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Validation of the Turkish Version of the Sarcoidosis Health Questionnaire: a cross-sectional study

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Abstract. *Objective and aim:* sarcoidosis, a multisystemic granulomatous disease, generally results in a lower quality of life (qol) because of its unexpected course and diverse clinical symptoms. The Sarcoidosis Health Questionnaire (SHQ) evaluates the QoL for people with sarcoidosis in terms of their health. This study set out to validate the SHQ in a group of Turkish sarcoidosis patients. *Methods:* The study included a total of 146 adult sarcoidosis patients (63 male and 83 female; mean age, 44±3.6 years; range, 27-63 years) between August 2020 and September 2021. The processes of the testing procedure for cultural adaptation and translation included preparation, forward translation, translation reconciliation, back-translation and back-translation review, harmonization, finalization, and proofreading. The participants filled out three questionnaires, including the SHQ, 36-Item Short Form (SF-36) Health Survey, and King's Sarcoidosis Questionnaire (KSQ), and underwent pulmonary function tests (PFTs). *Results:* Of the patients, 95% had lung involvement, with a mean number of 1.3 organs involved. Each SHQ component displayed a moderate to high internal consistency, ranging from 0.806 to 0.844. The whole scale's Cronbach's alpha value was 0.781. The SHQ total score significantly correlated with physical component summary ($p< 0.001$, $r=0.360$) and mental component summary ($p<0.001$, $r=0.352$) scores of SF-36, and the general health status ($p< 0.001$, $r=0.478$), medication component ($p<0.001$, $r=0.456$), and eye component scores of KSQ ($p<0.001$, $r=0.545$). The grouping of patients by organ involvement ($p=0.01$), oral steroid medication ($p<0.001$), and symptom type ($p=0.021$) revealed significant differences in the overall SHQ scores. *Conclusion:* The Turkish version of SHQ can be a valid and accurate measureto evaluate the health status of sarcoidosis patients in Turkey. When combined with normal physiological, radiological, and serological examinations, SHQ can assess the QoL of sarcoidosis patients and give useful new information.

Key words: sarcoidosis, quality of life, validity

Introduction

Sarcoidosis is a disorder of unknown etiology that affects multiple systems and has a wide spectrum of clinical symptoms typically relevant to the organs affected(1). Despite its low mortality rate, sarcoidosis often progresses to a chronic illness with accompanying morbidity. Younger individuals of working age are often affected by sarcoidosis; as a result, their quality of life (QoL) and health condition may be adversely affected along with the inability to manage a chronic illness and the uncertainty that comes with it.

Positron emission tomography (PET) or progressive computed tomography (CT) findings or worsening pulmonary function tests (PFT) findings are indicative of disease progression. Likewise, multiorgan involvement helps predict disease course (1) However, studies have shown no significant

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correlation between these measurements showing disease activity or progression and quality of life parameters such as fatigue, depression, and pain (2). Therefore, objective evaluation of conditions such as depression, social dysfunction, and fatigue, which are a concern for patients and affect their quality of life, cannot be done adequately in clinical practice. Moreover, some studies have found a weak correlation between patient global assessment and physician global assessment, showing that physicians and patients do not agree on the evaluation of symptoms (3,4). Therefore, it has been suggested that evaluating patients with sarcoidosis for QoL and health status could assist close this gap, facilitating treatment and communication while completing current clinical evaluations (4). One of the health-related surveys that are specific to sarcoidosis is the Sarcoidosis Health Questionnaire (SHQ), which was created by Cox et al.in the United States (US) (4). They stated that compared to the 36-item Short Form (SF-36) of the comprehensive Medical Outcomes Study and the respiratory-specific St. George's Respiratory Questionnaire (SGRQ), a disease-specific tool to evaluate the impact on respiratory quality of life, SHQ was more responsive to variations in some affected organ systems (5,6).

Although the reliability and validity of this questionnaire in evaluating health status in different ethnic groups have been demonstrated in the literature, this scale has not been validated in Turkish patients (7,8). This study set out to determine the reliability and validity of the Turkish version of SHQ in Turkish patients with sarcoidosis.

Patients and methods

The study included 146 Turkish patients who were found to have granuloma by biopsy and diagnosed with sarcoidosis based on clinical, radiological, and laboratory findings between August 2020 and September 2021. The purpose of the study was disclosed to the participants. They provided signed informed consent. The study was planned following the guidelines of the Helsinki Declaration. The local ethics committee approved the study (approval number: 09/08/2019-E.54842).

The exclusion criteria were as follows: inability to understand and respond to the questionnaires because of an intellectual disability or a language barrier, coexisting conditions that had a significant negative impact on their health (such as sarcoidosis-unrelated heart failure, malignancy, and collagen vascular disorders), or instability as determined by their treating physician. Completion of less than 85% of any of the relevant questionnaires resulted in the withdrawal of patients from the study.

According to international guidelines, the diagnosis of sarcoidosis was made in the presence of a consistent clinical picture and confirmation of the disease pathologically or by bronchoalveolar lavage (BAL) (9). Chest radiographs, pulmonary function tests (PFTs), blood tests, electrocardiogram (EKG or ECG), and echocardiogram (echo) were all performed on each patient (10,11). A Case-Control Epidemiologic Study of Sarcoidosis (ACCESS) Organ Involvement Index was used to determine the current level of organ involvement (12).

Assessment questionnaires

Patients were interviewed and asked to complete the three questionnaires on their own when they attended the planned outpatient visit. Each patient completed the questionnaires in the same order.

36-Item Short Form (SF-36) Health Survey: SF-36 is a credible and validated questionnaire to assess individuals in Europe with a range of illnesses, such as sarcoidosis and chronic obstructive pulmonary disease (13,14). It contains 36 items scored on a range of 0 to 100, which are averaged to create the eight domain scores. These subscale scores from eight domains are then aggregated into standardized T-scores with mean and standard deviation values of 50 and 10, respectively, to provide two summary scores: physical component summary (PCS) and mental component summary (MCS). Higher scores indicate a higher quality of life.

King's Sarcoidosis Questionnaire (KSQ): KSQ is a sarcoidosis-specific questionnaire with 6 components assessing QoL in the last 2 weeks, organ involvement (lung, skin and eye) and medications used by patients (15). It has been validated in Turkish.

Sarcoidosis Health Questionnaire (SHQ): SHQ is a 29-item sarcoidosis-specific questionnaire to assess QoL, consisting of three domains: daily functioning, physical functioning, and emotional functioning. Each item is scored on a 7-point scale. The total score and each domain score vary from 1 to 7. Higher scores denote higher QoL (4). For patients who had incomplete responses to the questions, adjusted total

and domain scores were determined by summing the scores and dividing by the number of responded questions instead of the total number of questions.

Translation and face validity: Permission was taken from the authors of the original scale. The guidelines for the process of cross-cultural adaptation of self-report measures were employed during the translation process (16). The English version of SHQ was translated into Turkish by two independent translators—one of the authors and a qualified translator both of whom were native Turkish speakers fluent in English. These translations were done separately, after which they were compared. The disparities between the two translations were addressed, and the final form of the translation was chosen. This final Turkish version was translated back into English by two different native English speakers who were not aware of the original version of the scale. Discrepancies were found and examined after comparing this version to the original scale. The back-translation and the original version of the scale were compared in order to demonstrate the variations between the original and the translated versions. The translators reached a consensus on satisfactory compliance with the original scale after evaluating the discrepancies between the translated versions. The Turkish version of SHQ was created during the translation and back-translation processes of the questionnaire. To determine whether the patients had any questions regarding the items' meaning, the final version of SHQ was applied to a pilot sample of patients. The questionnaire was implemented by the researcher on sarcoidosis patients. The patients were asked to clarify their comprehension after hearing each item read aloud, as well as the option they selected and their reasoning behind it. Additionally, where appropriate, it was verified that the patients had correctly comprehended the questions by asking them to elaborate on their responses or provide examples. It was seen that all questions were fully understood.

Statistical analysis

SPSS for Windows version 22.0 software was utilized for statistical analyses (IBM Corp., Armonk, NY, USA). In all statistical analyses, the limit value of type 1 error was set at 0.05. While categorical data were reported as numbers and percentages, continuous variables were presented as mean standard deviation (SD) or median and interquartile range (IQR). The assumption that the data would follow a normal distribution was examined using the Kolmogorov-Smirnov test. For statistical analysis, non-parametric tests were utilized when the data were non-normally distributed. Results were considered significant at p-values <0.05.

Reliability

Cronbach's alpha was used to examine the scale's internal consistency, and the intra-class correlation coefficient (ICC) between test and retest scores was used to measure its stability over time (17,18). Good reliability was defined as an ICC between 0.75 and 0.9, while excellent reliability was defined as a value higher than 0.90.

Construct validity

Scales of SF-36 and KSQ were utilized to examine the SHQ's convergent validity. Better convergence was indicated by higher correlation coefficients. Taking into account the non-normal distribution of the variables, Spearman's rho was used to examine the correlation between the mentioned variables. Correlation coefficient values were evaluated as follows: 0, no correlation; 0.1-0.3, weak correlation; 0.4-0.6, moderate correlation; 0.7-0.9, strong connection; 1.0, perfect correlation.

Results

The study included a total of 146 adult sarcoidosis patients (63 male and 83 female; mean age, 44±3.6 years; range, 27-63 years). Of the patients, 95% had lung involvement, with a mean number of 1.3 organs involved, a mean forced expiratory volume in 1 second (FEV1) of 96.7%, and a forced vital capacity (FVC) of 101.6%. Current symptoms were observed in 84% of patients and 27% were on immunosuppressant medication. The clinical and demographic characteristics of sarcoidosis patients are illustrated in Table 1.

Most patients completed the questionnaire in less than 5 minutes, and the computation took an average of 10 minutes. Every question had a 100% response rate. None of the items allowed for multiple responses. Each SHQ parameter had a strong internal consistency, ranging from 0.806 to 0.844, as

Table 1. Baseline characteristics of study participants (*n*=146).

Characteristic	Mean ± SD or n (%)	Range
Age, years	44 ± 3.6	27-63
Male, gender	63 (43)	
High school graduate	41 (28)	
Married	82 (56)	
Insurance	124 (85)	
Employed currently	101 (69)	
Smoking status		
-Current	32 (22)	
-Ex	16 (11)	
-Never	98 (67)	
Current symptoms	123 (84)	
Time since diagnosis, years	5.2 ± 3.2	1-23
Organ involved	1.3 ± 0.7	1-5
-Lungs	138 (94.5)	
-Skin	3 (2)	
-Eyes	7 (5)	
-Nervous system	2 (1.4)	
-Liver	1 (0.7)	
-Peripheral nodes	7 (4.8)	
-Ear, nose and throat	1 (0.7)	
Immunosuppressant		
-None	106 (73)	
-Prednisolone	26 (18)	
-Methotrexate	11 (7.5)	
-Azathioprine	1 (0.7)	
-Hydroxychloroquine	2 (1.4)	
FEV1% predicted	96.7 ± 77.2	38-100
FVC% predicted	101.6 ± 76.6	44-103
DLCO% predicted	79.4 ± 16.4	35-124

FEV1, percent predicted forced expiratory volume in 1 second; FVC, forced vital capacity; DLCO, diffusing capacity for carbon monoxide; SD, standard deviation.

shown in Table 2. The whole scale's Cronbach's alpha value was 0.781. The test-retest reliability ranged from 0.992 to 0.996 for the three components of the Turkish version, as indicated in Table 3. For the SHQ's total score, it was 0.994 (ICC=0.994 95% CI: 0.985-0.998; p<0.001).

The PCS and MCS scores of SF-36 were significantly correlated with the three-domain scores and total score of SHQ (r=0.282 to 0.496, p<0.05 for all). Additionally, the three domain scores and total score of SHQ showed a weak to significant correlation (rs= 0.393 to 0.593, p<0.001 for all) with the three KSQ component scores (general health status, medication, and eyes). The correlations between the questionnaires are shown in Table 4.

Table 5 illustrates the value of the HRQoL surveys for classifying patients based on clinical characteristics. Except for patients who were smokers, there were substantial differences in each domain and total scores of SHQ across all groups.

Discussion

This study proved the validity of the Turkish version of SHQ by demonstrating correlations between the SHQ scores and other questionnaires and clinical factors in Turkish sarcoidosis patients. The Cronbach's alpha values for all three domain scores and total SHQ score were likewise higher than the value of 0.60 necessary to demonstrate construct validity, indicating a satisfactory level of internal consistency. SHQ is a simple questionnaire that can be adapted to different settings, providing a reliable and valid instrument to determine the health-related QoL of Turkish patients with sarcoidosis. Moreover, it is also a self-report questionnaire that can be administered without the requirement for supervision, is easily scored, and only takes about 10 minutes to complete.

Table 2. Internal Consistency of the Turkish version of the Sarcoidosis Health Questionnaire.

Questionnaire Item	N	Items	Correlated item-total Correlation	Scale variance if deleted	Cronbach's alpha
Daily functioning (items 2, 3, 5, 8, 14, 15, 16, 17, 20, 21, 23, 27, 28)	146	13	0.749	7.919	0.806
Physical functioning (items 1, 6, 10, 11, 13, 25)	146	6	0.629	8.174	0.857
Emotional functioning (items 4, 7, 9, 12, 18, 19, 22, 24, 26, 29)	146	10	0.654	8.435	0.844
Total	146	29	0.809	7.621	0.781

Table 3. Stability of the Turkish version of the Sarcoidosis Health Questionnaire.

	Initial Score mean (SD) (n=20)	Retest score mean (SD) (n=20)	ICC (95% CI)
Daily functioning	4.01 (0.98)	4.02 (0.933)	0.992 (0.980-0.987)
Physical functioning	3.91 (0.99)	3.93 (0.97)	0.992 (0.980-0.987)
Emotional functioning	4.04 (1.14)	4.05 (1.14)	0.996 (0.990-0.998)
SHQ total score	3.91 (0.88)	3.90 (0.88)	0.994 (0.985-0.998)

SD, Standard Deviation; SHQ, Sarcoidosis Health Questionnaire; ICC, Intraclass Correlation Coefficient.

Table 4. Concurrent Validity.

SHQ								
	DF		**PF**		**EF**		**Total**	
	p	***r***	***p***	***r***	***p***	***r***	***p***	***r***
SF-36								
-PCS	***<0.001****	0.496**	***0.001****	0.282**	***<0.001****	0.368**	***<0.001****	0.360**
-MCS	***<0.001****	0.376**	***0.001****	0.262**	***<0.001****	0.414**	***<0.001****	0.352**
King's Sarcoidosis Questionnaire								
-General Health Status	***<0.001****	0.593**	***<0.001****	0.426**	***<0.001****	0.527**	***<0.001****	0.478**
-Lung	0.115	0.118	0.510	0.55	0.104	0.210	0.310	0.850
-Medication	***<0.001****	0.449**	***<0.001****	0.357	***<0.001****	0.414**	***<0.001****	0.456**
-Skin	0.244	0.090	0.925	0.08	0.720	0.385	0.610	0.464
-Eyes	***<0.001****	0.572**	***<0.001****	0.440**	***<0.001****	0.393**	***<0.001****	0.545**
PFT								
-FVC, %	0.929	0.007	0.70	0.151	0.458	0.059	0.381	0.077
-FEV_1, %	0.790	0.220	0.949	0.05	0.293	0.088	0.663	0.036
-DLCO	0.112	0.132	0.107	0.197	0.640	0.039	0.997	0.010

**r=Spearman's rho coefficient; * p<0.05, statistically significant.
SHQ-DF, Sarcoidosis Health Questionnaire-Daily Functioning; SHQ-PF, Sarcoidosis Health Questionnaire–Physical Functioning; SHQ-EF, Sarcoidosis Health Questionnaire –Emotional Functioning; SHQ Total, Sarcoidosis Health Questionnaire –Total; SF-36 PCS, Short Form 36 Physical Component Summary, SF-36 MCS, Short Form 36 Mental Component Summary; PFT, Pulmonary Function Test.

Patient-reported outcome instruments are increasingly used in routine clinical practice and clinical studies (19). Today, health status is a standard outcome measure of health. SHQ is a self-administered questionnaire specific to sarcoidosis patients. The validation of SHQ in other populations can encourage international collaboration to determine, improve and compare the health status of sarcoidosis patients who are usually severely affected by the condition. No major cultural difference was documented during the translation phase of the questionnaire into Turkish and the patient interviews, thus the questionnaire was considered an understandable and appropriate instrument of data collection for Turkish patients with sarcoidosis.

Three sarcoidosis-specific patient-reported outcome measures, including SHQ, KSQ, and sarcoidosis assessment tool (SAT), have been reported in the literature (20). The number of questions in KSQ and SHQ and the time required to complete the questionnaires are the same, with similar Cronbach's alpha values, while SAT has a higher number of questions and requires a longer time to complete. Moreover, there are 5 domains in KSQ and 8 domains in SAT, but only 3 domains in SHQ (20). Of these questionnaires, only KSQ was validated in Turkish

Table 5. Comparison of SHQ scores by clinical characteristics of patients.

	n	SHQ-DF	SHQ-PF	SHQ-EF	SHQ-Total
		Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
Symptoms					
-Yes	107	4.12 ± 1.02	3.65 ± 1.07	3.80 ± 1.03	3.96 ± 1.092
-No	39	4.79 ± 1.11	4.21 ± 1.27	4.27 ± 1.09	4.41 ± 1.01
p-value		***0.001****	***0.016****	***0.024****	***0.021****
Use of oral steroid					
-Yes	25	4.6 ± 0.87	3.9 ± 1.113	4.15 ± 0.95	4.32 ± 1.02
-No	111	3.03 ± 0.98	3.1 ± 1.10	3.16 ± 1.12	3.24 ± 0.99
p-value		***<0.001****	***0.002***	***<0.001****	***<0.001****
Smoking cigarette					
-Yes	32	4.41 ± 1.18	3.75 ± 0.91	4.15 ± 0.94	4.43 ± 1.43
-No	114	4.27 ± 1.02	3.81 ± 1.21	3.85 ± 1.10	3.9 ± 0.93
p-value		0.524	0.733	0.147	0.101
Organ involvement					
One or two organs		4.3 ± 1.04	3.9 ± 1.13	3.9 ± 1.07	4.16 ± 1.08
Three or more organs		3.4 ± 1.1	2.8 ± 0.94	3.3 ± 0.92	3.2 ± 0.76
p-value		***0.006****	***0.002****	***0.038****	***0.001****

SHQ-DF, Sarcoidosis Health Questionnaire-Daily Functioning; **SHQ-PF,** Sarcoidosis Health Questionnaire–Physical Functioning; **SHQ- EF,** Sarcoidosis Health Questionnaire –Emotional Functioning; **SHQ Total,** Sarcoidosis Health Questionnaire –Total

in 2017 (21). Despite being evaluated in many languages, the number of studies evaluating the correlation between the KSQ and the SHQ instruments is limited. Our study demonstrated a significant relationship between SHQ and the KSQ domains other than the lung and skin domains. The probable cause of this can be explained by the evaluation of organ-specific health status with KSQ (22). However, it is important to note the high stability of SHQ in Turkish patients and the correlation of its internal consistency with validated but non-sarcoidosis-specific quality-of-life scales in our study. We think that communication between clinicians and patients may be improved by SHQ and this instrument may allow for addressing issues such as fatigue, musculoskeletal pain, and depression, which are not usually talked about during an interview. Therefore, our study is valuable both in terms of showing the relationship between the sarcoidosis-specific QoL and the validity and reliability of the Turkish version of SHQ, which is one of the scales to measure the sarcoidosis-specific QoL after KSQ. However, there is a need for further studies to confirm the correlation of these questionnaires with each other and compare the ease of use in routine practice.

SHQ has been validated in several languages in the literature. For the first time, it was validated by Cox et al. in 2003 (4). As a result of the study, this scale was found to be correlated with SF-36 and St. George's Respiratory Questionnaire Activity scales. Tanizawa et al. also found that the Japanese version of this scale was reliable and valid, showing a correlation with SF- 36 and St. George's respiratory scales (7). In another study, this scale was validated in different languages (Hindi, Polynesian, and European), and it was determined to be correlated with the SF-36 components and the Fatigue Severity Scale (FSS) (8). Our study investigated the correlation of SHQ with 5 subcomponents of KSQ and two subcomponents of SF-36. The significant correlation between the Turkish version of SHQ and the components of KSQ other than the lung and skin subscales and the high ICC value examined to evaluate the stability of the scale showed that the scale was reliable and valid. No significant correlation was found between SHQ and its subcomponents and pulmonary function tests (PFTs). In the literature, studies are showing a weak relationship between PFT and its subcomponents and SHQ (4,23-25). Our results are consistent with the results of these studies. Therefore, there is a need for studies to verify this result.

Various racial and ethnic populations may experience different clinical symptoms of sarcoidosis. Sarcoidosis is less severe in Japan than in Western nations, but it is more likely to affect the eyes and the heart (29,30). Multiorgan involvement and severe lung involvement are more common in black patients with sarcoidosis in the USA (31). Accordingly, health-related QoL and its association with certain clinical traits may vary in different populations. This suggests that ethnicity affects the SHQ score, albeit indirectly. In addition, SHQ provides a more detailed evaluation of the emotional, physical, and daily functions that affect the QoL of sarcoidosis patients compared to the KSQ scale. KSQ has more organ format modules. These may be the reasons why no correlation has been found between the SHQ scale and the lung and skin component scores of KSQ in our study. Other studies have also shown that the lung domain of KSQ is not associated with the physical health, psychological health, social relationships, and environmental health domains of the World Health Organization Quality of Life-Brief questionnaire and the index score of Euroqol-5D-5 (32). Our study has two potential limitations. The first is the cross-sectional design of the study. Therefore, the effect of important parameters such as treatment, organ involvement, and symptom presence on SHQ could not be specifically determined. It is believed that this will be verified by prospective studies to be conducted in the future. The second limitation is that the population included in the study consisted of patients followed up in a tertiary hospital. Since this could be a bias, the results may not apply to patients followed up in community settings.

Conclusions

We have established the reliability and validity of the Turkish version of SHQ. When combined with normal physiological, radiological, and serological examinations of the illness, SHQ can assess the QoL of sarcoidosis patients and give useful new information.

Conflicts of Interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

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