Outcome measurement in SLE patient: Indonesian version of RAND SF-36 summary scores and some scales were not reliable

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Abstract. Systemic Lupus Erythematosus (SLE) is a chronic autoimmune disease that can attack many organs with varying degrees of severity. This can affect quality of life (QOL). SF36 is a commonly used QOL test. This study aims to report the validity and reliability test of the Indonesian Version of RAND SF-36 in SLE patients. This research uses a cross sectional method and tested it on 19 eligible respondents. To test the reliability and validity of the questionnaire, analysis of the Cronbach coefficient and Pearson correlation was carried out. All subjects were women with an average age of 22.37 ± 5.10 years, the majority had secondary education (66.7%), were not married (79.2%), had no comorbidities (31.6%), and the duration of SLE was more than 3 years (62.5%). All of them used steroids as SLE therapy and also Mycophenolate mofetil (68.8%). The total value of Cronbach's alpha is 0.723 > 0.7, only two items were deemed appropriate RE scale (0.778) and GH scale (0.724). The validity sig value is < 0.005. In general, this study provides evidence that the Indonesian version of the RAND-SF 36 can be used to assess the QOL of SLE patients. However, there are limitations to the reliability of the scales. Further research or adjustments to the questions in the Indonesian version are required to enhance the reliability of the assessment.

1 Introduction

Systemic Lupus Erythematosus (SLE) is a rare and challenging disease to diagnose. It manifests in a wide range of clinical presentations, from oligosymptomatic forms with minimal impact on the patient's daily life to fulminant, life-threatening conditions [1]. The prevalence of systemic lupus erythematosus (SLE) in the general population exhibits considerable variation, with incidence rates ranging from 1.18 (0.16-3.68) per 100,000 person-years in Central Asia to 13.74 (3.2-31.82) per 100,000 person-years in Central Europe. It appears that women are more susceptible to SLE than men [2,3]. SLE primarily affects women of reproductive age (15-44 years), making it one of the most common

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autoimmune illnesses distinguished by gender. SLE, a prevalent reproductive-age illness, appears to have a hormonal component to its pathophysiology, which also presents a number of medical and psychosocial problems [4].

The disease causes a wide range of clinical symptoms. Due to its chronic and widespread nature, it has a profound impact on the patient's quality of life (QOL) over time. The survival rate of SLE patients in developing countries is lower than in high-income countries. This is due to higher mortality rates, poor intervention, and infectious comorbidities [5].

Quality of life is the patient's subjective perception of the disease. It determines the approach to the disease, the ability to cope with daily tasks, and the level of satisfaction from new life situations [1]. The measurement of health-related quality of life (HRQoL) has traditionally relied on two basic approaches: the use of generic questionnaires and the use of disease-specific questionnaires. Generic questionnaires were developed for general use and can be used across a wide range of diseases and populations. Such instruments permit comparisons with other groups and other conditions and allow measurement of dysfunction for individuals experiencing more than one condition [3]. The SF-36 was originally designed as an HRQoL assessment tool for populations with uncomplicated chronic medical conditions [6].

Given that the majority of SLE patients require long-term treatment, it is critical to evaluate how treatment affects their QOL. Nonetheless, just a few research have investigated the instruments used to assess QOL in SLE. The SF-36 is a widely used questionnaire for assessing QOL. However, these measures typically fail to identify SLE-specific symptoms and side effects, which can be attributed to variances in language sensitivity among SLE patients [7]. This has the ability to alter how they perceive and rate their QOL. The SF-36 questionnaire, translated into Indonesian, is rarely used to assess the QOL of SLE patients. The major goal of this study was to determine the reliability and validity of the Indonesian SF-36 in SLE patients.

2 Material and Methods

2.1 Study Design and Subject

The design used in this research was a cross-sectional study conducted at the Sahabat Cempluk Lupus Community which was carried out from December 2023 to January 2024. We collected information on sociodemographic characteristics, such as age, gender, education level, marital status, comorbidity status and duration of SLE. Each participant was asked to fill out a questionnaire themselves with general provisions.

This research was approved by the Health Research Ethics Committee of the Jenderal Achmad Yani College of Health Sciences with number SKep/516/KEP /XI/2023. This research involved people aged over 14 years with a history of SLE.

2.2 Instrument

The RAND SF-36 translated into Indonesian consists of 36 questions categorized into 8 health concepts (Table 2) and one item that provides an indication of changes in health perceptions. The assessment method refers to the RAND 36-Item Health Survey 1.0 instrument.

The first step is that the numerical values that have been coded previously are coded again according to the assessment key given in Table 1.

Table 1. Recoding Items

Item Number	Change original response category to recoded value of			
	Response category	value	response category	value
1, 2, 20, 22, 34, 36	1	100	4	25
	2	75	5	0
	3	50		
3, 4, 5, 6, 7, 8, 9, 19, 11,12	1	0	3	100
	2	50		
13, 14, 15, 16, 17, 18, 19	1	0	2	100
21, 23, 26, 27, 30	1	100	4	40
	2	80	5	20
	3	60	6	0
24, 25, 28, 29, 31	1	0	4	60
	2	20	5	80
	3	40	6	100
32, 33, 35	1	0	4	75
	2	25	5	100
	3	50		

Each item is given a score from 0 as the lowest value to 100 as the highest value. The score represents a percentage of the total possible scores achieved. A high score determines a better health condition. Next, items in the same scale are averaged to produce 8 scale scores that list the items averaged to create each scale (Table 2).

Table 2. Averaging Items to Form Scales

Scale	Number of Items	After recording per table 1, average the following items
1.	Physical functioning	10
2.	Role limitations due to physical health	4
3.	Role limitation due to emotional problems	3
4.	Energy/fatigue	4
5.	Emotional well-being	5
6.	Social functioning	2
7.	Pain	2
8.	General health	5

2.3 Data Analysis

All data was documented in research form. Data were validated and processed using SPSS version 29 and SmartPLS 4 (Fig. 1). Data were analysed using the Pearson-product moment correlation method and construct validity-discriminant validity to validate the results. Reliability was determined based on Cronbach's alpha internal consistency measurements and intraclass correlation coefficient (ICC). The Pearson correlation coefficient is considered to be strong if its value is greater than 0.5 [8], while the Cronbach alpha value is deemed to be good if its value is greater than 0.7 [9].

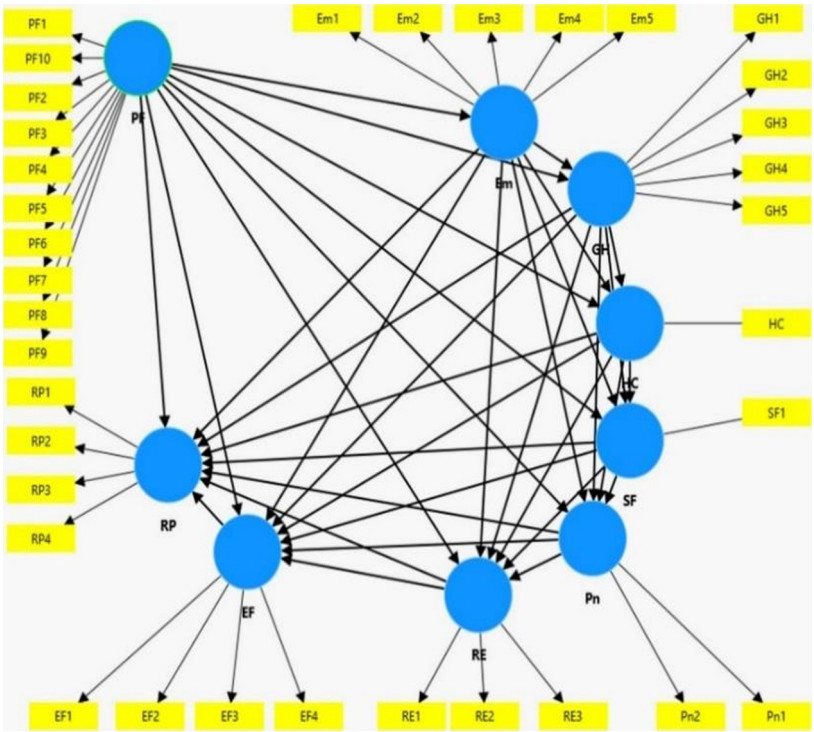

Fig. 1. Conceptual model of smart PLS structure [10]

3 Results and Discussion

Sociodemographic characteristics of 19 SLE patients who were evaluated at the Sahabat Cempluk Lupus Community which was carried out from December 2023 to January 2024. (see Table 3).

Table 3. The sociodemographic characteristics of participants with SLE at The Sahabat Cempluk Lupus Community

		Frequency N =24	Percent (%)			Frequency N =24	Percent (%)
Age (y.o)	15-24	14	70.8	**Marital status**	Yes	3	15.8
	25-44	5	29.2		No	16	79.2
	Mean ± SD	22.37 ± 5.10					
Gender	Female	19	95.8	**With Comorbid**	Yes	6	68.4
	Male	0	4.2		No	13	31.6
Education	Kindergarten-Elementary	1	4.2	**Duration of SLE**	< 1 year	3	12.5
	Junior High School-Associate	16	66.7		1 year until < 2 year	4	16.7
	Bachelor-PhD	7	29.2		2 year – until < 3 year	2	8.3
					>= 3 years	15	62.5

In this study, all subjects were women with an average age of 22.37 ± 5.10 years, the majority had secondary education (66.7%), were unmarried (79.2%), had no comorbidities (31.6%) and duration of SLE more than 3 years (62.5%).

Table 4. Medicine use by Patient at The Sahabat Cempluk Lupus Community

	Yes		No	
	Frequencies	**Percent (%)**	**Frequencies**	**Percent (%)**
Methylprednisolon and other steroid	19	100	0	0
Mycophenolate Mofetil	13	68.4	6	31.6
Hydroxykloroquin	4	21.1	15	78.9
Cyclosporine	2	10.5	17	89.5
Azathioprine	1	5.3	18	94.7

The profile of treatment received by participants was that all participants used corticosteroid drugs, including methylprednisolone, followed by Mycophenolate Mofetil (68.4%), Hydroxychloroquine (21.1%), Cyclosporin (10.5%) and Azathioprine (5.3%) (Table 4). Corticosteroids represent the foundation of SLE treatment due to their rapid and potent anti-inflammatory and immunosuppressive properties. In the United States, approximately 70% of SLE patients will receive corticosteroids [11,12]. The goal of lupus treatment is to maintain the lowest level of activity by using immunomodulators, appropriate immunosuppression and avoiding known triggers, preventing organ damage due to active lupus, reducing comorbidities due to lupus and its treatment and overcoming fatigue and pain that often occur not associated with active lupus [13].

Subjectivity, multidimensionality, and well-being are essential to QOL assessments. QOL is a latent characteristic that cannot be easily measured. To accomplish this, it must be converted into indications for its component dimensions and domains. Validating the indicators ensures their validity, relevance, representativeness, and appropriateness. QOL assessment delivers indicators as items that may be rated using response scales. The findings are presented as profile domain scores or a composite indicator of QOL [14]. In order to be considered credible, research findings must be based on reliable and rigorous assessment methods. Consequently, it is of the utmost importance that any assessment instrument employed to quantify study outcomes be subjected to rigorous testing for reliability and validity prior to publication or citation [9,15].

3.1 Validity

The content validity of the RAND SF-36 as a generic tool has been previously established. However, it is acknowledged that the tool may lack the capacity to assess content areas that are relevant to certain populations [6]. The translation of the SF-36 has not undergone significant changes because the Indonesian people are already familiar with the terms and activities mentioned in the questionnaire. An evaluation of the validity of the Indonesian version of the SF-36 indicates that this questionnaire is valid for use as a tool for assessing the QOL of SLE patients. To assess the validity of the criteria, we employed the Pearson test, and the results obtained for all scales were at significance levels below 0.05. (Table 5).

Table 5. Pearson Test Result

	PF	RP	RE	EF	Em	SF	Pn	GH
Sig (2 tailed) Total	0.004	0.000	0.045	0.010	0.000	0.006	0.005	0.042

With regard to construct validity, the results of this questionnaire demonstrate good discriminant validity. Discriminant validity refers to the extent to which constructs are truly different from each other empirically. It also measures the degree of differences between overlapping constructs. Discriminant validity can be assessed using cross-loading indicators, Fornell & Larcker criteria and Heterotrait-monotrait (HTMT) correlation ratios. HTMT was able to achieve higher levels of specificity and sensitivity (97% to 99%) compared with cross-loading (0.00%) and Fornell-Lacker (20.82%) criteria. HTMT values close to 1 indicate a lack of discriminant validity. Using HTMT as a criterion involves comparing it to a predetermined threshold. If the HTMT value is higher than this threshold, it can be concluded that discriminant validity is lacking [16].

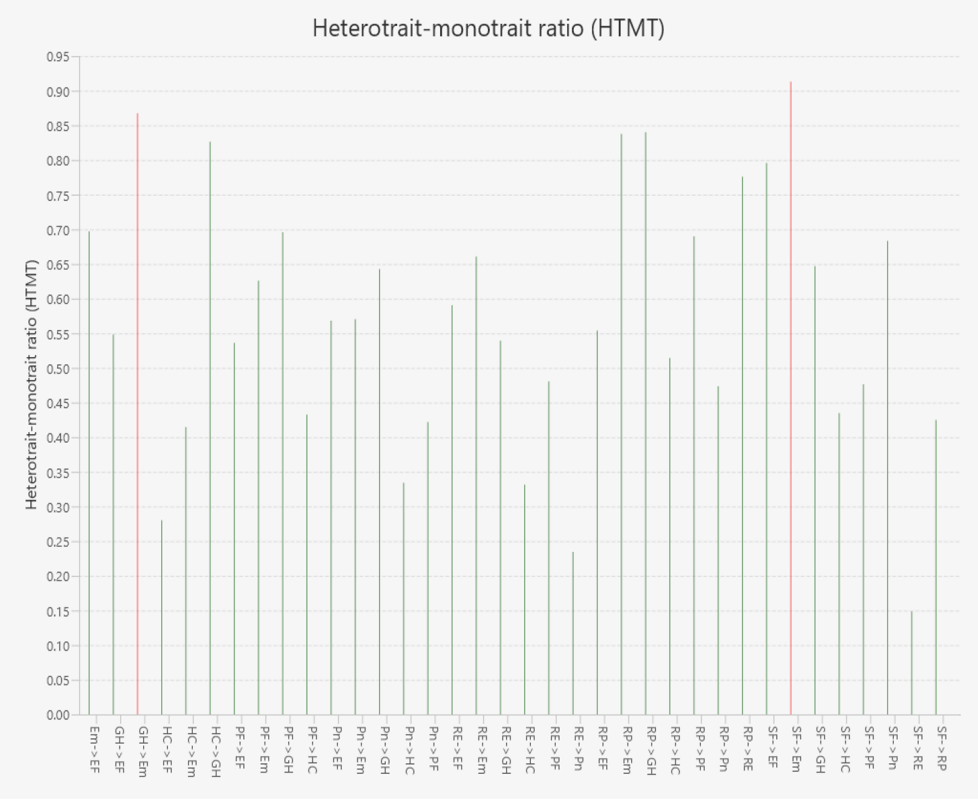

Fig. 2. Discriminant validity – HTMT bar (10)

Henseler et al. (2015) proposed a 0.90 threshold value for structural models that share highly comparable conceptual components. In such cases, HTMT scores above 0.90 indicate the absence of discriminant validity. However, when the conceptions are conceptually dissimilar, a lower, more conservative threshold value is recommended, such as 0.85 [7,17].

From the HTMT results, the value (in red) in Fig. 2 shows a discriminant validity problem according to the HTMT 0.90 criterion. This means that the HTMT criteria detect collinearity problems between latent constructs (multicollinearity). The Emotional Well-Being (Em)-

Social Functioning (SF) construct is problematic. Perhaps most of the construct items measure the same thing. In other words, it contains respondents' perception items that overlap in the affected construct.

3.2 Reliability

The most commonly employed measure of internal consistency is Cronbach's alpha, which gauges reliability based on the interrelationship of observed item variables. Higher values indicate a higher level of reliability, while lower values indicate a lower level of reliability. In exploratory research, a composite reliability/Cronbach alpha value between 0.60 and 0.70 is deemed acceptable, while in more advanced stages the value must be higher than 0.70 [16] Nevertheless, values above 0.90 are considered to be suboptimal, with values above 0.95 being highly undesirable.

In this study, the overall Cronbach alpha value obtained was 0.720, exceeding the 0.70 threshold. Additionally, for each scale, only two items were deemed appropriate: the role limitations due to RE scale and the General health scale (Table 6). Furthermore, Cronbach alpha values of less than 0.7 are classified as slightly low for Energy/fatigue, Social functioning, and Pain, as well as at a reasonable classification for Role limitations due to physical health and Emotional well-being [9].

Table 6. Cronbach alpha Result

Scale	Number of item	Cronbach's Alpha	
		Value	Value Total
PF	10	0.680	0.723
RP	4	0.646	
RE	3	0.778	
EF	4	0.687	
Em	5	0.669	
SF	2	0.685	
Pn	2	0.690	
GH	5	0.724	

Physical functioning (PF); Role limitations due to physical health (RP); Role limitations due to emotional problems (RE); Energy/fatigue (EF); Emotional well-being (Em); Social functioning (SF); Pain (Pn); General health (GH)

Similar findings regarding the Social Function scale were also reported by other studies, with Cronbach alpha values <0.07. These studies included the use of the scale in cases of brain tumours (0.527) [18] and in post-coronary artery bypass grafting (0.63) [19]. This may be attributed to cultural differences, where mental health and social relationships are of significant importance in relation to vitality. [18] This may be attributed to the SF-36's capacity to adapt to this population and its ability to detect clinically significant changes over time. A further limitation of this study is that it recruited a relatively small sample of conservatively managed individuals, representing a small proportion of SLE patients. Furthermore, the selection of a specific measure over another is contingent upon the objective of HRQoL assessment, the specific HRQoL domain, and the SLE disease state pertinent to the research question [20].

A further limitation of this study is that it recruited a relatively small sample of conservatively managed individuals, representing a small proportion of SLE patients. Some

of our findings are comparable to those previously published with the SF-36, which provides further evidence of its generalisability [21].

In conclusion, the suitability of the SF-36 as a tool to assess HRQoL in SLE patients may be limited by the low response to change in this population. Validity analysis showed that the SF-36 questionnaire could be used in SLE patients, while reliability analysis showed that only the RE and GH scales met all the criteria for assessing changes in HRQoL. The limited number of subjects in this study can affect the validity and reliability of the analysis. It is hoped that similar research can be carried out in the future with a larger number of subjects

4 Conclusion

The results of this study indicate that the Indonesian version of the RAND-SF 36 is a valid and reliable instrument for assessing the QOL of patients with SLE. Nevertheless, the scales are not without limitations in terms of reliability. Further research or adjustments to the questions in the Indonesian version are necessary to enhance the reliability of the assessment.

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