Adaptation and validation of the Systemic Lupus Erythematosus Quality of Life Questionnaire (L-QoL) for use in Bulgaria

Daliya Tsvetanova Pencheva[1,2], Anna Coffey[3], Stephen P. McKenna[3,4], Simeon Valentinov Monov[2]

[1]Department of Physiology and Pathophysiology, Medical University of Sofia, Sofia, Bulgaria, [2]University Clinical Hospital "St. Ivan Rilski", Sofia, Bulgaria, [3]Galen Research Ltd, Manchester, UK, [4]School of Health Sciences, University of Manchester, Manchester, UK

Background

Systemic Lupus Erythematosus (SLE) is a heterogeneous disease with complex pathogenic mechanisms and multiple clinical manifestations, leading to a significant deterioration in quality of life (QoL), both in relation to the disease itself and its complications, and as a result of ongoing therapy.[1]

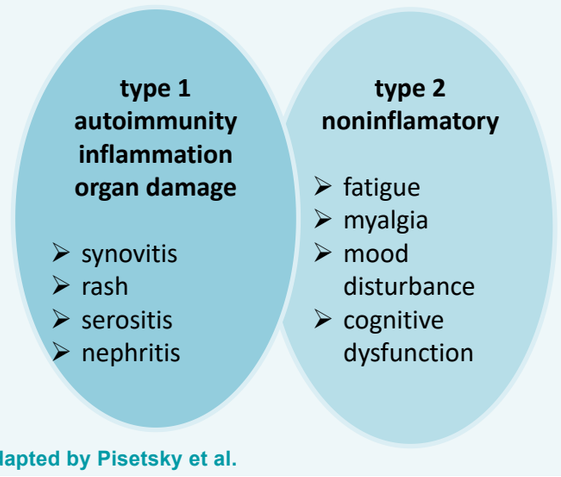
The Systemic Lupus Erythematosus Quality of Life Questionnaire (L-QoL) is a SLE-specific questionnaire that assesses need-based QoL. It consists of 25 items, with a dichotomous response format (True/Not true). A higher score indicates worse QoL.[2]

Therapeutic targets in SLE

- Remission (DORIS definition)[3]
- Low disease activity (LLDAS)[4]
- Treat-to-target in SLE[5]

The need for assessing QoL in lupus

QoL could correlate poorly with disease activity and damage accrual.[5] One reason for this discrepancy could be explained by the new disease model for SLE that features subtypes to categorise two main groups of symptoms into type 1, typically related to inflammation and treated with immunosuppressants, and type 2, which covers common complaints of fatigue, insomnia and depression, with the latest having impaired QoL despite a low disease activity.[6]



*Adapted by Pisetsky et al.

The conceptual model underlying the L-QoL is the needs-based model of QoL that evaluates the ability of individuals to satisfy their human needs, rather than measuring symptoms and physical limitations.[7] This model has been used in the development of more than 30 disease-specific PROMs.[8-9]

Aim to adapt and validate the L-QoL for use in Bulgaria.

Methods

The development of the Bulgarian version involved three stages: translation, field testing and psychometric evaluation. Translation was conducted by an expert linguist working with a developer of the original L-QoL, followed by interviews with monolingual lay individuals. Face and content validity of the translation were assessed by cognitive debriefing interviews with Bulgarian SLE patients. Finally, the L-QoL was validated by administering the questionnaire to a random sample of SLE patients on two occasions, two weeks apart to evaluate its reliability and validity. At the first administration, participants also completed a comparator questionnaire the SF-36 - a generic measure of health status.[10]

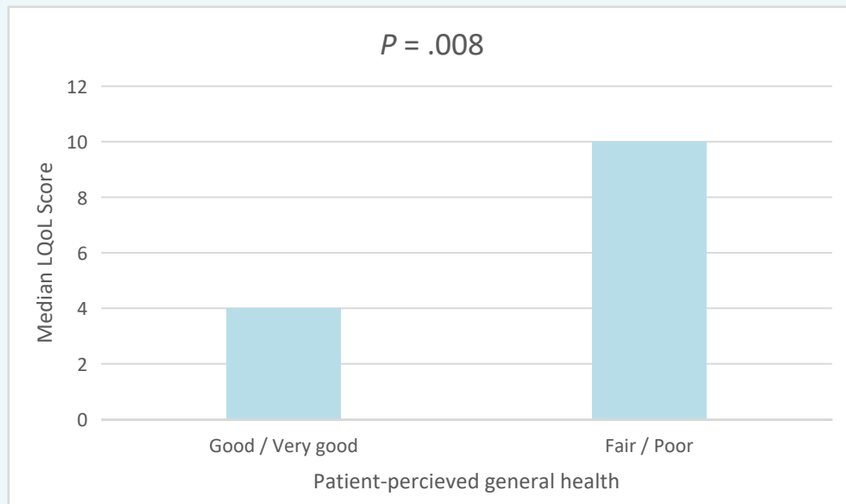
Results

The psychometric study included 51 lupus patients. Demographic and disease information of the sample are presented in Table 1.
The validation survey demonstrated that the new language version has excellent internal consistency (Cronbach's alpha = 0.92) and test–retest reliability (0.97).

Convergent validity was established by correlating scores on the L-QoL with those on the SF-36. Table 2 shows the correlations between scores on the L-QoL and those on the SF-36 sections at Time 1.

The strongest correlation was observed between L-QoL scores and the social functioning section of the SF-36.

Known group validity was established by the ability of the Bulgarian L-QoL to distinguish between subgroups of patients, who differed in their perceived general health, disease severity and presence of a flare (Fig 1).



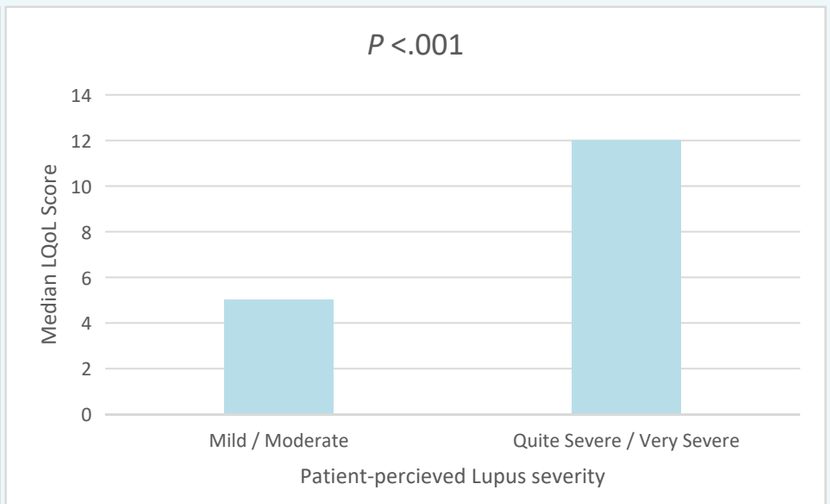


Figure 1: Mean L-QoL scores by general health and disease activity *Mann Whitney U tests

Table 2. Descriptive statistics and correlations between L-QoL and SF-36 section scores (n = 51)

	Median	Q1-Q3	Min-Max	% scoring min	% scoring max	Correlations with L-QoL
L-QoL (Time 1)	6.0	2.0 – 11.0	0.0 – 24.0	13.7	2.0	
SF-36 sections (Time 1)						
Physical Functioning	70	45.0 – 85.0	10.0 – 100.0	2.0	13.7	- 0.67*
Physical Role Limitations	56.3	43.8 – 93.8	0.0– 100.0	3.9	17.6	-0.74*
Bodily Pain	55.6	33.3 – 88.9	0.0– 100.0	3.9	19.6	-0.59*
General Health	50.0	35.0 – 55.0	10.0 – 100.0	3.9	2.0	-0.53*
Vitality	31.3	43.8 – 68.8	0.0– 100.0	2.0	3.9	-0.73*
Social Functioning	75.0	50.0 – 100.0	12.5– 100.0	2.0	25.5	-0.76*
Emotional Role Limitations	75.0	50.0 – 91.7	0.0– 100.0	2.0	21.6	-0.70*
Mental health	65.0	50.0 – 80.0	10.0– 100.0	2.0	3.9	-0.54*
L-QoL (Time 2)	6.0	1.0 – 12.0	0.0 – 24.0	17.6	2.0	

L-QoL: Systemic Lupus Erythematosus Quality of Life Questionnaire; SF-36: 36-item Short Form Health Survey; Q1-Q: Interquartile range * Correlation is significant at p < 0.01

Table 1. Demographic and disease information of the sample (n=51)

Age (years)		
Mean (SD); Minimum - Maximum (Range)	42.4 (10.9)	18.6 – 68.7
Disease Duration (years)		
Mean (SD); Minimum – Maximum (Range)	10.9 (9.5)	1 - 40
Gender	n	%
Male	3	5.9
Female	48	94.1
Marital status		
Married/Living as married	34	66.7
Divorced	5	9.8
Widowed	1	2.0
Single	11	21.6
Work status		
Full-time	31	60.8
Part-time	4	7.8
Retired	2	3.9
Homemaker	1	2.0
Retired due to illness	4	7.8
Long term sick leave	2	3.9
Unemployed	7	13.7

Discussion

- The new language version demonstrated excellent internal consistency, test-retest reliability and was capable of detecting meaningful differences between SLE patients in terms of perceived ratings of disease severity, general health and presence of flare. These findings are similar to the results in the original validation studies.[2]
- Despite being recommended by the British Society for rheumatology for use in SLE patients, the recommended use of the SF-36 is not supported by the current study due to its poor psychometric properties.[11]
- The high ceiling effects for five of the SF-36 sections indicates that it is poorly targeted to SLE patients. This is not surprising given that it is a generic measure intended for use with any disease group. Since the L-QoL was derived from qualitative interviews with lupus patients, all items are relevant to respondents.[2]
- **The L-QoL has an advantage over other outcome measures as it provides a single unidimensional score for each respondent, representing the overall impact of SLE and its treatment on the patient.**

Conclusion

The Bulgarian instrument is the first successfully validated language version of the questionnaire and is therefore recommended for routine use and in clinical studies with Bulgarian SLE patients.

*References:*1.Kaul, A., Gordon, C., Crow, M. et al. Systemic lupus erythematosus. Nat Rev Dis Primers 2 2016; 16039. 2.Doward LC, McKenna SP, Whalley D, et al. The development of the L-QoL: a quality-of-life instrument specific to systemic lupus erythematosus. Ann Rheum Dis. 2009; 68:196–200.3. van Vollenhoven RF, Bertsias G, Doria A, et al. 2021 DORIS definition of remission in SLE: final recommendations from an international task force Lupus Science & Medicine 2021; 8:e000538. 4. Franklyn K, Lau CS, Navarra SV et al. Definition and initial validation of a Lupus Low Disease Activity State (LLDAS). Ann Rheum Dis. 2016; 75(9):1615-21. 5. van Vollenhoven RF, Mosca M, Bertsias G et al. Treat-to-target in systemic lupus erythematosus: recommendations from an international task force. Ann Rheum Dis. 2014; 73(6):958-67. 6. Pisetsky DS, Clowse MEB, Criscione-Schreiber LG et al. A Novel System to Categorize the Symptoms of Systemic Lupus Erythematosus. Arthritis Care Res (Hoboken) 2019; 71(6):735-741. 7. Hunt SM, McKenna SP The QLDS: a scale for the measurement of quality of life in depression. Health Policy 1992; 22:307– 319.8. McKenna S, Doward L, Whalley D et al. Development of the PsAQoL: a quality of life instrument specific to psoriatic arthritis. Ann Rheum Dis 2004; 63:162–169.9.Doward L, Spoorenberg A, Cook S et al. Development of the ASQoL: a quality of life instrument specific to ankylosing spondylitis. Ann Rheum Dis 2003; 62:20–26. 10. Ware JE Jr (2000) SF-36 health survey update. Spine 25:3130–3139. 11 Gordon C, Amissah-Arthur MB, Gayed M et al. The British Society for Rheumatology guideline for the management of systemic lupus erythematosus in adults, Rheumatology 2018;57:e1e45

Contact details

Daliya Ts Pencheva; Email: daliyapencheva@yahoo.com