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Psychometric analysis and validation of the Persian translation of the systemic sclerosis questionnaire (SySQ)

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Abstract:

BACKGROUND: Scleroderma is a complex multisystem disorder that could have effects on the quality of patients' lives. This study was conducted by determining the psychometric properties of the Persian version of the systemic sclerosis questionnaire (SySQ) that specifically assesses indications and functional limitations of scleroderma patients.

MATERIALS AND METHODS: In the present cross-sectional study, the method included: translation and back translation. Psychometric properties of the questionnaire including its content and face validity were assessed. Internal consistency with the SySQ (Cronbach's alpha) and reproducibility was by test–retest method. The factor structure of the questionnaire was evaluated using exploratory factor analysis. The convergent validity of the SySQ was assessed using the General Health Assessment Scale (HAQ).

RESULTS: Altogether 32 SySQ items, the internal consistency coefficient (Cronbach's alpha) of the whole tool was 0.906. The content validity index was 0.98 and the content validity ratio was 0.796, there was a significant relationship between the questions and the relevant factors in the factor analysis. The correlation coefficient = 0.953 for the instrument. The correlation of SySQ dimensions with HAQ questionnaire dimensions in convergent validity showed that musculoskeletal dimensions, general condition, and cardiorespiratory of the questionnaire are correlated with all dimensions of the HAQ questionnaire.

CONCLUSION: The Persian version of the questionnaire SySQ with competency is valid and reliable and is suitable for measuring specific changes in Persian systemic sclerosis patients.

Keywords:

Psychometrics, reliability, systemic sclerosis, validity

Introduction

The quality of life of scleroderma patients can be affected by the disease process. Scleroderma[1] is a complex multisystem disorder.[2] It is a chronic disease with an unknown cause and autoimmune origin, which is associated with excessive collagen secretion and connective tissue problems[3] and is characterized by fibroblast dysfunction. This disease affects the walls of blood vessels, as well as the skin of the internal organs of the body.[4,5]

It is crucial to note that scleroderma is a long-term disease[6] that progressively affects various organs of the body.[7] Consequently, it leads to severe disabilities in the physical and mental social functioning of patients, such as the inability to work and participate in family life, the disruption of personal hygiene, the fear of disease progression, and dissatisfaction with the body image because skin stiffness leads to changes in the appearance,[1] digital wounds, and oral and dental problems. In addition, the involvement of the gastrointestinal system, shortness of breath, general pain and

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fatigue, and the development of disability over time cause a high level of depression, anxiety, and mental health challenges and reduce the quality of life. With the progression of the disease, more negative effects of diffuse symptoms on functional limitations and quality of life are observed.[8,6]

Conducting this research is important because of face the various challenges that patients with scleroderma, in the physical, mental, emotional, social, economic, and spiritual dimensions of life, there is a fundamental need to specifically assess and gauge the potential and functional impact of the disease on the general and visceral symptoms in these patients. To do it, measuring and evaluating the patients' performance and well-being from their point of view can reveal their health status at different stages of the disease, and as a criterion for determining recovery, it provides critical information for the medical staff (1, 5, and 9). Therefore, it is imperative to use a tool that can show the growing need to treat and care for scleroderma patients at different dimensions, along with the treatment of symptoms.[9]

There are a few instruments for studying various problems and treatment efficacy in SSc.[10]

Some validated questionnaires have been used for systemic sclerosis patients such as health-related QoL (HRQoL),[7,11] the health assessment questionnaire disability index (HAQ-DI) for functional evaluation, the hospital anxiety and depression scale (HADS) for cognitive assessment, and the visual analog scale (VAS) for the assessment of other symptoms of disease[12] that suggested for use in rheumatoid problems. However, the VAS does not cover the whole effects and functional limitations of SSc patients.[13-15]

The disability index of the Health Assessment Questionnaire (HAQ) is a tool that predicts survival and is designed for rheumatoid arthritis but has little correlation severity of the disease.[5,16] Despite measuring the activity, side effects, and assessment of therapeutic response, in SS, few assess functionality. That is the main indicator of the speed of disease progression in every patient in this situation, Ruof *et al*.[6] designed a self-administered functionality questionnaire [SySQ], that assesses activities and the intensity and frequency of symptoms with the functional impact in systemic sclerosis. This questionnaire was designed in German originally and has been validated in other languages, but until now did not translate into Persian. Therefore, our objective is to validate the SySQ trans-culturally for Iranian patients with SS and assess its relationship with the HAQ scale.[17]

Following the necessary investigations, the author translated and psychoanalyzed the systemic sclerosis questionnaire (SySQ) because this tool offers a more comprehensive assessment of the characteristics and challenges of scleroderma disease at various dimensions compared to the other existing tools. To clinically use English questionnaires in another population, as they are used among English-speaking patients, their psychometric properties must be verified in order to be sure of their reliability; therefore, the author translated and psychometrically tested the SySQ in the hopes that it will be a beneficial tool in clinical practice, research, and nursing education.[1,18]

Materials and Methods

Study design and setting

This was a cross-sectional study that was part of a larger investigation. It was conducted from January 2022 to August 2022 at Hafez Hospital affiliated with Shiraz University of Medical Sciences and Rare Diseases Foundation of Iran.

Study participants and sampling

For the collection of samples, scleroderma patients were invited to voluntary participate and the inclusion criteria have diagnoses of scleroderma and have the physical, mental, and cognitive capacity to participate in the study.

Ethical consideration

The participants signed an informed consent form to participate in the study.

All procedures were carried out according to the Declaration of Helsinki. The collection and analysis of samples were conducted after obtaining approval and receiving the code of ethics from the Ethics Committee of Shiraz University of Medical Sciences (IR.SUMS.REC 1399.1211).

Data collection tool and technique

The self-performance and symptoms report, specific effects, and functional limitations questionnaire (SySQ) for patients with scleroderma were designed by Ruof *et al*. (1999). This questionnaire contains 32 questions, which are divided into four categories (general condition, gastrointestinal, musculoskeletal, and cardiopulmonary symptoms), and it is scored using a Likert scale (grades 1–4). Regarding the ability to perform an activity (0 indicates "no problem" and 3 indicates "disabled"), the intensity of symptoms (0 corresponds to "no problem" and 3 corresponds to "very severe"), and the frequency of symptoms (0 indicates "never" and 3 indicates "always").[5,16]

Translation process

Before the start of the study, permission to translate the questionnaire into the Persian language was obtained

from the designer of the questionnaire, based on the guide of Beaton *et al*. It was translated into the Persian language, and cultural compatibility was given.[19] and then the validity and reliability of the translated version were measured.

The translation from English to Persian was done independently by two translators fluent in English. The translation was done conceptually and attention was paid to the translation of the items with simplicity, clarity, and transparency to ensure that it is understandable to ordinary people. To combine and adapt the translations and to create a single version, the opinions of relevant researchers and experts were used and the first translated versions were compared with each other, and then, in the reverse translation stage, it was conceptually translated from Persian to English. The differences and contradictions of these versions were corrected and finally, by merging the initial translations, the final version of the Persian translation was obtained. At the same stage, proposed amendments by a board consisting of experts and researchers, translators, two medicine, and four members of the university's faculty with doctoral and master's degrees in nursing with experience, were applied. Then, the opinion of 20 participants was surveyed about their understanding of the items and the level of acceptance of the questionnaire, and in this way, the final version translated into Persian was approved by the experts and the target group.

Considering that the validity and reliability of the tool may be affected during the translation process, after the translation of the tool, all the following steps were carried out to confirm the validity (qualitative face validity, qualitative content validity, and structural validity of the exploratory analysis type) and reliability (internal consistency and temporal stability) of the tool.

Data analysis: the sample size was 109 voluntary patients. SPSS software version 21 was used for data analysis. $P \leq 0.05$ was considered significant in all the analyses.

Validity

Content validity

To determine the content validity using the qualitative method, the questionnaire was given to 14 expert faculty members with experience in the field of nursing patients, and after the qualitative review of the instrument, it was requested. According to grammar criteria, use of appropriate words, placement of phrases in the right place, and proper scoring, feedback provides the necessary quantitatively determine the content validity, the questionnaire was provided to the expert academic faculty members in the field of nursing the patients and to determine the content validity ratio (CVR), they commented on the necessity of the items in the questionnaire. Their answers were presented on a 3-point Likert scale ("it is necessary," "it is useful but not necessary," and "it is not necessary"). Then, the answers were quantified. According to Lawshe's table and the number of participants, items that have a CVR of less than 0.51 are eliminated.[18]

To determine the content validity index (CVI), the criterion of relevance was used for each of the items and the participants were asked to rate the relevance of the questionnaire items in a 4-point Likert scale (1. "Not relevant," 2. "Somewhat relevant," 3. "Relevant," 4. "Completely relevant"). The calculation of the CVI for each item ranked 3 or 4 was performed using the formula of the CVI. The minimum CVI value was considered to be 0.79 at the 5% level of significance.[20]

Face validity

To evaluate the face validity in a qualitative manner, the items of the questionnaire were examined in terms of difficulty, ambiguity, and proportionality. The researcher then interviewed 20 members of the university faculty and scleroderma patients with enough experience with the disease and received their corrective comments about the items. All items of the questionnaire became confirmed and maintained.

Construct validity

Factor analysis was used as a suitable method to categorize the questions. Despite the limitation of patients' participation in the research due to the rarity of the disease, weakness, and disability and the origin of auto-immunity in the conditions of Corona, sampling with an acceptable volume was done based on reliable sources. There is no consistent consensus on the optimal sample size. Some sources suggest that the sample size should not be less than 100 people[21] while others have suggested even three participants for each variable[22] in the initial questionnaire by Ruof *et al*. 2018. It was prepared with the participation of 62 patients with systemic sclerosis,[23] so in this study, 109 participating patients completed the questionnaire. Of course; first, Kaiser–Meyer–Olkin (KMO) was used to measure sampling adequacy. Also; Bartlett's test was used to determine the correlation between the variables and the significance of the matrix.[24]

Convergent validity

The convergent validity of the SySQ was evaluated using the Stanford HAQ.

The complete form of the HAQ was developed in 1978 by James F. Fries *et al*. at Stanford University and includes five subscales. One of these subscales is the disability index (HAQ-DI), which has been used many times as an

independent questionnaire. This scale, which measures a person's functional ability, has been referred to as HAQ in many articles.[25]

In total, the complete tool consists of 20 questions. The initial form of the disability scale had eight domains and each domain included two to three questions. This tool determines the patient's degree of disability on a scale of 0–3; a higher score denotes a higher level of disability. The use of DI-HAQ was initially proposed in the field of rheumatology and it has been widely utilized for rheumatic diseases; thus, it is regarded as more of a generic tool. The validity and reliability of its 20-question form were examined in patients with rheumatoid arthritis by Rast Manesh *et al*.,[26] and in some studies, this 20-question version was used.[27]

Reliability

To confirm the reliability of the questionnaire for scleroderma patients, the internal consistency and stability methods were used. Internal consistency emphasizes the similarity or uniformity of the components of a test,[28] and in this questionnaire, it was reported with Cronbach's alpha. To verify the internal consistency of the instrument, $\alpha \geq 0.7$ was considered acceptable. To check the time stability of the tool, the test–retest approach was employed. In total, 12 scleroderma patients were evaluated with the SySQ after two weeks.

Results

Participants' characteristics and frequency.

A total of 109 participants were included in this study.

Of these patients, 90.7% were female, 77.8% were married, and 31.5% were employed. 50.1% had an education level higher than a high school diploma, and 16.7% had a bachelor's degree or higher education. Their mean age was 47.68 ± 10.48 years.

The content validity of the translated instrument was evaluated by examining the relevance, clarity, and simplicity. CVR and CVI were reported to be 0.796 and 0.98, respectively.

Construct validity

To determine the ability of the questionnaire to analyze the exploratory factor in the musculoskeletal, cardiorespiratory, gastrointestinal, and general condition domains, the Kaiser–Meyer–Olkin (KMO) test indicated the adequacy of the number of samples for analysis. Bartlett's test also showed that the correlation matrix between the questionnaire items has no problem with analysis.

Factor analysis for the musculoskeletal domain is as follows: KMO = 0.829; Bartlett test, Chi-square = 490.424; *P* value <0.001.

Therefore, using the rotated component matrix: Varimax factor analysis, we obtained the following classifications for the musculoskeletal domain [Table 1].

Factor analysis for the gastrointestinal domain is as follows: KMO = 0.724; Bartlett test, Chi-square = 259.920; *P* value <0.001.

Therefore, we obtained the following classifications using the rotated component matrix: Varimax factor analysis for the gastrointestinal domain [Table 2].

Factor analysis for the general condition domain is as follows: KMO = 0.740; Bartlett test, Chi-square = 293.347; *P* value <0.001.

Therefore, using the factor analysis of the rotated component matrix: Varimax, we obtained the following classifications for the general condition domain [Table 3].

Table 1: Classification of the quality of life questionnaire items in scleroderma patients (musculoskeletal domain)

Classification	Subject and title	Component		
		1	2	3
Finger function and hand ability	5. The ability to turn off the faucet	0.580		
	1. The ability to cut meat with a knife	0.628		
	3. The ability to wear socks	0.692		
	2. The ability to take a bath and dry oneself	0.797		
	4. The ability to apply cream on the body	0.861		
	24. The feeling of weakness in the hands when holding things			0.777
	25. Dropping things			0.882
The ability and strength of the legs	8. The ability to walk	0.511		
	6. The ability to get up from a chair without a handle		0.771	
	7. The ability to lie down and get up from bed		0.840	
	9. The ability to climb stairs		0.764	

Table 2: Classification of the quality of life questionnaire items in scleroderma patients (gastrointestinal domain)

Classification	Subject and title	Component		
		1	2	3
The condition of the mouth	10. The ability to eat large pieces of food			0.824
	11. The ability to eat apples			0.874
The condition of the esophagus	28. Difficulty in swallowing	0.814		
	29. Pain when swallowing	0.891		
	30. The feeling of suffocation while eating	0.840		
The condition of the stomach	31. The feeling of heartburn		0.921	
	32. The feeling of nausea		0.864	

Table 3: Classification of items in the quality of life questionnaire in scleroderma patients (general condition)

Classification	Subject and title	Component	
		1	2
Stiffness and pain in the limbs	13. Feeling of stiffness in the hands	0.702	
	14. Feeling of stiffness in the arms	0.775	
	15. Feeling of stiffness in the legs	0.652	
	16. Feeling pain in the hands in the cold		0.854
	17. Feeling pain in the legs in the cold		0.873
	26. Feeling pain in the hands	0.691	
	12. Feeling pain in the fingers when touching or holding objects	0.517	
	27. Cold hands		0.558

Factor analysis for the cardiorespiratory domain is as follows: KMO = 0.846; Bartlett test, Chi-square = 284.016; *P* value <0.001.

Therefore, using factor analysis with the component analysis method, we obtained the following classification for the cardiorespiratory domain [Table 4].

Convergent validity

Evacuating the correlation of the SySQ domains with the HAQ questionnaire domains showed that the musculoskeletal, general condition, and cardiorespiratory domains from the SySQ questionnaire are correlated with all the domains of the HAQ.

However, the gastrointestinal domain from the SySQ questionnaire in scleroderma patients only has a correlation with the domains of walking (P = 0.04), grasping (P = 0.03), and other activities (P = 0.04), as well as the overall average of HAQ (P = 0.01), whereas it has no correlation with other domains, including dressing, getting up, eating, personal hygiene, and stretching ability from the health status questionnaire [Table 5].

Reliability

The correlation coefficient for test–retest with 14-day interval was the intraclass correlation coefficient (ICC), which was equal to 0.953, and the confidence interval was between 0.930 and 0.971. Given the high value of ICC, it can be concluded that the questionnaire has high reliability.

Moreover, for the musculoskeletal domain, ICC was 0.888, and the confidence interval was between 0.835 and 0.930.

For the gastrointestinal domain, ICC was 0.839, and the confidence interval was between 0.754 and 0.902.

For the general condition domain, ICC was 0.887, and the confidence interval was between 0.703 and 0.871.

Finally, for the cardiorespiratory domain, ICC was 0.877, and the confidence interval was between 0.813 and 0.924.

For all the questions, Cronbach's alpha was generally obtained as α = 0.906.

Discussion

Despite the various difficulties of scleroderma patients in all aspects of life, so far there has not been a Persian questionnaire that specifically assesses the condition and functional limitations and symptoms of scleroderma patients that affect the quality of life of these patients; therefore, this study was conducted with the aim of translating and psychometrically evaluating the SySQ.

Since it is crucial to consider a tool's validity and reliability in order to use it,[29] after translating this questionnaire into personal language, it was analyzed in terms of psychometrics and structure. According to Norbic, to evaluate a research tool, at least the following four standards should be examined: 1) At least one content validity, 2) one structure validity, and 3) two types of stability assessments such as internal consistency and test–retest.[30]

Therefore, in the present research, content validity, face validity, construct validity, and internal consistency, as well as the reliability of the questionnaire were evaluated.

To determine the validity of the form and content, the opinion of experts was used. To determine the content validity, the Lawshe table was employed.[28]

It was found that the Persian version of SySQ has high content validity with CVR = 0.796 and CVI = 0.98. According to experts, a CVI score higher than 0.79 is considered acceptable,[31] and all 32 questions of the questionnaire were in this standard range. Therefore, no question was removed.

In construct validity, the question of what construct this tool measures and whether is it sufficient to measure the existing constructs is addressed.[32,33]

In this study, to confirm the validity of the construct, the 32 items of the questionnaire on functional limitations and symptoms of scleroderma patients that affect the quality of life patients were investigated by the factor analysis method. Construct validity was verified in the musculoskeletal, gastrointestinal, general, and cardiorespiratory domains, and the factor load was reported to be 0.511–0.921 In addition, the KMO criterion and Bartlett's sphericity test confirmed the data and the suitability of the factor analysis model in all domains. Considering the cutoff point of 0.5 and above, all the questionnaire items were retained.

In this study, the convergence of the SySQ questionnaire for scleroderma patients with HAQ was evaluated, and the musculoskeletal, general, and cardiorespiratory domains of the SySQ questionnaire were correlated with all the domains of the HAQ. While in the Brazilian translation by Machado *et al*. (2014), despite the strong correlation between the gastrointestinal domain of SySQ and the respiratory domain of HAQ, no statistical correlation was observed between SySQ and HAQ domains.[5]

However, in the study by Cruz-Domínguez *et al*. (2019), Spearman's correlation coefficient between the HAQ and SySQ scales was moderate.[34]

Although it is known as one of the most significant criteria for measuring the quality of the instrument, the reliability of the instrument is necessary but insufficient.[35] Therefore, the researcher must be sure of the internal consistency of the instruments with several domains and scales.[36]

In this study, Cronbach's alpha coefficient was used to measure reliability. Values over 70% are acceptable and the closer they are to one, the reliability is higher.[37] Thus, the high Cronbach's alpha coefficients of the obtained reliability indicated the high consistency of the translated instrument.

Moreover, to evaluate the stability of the translated tool, the correlation coefficient for the test–retest was used. The overall ICC was obtained to be 0.953. In addition, the ICC was 0.888 for the musculoskeletal domain, 0.839 for the gastrointestinal domain, 0.887 for the general condition domain, and 0.877 for the cardiorespiratory domain. These results indicate the high reliability of the Persian version of the SySQ questionnaire.

Similar to this study, in the Brazilian translation of the questionnaire by Machado *et al*., the ICC for the musculoskeletal domain, the general condition domain, and the cardiorespiratory domain was very good and excellent, but for the digestive domain, it was averaged and the α value varied from acceptable to excellent.[5]

In addition, for the Spanish translation of this questionnaire, Cruz-Domínguez *et al*. (2019) obtained an excellent α for internal consistency and reported reproducibility with Cohen's kappa, 0.911 initially and

Table 4: Classification of the quality of life questionnaire items in scleroderma patients (cardiorespiratory domain)

Classification	Subject and title	Component 1
Oxygen intake disorders	18. Shortness of breath while walking on a smooth path	0.827
	19. Shortness of breath when climbing the stairs	0.760
	20. Shortness of breath when changing clothes	0.813
	21. Coughing	0.736
	22. Wheezing	0.658
	24. Difficulty in taking deep breaths	0.847

Table 5: Correlation between SySQ domains and HAQ domains

SySQ HAQ	Musculoskeletal symptoms	*P*	Gastrointestinal symptoms	*P*	General symptoms	*P*	Cardiopulmonary symptoms	*P*
Dressing up	0.627	<0.001	0.272	0.08	0.475	0.00	0.365	<0.001
Stand up	0.646	<0.001	0.099	0.52	0.389	0.04	0.440	0.01
Eating	0.723	<0.001	0.230	0.13	0.522	<0.001	0.537	<0.001
Walking	0.722	<0.001	0.312	0.04	0.497	<0.001	0.722	<0.001
Personal hygiene	0.593	<0.001	0.281	0.06	0.462	0.01	0.381	<0.001
Reaching objects	0.553	<0.001	0.236	0.13	0.472	<0.001	0.558	<0.001
Grasping objects	0.623	<0.001	0.322	0.03	0.519	<0.001	0.297	0.03
Other activities	0.727	<0.001	0.309	0.04	0.512	<0.001	0.619	<0.001
HAQ mean	0.875	<0.001	0.402	0.01	0.633	<0.001	0.715	<0.001

0.618 after two weeks.[34] The similarity of the results obtained in these studies can be due to the specificity of the questionnaire in terms of the symptoms and challenges of scleroderma patients.

In this study, the questionnaire has been evaluated, with wider and more comprehensive dimensions, (content validity, face validity, construct validity, convergent validity, and reliability) compared to other studies, and more importantly, the results have been from good to excellent, and this provides the strength and validity of the Persian questionnaire. But other translations have examined the questionnaire in a more limited way and in someone have adopted relatively lower results.

So, the Persian version of this questionnaire is eligible for evaluation and shows the condition, specific symptoms, and functional limitations of scleroderma patients. This questionnaire can be effective in reducing the complications of the disease, maintaining and improving the patient's recovery at any level of the disease. Therefore, the author hopes that the findings of this research will help to a better quality of life, development of management, care, and educational and targeted treatment programs in various fields including nursing of disease.

Limitations and recommendation

One of the limitations of this disease is that it is in the category of rare diseases with few facilities and support, and due to poor health, weakness, and weakness of the immune system in Corona conditions, it makes it difficult for patients to participate in research. In addition, it is challenging to obtain samples due to the limited number of treatment centers dedicated to these patients. In addition, this questionnaire does not specifically assess important factors such as Raynaud's phenomenon and kidney problems.

Conclusion

The aim of this study was to conduct a psychometric analysis of the Persian version of the SYSQ effective on quality of life questionnaire in scleroderma patients. The findings of the study showed that this questionnaire has good content validity, construct validity, and reliability and can be useful in the assessment of Persian-speaking patients. Using this tool, the challenges and the process of the disease and its treatment can be examined more accurately. The findings of this study can be helpful to researchers, nursing managers, and nurses. This study can be used as a basis for further studies to pave the way for the evaluation of these patients by considering other characteristics of the disease and adding wider domains of the patient's issues, including kidney problems and Raynaud's phenomenon, to the questionnaire.

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Conflicts of interest

There are no conflicts of interest.

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