

Translation and Validation of Indonesian Version of Scleroderma Health Assessment Questionnaire

Irma Ruslina Defi,¹ Jennie,² Vitriana,¹ Farida Arisanti¹

¹Department of Physical Medicine and Rehabilitation Faculty of Medicine Universitas Padjadjaran/
Dr. Hasan Sadikin General Hospital Bandung, Indonesia, ²Faculty of Medicine
Maranatha Christian University, Bandung, Indonesia

Abstract

Systemic sclerosis (SSc) or scleroderma is a chronic autoimmune disease characterized by vasculopathy, fibrosis, and autoimmunity. Scleroderma health assessment questionnaire (SHAQ) is a measurement of SSc that is more specific than health assessment questionnaire (HAQ) disability index (DI) to measure disability and function. The aim of this study was to translate SHAQ into Indonesian language and assess its validity and reliability. The SHAQ was translated into Indonesian language and then back translated to ensure the meaning. The Indonesian version was then applied to the SSc outpatients. The validity of HAQ-DI and VAS scores was assessed using Pearson Product Moment Correlation and Cronbach's alpha for the reliability test of SSc HAQ score. To determine the convergent validity, comparisons were made between HAQ-DI, scleroderma visual analog scale (VAS), and short form 36 (SF 36). Eighteen females, ranging between 42 to 66 years old, were included in this study from December 2019 to February 2020. The results of the validity test in all variables of HAQ-DI and SSc-VAS were valid (r -count >0.361). Cronbach's alpha for these variables were higher than the standardized items (r >0.700), reflecting very good reliability and acceptable. There was a statistically significant correlation between SSc HAQ score and HAQ-DI with most of SF-36 physical domains, except for general health. The Indonesian version of SHAQ demonstrates a good construct and discriminant validity as well as the reproducibility. Thus, it can be used for measuring disability in systemic sclerosis patients.

Key words: SHAQ, short form 36, systemic sclerosis, VAS

Translasi dan Validasi *Scleroderma Health Assessment Questionnaire* versi Bahasa Indonesia

Abstrak

Sklerosis sistemik atau skleroderma merupakan penyakit autoimun kronik dengan vaskulopati, fibrosis dan autoimunitas. *Scleroderma health assessment questionnaire* (SHAQ) menilai disabilitas dan fungsi pada pasien sklerosis sistemik lebih spesifik dibanding dengan *health assessment questionnaire* (HAQ) *disability index* (DI). Tujuan dari penelitian ini adalah menerjemahkan SHAQ ke dalam bahasa Indonesia dan menilai validitas serta reliabilitasnya. *Scleroderma health assessment questionnaire* diterjemahkan ke bahasa Indonesia dan kemudian dilakukan translasi balik, lalu kuesioner diisi oleh pasien sklerosis sistemik rawat jalan. Tes validitas HAQ-DI dan *visual analog scale* (VAS) dinilai dengan korelasi Pearson dan reliabilitas menggunakan Cronbach's alpha. Perbandingan antara HAQ-DI, *scleroderma-VAS* dan *short form 36* (SF 36) dilakukan untuk menilai validitas konvergen. Subjek terdiri dari 18 orang wanita yang berusia antara 42 sampai 66 tahun dari Desember 2019 sampai Februari 2020. Hasil validitas pada semua parameter HAQ-DI dan SSc-VAS ditemukan valid (r hitung >0,361). Terdapat reliabilitas yang baik dilihat dari nilai *Cronbach's alpha* yang lebih tinggi dari nilai r tabel (r >0,700). Terdapat korelasi yang signifikan antara *skleroderma-HAQ* dan HAQ-DI dengan domain SF-36 kecuali domain kesehatan umum. Simpulan, bahwa SHAQ versi Indonesia memiliki konsep dan validitas diskriminan serta reproduktifitas yang baik sehingga dapat digunakan untuk menilai disabilitas pada pasien sklerosis sistemik.

Kata kunci: SHAQ, *short form 36*, sklerosis sistemik, VAS

Corresponding Author: Irma Ruslina Defi, Department of Physical Medicine and Rehabilitation, Faculty of Medicine, Universitas Padjadjaran/Dr. Hasan Sadikin General Hospital Bandung, Jalan Pasteur No. 38 Bandung, West Java, Indonesia, Email: irma.ruslina@unpad.ac.id

Introduction

Systemic sclerosis (SSc) is a chronic autoimmune disease that involves the connective tissues and multiorgan system. The SSc has three main characteristics, namely vasculopathy, fibrosis, and autoimmunity.¹In a cross-sectional study, SSc is observed to have a significantly lower health-related quality of life (HRQoL) compared to the general population.²

Incidence of SSc ranges from 4 to 43 individuals per million population annually, with a prevalence rate ranging from 70 to 340 cases per million population,³ and affects female populations more than male with a proportion of 4:1. Symptoms of Raynaud's phenomenon, skin thickening, and internal organ dysfunction are observed in these individuals with females experience Raynaud's phenomenon more frequently than males with a ratio of about 9:1.^{4,5} According to data obtained from dr. Hasan Sadikin General Hospital Bandung in 2017, SSc is the third most common disease in the Rheumatology Department with an increasing incidence from 189 patients per year in 2013 to 196 patients per year in 2014.⁶

The health assessment questionnaire (HAQ) disability index (DI) is an assessment tool that was initially used to measure disability and function in rheumatoid arthritis. This index has been validated and used in several SSc studies.⁷ The HAQ DI was considered to be not adequately specific for SSc measurement that Steen and Medsger⁸ then published the scleroderma health assessment questionnaire (SHAQ) in 1997. The SHAQ itself consists of HAQ-DI (eight domains) with the addition of five analog visual scales (VAS) to assess digital ulcers, Raynaud's phenomenon, gastrointestinal and lung symptoms, and overall diseases.

Systemic sclerosis treatment should include improving quality of life, hence it is necessary to assess disability and function using a reliable and valid measurement. SHAQ is a good measurement to do this. However, no Indonesian version of SHAQ has been adapted and validated to evaluate the SSc patients in Indonesia. The need for the Indonesian version is imminent because the SHAQ questionnaire can help to evaluate the improvement of the therapy and rehabilitation program provided to Indonesian SSc patients. This study aimed to make a standardized Indonesian version of SHAQ available by adapting it into Indonesian and test it for its validity, reliability, and its correlation with SF-36.

Methods

Eighteen female patients between the age of 19 and 66 years were included in this study during the period of December 2019 to February 2020. This study was approved by the Ethics Committee for Health Research of dr. Hasan Sadikin General Hospital Bandung, Indonesia, through the issuance of an ethical clearance number LB.02.01/X.6.5/142/2019. Informed consent was obtained from all subjects after a full explanation of the purpose and procedures used for the study was provided with a guarantee on anonymity and data confidentiality. All samples were taken according to the Declaration of Helsinki.⁹ Patients were recruited from the rheumatology outpatient clinic of dr. Hasan Sadikin General Hospital, Bandung, Indonesia. Patients were included in the study if they fulfilled the preliminary classification criteria of SSc based on the American College of Rheumatology and European League Against Rheumatism (ACR/EULAR) in 2013¹⁰ and were native Indonesian with good command and abstract thought to understand the concept of VAS. Patients with significant cognitive impairment were excluded. The objective of the study was explained to each of the patients before they fill out the questionnaires. After the participants gave consent, they were asked to fill in the self-administered questionnaires that included the Indonesian versions of SHAQ and the SF-36. Authorization was obtained from the authors of SHAQ for its use in the present study. The HAQ-DI, SHAQ VAS, and SF-36 were used in this study due to their ability in assessing the relationship between different SSc patients' quality of life. HAQ-DI consists of 20 items which are divided into eight domains of dressing and grooming, arising, eating, walking, hygiene, reach, grip, and activities. The response to each item ranges from "without any difficulty (0)" to "with some difficulty (1)", "with much difficulty (2)", and "unable to do (3)". For example, if the patient needs any device or help to do activities in any of the domains, he or she will automatically receive score 2. The highest scores in each domain are added and then divided by 8 to determine the HAQ-DI. The final score will range between 0 and 3, with higher scores showing more disability.⁶

The SHAQ consists of HAQ-DI with five additional VAS questions: "in the past week, how much have your Raynaud's phenomenon, digital ulcers, gastrointestinal and lung symptoms, and overall diseases interfered with your activity?" The answer is marked on a 15 cm long VAS line

starting from “does not interfere” to “very severe limitations”. The VAS score is multiplied by 0.2 to obtain the final score. The score ranges from 0 to 3, representing the minimum limitation to the maximum limitation⁸. George et al.¹¹ has constructed a global score that is referred to as the “SSc HAQ score”, with a score ranging from 0 to 3, which is a new measurement for pooling the five organ VAS into calculation. This new variable is calculated as follows: SSc HAQ score= (8 HAQ-DI domains scores + 5 VAS scores) divided by 13.

Short Form 36 (SF-36) is a questionnaire consisting of 36 items that evaluate the quality of life in eight domains: physical functions, physical role, bodily pain, general health, vitality, social functions, emotional role, and mental health. Each domain is assessed by its specific score, which ranges from 0 to 100, with a higher score shows a better health status.¹² Laras, Perwitasari, and Khoirunisa¹³ have already translated and validated the Indonesian version of SF-36 in autoimmune patients.

The initial English version of SHAQ was first translated into Indonesian by two translators, informed and uninformed about the objective of the questionnaire (T1, T2). Both of the translators and a physician who participated in the study compared and discussed the translation results until an agreed translation version was achieved (T12). Back translation was carried out by two different uninformed certified translators with non-clinical background into English, as the original language used for this questionnaire (BT1, BT2). The translations were then reviewed by the experts to reach a consensus on the final Indonesian version of SHAQ. Subsequently, all translated versions were compared and evaluated, and a final version was made.

The cognitive debriefing was performed on five patients with SSc using the final Indonesian version. There was a difficulty in understanding the term “Raynaud’s phenomenon” in four out of five patients. We added a description using brackets after the “Raynaud’s phenomenon” to explain the meaning of this item, which is “fingers that alternate in color between purple, paleness, and red, due to the cold”, according to the Brazilian Portuguese version of SHAQ.¹⁵ Cognitive debriefing was carried out one more time on a new group of five patients with SSc and all patients were able to understand the questions. No major modification was needed for other items.

The normality of the variables were analyzed using the Shapiro-Wilk test and were reported in mean±standard deviation (SD). Validity testing

of HAQ-DI and VAS was performed by using data obtained from the results of the questionnaire. Pearson Product Moment Correlation was used for this purpose, with the questionnaire considered valid if the Pearson Product Moment correlation coefficient value was greater than the correlation coefficient value table.¹⁴ Reliability testing of SSc HAQ score was carried out using the Cronbach Alpha and the reliability was established if the coefficient value or r was ≥0.7. Convergent validity was carried out to assess the correlations between HAQ-DI, VAS, SSc HAQ, and SF-36 health scores in terms of quality of life. Moderate to high associations were expected between HAQ-DI and SSc HAQ score with the

Table 1 SSc Patient Demographic Characteristics

Variable	n=18 (mean±SD)
Age (years)	42.72±12.809
Occupation	
No occupation (housewives)	10 (55.6%)
With occupation	8 (44.4%)
Education level	
Elementary school	0 (0%)
Junior high school	5 (27.8%)
Senior high school	6 (33.3%)
Diploma	7 (38.9%)
SHAQ	
HAQ DI	0.66±0.654
VAS pain	1.09±0.708
VAS intestinal	0.68±0.647
VAS breathing	0.71±0.549
VAS raynaud’s phenomenon	1.12±0.690
VAS finger ulcer	1.16±0.889
VAS overall disease severity	1.33±0.852
SF-36	
Physical functioning	68.19±24.581
Role limitation-physical	51.38±40.649
Body pain	66.25±18.928
General health	62.72±18.991
Vitality	65.83±16.382
Social function	76.80±17.880
Role limitation-emotional	44.44±48.508
Mental health	73.72±21.795

SHAQ= scleroderma health assessment questionnaire; HAQ= health assessment questionnaire; VAS= visual analogue scales; SF-36= short form 36

Table 2 Validity Testing of HAQ Variables Using Pearson’s Correlation Coefficient

Variable	Question Item	Total Item Correlation (r-count) Perception Rate	Significant Level	Conclusion
Dressing & Grooming	1	0,731	0,361	Valid
	2	0,765	0,361	Valid
Arising	1	0,746	0,361	Valid
	2	0,784	0,361	Valid
Eating	1	0,817	0,361	Valid
	2	0,794	0,361	Valid
	3	0,634	0,361	Valid
Walking	1	0,699	0,361	Valid
	2	0,714	0,361	Valid
Hygiene	1	0,624	0,361	Valid
	2	0,739	0,361	Valid
	3	0,604	0,361	Valid
Reach	1	0,739	0,361	Valid
	2	0,906	0,361	Valid
Grip	1	0,771	0,361	Valid
	2	0,741	0,361	Valid
	3	0,813	0,361	Valid
Activities	1	0,819	0,361	Valid
	2	0,813	0,361	Valid
	3	0,680	0,361	Valid

SF-36 physical items. For validity and reliability testing, the SPSS 13 software was used.

Results

Eighteen SSc patients completed the final SHAQ-DI and SF-36 questionnaires. The demographic characteristics and distribution of the sample are presented in Table 1. All subjects were female aged between 42 to 66 years old with the

mean age (\pm SD) of 42.72 \pm 12.809. Most of them were housewives (55.6%) and had a diploma education (38.9%). At baseline, the mean (\pm SD) HAQ-DI score was 0.66 \pm 0.65, indicating the presence of mild to moderate disability among the SSc patients in this study.

To test the item validity, the Pearson Product Moment was used. The variable value correlation and the obtained total value were compared with the reference to the significant level table. The results of the validity testing in all variables

Table 3 Validity Testing of VAS Variables Using Pearson’s Correlation Coefficient

Variable	Total Item Correlation (r-count) Perception Rate	Significant Level	Conclusion
VAS pain	0.734	0,361	Valid
VAS intestinal	0.540	0,361	Valid
VAS Breathing	0.585	0,361	Valid
VAS Raynaud’s	0.877	0,361	Valid
VAS finger ulcer	0.872	0,361	Valid
VAS overall disease severity	0.915	0,361	Valid

VAS=visual analogue scales

Table 4 Reliability Testing of SSc HAQ Score

Variable	Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	n of Items	Conclusion
SSc HAQ score	0.954	0.700	20	Reliable

SSc HAQ score= (8 HAQ domains + 5 SSc VAS)/13 (Georges, 2005); HAQ= health assessment questionnaire; VAS= visual analogue scale

of HAQ-DI showed that all variables were valid (r-count >0.361) (Table 2). The same was also true for all variables of VAS (Table 3).

The reliability of SHAQ based on the use of the SSc HAQ score was presented in Table 4. The value of Cronbach's alpha was higher than the standardized items (Cronbach's alpha >0.700), meaning that the Indonesian version of the SHAQ questionnaire for SSc patients in this study was highly reliable and acceptable.

Convergent validity was assessed to see the correlation between HAQ DI, SSc HAQ score, SSc-VAS domains, and SF-36 domains (Table 5). The HAQ-DI, SSc HAQ score, and SSc-VAS presented a correlation with the SF-36 component scores. There was a moderate negative correlation

between the SF-36 physical functioning and HAQ-DI scores (r=-0.557) and SSc HAQ score (r=-0.557) with a moderate negative correlation between role limitation-physical and HAQ-DI (r=-0.664), SSc HAQ score (r=-0.512) and VAS intestinal (r=-0.589). Moderate negative correlation were seen between the body pain and HAQ-DI (r=-0.694), SSc HAQ score (r=-0.539), VAS pain (r=-0.478) and VAS Raynaud's (r=-0.545) while a moderate negative correlation was observed between vitality and HAQ-DI (r=-0.606), SSc HAQ score (r=-0.602) and overall disease severity VAS (r=-0.484). A moderate negative correlation was identified between role limitation-emotional with HAQ-DI (r=-0.677) and SSc HAQ score (r=-0.551) and a moderate

Table 5 Convergent validity. Pearson and Spearman's Correlation Coefficients Matrix Between HAQ-DI, SSc HAQ Score, VAS and SF-36 Dimensions

Variable	HAQ-DI	SSc HAQ Score	Pain VAS	Intestinal VAS	Breathing VAS	Raynaud's phenomenon VAS	Finger Ulcer VAS	Overall Disease Severity VAS
Physical functioning (PF)	-0.557**s	-0.538*	-0.185 ^s	0.361 ^s	-0.145 ^s	-0.231 ^s	-0.351 ^s	-0.387 ^s
Role limitation-physical (RP)	-0.664**s	-0.512*	-0.248 ^s	-0.589**s	0.018 ^s	-0.134 ^s	0.027 ^s	-0.195 ^s
Body pain (BP)	-0.694**s	-0.639*	-0.478**s	-0.083 ^s	0.101 ^s	-0.545**s	-0.237 ^s	-0.425 ^s
General health (GH)	-0.357 ^s	-0.272	0.005 ^s	-0.205 ^s	-0.114 ^p	-0.196 ^p	-0.115 ^p	-0.115 ^p
Vitality (VT)	-0.606**s	-0.602**	-0.280 ^s	-0.139 ^s	-0.175 ^p	-0.483 ^p	-0.391 ^p	-0.484**p
Social function (SF)	-0.374 ^s	-0.249	-0.045 ^s	-0.590 ^s	-0.045 ^s	-0.275 ^s	-0.121 ^s	-0.070 ^s
Role limitation-emotional (RE)	-0.677**s	-0.551*	-0.092 ^s	-0.419 ^s	-0.283 ^s	-0.334 ^s	-0.161 ^s	-0.236 ^s
Mental health (MH)	-0.168 ^s	-0.229	-0.006 ^s	-0.036 ^s	-0.274 ^p	-0.173 ^p	-0.493**p	-0.247 ^p

Note: *p<0.05; ** p<0.01; r= correlation coefisien; p= pearson; s= spearman ; SHAQ=scleroderma health assessment questionnaire; HAQ-DI= health assessment questionnaire disability index; VAS= visual analogue scales; SF-36= short form 36. SSc HAQ Score= (8 HAQ domains + 5 SSc VAS)/13 (Georges, 2005)

negative correlation was seen between mental health and VAS finger ulcers ($r=-0.493$). All correlations were statistically significant at 0.01 and 0.05 levels.

Discussion

The present study confirms the value of the SHAQ and demonstrates the psychometric properties in Indonesian SSc patients. The psychometric properties were indicated by the validity and reliability score as shown in Table 2, Table 3, and Table 4. These also show that Indonesian version of SHAQ has a good construct and discriminant validity. This study has a similar problem with regards to a cross-cultural adaptation as in the Brazilian Portuguese version of SHAQ,¹⁵ which is the patients' ability to understand the term "Raynaud's phenomenon". The Brazilian Portuguese adds a description after the "Raynaud's phenomenon" to explain the meaning of this term, which is "fingers that alternate in color between purple, paleness and red, due to the cold". With the same constraints, this study also add the same description as the previous study to explain the "Raynaud's phenomenon" so subjects can understand this question. Just like the study conducted by Karadag et al.,¹⁶ these difficulties might be related to the demographics of the study population with the majority is unemployed women (housewives) with lower socio-cultural status.

All items in the Indonesian version of HAQ-DI and SSc-VAS presented a significant result when tested for item validity to assess the feasibility of the items. To determine whether an item is feasible or not, it should be tested for the significance of the correlation coefficient test at 0.05 significance level, meaning that an item is considered feasible if it has a significant correlation to the total score.¹⁴

The invalid results of the validation test will affect the reliability test. However, if the validity does not exceed half of the contents of the dimension, this will not affect the overall reliability of the questionnaire.¹⁴ Georges et al.¹¹ proposed the use of combined score obtained by pooling the eight domains of the HAQ-DI and the five VAS scale, which is referred to as the "SSc HAQ score" to assess the multisystemic characteristics of SSc more accurately. The reliability test in this study used this SSc HAQ score. The results of the reliability show that, in general, the items in the Indonesian version of SHAQ are

adequately reliable to be used on SSc patients. Quality of life was assessed using the SF-36 questionnaire and, as expected, there was a statistically significant correlation between this SSc HAQ score and HAQ-DI with most of SF-36 physical domains (FC, RP, DP), except for the general health (GH). In a cross-sectional study, it is identified that the main factors associated with the quality of life in SSc patients are functional disability and the anxiety.¹⁸

George et al.¹¹ stated that there is an influence on the mood of the patients as an ultimate part of the appreciation of their disability in any native language people. Based on a systematic review, the prevalence of depressive symptoms among SSc patients in a study is 65%, where patients have depression symptoms that might be associated with joint pain and other symptoms and their duration and severity.¹⁹ The pathogenesis of depression symptoms in autoimmune disease might result from the autonomic and immunological pathways and also changes in the cognitive, behavioral, and social status of the SSc patients.²⁰

The limited number of subjects in this study might affect the convergent validity results, with just a few of VAS domains correlate with the physical domain of SF-36. Furthermore, many of the factors will influence pain and eventually affect the score of VAS domain, where physical impairment is often associated with reductions in both physical and mental health of patients with systemic scleroderma.¹⁷ There is no correlation between the social function with all domains of SF-36, which may be related to the demographic data of occupation because the majority of subjects in this study are housewives (unemployed) so the scope of socialization is reduced in non-working people.

There are just several significant correlations found between the VAS domains and SF-36 domains in this present study. Orlandi et al.¹⁵ stated that changes in VAS scores can be affected by changes in weather and can sufficiently change the symptoms of the disease, thus affecting the statistical results of SHAQ.

The preliminary results from this study demonstrated the potential value of SHAQ Indonesian version questionnaire for systemic scleroderma patients. This questionnaire can be used in an outpatient setting due to its ease and efficiency that enable the clinicians to apply them as a part of routine care in the evaluation of SSc patients.¹⁶

The strength of this study is that the Indonesian version of SHAQ is the first study

that has been done in Indonesia and has been able to prove that this version is valid and reliable. The limitation of this study include the fact that the Indonesian version of SHAQ can only be applied to the general type of SSc, and has not included a detailed explanation of the subtype of SSc. Further study with the specific subtype of SSc is therefore needed. The Indonesian version of SHAQ demonstrated a good construct and discriminant validities, as well as good reproducibility. Thus, it can be used for measuring disability and function of systemic sclerosis patients in clinical practice or research.

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