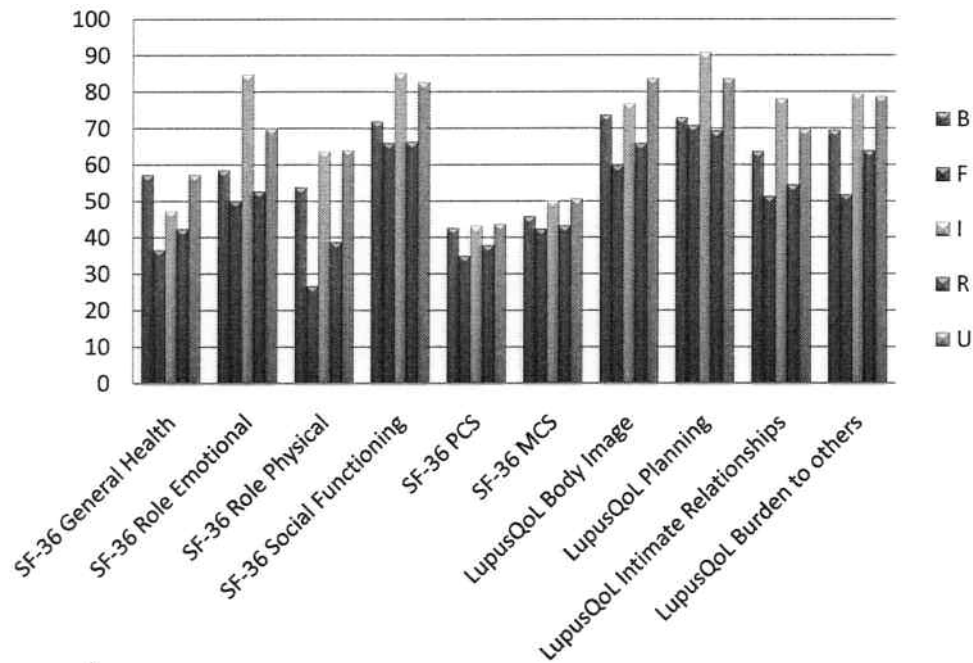


Figure 2. Mean scores of noncomparable domains in Medical Outcomes Study Short-Form 36 (SF-36) and the LupusQoL questionnaire in patients with clinically significant change in disease activity. B: baseline; F: flare; I: improvement; R: remission; U: unchanged.

Table 3. Means of comparable and noncomparable domains in the SF-36 and LupusQoL questionnaires in patients with clinically significant change in disease activity.

Type of Patient Visit	Comparable Domains							
	SF-36 Bodily Pain	LupusQoL Pain	SF-36 Physical Functioning	LupusQoL Physical Health	SF-36 Mental Health	LupusQoL Emotional Health	SF-36 Vitality	LupusQoL Fatigue
B, n = 41	65.9 ± 26.1	71.9 ± 25.8	65.7 ± 26.5	69.1 ± 22.6	67.5 ± 23.1	75.3 ± 24.5	50.6 ± 27.7	65.8 ± 25.9
F, n = 14	52.1 ± 30.9	56.5 ± 31.2	55.0 ± 31.6	56.4 ± 30.7	57.4 ± 21.0	67.8 ± 22.7	35.0 ± 22.4	46.8 ± 26.6
I, n = 11	72.0 ± 25.0	85.6 ± 18.6	72.7 ± 20.6	75.2 ± 14.7	68.7 ± 17.7	85.5 ± 12.4	52.4 ± 26.8	68.3 ± 19.8
R, n = 127	55.6 ± 27.6	65.9 ± 24.1	56.0 ± 28.5	64.9 ± 23.3	59.1 ± 23.5	68.6 ± 24.4	42.3 ± 26.7	54.0 ± 27.0
U, n = 183	71.3 ± 25.8	80.8 ± 20.7	69.0 ± 26.2	76.4 ± 20.3	75.5 ± 18.7	83.4 ± 19.9	57.3 ± 23.6	71.4 ± 24.1
	Noncomparable Domains							
	SF-36 General Health	SF-36 Role Emotional	SF-36 Role Physical	SF-36 Social Functioning	LupusQoL Body Image	LupusQoL Planning	LupusQoL Intimate Relationships	LupusQoL Burden to Others
B, n = 41	57.3 ± 26.3	58.5 ± 45.8	53.8 ± 44.1	71.9 ± 26.6	73.7 ± 27.9	72.9 ± 28.3	63.7 ± 37.7	69.5 ± 27.4
F, n = 14	36.6 ± 26.1	50.0 ± 46.6	26.7 ± 42.1	66.0 ± 30.3	59.7 ± 27.3	70.8 ± 36.7	51.3 ± 38.7	51.7 ± 38.5
I, n = 11	47.3 ± 28.6	84.8 ± 31.1	63.6 ± 50.4	85.2 ± 20.7	76.8 ± 18.5	90.9 ± 15.5	78.1 ± 36.4	79.5 ± 16.8
R, n = 127	42.3 ± 26.7	52.6 ± 45.9	38.7 ± 43.9	66.3 ± 29.5	65.9 ± 26.6	69.3 ± 27.3	54.5 ± 33.8	63.9 ± 28.1
U, n = 183	57.3 ± 23.6	70.0 ± 42.3	64.0 ± 43.0	82.7 ± 24.4	83.8 ± 21.9	83.6 ± 22.7	69.8 ± 35.2	78.8 ± 22.9
	SF-36 PCS	SF-36 MCS						
B	42.6 ± 10.9	45.8 ± 13.8						
F	34.9 ± 12.7	42.3 ± 11.7						
I	43.2 ± 11.0	50.1 ± 8.7						
R	37.9 ± 11.3	43.2 ± 13.6						
U	43.7 ± 10.0	50.6 ± 10.7						

SF-36: Medical Outcomes Study Short-Form 36 questionnaire; LupusQoL: Lupus Quality of Life questionnaire; B: baseline; F: flare; I: improvement; R: remission; U: unchanged; PCS: physical component summary scores; MCS: mental component summary scores.

Table 4. Responsiveness of SF-36 and LupusQoL questionnaires in comparable and noncomparable domains.

	Comparable Domains							
	Effect Size Change from Previous Visit							
	SF-36 Bodily Pain	LupusQoL Pain	SF-36 Physical Functioning	LupusQoL Physical Health	SF-36 Mental Health	LupusQoL Emotional Health	SF-36 Vitality	LupusQoL Fatigue
F	0.03	0.02	0.07	0.02	0.03	0.05	0.09	0.21
I	0.02	0.41	0.05	0.35	0.20	0.30	0.15	0.30
R	0.02	0.03	0.03	0.01	0.05	0.01	0.02	0.02
U	0.01	0.00	0.00	0.00	0.01	0.02	0.00	0.00

	Noncomparable Domains							
	Effect Size Change from Baseline Visit							
	SF-36 General Health	SF-36 Role Emotional	SF-36 Role Physical	SF-36 Social Functioning	LupusQoL Body Image	LupusQoL Planning	LupusQoL Intimate Relationships	LupusQoL Burden to Others
F	0.02	0.16	0.50	0.20	0.04	0.06	0.04	0.24
I	0.10	0.00	0.16	0.09	0.27	0.16	0.00	0.28
R	0.00	0.02	0.05	0.04	0.05	0.01	0.00	0.02
U	0.00	0.01	0.04	0.00	0.03	0.00	0.01	0.01

	SF-36 PCS	SF-36 MCS
F	0.20	0.02
I	0.04	0.14
R	0.02	0.02
U	0.00	0.05

SF-36: Medical Outcomes Study Short-Form 36 questionnaire; LupusQoL: Lupus Quality of Life questionnaire; F: flare (14 visits in 10 patients); I: improvement (11 visits in 8 patients); R: remission (127 visits in 23 patients); U: unchanged (183 visits in 34 patients); PCS: physical component summary scores; MCS: mental component summary scores.

An additional useful characteristic of HRQOL measures is their responsiveness over time. We assessed the responsiveness by measuring the ES and SRM (responsiveness measures) of SF-36 and LupusQoL while using disease activity as the external anchor. Using this approach we demonstrated that both SF-36 and LupusQoL are responsive measures, changing with disease activity. Although previous studies demonstrated that HRQOL measures do not change with disease activity, these were either cross-sectional, or measured HRQOL at yearly intervals^{2,3,11,32}. Our patients were evaluated monthly and therefore could more easily detect changes in disease activity over time and responsiveness when a clinically significant change in disease activity occurred. More importantly, the statistical measures (ES/SRM) adopted in our study have helped us to identify the responsiveness properties of SF-36 and LupusQoL. A few studies and recent clinical trials have shown that change in disease activity over time correlates with change in HRQOL measures if determined at 1 month, 3 months, and 6 months^{13,33,34}.

Patients in our study presented relatively low disease activity (SLEDAI-2K = 2.0, median), with the majority of the patients in remission. The major domains affected in the LupusQoL include fatigue and intimate relationships, and in the SF-36, vitality, general health, role physical, MCS, and

PCS. A cross-sectional US study of the LupusQoL questionnaire administered to 186 patients observed that all scores were lower than those in our study. However, in that study patients had higher disease activity (SLEDAI-2K = 4, median)³⁵. The mean scores of the domains of LupusQoL in our study are consistent with the results of McElhone, *et al*¹⁵ in a group of 120 patients that included patients with no current disease activity and those with mild disease as determined by the British Isles Lupus Assessment Index.

Our study has a few limitations. First, we enrolled patients with mild disease activity, and most of the patients were in remission. As expected, the SF-36 and LupusQoL scores in this group of patients were stable over time. Second, the sample of patients who experienced change in disease activity as flare and improvement was small (14 visits with flares and 11 with improvements). Despite this we were able to demonstrate clinically significant change in disease activity that was reflected in changes in HRQOL when a clinically significant change in disease activity occurred as reflected by the responsiveness of SF-36 and LupusQoL in some domains. Another limitation of our study was the sample size, which was 41 patients. Although the statistical analysis on responsiveness was conducted on 376 patient visits, a larger sample size should be included in future stud-

Table 5. Responsiveness of SF-36 and LupusQoL (SRM) in comparable and noncomparable domains.

	Comparable Domains SRM Change from Previous Visit							
	SF-36 Bodily Pain	LupusQoL Pain	SF-36 Physical Functioning	LupusQoL Physical Health	SF-36 Mental Health	LupusQoL Emotional Health	SF-36 Vitality	LupusQoL Fatigue
F	0.04	0.04	0.12	0.03	0.04	0.08	0.18	0.67
I	0.06	0.73	0.23	0.51	0.43	0.45	0.30	0.53
R	0.02	0.05	0.03	0.01	0.09	0.02	0.02	0.05
U	0.02	0.01	0.00	0.01	0.03	0.04	0.01	0.01
	Noncomparable Domains SRM Change from Baseline Visit							
	SF-36 General Health	SF-36 Role Emotional	SF-36 Role Physical	SF-36 Social Functioning	LupusQoL Body Image	LupusQoL Planning	LupusQoL Intimate Relationships	LupusQoL Burden to Others
F	0.08	0.18	0.64	0.42	0.07	0.17	0.14	0.49
I	0.40	0.00	0.30	0.24	0.39	0.36	0.00	0.37
R	0.00	0.03	0.10	0.05	0.09	0.02	0.01	0.03
U	0.01	0.02	0.05	0.01	0.07	0.01	0.06	0.02
	SF-36 PCS	SF-36 MCS						
F	0.30	0.03						
I	0.09	0.60						
R	0.03	0.03						
U	0.00	0.10						

SF-36: Medical Outcomes Study Short-Form 36 questionnaire; LupusQoL: Lupus Quality of Life questionnaire; SRM: standardized response mean; PCS: physical component summary scores; MCS: mental component summary scores; F: flare (14 visits in 10 patients); I: improvement (11 visits in 8 patients); R: remission (127 visits in 23 patients); U: unchanged (183 visits in 34 patients).

ies to have enough power to detect a difference between LupusQoL and SF-36.

LupusQoL and SF-36 were equivalent in assessing the HRQOL over time in this group of patients with SLE. SF-36 and LupusQoL showed a small to moderate responsiveness when a clinically significant change in disease activity occurred. Both LupusQoL and SF-36 are easily completed by patients and correlate very well with each other^{15,22,35}. Future studies with a larger sample of patients with moderate to severe disease activity are required to determine utility of LupusQoL compared to the SF-36. Further, this study confirms that the assessment of HRQOL in patients with SLE should be determined monthly in clinical trials if the objective is to evaluate responsiveness.

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