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Translation and Validation of a Persian Version of the Severe Respiratory Insufficiency Questionnaire (SRI)

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Background: Using Health-related quality of life (HRQL) in chronic patients with severe respiratory insufficiency (SRI) requires a valid instrument. Hence, this study aimed to translate and validate the Persian version of the Severe Respiratory Insufficiency Questionnaire in chronic patients with severe respiratory insufficiency.

Materials and Methods: In this methodological study, the original version of the HRQL questionnaire in chronic patients with SRI was translated based on the approach presented by Wild et al. Face validity, content validity such as content validity index (CVI) and content validity ratio (CVR), convergent, and discriminant validity were evaluated. Moreover, construct validity evaluation was conducted by exploratory and confirmatory factor analyses (EFA & CFA). Reliability was also evaluated by calculating Cronbach's alpha and test-retest intraclass correlation coefficient (ICC). SPSS-16 and AMOS-24 software were used for data analysis.

Results: The target group approved the face validity of the questionnaire and the content validity index was 0.94. In total, 500 chronic patients with severe respiratory insufficiency participated in the construct validity. Seven factors were extracted in exploratory factor analysis as respiratory complaints, physical functioning, social relationship, anxiety, attendant symptoms and sleep, social functioning, and psychological well-being. These factors explained 73.91% of the total variance of the concept of HRQL in chronic patients with SRI. All factors confirmed in confirmatory factor analysis based on model fit indices [Comparative Fit Index (CFI)=0.94, Goodness of fit index (GFI)=0.94, Minimum Discrepancy Function by Degrees of Freedom divided (CMIN/DF) =2.99, and Root Mean Square Error of Approximation (RMSEA)=0.01]. Convergent and discriminant validity were also confirmed. Moreover, Cronbach's alpha coefficients of 0.84 and intraclass correlation coefficient of 0.82-0.96 with 15-day intervals confirmed the internal consistency of the instrument.

Conclusion: According to the findings of the present study, the Persian version of the SRI questionnaire, with 7 subscales and 40 items, is a valid and reliable instrument to assess the HRQL in chronic patients with SRI.

Keywords: Translation; Validity; Health-related quality of life; Severe respiratory insufficiency questionnaire

INTRODUCTION

The growing number of people suffering from chronic diseases such as cardiovascular diseases, respiratory disease, cancer, and diabetes, as well as their quality of life, is one of the challenges of the health system in the 21st century (1). However, chronic patients with respiratory

failure (CRF) are considered one of the priorities of the World Health Organization (WHO) because it affects millions of people worldwide (2). It is the third leading cause of death, with an annual mortality rate of higher than 9.5 million people in the world (3). Accurate statistics on chronic respiratory insufficiency (CRI) in Iran are not available; however, the mortality rate due to this disease was equal to 9.8% of all deaths in 2019 (4).

CRI refers to a problem in the function of the respiratory system when it is unable to sustain arterial blood gases at an acceptable level. It is classified into two categories, i.e., hypoxemic, such as pulmonary fibrosis, and hypercapnic respiratory failure, including chronic obstructive pulmonary disease (COPD), neuromuscular disorders (NMD), and severe and refractory asthma (5). In all types of this disease, patients continuously experience disruptions in their daily physical and functional activities, problems in their mental and psychological conditions, such as fatigue, fear, anxiety, isolation, dependence on others, depression, and social problems due to the progressive nature and exacerbation of respiratory symptoms (6). They always require long-term drug use and oxygen therapy to improve the signs and symptoms of the disease affecting their quality of life (7). This leads to exorbitant costs in pharmacological/non-pharmacological treatments, time expenditure, frequent hospitalizations, and many other problems in the family and community (8).

WHO estimates that by 2050, the incidence of chronic diseases such as respiratory insufficiency and changes in the quality of life will increase with the growing population (9). Quality of life is defined as one's perceptions of physical and mental status, level of independence, social relationships, interaction with the environment, and personal sets of beliefs and values (10). Correspondingly, health-related quality of life (HRQL), as part of the overall quality of life, comprises mental, emotional, social, and physical perceived well-being and reflects the subjective and objective evaluation of patients and how they respond to the disease (11). Wilson and Cleary define it as being pleased and satisfied with one's aspects of life, both affected by health and affecting the person's health (12).

HRQL is one of the most multifaceted and essential concepts of clinical research on chronic diseases; researchers constantly investigate how to assess its various aspects with an appropriate instrument (13). Assessing this concept can improve clinical decision-making, evaluating the quality of medical and nursing interventions, and monitoring the severity, progression, and prognosis of the disease (14). In addition, such instruments can lead to reliable results in measuring HRQL changes, effective treatment programs, predicting future outcomes, and policymaking in the health system of any society (15). Furthermore, they can contribute to the care and treatment of patients by having discriminatory, evaluative, and predictive properties (14).

The most common instrument used to measure HRQL in patients with CRI has been the severe respiratory insufficiency questionnaire (SRI), developed by Windisch et al. in the German language in 2003 (16). It was employed in several countries, including Finland, England, Portugal, Japan, Norway, China, Spain, and Chile (17), due to the importance of cultural adaptation and validation in different research communities.

Nevertheless, measuring HRQL has been neglected in research, education, and clinics in our country. Due to the importance of the growing incidence of respiratory insufficiency and HRQL, there is a need for local and specialized instruments, specifically adapted for the individual and social conditions of patients, facilities, existing treatment and care conditions, and culture. Therefore, the present study aimed to determine the translation and validation of the HRQL questionnaire in chronic patients with SRI.

MATERIALS AND METHODS

This methodological study was conducted from 2019 to 2020 in hospitals affiliated with Golestan University of Medical Sciences in northeastern Iran. The instrument

investigated in this study was the HRQL questionnaire in SRI (HRQL-SRI), developed by Windisch et al. in German language in 2003. It contains 49 items and 7 subscales, namely, respiratory complaints, physical functioning, attendant symptoms and sleep, social relationships, anxiety, psychological well-being, and social functioning. The five-point Likert scale included "completely untrue" (-2), "mostly untrue" (-1), "sometimes true" (0), "mostly true" (+1), and "always true" (+2). The total score of the questionnaire ranged from 0-100, and scoring was done in 4 ranks: 0-25% were classified as very undesirable, 26-50% (undesirable), 51-75% (relatively desirable), and 76-100% (desirable). The questionnaire developers reported Cronbach's alpha coefficient was > 0.7 in all subscales (16). The process of assessing the psychometric properties of the instrument COSMIN's guidelines was considered. Psychometric properties of HRQL-SRI included translating the original questionnaire, calculating the initial reliability, assessing the face, content, convergent, and construct validities along with the reliability of the questionnaire, responsiveness, and interpretability.

Translating the questionnaire

The researchers began the process of translating HRQL-SRI into Persian based on the protocol presented by Wild et al. (18) after obtaining written permission from Professor Windisch. Initially, two fluent translators (one of them was familiar with the field of study) independently translated the HRQL-SRI questionnaire from German into Persian. Afterward, the research team reviewed the translations for semantic clarity and resolved the differences and contradictions between the translated texts. Lastly, the final version of the instrument was approved by integrating the original translations. In the review and synchronization stage, the corresponding Persian translations and the original sentences were compared. Following this step, the final Persian version was translated into German by two other translators, not involved in the translation process in the previous step.

The original and the German versions were sent to the instrument developer, who approved them after examining the conceptual and linguistic comprehension and functional differences of each item. The research team reviewed and applied his suggestions in a meeting. At the end of the translation process, the final translated version, entitled HRQL-SRI-P, was cognitively confirmed by several respiratory patients as a target group, and then the translated version entered the process of assessing the psychometric properties.

Psychometric properties

Initial reliability

Before entering the validation stage, the initial reliability of HRQL-SRI-P was calculated using internal consistency. That is, 30 chronic respiratory patients hospitalized in the clinical setting were selected by convenience sampling with inclusion criteria and completed the SRI questionnaire. The data were fed into SPSS-16, and the internal consistency of the items was assessed. Cronbach's alpha coefficient > 0.7 indicates acceptable internal consistency (19).

Face validity assessment

The researchers evaluated the face validity of HRQL-SRI-P both quantitatively and qualitatively. Through face-to-face interviews, 12 respiratory patients hospitalized (target group) in the setting, were selected by convenience sampling with inclusion criteria and the SRI questionnaires were completed. They included 6 females and 6 males: 3 with SRI (COPD), 1 with NMD suffering from respiratory insufficiency, 1 with persistent asthma, and 1 with pulmonary fibrosis. Their comments were gathered regarding the comprehension difficulty, ambiguity, and understanding of the concepts in each item.

To evaluate the face validity quantitatively, the impact factor of the items was calculated using this formula: Impact Score = Frequency% × Importance (20). The target group scored each item in the translated version of HRQL-SRI based on a 5-point Likert scale; i.e., "It is important" (5 points), "It is quite important" (4 points), "It is fairly important" (3 points), "It is somewhat important" (2 points), and "It is not important" (1 point). If the impact

score for each item was greater than 1.5, it was deemed eligible and was retained for subsequent analysis.

Content validity assessment

The content validity assessment of HRQL-SRI-P was performed both quantitatively and qualitatively. In the qualitative content validity, 15 members of the experts' panel were asked to score the content of the translated version of the questionnaire and to comment on scoring, clarity, simplicity, item allocation, wording, and grammar in open suggestion boxes next to each question. These experts included medical and nursing specialists and researchers working on respiratory diseases in the field of internal medicine and respiration (4 people), neurologists (2 people), nursing faculty members and researchers (3 people), experienced head nurses working in the internal medicine ward, respiratory ward or acute respiratory intensive care unit (3 people), educational supervisors (2 people), and psychiatrist (1 person).

Content validity ratio (CVR), content validity index (CVI), modified Kappa statistics (K *), and scale content validity index (S-CVI / Average) were calculated for quantitative content validity. To calculate the CVR, an expert panel (15 people) was asked to comment on the "necessity" of the items in a 3-point Likert scale, i.e., "not necessary" (1 point), "useful but not necessary" (2 points), and "necessary" (3 points). The minimum CVR value required for retaining an item with 15 experts is 0.49 based on the Lawshe table (21).

To calculate the CVI, the panel of experts rated each item concerning relevancy based on a 4-point Likert scale, i.e., "It is not relevant" (1 point), "It is relevant to some extent" (2 points), "It is relevant" (3 points), and "It is completely relevant" (4 points). CVI values of 0.78 and higher were acceptable. After accomplishing the CVI, the modified Kappa statistic was calculated; the modified Kappa statistic scores of 0.74 and higher were excellent. The mean scores of the scale content validity index (S-CVI/Average) can be considered as the CVI of the total instrument. A score of 0.9 and higher is considered acceptable (22).

Construct validity assessment

To evaluate the construct validity of HRQL-SRI-P, exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) were performed. There is no consensus on determining the sample size in the construct validity, and various values for adequate sample size have been presented in this regard. However, the Comrey and Lee guideline on the adequacy of the sample size in factor analysis considers a sample size of 500 to be appropriate for factor analysis (23). In the CFA, the number of factors determines the minimum sample size; the recommended sample size for CFA is about 20 samples for each factor.

In the present study, out of the total sample size (500 patients), 200 patients with chronic respiratory disease hospitalized in the respiratory ward were allocated to CFA and 300 to EFA. To collect the samples, the necessary information was obtained from the informatics centers of the hospitals. Considering the bed occupancy rate, sampling was done by proportionately allocating patients from inpatient wards of neurology, respiratory internal medicine, general internal medicine, and intensive care units in hospitals located in the east and west of Golestan province from August 2020 to February 2021.

Inclusion criteria included confirmed diagnosis of respiratory insufficiency by a pulmonologist, history of COPD, asthma, pulmonary fibrosis, respiratory insufficiency due to NMD, being affected by the disease for at least 6 months, and age ≥40 years. Moreover, patients with a history of non-invasive supportive ventilation or long-term oxygen therapy who were aware of time and place were included in the study.

Kaiser-Meyer-Olkin (KMO) test was employed to determine the adequacy of sample size, and Bartlett's Test of Sphericity was utilized to determine the correlation in the data matrix. Values of 0.8 and higher are acceptable for KMO (24). In the present study, we evaluated the factor structure of the HRQL-SRI questionnaire by estimating the maximum likelihood and using varimax rotation. Furthermore, the criterion for selecting the factors was

factor loading of greater than 0.3 and eigenvalues of greater than one (25).

In CFA, researchers seek to fit the existing data into the model. To achieve this goal, several fit indices were used. These indices included χ^2, goodness-of-fit index (GFI), adjusted goodness-of-fit index (AGFI), root mean squared error of approximation (RMSEA), normed fit index (NFI), degrees of freedom ratio (DF), incremental fit index (IFI), comparative fit index (CFI), *p*-value, and CMIN / DF (26).

Convergent validity assessment

Convergent validity was assessed by average variance extracted (AVE) and composite reliability (CR) based on the Fornell and Larcker criterion. To confirm convergent validity, AVE values must be greater than 0.5, and CR values must be greater than AVE. In addition, the convergent validity of a questionnaire is acceptable when all its items closely correlate with each other and share a large variance (27).

Reliability assessment

In the present study, we measured the relative consistency by the test-retest method, i.e., 30 patients with chronic respiratory disease who were selected by convenience sampling method completed the HRQL-SRI-P questionnaire twice with a 15-day interval. Intra-class Correlation Coefficient (ICC) was calculated using a two-way mixed-effect model with acceptable values of greater than 0.8. Moreover, Cronbach's alpha, McDonald's omega, and average inter-item correlation were measured for internal consistency. Cronbach's alpha of greater than 0.7 was considered acceptable and standard error of measurement (SEM) was also used to evaluate the absolute reliability using the following formula (28):

$$SEM=SD\sqrt{(1-ICC)}$$

After the reliability evaluation, the responsiveness and interpretability of HRQL-SRI-P were determined.

In the present study, in all steps of the psychometric process, the researcher collected the data by being present in the setting, so there was no missing data.

Data analysis

Exploratory factor analysis of data was done in SPSS-16 software and also confirmatory factor analysis was performed using Analysis of Moment Structure software (AMOS-24).

Ethical considerations

This study is part of a Ph.D. dissertation with the ethics code of IR.GOUMS.REC.1399.097 approved by the Ethics Committee of Golestan University of Medical Sciences. Written informed consent was obtained from the patients participating in this research and assured them about the confidentiality of the information and their unconditional withdrawal from the study.

RESULTS

A total of 500 patients participated in this study, including 263 (52.6%) males. Besides, 144 (28.8%) of them ranged from 61 and 70 years old, and 414 (82.8%) were married (Table 1).

Table 1. Participants' demographic characteristics

Characteristics		Number s	%
Gender	Male	263	52.6
	Female	237	47.4
Age category (years)	20-30	17	3.4
	31- 40	65	13
	41- 50	113	22.6
	51- 60	101	20.2
	61- 70	144	28.8
	71- 80	60	12
Marital status	Single	31	62
	Married	414	82.8
	Widowed	48	9.6
	Divorced	7	1.0
Employment status	Housewife	179	35.8
	Farmer	33	6.6
	Employee	54	10.8
	Rancher	19	3.8
	Baker	19	3.8
	Worker	196	39.2
Educational status	High school dropouts	342	68.4
	Diploma	102	20.4
	University	56	11.2
Type of CRF	Asthma	191	38.2
	COPD	229	45.8
	Pulmonary fibrosis	60	12
	NMD	20	4

Initial reliability

In the initial reliability assessment, all subscales obtained Cronbach's alpha between 0.72 and 0.89, indicating the initial reliability of the questionnaire.

Face validity

In the qualitative face validity assessment, 5 items (13, 19, 30, 38, and 46) were reviewed and revised based on the comments posed by the target group. The item impact score of all items was accepted (IIS> 1.5) in the quantitative face validity; so, they remained in the questionnaire.

Content validity

In the qualitative content validity assessment, the researchers revised 5 items (5, 9, 15, 17, 18, and 31) according to the comments of the experts' panel. Furthermore, the Likert scale changed to "never" (1), "seldom" (2), "sometimes" (3), "often" (4), and "always" (5) based on the nature of the questions. On the other hand, the researchers omitted 4 other items (3, 6, 7, and 14) due to low CVR (< 0.49) in the quantitative content validity assessment. However, the CVI was acceptable for all items (> 0.78), and the modified Kappa statistics' value was between 0.86 and 1.00 for all items. Moreover, the S-CVI/AVE gained an acceptable value of 0.941.

Construct validity

In the present study, the KMO index was 0.933; therefore, the number of samples (respondents) was sufficient for factor analysis. Furthermore, Bartlett test value of less than 0.5, Approx. A Chi-Square of 1.44 with a df of 990 indicates that factor analysis is appropriate to identify the structure of the factor model and rejects the hypothesis that the correlation matrix was known (Table 2). With the factor load ≥ 0.3 and Eigenvalue >1, after varimax rotation on items and transpositions, the results of EFA illustrated that by removing the two items of 36 and 49 from the analysis, the remaining 43 items were inserted in 7 Subscales (Figure 1). These seven subscales accounted for 73.91% of the variance. As Table 3 demonstrates, the respiratory complaint subscale had the highest level of variance (32.910%), and the psychological well-being subscale had the lowest (4.882%).

Table 2. KMO and Bartlett test in structural validity

KMO	0.933	
Bartlett's test	Approx. Chi-Square	1.444E4
	Degrees of freedom	990
	Sig	0.00

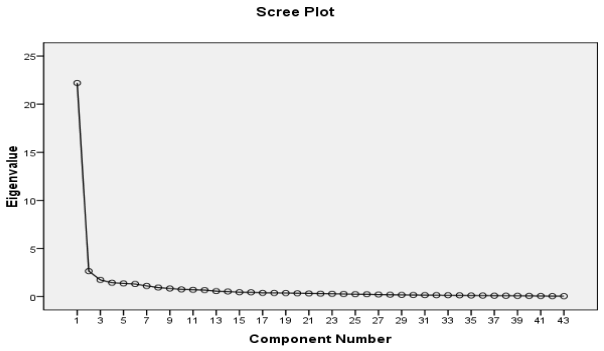

Figure 1. Scree plot for the exploratory factor analysis

In the present study, after performing CFA, items 2, 43, and 45 were also removed from the instrument, and the fit indices of the obtained model properly confirmed the omission of three factors. At this stage, item 42 was transferred from the "attendant symptoms and sleep" subscale to the "physical functioning" subscale, and item 48 moved from the "social functioning" to the "psychological well-being" subscale (Figure 2).

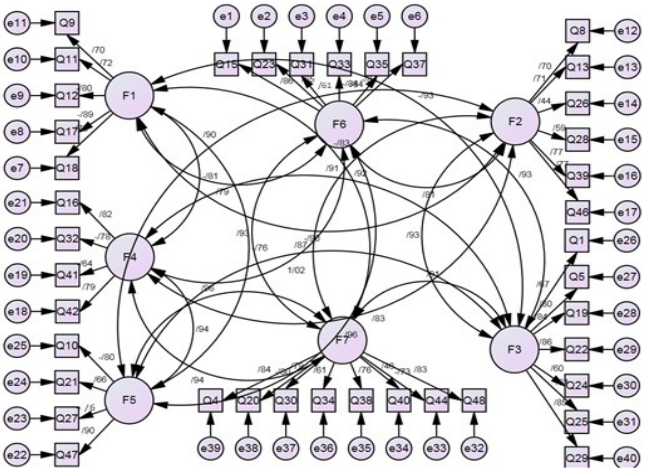

Figure 2. The confirmatory factor analysis model of HRQL-SRI-P

F1 Attendant symptoms and sleep, **F2** Anxiety, **F3** Respiratory complaints, **F4** Physical functioning, **F5** Social relationships, **F6** Social functioning, **F7** Psychological well-being

Table 3. The seven factors of the HRQL-SRI-P and their items

Factor Item	Factor Loading	Eigenvalue	Variance %
Respiratory Complaints			
Q1. It is difficult for me to go upstairs.	0.606		
Q2. I suffer from respiratory problems while eating.	0.732		
Q5. I suffer from respiratory problems even without doing physical activity	0.613		
Q19. I have shortness of breath.	0.708	14.810	32.910
Q22. I have respiratory problems while speaking.	0.564		
Q24. I cough a lot.	0.776		
Q25. I have sputum.	0.837		
Q29. I have respiratory problems while doing physical activity.	0.620		
Physical Functioning			
Q16. It is difficult for me to do the house chores.	0.860		
Q32. I can go shopping.	0.797	4.491	9.980
Q41. I can dress on my own.	0.719		
Q45. Respiratory problems interfere with my daily activities.	0.810		
Social Relationship			
Q10. I communicate easily with people.	0.810		
Q21. I feel lonely.	0.390	3.364	7.476
Q27. I feel well when I am with my friends or acquaintances.	0.782		
Q43. I feel isolated.	0.739		
Q47. I have lost contact with others due to respiratory problems.	0.770		
Anxiety			
Q8. I'm worried my illness might get worse.	0.542		
Q13. I'm afraid of respiratory problems at night.	0.601		
Q26. I avoid situations where respiratory problems embarrass me.	0.708	2.980	6.622
Q28. I'm afraid of dyspnea.	0.789		
Q39. Respiratory problems bother me in public places.	0.514		
Q46. My family life is oppressed by my illness.	0.669		
Attendant Symptoms and Sleep			
Q9. I fall asleep easily.	0.504		
Q11. I feel dizzy.	0.632		
Q12. I wake up at night due to respiratory problems.	0.574	2.844	6.320
Q17. I wake up during the night.	0.569		
Q18. I sleep well during the night.	0.444		
Q42. I'm tired during the daytime.	0.735		
Social Functioning			
Q15. I am confined to home.	0.856		
Q23. Visitors make me tired.	0.465		
Q31. Marriage issues have been disrupted by my illness.	0.745	2.574	5.721
Q33. I can pursue my favorite hobbies.	0.717		
Q35. Communication with my friends and acquaintances is limited due to my illness.	0.721		
Q37. I can participate in social activities.	0.784		
Q48. I have limited free time.	0.658		
Psychological Well-Being			
Q4. I feel helpless.	0.670		
Q20 I am optimistic about the future.	0.701		
Q30. I'm irritable due to the limitations imposed by the illness.	0.514	2.197	4.882
Q34. I am sensitive and irritable.	0.683		
Q38. I am sad.	0.582		
Q40. I am nervous.	0.416		
Q44. I can get on well with my illness.	0.722		

As Table 4 illustrates, fitness indices also revealed that the data of this study have a good fit with the obtained factor structure (CFI=0.94, AGFI=0.97, NFI=0.95, df=860, CMIN/df=2.99, RMSEA=0.01, IFI=0.94, GFI=0.94, p-Value=0.05, $\chi 2$=2573.74).

Consequently, we omitted 9 out of 49 items from the original questionnaire. Ultimately, HRQL-SRI-P factor structure was confirmed with 40 items and 7 subscales, including "respiratory complaint" (7 items), "physical functioning" (4 items), "attendant symptoms and sleep" (5 items), "social relationship" (4 items), "anxiety" (6 items), "psychological well-being" (8 items), and "social functioning" (6 items).

Convergent and discriminant validity assessment

The results of the convergent validity (Table 5) demonstrated that AVE values were greater than 0.5 and CR values were greater than AVE for all factors, indicating an appropriate and acceptable level of convergent validity.

Reliability assessment

Furthermore, Cronbach's alpha coefficient indicated a desired and acceptable level of data reliability; that is, the total alpha was 0.84, and they were between 0.79 and 0.89 for the subscales. The estimated McDonald's omega and average inter-item correlation values were greater than 0.8 and 205, respectively. Moreover, the ICC of the instrument was obtained at 0.824 through test-retest (Table 6).

According to MIC and SDC values, all subscales were responsive to HRQL-SRI-P changes.

MIC=Effect size × SD

SDC=1.96×$\sqrt{}$ 2 × SEM

If, MIC>SDC

To determine the interpretability of HRQL-SRI-P, the mean and standard deviation of the reference population were calculated. The results showed that the highest and lowest values of the subscales were psychologic well-being, and Physical Functioning respiratory complaints, respectively (Table 7).

Table 4. Goodness of fit indices in confirmatory factor analysis

Indices Model	$\chi 2$	Df	p-value	CMIN / DF	GFI	RMSEA	AGFI	NFI	IFI	CFI
Corrected	2573.74	860	0.05	2.99	0.94	0.01	0.97	0.95	0.94	0.94

RMSEA (root mean score error of approximation), CFI (comparative fit index), IFI (incremental fit index), GFI (goodness of fit index), AGFI (adjusted goodness of fit index), NFI (normed fit index).

Table 5. Convergent validity and divergent validity of HRQL-SRI-P

Subscales	AVE	MSV	ASV	CR
Respiratory complaints	0.50083	0.32140	0.29574	0.8214
Physical functioning	0.68587	0.45231	0.38521	0.76041
Attendant symptoms and sleep	0.59471	0.44324	0.25614	0.79689
Social relationships	0.70585	0.63270	0.56287	0.7852
Anxiety	0.73511	0.62841	0.52174	0.8091
Psychological well-being	0.58466	0.23187	0.16374	0.7254
Social functioning	0.50399	0.39645	0.30254	0.7145
Total	0.61586	0.443769	0.355426	0.773271

Table 6. Internal consistency, and stability of HRQL-SRI-P

Subscales	α (95% CI)	ICC	Omega
Respiratory complaints	0.89 (0.782- 0.897)	0.899	0.8977
Physical functioning	0.79 (0.347- 0.824)	0.824	0.9378
Attendant symptoms and sleep	0.80 (0.547- 0.873)	0.823	0.9625
Social relationships	0.83 (0.413- 0.869)	0.897	0.8450
Anxiety	0.82 (0.524- 0.891)	0.804	0.9311
Psychological well-being	0.85 (0.682- 0.893)	0.871	0.8364
Social functioning	0.88 (0.572- 0.896)	0.841	0.82635
Total		0.824	

Table 7. Responsiveness and interpretability of HRQL-SRI-P

Subscales	Mean change	SD /Baseline mean	Effect size	MIC	SEM	SDC
Respiratory Complaints	0.412±0.22	1.23	1.54	1.8	0.00649	0.017
Physical Functioning	0.383±0.24	0.95	0.32	0.3	0.00484	0.012
Attendant Symptoms and Sleep	0.443±0.23	1.08	0.85	0.9	0.00447	0.012
Social Relationship	0.509±0.25	0.85	0.79	0.6	0.00563	0.015
Anxiety	0.520±0.26	0.97	0.98	0.65	0.00552	0.015
Psychologic Well-Being	0.525±0.23	1.24	1.55	1.9	0.00613	0.016
Social Functioning	0.485±0.20	1.32	0.57	0.75	0.00551	0.015

DISCUSSION

Evaluating and improving HRQL is an important objective in managing chronic patients with SRI. To date, several studies evaluating the HRQL in such patients mainly required a valid, standard, and reliable questionnaire. Although researchers in various studies have used a variety of instruments to measure HRQL in patients with CRF, Oga et al. and Struik et al. revealed that HRQL-SRI is a valid and reliable instrument with discriminatory, evaluative, and predictive properties compared with other questionnaires used in these patients (14, 29).

To evaluate the psychometric properties of the HRQL-SRI questionnaire, it was first translated into Persian based on the protocol presented by Wild et al in the present study (18). The process of translation and cultural adaptation and performing the procedure step by step based on a specific pattern, increases the quality of the outcome (30). Qualitative face validity was confirmed by making minor changes in some items of the instrument based on the comments of the target group. On the other hand, the quantitative face validity was considered appropriate for each item according to the impact score of greater than 1.5; face validity contributes to the target group's understanding of the items in the questionnaire (31). The qualitative content validity of the questionnaire was confirmed after revising some items and changing the Likert scale format by a panel of experts. The results of examining the necessity of items by CVR disclosed that 4 items should be removed because of not obtaining the minimum acceptable score, while this index has not been reported in other similar studies (17, 32). The extent to which each item was relevant to the construct was evaluated and approved by a panel of experts. They believed that content validity assessment is necessary to ensure the important and comprehensive features of the concept's coverage. If the panel of experts is more knowledgeable and experienced, content validity will be performed more reliably (33).

The results of EFA in the present study indicate that HRQL-SRI-P has 7 subscales that explain 73.91% of the total variance of the concept of HRQL in chronic patients with SRI. This finding was almost similar to that of the English version (70%), and the Portuguese version (72%), and was higher than the original German version (59.8%) of the questionnaire. Explaining the variance of more than 50% indicates the appropriateness of the extracted factors and also the appropriateness and adequacy of the construct validity of the questionnaire (34). In line with the present study, the results of EFA also reported seven factors for the HRQL-SRI questionnaire in versions employed in Finland, Japan, and Germany (16, 32, 35).

Comparing the factor structure of HRQL-SRI in different societies demonstrates variety in the cultural contexts; For example, Valko et al. reported 13 factors explaining 73.8% of the total variance when investigating the psychometric properties of the HRQL-SRI questionnaire (36). Correspondingly, in the research conducted by Ribeiro et al., 13 factors were found that explained 73% of the variance (37). According to Hair et al., if the amount of explained variance is more than 50%, factor extraction is appropriate (34). The discrepancy in the amount of similarity in different versions of the instrument can be attributed to the culture and life patterns of the patients and the clinical settings in every country (36, 37).

Furthermore, the findings of the present study confirmed that among the extracted factors, the highest variance (variance=32.910%) belongs to the "respiratory complaints" subscale. After accomplishing EFA, CFA was utilized to confirm the existing structural model. This test not only evaluates the latent factors more definitively and accurately but also demonstrates the path of relationships between manifest and latent variables (38). Our study has confirmed the fit of the 7-factor model of HRQL in chronic patients with SRI based on standard indices, showing that the developed conceptual model is consistent with the data obtained from the statistical community. In this study, "respiratory complaints" were the first extracted factor with items related to asthma, cough, and sputum. These symptoms are the most important and common complaints of patients with CRI, affecting their HRQL (39). This factor is consistent with the symptoms of the St. George's Respiratory Questionnaire (40).

Another subscale is "attendant symptoms and sleep" focusing on secondary symptoms associated with sleep disorders, ability to sleep at night, and fatigue during the day. Malik et al. believe that sleep disorders in chronic patients with respiratory insufficiency have a profound effect on disease management and reduce HRQL in these patients (41). Likewise, Kamkar et al. found that insufficient sleep significantly decreases the quality of life and function among patients (42).

The other subscale identified in this study is "social relationships", encompassing the relationships with others and feelings of loneliness and isolation. Researchers believe that social relationships and active living help improve the quality of life in these patients (43, 44). Consistent with the results of the study conducted by Valko et al., "anxiety" is the fourth subscale recognized in this study; it is related to disease and social anxiety (36). As Willgoss et al. state, social anxiety and anxiety due to respiratory distress affect physical function and HRQL (45). The "psychological well-being" factor with the most number of items assesses depression, feelings of hopelessness, and coping with the illness. It is recognized as an important subscale associated with positive health outcomes. Dean et al. investigated "psychological well-being" and attempted to predict HRQL; they indicated that HRQL decreases with an increase in isolation and depressive symptoms (46). Other subscales, including "social functioning" and "physical functioning", focus on free time, social interactions, and daily activities, respectively.

Convergent validity evaluation in the present study showed that all subscales enjoyed acceptable convergent validity, and the items in each component were correlated to each other with a high variance.

In this study, evaluating McDonald's omega, average inter-item correlation, and Cronbach's alpha indicated appropriate and acceptable internal consistency in the subscales and the entire questionnaire. Similarly, other studies revealed that various versions of HRQL-SRI enjoyed good internal consistency; for example, Kotanen et al. reported Cronbach's alpha between 0.67 and 0.8 in the subscales for the Finnish version (32). Similarly, Chen et al, investigating the psychometric properties of the Chinese version of HRQL-SRI, reported the internal consistency between 0.71 and 0.92 in the subscales (47). Moreover, the ICC index was utilized to assess the stability and repeatability of the questionnaire. In the present study, the ICC value ranged between 0.804 and 0.899. According to Sarhadi et al., a stability value of greater than 0.8 is highly desirable (48). In line with the stability values reported in the present study, another study working on the Finnish version of HRQL-SRI found that the instrument's stability ranged between 0.93 and 0.97 (32). Confirming the internal consistency in the Persian version and other versions performed in other countries indicates the homogeneity of the items and the repeatability of the instrument.

All subscales in HRQL-SRI-P were responsive to changes over time Also, the psychological well-being subscale had the highest average. This is in line with the study of Fadaeeaghdam et al. It can be said that most of the patients were old and adapted themselves to the limitations caused by old age (49). Furthermore, the

physical functioning subscale was reported with the lowest mean in health-related quality of life. This is congruent with Tokuno et al. and Huttmann et al. (50, 51).

Applying standard instruments compatible with the culture can facilitate data collection from the patient, improve the relationship among the patient, nurse, and physician, and enhance the process and outcome of care (52). This study attempted to evaluate the psychometric properties and cultural compatibility of the HRQL-SRI questionnaire in the Iranian context. One of the strengths of the present study was the large sample size and data collection from a center with greater variety compared to other evaluated psychometric versions of the SRI questionnaire. The findings of this study are subject to at least two limitations. The first limitation is the lack of using spirometry tests as a clinical indicator in respiratory patients due to the coincidence of sampling with COVID-19 and the risk of virus transmission among the patients. Another limitation is the heterogeneous distribution of the patients with the predominance of COPD patients compared to those with NMD and pulmonary fibrosis due to the characteristics of the study population.

CONCLUSION

HRQL-SRI-P as a valid and reliable questionnaire with 40 items and 7 subscales can accurately evaluate chronic patients with SRI from all dimensions. The evaluation results can be effective in clinical decision-making with the aim of changes in treatment-care programs, reducing the severity of the disease and predicting the outcomes. Therefore, it is recommended to use the HRQL-SRI-P questionnaire to monitor the severity and progress of the disease and evaluate treatment interventions. HRQL-SRI-P questionnaire as the first Iranian questionnaire can be used for all researchers and lecturers of medical sciences universities, clinical research centers, and nurses working in respiratory wards and intensive care units.

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Transparency declaration

The authors declare that there is no conflict of interest.

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