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Korean LupusPRO: Cross-Cultural validation study for systemic lupus erythematosus

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Abstract

Objective: To establish the reliability and validity of the Korean version of LupusPRO version 1.7 (v1.7) for systemic lupus erythematosus (SLE) patients.

Methods: LupusPRO v1.7 was translated into Korean, followed by pretesting among five native Korean speakers. We administered the LupusPRO v1.7 survey to five SLE patients and made minor changes to clarify the language. Then, 133 SLE patients participated in the validation procedure. In each domain, the internal consistency reliability (ICR) and test-retest reliability (TRR) were assessed using Cronbach's alpha and the intra-class correlation coefficient (ICC), respectively. Criterion validity was evaluated using Spearman's correlation coefficient with the other measures such as SF-36, EQ-5D VAS, and SELENA-SLEDAI PGA. Construct validity was assessed by confirmatory factor analysis (CFA) using the unweighted least square estimation method.

Results: The mean age of the 133 patients was 36.14 years, and 97% of them were women. Analysis of 130 returned questionnaires revealed that most ICRs of the Korean LupusPRO v1.7 domains were acceptable, with Cronbach's alphas in the range of 0.579–0.949, and most TRRs were good with ICCs from 0.582 to 0.851. Criterion validities presented significant correlations between the LupusPRO v1.7 and other measures validated. In the analysis of the CFA model, the goodness of fit indices demonstrated an acceptable fit. Factor loadings for most individual items were between 0.548 and 0.985. The average variance extracted (AVE) and composite reliability (CR) of most domains were greater than 0.5 and 0.7, respectively, demonstrating acceptable convergent and discriminant validities.

Conclusions: The Korean version of LupusPRO v.17 had acceptable reliability and validity.

Keywords

systemic lupus erythematosus, patient-reported outcome, quality of life

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Introduction

Systemic lupus erythematosus (SLE) is a chronic autoimmune disease characterized by heterogeneous multisystem involvement.[1] Thus, clinical features in individual patients can be quite variable, ranging from mild joint and skin manifestations to severe or life-threatening major organ involvement.[2] It is also difficult to predict clinical events in the random course of remissions and relapses.[3] Eventually, organ damage accumulated through recurrent lupus flares and treatment-related complications affects patients' healthcare outcomes and mortality.[4]

Advances in therapeutic approaches have significantly improved the outcomes of SLE patients in the past couple of

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decades.[5] However, current management is still limited by early drug discontinuation or non-adherence due to adverse effects, physical impairment, and cognitive deficits.[6] According to recent guidelines for managing SLE patients, the therapeutic goals should be to prevent organ damage, induce remission of disease symptoms, minimize complications, and improve the quality of life (QoL).[7] Among them, QoL improvement is especially important for patient care because of the high disease burden in SLE patients.[8]

Several valid measures are available to assess QoL in SLE patients. Some are generic, such as the 36-Item Short Form Survey (SF-36),[9] and others are disease-specific, such as the Systemic Lupus Erythematosus–Specific QOL,[10] the SLE-QoL questionnaire,[11] and Lupus-QOL.[12] Compared with the generic measures, disease-specific measures allow identification of organ-specific clinical manifestations in SLE patients.

The Lupus Patient-reported Outcome (LupusPRO) questionnaire version 1.7 (v1.7) was developed and validated for SLE patients in the United States in 2012; it measures both health-related quality of life (HRQoL) and non-health-related quality of life (non-HRQoL).[13] It was developed based on data from female and male SLE patients, and it uses gender-neutral language to best capture the impact of SLE irrespective of gender. It allows clinicians to quantify the disease burden for SLE patients by considering data on the adverse effects of medication, coping, and procreation from the patient self-report. LupusPRO v1.7 has already been cross-culturally validated in other English-speaking countries (Canada and Philippines) and after translation to other languages, including Spanish, French, Turkish, Hindi, Chinese, Japanese, and Arabic.[14–22] Moreover, LupusPRO version 1.8 (v1.8) was developed and validated for SLE patients in 2015. Herein, we conducted this study to establish the reliability and validity of the Korean LupusPRO v1.7 for SLE patients in Korea.

Materials and methods

LupusPRO v1.7 consists of two constructs: HRQoL and non-HRQoL. The HRQoL construct includes lupus symptoms, cognition, lupus medications, procreation, physical health, pain/vitality, emotional health, and body image.[13] The non-HRQoL construct includes desires/goals, social support, coping, and satisfaction with care. The LupusPRO v1.7 questionnaire consists of 43 items (30 for HRQoL and 13 for non-HRQoL) related to the previous four weeks of the patients' lives, and each item has five options for answers that range from "none of the time" to "all of the time." The individual domain scores, total HRQoL score, and non-HRQoL score range from 0 to 100, with higher scores indicating a better QoL.

Translation and cross-cultural adaptation

The forward and backward translation method was used for the cross-cultural adaptation of LupusPRO v1.7, followed by pretesting with five native Korean speakers. After obtaining permission from the developer of LupusPRO v1.7, Dr Jolly, the adapted Korean LupusPRO v1.7 questionnaire was administered to five Korean SLE patients. Finally, the cross-culturally adapted Korean version of LupusPRO v1.7 was verified by a panel of experts, including two rheumatologists and one methodologist, with minor changes to clarify the language.

Study population for cross-cultural validation

We enrolled patients who visited the outpatient clinic at a university hospital in Korea between September 2017 and July 2018. They satisfied the following inclusion criteria: (a) age ≥ 19 years, (b) native Korean speaker, (c) fulfillment of 1997 ACR classification criteria for SLE,[23] and (d) ability to understand and complete the questionnaire.

All participants were included in the KORNET registry, which contains information on the outcome variables of patients, including analysis of LupusPRO v1.7 responses, from a multi-center prospective cohort in Korea.[24]

Outcome measures

SF-36. The SF-36 is a generic patient-reported outcome measure.[25,26] The physical component score (PCS) consists of physical functioning, role limitations (physical), bodily pain, and general health. The mental component score (MCS) consists of social functioning, role limitations (emotional), vitality, and mental health. A higher score indicates a better QoL.

EuroQoL 5-Dimension visual analogue scale (EQ-5D VAS). The EQ-5D developed by the EuroQoL Group is a reliable measure of an individual's HRQoL and utility values.[27,28] The five dimensions of the EQ-5D include mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-5D VAS is a self-reported health state on a scale from 0 to 100, with higher scores indicating a better HRQoL.

Safety of Estrogens in Lupus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI). The SELENA-SLEDAI, which consists of 24 different disease descriptors, is an outcome measure for disease activity in SLE patients.[29,30] The total SELENA-SLEDAI score is a weighted sum of those descriptors and ranges from 0 to 105, with a higher score representing a more significant degree of disease activity. The SELENA-SLEDAI also contains the Physician's Global Assessment (PGA) scale with a 4-point Likert scale ranging from 0 (inactive) to 3 (very active disease).

Systemic lupus international collaborating Clinics/American college of rheumatology (SLICC/ACR) Damage Index (SDI). The SLICC/ACR Damage Index (SDI) measures the damage that has accumulated since the diagnosis of SLE.[31] The damage was defined as non-reversible changes in 12 organs and systems that were present for at least 6 months. The damage is assessed by 39 items, theoretically to a maximum of 47 points, with higher scores representing more severe organ damage.

Statistical analysis

Numbers are presented as frequency (%) or mean ± SD. Cronbach's alpha and ICC were estimated to assess the internal consistency reliability (ICR) and test-retest reliability (TRR), respectively. Spearman's correlation assessed the criterion validity with the other measures. To establish the TRR, LupusPRO v1.7 was administered twice over a 2-week period. Confirmatory factor analysis (CFA) with an unweighted least square (ULS) method assessed the construct validity. All statistical analyses were performed using SAS 9.4 (SAS Institute Inc., Cary, NC) or R software version 3.4.2 (R Foundation for Statistical Computing, Vienna, Austria).

Ethical consideration

This study was approved by the Institutional Review Board (IRB) of Hanyang University Hospital (IRB file No. HYUH 2017-06-036). All participants provided written informed consent.

Results

Baseline characteristics of participants

A total of 134 SLE patients were enrolled. After excluding one patient who withdrew consent, 133 patients finally participated in the validation study (Figure 1). Their baseline characteristics are presented in Table 1. The mean (SD) age of the patients was 36.14 ± 9.61 years, and 129 (97.0%) were women. The mean (SD) duration of illness was 5.81 ± 5.70 years. Most of them were prescribed hydroxychloroquine (92.5%), and more than half were prescribed prednisolone (53.4%). The mean (SD) SELENA-SLEDAI score was 3.13 ± 3.28, and 15 (11.3%) patients had a score of more than 6, indicating active disease. The mean (SD) SDI score was 0.18 ± 0.46, with only 20 (15.0%) patients having a score of 1 or more. The mean scores on the Korean LupusPRO v1.7 were presented in Table 2. The mean (SD) values for the HRQoL and non-HRQoL constructs were 82.55 ±14.19 and 44.84 ± 11.20, respectively.

ICR

Except for lupus symptoms (0.682), lupus medications (0.579), and social support (0.619), the Cronbach's alphas of the other domains were in the range of 0.739–0.949, indicating acceptable to excellent ICR. Among them, the body image (0.949), cognition (0.942), and emotional health (0.934) components of the HRQoL construct demonstrated a high level of reliability (Table 3).

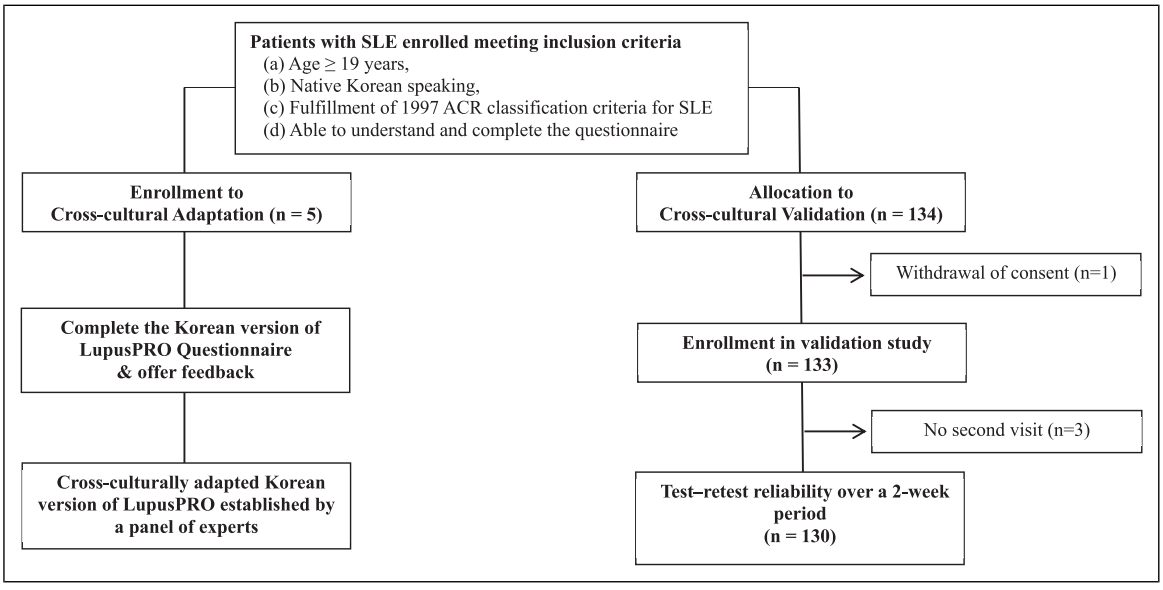

Figure 1. Adaptation and validation process of the Korean version of LupusPRO.

Table 1. Baseline characteristics of the study population (n = 133).

Characteristic	
Age (years)	36.14 ± 9.61
Sex	
Female	129 (97.0)
Male	4 (3.0)
Family history of disease	25 (18.8)
Education (years)	14.57 ±1.99
Employment status	
Employed	86 (64.7)
Unemployed	47 (35.3)
Marital status	
Never married	60 (45.1)
Currently married	69 (51.9)
Divorced or separated	4 (3.0)
Disease duration, year	5.81 ±5.70
Medication	
Prednisolone	71 (53.4)
Hydroxychloroquine	123 (92.5)
Azathioprine	11 (8.2)
Methotrexate	15 (11.3)
Mycophenolate mofetil	22 (16.5)
Cyclosporine	3 (2.3)
SELENA-SLEDAI	
Total score	3.13 ±3.28
Number of patients with SELENA-SLEDAI ≥ 6	15 (11.28)
PGA	0.85 ±0.78
SLICC/ACR Damage Index (SDI)	
SDI score	0.18 ±0.46
Number of patients with SDI ≥ 1	20 (15.04)

Values are presented as number (%) or mean ±SD.
SELENA-SLEDAI, Safety of Estrogens in Lupus National Assessment-Systemic Lupus Erythematosus Disease Activity Index; **SDI**, Systemic Lupus International Collaborating Clinics/American College of Rheumatology (SLICC/ACR) Damage Index

Table 2. Scores for each domain of LupusPRO in Korean patients with SLE (n = 133).

Domain	Mean ±SD
Health-related quality of life	82.55 ± 14.19
Lupus symptoms	85.90 ± 19.36
Cognition	81.49 ± 22.54
Lupus medications	83.37 ± 20.91
Procreation	83.08 ± 26.21
Physical health	92.56 ± 13.62
Pain/vitality	79.10 ± 20.40
Emotional health	69.67 ± 25.19
Body image	85.23 ± 23.67
Non-health-related quality of life	44.84 ± 11.20
Desires/goals	79.98 ± 20.95
Social support	15.04 ± 20.28
Coping	23.87 ±25.12
Satisfaction with care	60.48 ± 20.52

SLE, systemic lupus erythematosus

TRR

After administering the questionnaire twice over 2 weeks, we analyzed the TRR in each domain of LupusPRO v1.7 based on 130 patients using the identical questionnaire. The ICCs of all domains were in the range of 0.582–0.851, indicating good to excellent TRR. The ICCs showed that the HRQoL construct has a higher degree of similarity than the non-HRQoL construct (Table 3).

Criterion validity

We calculated Spearman's correlation coefficients between the other measures and each LupusPRO v1.7 domain (Table 3). Except for "procreation," HRQoL domains of LupusPRO v1.7 had significant positive correlations with PCS/MCS on SF-36 (0.274–0.729) and EQ-5D VAS (0.276–0.537), indicating a strong to weak positive relationship between the two measures. In addition, we also obtained correlations of all LupusPRO v1.7 domains with SF-36 sections and five dimensions of EQ-5D (Supplementary Tables 2 and 3). Except for "coping" and "procreation," HRQoL domains of LupusPRO v1.7 also had significant negative correlations with SELENA-SLEDAI PGA (−0.335, −0.182), indicating a moderate to weak negative relationship. Correlations between "desire/goals," non-HRQoL domain of LupusPRO v1.7, and other measures were comparable with those between HRQoL domains and other measures (0.553/0.611 for PCS/MCS on SF-36, 0.461 for EQ-5D VAS, and −0.295 for SELENA-SLEDAI PGA, respectively).

Construct validity using CFA

In the CFA of the Korean LupusPRO v1.7, we assessed the goodness of fit for the hypothesized item-to-scale relationships using fit indices: SRMR = 0.071, RMSEA = 0.047, CFI = 0.983, and TLI = 0.980 (Table 4). These results significantly supported the conceptual framework of LupusPRO v1.7. Except for four items, that is, "ability to have baby" (1.070), "focus on making situation better" (1.058), "comfort/strength from religion" (0.370), and "Dr accessible" (0.270), the factor loadings for individual items were in the range of 0.548–0.985, implying an excellent to a good relationship between each item and its domain. Except for two domains, that is, "lupus symptoms" (0.400 and 0.664) and "lupus medications" (0.416 and 0.581), average variance extracted (AVE) or composite reliability (CR) of other domains was greater than 0.5 or 0.7, respectively, demonstrating acceptable convergent validity (Table 4). Most squares of factor correlations were estimated less than the

Table 3. Reliability and validity of LupusPRO (n = 133).

	ICR	TRR	SF-36						SELENA-SLEDAI					
			PCS		MCS		EQ-5D VAS		Total score		PGA		SDI	
Domain	Cronbach's alpha	ICC (n=130)	Rho	*p*	Rho	*p*	Rho	*p*	Rho	*p*	Rho	*p*	Rho	*p*
Health-related quality of life														
Lupus symptoms	0.682	0.755	0.327	<0.001	0.354	<0.001	0.317	<0.001	−0.194	0.025	−0.235	0.006	−0.069	0.428
Cognition	0.942	0.759	0.390	<0.001	0.375	<0.001	0.360	<0.001	−0.031	0.724	−0.051	0.558	−0.134	0.123
Lupus medications	0.579	0.690	0.274	0.001	0.374	<0.001	0.276	0.001	−0.268	0.002	−0.335	<0.001	0.054	0.540
Procreation	0.745	0.714	0.094	0.280	0.133	0.128	0.019	0.831	−0.098	0.262	−0.023	0.795	0.167	0.055
Physical health	0.821	0.782	0.606	<0.001	0.491	<0.001	0.418	<0.001	−0.150	0.085	−0.224	0.010	−0.143	0.100
Pain/vitality	0.861	0.849	0.729	<0.001	0.603	<0.001	0.537	<0.001	−0.103	0.237	−0.182	0.036	−0.116	0.186
Emotional health	0.934	0.851	0.476	<0.001	0.647	<0.001	0.429	<0.001	−0.157	0.071	−0.257	0.003	−0.100	0.252
Body image	0.949	0.829	0.388	<0.001	0.536	<0.001	0.316	<0.001	−0.170	0.051	−0.212	0.014	−0.078	0.375
Non-health-related quality of life														
Desires/goals	0.895	0.710	0.553	<0.001	0.611	<0.001	0.461	<0.001	−0.139	0.111	−0.295	0.001	−0.129	0.139
Social support	0.619	0.582	−0.431	<0.001	−0.331	<0.001	−0.273	0.002	0.232	0.007	0.326	<0.001	0.175	0.044
Coping	0.739	0.710	−0.292	0.001	−0.189	0.030	−0.094	0.281	0.099	0.257	0.109	0.212	0.191	0.028
Satisfaction with care	0.756	0.668	0.148	0.089	0.186	0.032	0.157	0.072	−0.070	0.427	−0.093	0.288	0.051	0.562

ICR; internal consistency reliability, TRR; test–retest reliability, ICC; intra-class correlation; SF-36, 36-Item Short Form Survey; EQ-5D VAS, EuroQoL 5-dimension visual analogue scale; SELENA-SLEDAI, Safety of Estrogens in Lupus National Assessment-Systemic Lupus Erythematosus Disease Activity Index; PGA, physician global assessment; SDI, Systemic Lupus International Collaborating Clinics/American College of Rheumatology (SLICC/ACR) Damage Index; Rho, Spearman's correlation coefficient; PCS, physical component score; MCS, mental component score

Table 4. Confirmatory factor analysis using unweighted least square estimation.

Factor	Domain	Factor loadings	AVE	CR
Factor 1	Lupus symptoms	—	0.400	0.664
	Loss of hair	0.645	—	
	New flare	0.548	—	
	Lupus flare	0.718	—	
Factor 2	Cognition	—	0.893	0.943
	Poor memory	0.904	—	
	Lack of concentration	0.985		
Factor 3	Lupus medications	—	0.416	0.581
	Meds cause side effect	0.616	—	
	Concerned over number of medications	0.661		
Factor 4	Procreation	—	0.855	0.907
	Ability to have baby	1.070	—	
	Ability to prevent pregnancy	0.555		
Factor 5	Physical health	—	0.492	0.822
	Taking care of personal needs	0.639	—	
	Getting in and out of bed	0.582		
	Fulfilling family responsibilities	0.799		
	Taking care of dependents	0.678		
	Burden to family	0.742		
Factor 6	Pain/vitality	—	0.569	0.861
	Woke up feeling worn out	0.700	—	
	Felt pain	0.761		
	Unable to do usual activities	0.653		
	Performing activities take long	0.786		
	Limited in kinds of activities	0.817		
Factor 7	Emotional health	—	0.707	0.935
	Worried about lupus impact	0.892	—	
	Worried about losing income	0.740		
	Anxious	0.867		
	Depressed	0.876		
	Concerned lupus lead to more health problems	0.839		
	Concerned lupus last a long time	0.829	—	
Factor 8	Body image	—	0.785	0.948
	Dislike my appearance	0.904	—	
	Thought less of myself	0.985	—	
	Lacked control over appearance	0.900	—	
	Self-conscious about appearance	0.819	—	
	Embarrassed about how others perceived me	0.808	—	
Factor 9	Desires/goals	—	0.677	0.893
	Ability to plan	0.805	—	
	Overall life satisfaction	0.801	—	
	Enjoyment of life	0.820	—	
	Fulfill career goals	0.854	—	
Factor 10	Social support	—	0.587	0.692
	Receive support from friends	0.557	—	
	Receive support from family	0.804	—	
Factor 11	Coping	—	0.661	0.828
	Focus on making situation better	1.058	—	
	Learned to live with lupus	0.730	—	
	Comfort/strength from religion	0.370	—	
Factor 12	Satisfaction with care	—	0.493	0.778
	Dr. accessible	0.270	—	
	Dr. understood	0.906	—	
	Dr. provided information	0.862	—	
	Dr. discussed/monitored side effects	0.692	—	

(continued)

Table 4. (continued)

Factor	Domain	Factor loadings	AVE	CR
Test of model fit	Chi square statistic	1232.063	—	
	Degree of freedom	794	—	
	SRMR	0.071	—	
	RMSEA	0.047	—	
	CFI	0.983	—	
	TLI	0.980	—	

AVE; average variance extracted, CR; composite reliability, SRMR; standardized root mean square residual, RMSEA; root mean square of error approximation, CFI; comparative fit index, TLI; Tucker-Lewis index

corresponding AVE, supporting acceptable discriminant validity (Supplementary Tables 4 and 5).

Discussion

SLE is characterized by a persistent or relapse–remission condition that can decrease physical, psychological, and socioeconomic functioning over time.[32] It also results in irreversible damage to the affected organs or tissues, which reduces QoL and increases mortality in SLE patients.[33] Recent therapeutic strategies suggest that clinicians should consider a personalized approach with perspective of achieving clinical remission and drug tapering to improve patient outcomes.[34] Indeterminate and multi-dimensional factors influence the QoL of SLE patients, making it extraordinarily difficult for physicians to derive meaningful interpretations.[35] Nevertheless, measuring the QoL of individual patients is one of the most essential aspects in quantifying their functioning and predicting their morbidity and mortality.[36] A patient's perspective of QoL necessarily contains subjective components, such as the effects of treatment interruption, hospitalization rate, number of symptoms, and mental health status.[37] Thus, patient-oriented communication is necessary when assessing QoL to implement comprehensive therapeutic strategies.[38]

Patient self-reports have been found to measure the actual burden of disease on individuals and allow comparative evaluations of cost-effectiveness for future resource allocations and reimbursements.[39] LupusPRO was developed as a disease-specific questionnaire that measures QoL through the self-reports of SLE patients.[40] It is helpful for following the impact of lupus or its treatment on QoL in SLE patients. The assessment of subscale constructs enables physicians to understand patients' subjective experiences of disease progression and treatment effectiveness. LupusPRO allows physicians to ascertain factors relevant to disease activity, functional change, and patient well-being, improving the patients' overall health status.

Our study showed that the Korean version of LupusPRO v1.7 has acceptable internal consistency. The Cronbach's alphas for lupus symptoms, lupus medication, and social support indicated relatively low internal consistency, similar to the pattern found in a US study.[13] Cronbach's alpha is sensitive to the number of items, that is, the meaning intended for a domain becomes highly correlated as the number of items in the domain increases. Other explanations for the differences in Cronbach's alpha between domains include the use of multi-item scales, time intervals, practice patterns, and clinical characteristics. In addition, SLE affects mostly younger women, unlike other chronic diseases, and this could exacerbate psychological and emotional problems.

The ICCs of the non-HRQoL domains were lower than those of the HRQoL domains. Some domains related to non-HRQoL were observed heterogeneous variance on returned questionnaires and fewer included items. Nevertheless, the measure demonstrated overall consistency of measurement.

We found highly significant correlations between the HRQoL domains and the corresponding SF-36 domains and EQ-5D VAS score domains. Otherwise, weak or negative correlations were observed with non-HRQoL domains. In previous studies, there has been a poor association between mental component score and health status measures in the rheumatic disease group.[41] However, there is insufficient evidence for a negative relationship.[42] Non-HRQoL factors have multi-dimensional relationship with others. The efforts to elucidate and modify multivariable factors are crucial for achieving better outcomes.

Moreover, the weak correlations between the Korean LupusPRO v1.7 and SELENA-SLEDAI or SDI were similar to the results of studies performed in other countries.[14–22] The low correlation between measures in our study could be explained by the low disease activity and short disease duration of our patients. In addition, differences in the characteristics of the different questionnaires could contribute to the low correlations between them; SELENA-SLEDAI and SDI measure functional status and disease activity, whereas LupusPRO captures overall QoL in SLE patients. This could be strength for LupusPRO as it would have been less affected by irreversible damage.[43]

The convergent and discriminant validities of Korean LupusPRO v1.7 were confirmed by evaluating the item-to-scale relationships in CFA. To estimate the CFA parameters,

we used the ULS method, which is typically used for ordinal data such as Likert-type scale items in LupusPRO v1.7 because it outperforms other estimation methods in estimation accuracy.[44,45] "Dr accessible" (0.270) of factor 12 (satisfaction with care) unfortunately had a poor relationship. It is considered that the well-established healthcare system in Korea offers patients opportunities to access any specialty clinics and receive the first consultation without a referral letter. Moreover, the CFA results contained Heywood cases (i.e., parameter estimates with out-of-range values)[46,47] based on negative error variance. In other words, the estimated factor loadings were greater than 1 for the following items: "ability to have pregnancy" (1.070) and "focus on making situation better" (1.058). The domains of "procreation" and "coping" include three or fewer items, which is insufficient to establish a proper CFA model.

Cross-cultural validation of LupusPRO v1.7 has been conducted in several Asian countries, such as India, China, and Japan.[16,19,22] The ICR values for "lupus symptoms" were relatively low in Korea (0.682), India (0.606), Japan (0.43), and China (0.62) (Supplementary Table 6). Moreover, the ICR values for "social support" (0.62) and "coping" (0.54) were lower in Japan than in other countries. While the ICRs for "social support" (0.619) and "coping" (0.739) were relatively acceptable in Korea, the ICR for "social support" or "satisfaction with care" in a validation study in Europe showed relatively high values, ranging from 0.80 to 0.92. To address the reliability issue, we emphasized socio-cultural comparability. Our results reflect the influence of cultural characteristics and the healthcare system in Asia. It seems logical to adopt a measure in a culturally comprehensible form while maintaining its specificity and sensitivity to changes in the disease course.

Our study has several strengths. First, we demonstrated that the Korean LupusPRO v1.7 is a reliable and well-validated measure and that its two constructs and related items are functionally sensitive to QoL in SLE patients. The TRR for each domain of the Korean LupusPRO v1.7 was higher than that in other studies. We recognized that participants registered in the KORNET database generally had good compliance with examinations, which enabled them to complete their questionnaires accurately. That, in turn, produced relatively high reliability. Second, we analyzed criterion validity using both generic and disease-specific tools to assess the patients' QoL and established a broadly applicable measure with respect to patients' physical and mental health. To investigate construct validity, we applied CFA that could reduce the overall number of observed variables into latent factors. The CFA assisted in developing our hypothesis-based item-to-scale relationships and comparing corresponding factors in LupusPRO versions validated in the US, Europe, and Asia. The results of our factor analysis allowed us to emphasize and further examine the cross-cultural adaptation of our revised version of LupusPRO.

This study also has some limitations. First, the sample size was relatively small with inadequate diversity of socioeconomic circumstances and disease activity so that the participants who were enrolled in it probably had low disease activity, which may be associated with the lower SDI score. Second, mean values for social support and coping domains were relatively lower scores than other domains. It may be associated with vulnerability to stress in SLE patients and lack of support environment. Also, the direct translation of "say" was customary and strict word for Korean SLE patients to mention something, which could affect criterion validity with negative correlation in non-HRQoL domains. Third, we analyzed and showed that LupusPRO v1.7, which consists of 12 domains and 43 items, has sufficient psychometric properties. However, LupusPRO v1.8 was developed and validated to measure QoL in SLE patients by dividing pain/vitality factor in the HRQoL domain into sleep, pain, and vitality.[43] These separated domains were highly associated with lower QoL in SLE patients and represented potentially modifiable factors during treatment intervention. An additional validation study of the Korean version of LupusPRO v 1.8 would be necessary despite producing reliable results in this study.

Conclusions

This study showed that the Korean version of LupusPRO v1.7 is a valid and reliable patient-reported outcome questionnaire for assessing both HRQoL and non-HRQoL. LupusPRO can provide physicians with information from the patients' perspective and facilitate comprehensive therapeutic strategies for Korean SLE patients.

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Supplemental Material

Supplemental material for this article is available online.

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