

# Validity and Reliability of the Persian Version of the St. George Respiratory Questionnaire for COPD

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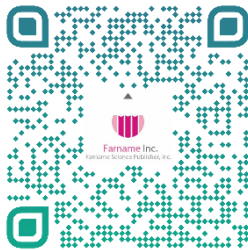
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## ABSTRACT

**Background & Objective:** Chronic obstructive pulmonary disease (COPD) is a common disease that causes 6% of deaths, 90% of which occur in low- and middle-income countries. Improving these patients' quality of life (QOL) is one of the primary treatment goals. The St. George's Respiratory Questionnaire (SGRQ) is used to measure the health status of patients with respiratory problems. This research aimed to assess the health status of patients with COPD after validating the Persian version of this questionnaire.

**Materials & Methods:** The study was performed from Feb to Oct 2016 in Shiraz, Iran. First, the Persian version of the questionnaire was validated using a back-translation technique by two translators, supervised by two researchers, and finally approved by two pulmonologists. The test-retest method was used to investigate the questionnaire's reliability. The questionnaire was used to assess the health status of 158 COPD patients with FEV<sub>1</sub>/FVC ratio ≤ 0.7 or FEV<sub>1</sub> < 80%, without exacerbation, cardiac disease, or recent hospitalization.

**Results:** The reliabilities of the first part (questions 1-7) and second part (questions 8-14) of the questionnaire was 0.64 and 0.90, respectively. The current health was good, fair, poor, and very poor in 7.6%, 22.2%, 44.9%, 22.8%, and 2.5% of the patients, respectively. The mean ± standard deviation (SD) scores calculated for symptoms, activity, and impact were 54.216 ± 23.725, 41.477 ± 24.996, and 37.482 ± 26.390, and the total score was 133.176 ± 69.284.

**Conclusion:** The Persian version of the SGRQ-C was valid and reliable. The patients with COPD at our center had a good health status.

**Keywords:** Pulmonary Disease, Chronic Obstructive; Quality of Life; St. George Respiratory



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## Introduction

Chronic obstructive pulmonary disease (COPD) refers to progressive respiratory conditions including emphysema and chronic bronchitis. It is characterized by cough, difficulty breathing, and airflow limitations, which are commonly associated with smoking (1). COPD is considered a common global health problem with an estimated prevalence of 10% and a substantial disease burden (2). It was the fourth cause of mortality in 1990, changed to third in 2010. It was reported that 90% of this disease occurs in low- and middle-income countries (3).

COPD significantly impairs patients' health-related quality of life (HRQOL). It was ranked among the top five diseases affecting patients' Quality of Life (QOL) in 2020 (4). One of the crucial features of the disease associated with QOL and mortality is disease exacerbations, which should be appropriately managed (5). Therefore, the evaluation of HRQOL is considered an essential step for

patients' management and policy-making (6). In randomized controlled trials, the primary outcome is usually the change in mean forced expiratory volume in the first second (FEV<sub>1</sub>) resulting from treatment. However, the functional measures that physicians might consider for management decisions may not be related precisely to the perception of the disease by the patient. In recent years, patient-reported outcomes (PROs) have been considered essential (7). Most COPD trials used lung function (usually FEV<sub>1</sub>) as the primary outcome. Whereas physicians usually make changes to therapy based on patients' symptoms. This leads to the development of PROs as methods for evaluating clinical information (8). This information is used to assess the efficacy of indacaterol and dual combination bronchodilators to improve the health status of COPD patients (9).

General questionnaires, like the Short Form Health Survey (SF-36), can only show the general QOL of patients. However, disease-specific questionnaires are more commonly used, as they specifically address the features of the target disease (10). The St. George's Respiratory Questionnaire (SGRQ) was designed by Jones et al. (11) to evaluate patients' health status with airway diseases and was used to measure the health status of patients with COPD. This standard questionnaire has been translated into several languages, such as Spanish (12), Swedish (13), and Chinese (14), with acceptable validity and reliability (Cronbach's coefficient alpha ( $\alpha$ ) >0.7) and have been used to investigate different conditions, such as patients with bronchiectasis (15), asthma (14), and COPD (13, 16). Although the Persian version of the SGRQ was also validated (17). The St. George's Respiratory Questionnaire for COPD patients (SGRQ-C) is a shorter version of the SGRQ, derived from the original version. It is valid for COPD, however, has not yet been validated in Persian. Due to the increasing COPD-related mortality in Iran and the tremendous economic burden caused by the disease in this country (18), we aimed to validate a standard measure for assessing COPD patient outcomes in Persian to provide a broader view of the health status of Iranian patients with COPD.

## Materials and Methods

### Study design

The study protocol was approved by the Ethics Committee of Shiraz University of Medical Sciences (code: IR.SUMS.med.REC.1394.S38). In the first phase of this study, the questionnaire was translated into Persian for assessing its validity and reliability, and in the second phase, the validated questionnaire was used to assess the health status of patients with COPD in the selected patients.

The SGRQ-C is a self-report questionnaire that contains 14 questions in the following two parts. The first part (questions 1-7) assesses the frequency of respiratory symptoms, and the second part (questions 8-14) assesses the current status of the patients. All questions are answered based on multiple-choice questions. The choices are weighed, and scorings are reported for symptoms, activity, and impacts (19).

In the first phase of the study, the UK/English version of the SGRQ-C was used to validate the Persian version. First, the questionnaire was translated by an expert translator into Persian, and the translated version was examined by a committee of two researchers for any necessary changes. Then another translator expert retranslated the Persian version into English. Two translators compared the English version (translated back from the Persian version) with the original text of the questionnaire (in English). They corrected the Persian translation differences and confirmed the Persian version. Two pulmonologists finally approved the Persian version. According to Iranian Islamic law, the word "dance" from

the section "g" of question 12 was omitted. The content validity ratio was obtained for each item of the questionnaire. The translated questionnaires were distributed among a panel of experts and asked whether each item was essential or valuable but not essential or unnecessary.

First, the test-retest method was used to assess the reliability of the Persian version. For this purpose, 30 patients with dyspnea at different stages of COPD who were referred to the same center were selected. After being informed about the study objectives, they signed the written informed consent and completed the prepared version of the questionnaire. Then a researcher interviewed them for any need for clarification of questions. After two weeks, the researcher asked the participants to complete the questionnaire again with the same protocol. The place and time of completing the questionnaire were based on the patient's preferences.

In the second phase of this study, the validated questionnaire was used to assess the health status of the patients in this study. First, the study's sample size was 160, based on the study by Ferrer et al. (20), considering error type I of 0.05 and power of 80%. The patients were selected sequentially from those referred to the lung lab of Shahid Faghih Hospital, affiliated with Shiraz University of Medical Sciences, from Feb to Oct 2016. Adult patients (aged >40 years) with the diagnosis of COPD based on the pulmonologist's diagnosis [according to the latest version of Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria, 2017] (21) who were referred for pulmonary function tests were considered for the study and patients who had an FEV<sub>1</sub>/FVC (forced expiratory volume in first second/forced vital capacity) ratio  $\leq$  0.7 were included into the study. Any patient with COPD exacerbation, cardiac disease, or requiring hospital admission was excluded from the study. After the selection of patients according to the above inclusion/exclusion criteria, the researcher explained the study objectives to the patients and how to complete the questionnaire, obtaining written informed consent from them for their participation. The patients who could read the questionnaire completed the questionnaire themselves, and for the others who could not, the researcher completed the questionnaire by interview. To decrease the chance of unfilled questionnaires, the researcher remained with the patients to ensure that all the questions were answered.

The health status of the patients (based on the questionnaire) and the demographic and spirometric results of the patients were recorded and reported in the results section.

### Statistical analysis

For the first phase of the study, Cronbach's coefficient alpha was calculated to assess the test-retest reliability; values <0.5 were considered unacceptable, 0.5-0.6 poor, 0.6-0.7 questionable, 0.7-0.9 acceptable, and >0.9 excellent (22). In the second phase of the study, patient's responses to the questionnaires were weighed according to the manual and mean  $\pm$  standard deviation (SD) of

scores which were reported for symptoms (with a maximum of 566.2), activity (with a maximum of 982.9), and impact (with a maximum of 1652.8), making a total score of 3201.9 for the whole questionnaire (19). The Spearman correlation coefficient was used to examine the correlation between total SGRQ-C and its sub-scales scores with FEV<sub>1</sub>% and FVC predicted.

The frequency (percentage) has been reported for qualitative variables. All statistical analyses were performed by the statistical software IBM SPSS Statistics for Windows version 21.0 (IBM Corp. 2012. Armonk, NY: IBM Corp.). The content validity ratio was calculated according to the  $CVR = [(E - (N / 2)) / (N / 2)]$  using the total number of experts (N) and the number who rated the object as essential (E) (23).

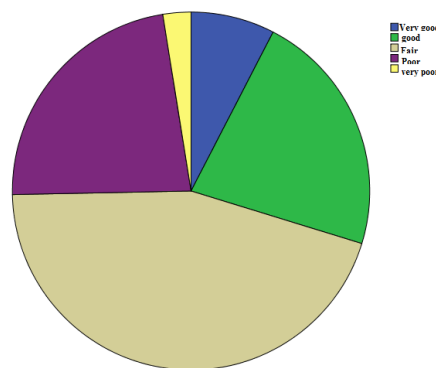
### Results

The test for internal consistency revealed a Cronbach's coefficient alpha of 0.641 and 0.642 for the whole questionnaire and the first part of the questionnaire (questions 1-7), respectively, and excellent internal consistency for the second part (questions 8-14) (Cronbach's coefficient alpha = 0.901). A correlation  $\geq 0.7$  indicated that questions are likely to measure the same construct (24). According to the reliability calculation after deleting each question, it was observed that Cronbach's coefficient alpha increased to 0.732 if question 4 was deleted.

After consultation with a panel of 5 experts, the CVR was 1 for questions 1-13, so they were valid, and 0.6 for question 14 (25). After validation of the questionnaires,

it was finally completed by 158 participants. The results of assessing patients' health status by the questionnaire are as follows:

The current health was scored as very good, good, fair, poor, and very poor in 7.6%, 22.2%, 44.9%, 22.8%, and 2.5% of the patients, respectively (Figure 1).



**Figure 1.** The frequency of the participant's answers to the general questions of current health status in St. George's Respiratory Questionnaire.

The sum of symptoms was 306.98, and the mean±SD score calculated for a symptom was 54.216±23.725%. The mean±SD of the sum of activity was 476.26, and the mean±SD score calculated for activity was 48.45±27.22%. The sum of impact was 619.51, and the mean±SD score calculated for impact was 37.48±26.390%. The total sum was 1405.20, and the mean±SD score calculated for the total score was 43.89±23.62% (Table 1).

**Table 1.** Demographic and the scores of the St. George's Respiratory Questionnaire of the studied patients

	Variable	Values
	Age(year)	54.15±13.44
Demographic data	Sex(male/female)	133/25
	BMI(Kg/m <sup>2</sup> )	24.64±4.86
	Symptoms	54.216 ± 23.725
The scores of St. George's Respiratory Questionnaire dimensions	Activity	48.45±27.22
	Impacts	37.48 ± 26.390
	Total score	43.89 ± 23.62

Values are presented as means±SD. BMI=body mass index.

A significant negative correlation was found between symptom, activity, total score, and FEV<sub>1</sub>. A significant positive correlation was found among all sub-scales of SGRQ-C. Body Mass Index (BMI) did not correlate with

domains of SQRQ-C (Table 2). A negative correlation between age and symptom score ( $r=-0.543$ ,  $p<0.01$ ) in the subgroup of patients with FEV<sub>1</sub>≥65% (Table 2) was found.

**Table 2. Correlation of lung function and other variables with SGRQ-C scores**

	Symptoms score	Activity score	Impacts score	Total score
	<b>r value</b>			
<b>FEV1</b>	-0.162*	-0.228**	-0.144	-0.187*
<b>FVC</b>	0.001	-0.130	-0.024	-0.056
<b>Gender</b>	0.146	0.098	0.96	0.119
<b>Age</b>	-0.097	0.058	-0.060	-0.028
<b>BMI</b>	-0.099	-0.028	-0.047	-0.050
<b>Current health</b>	0.505**	0.421**	0.442**	0.496**

\*\* P value<0.01, \* P value<0.05, r Values and p values were obtained by Spearman rank correlation analysis

## Discussion

The results of the first phase of the present study on the validation of SGRQ-C in Persian indicated excellent reliability (>0.9) in the second part. The Cronbach coefficient of 0.64 in the first part and in total was obtained which increased after deleting question 4. This question addressed the time of wheezing, which might be shown inaccurately by patients due to inattention or forgetting the time of the incident. Moreover, the reason could be the incomplete knowledge of patients in the present study on the correct definition or diagnosis of wheezing. The SGRQ has been validated in more than 35 languages, but the reliability coefficients varied in different languages. The Chinese version of the SGRQ indicated similar results to our study Chan et al. (26) reported Cronbach's coefficient>0.7, except in symptoms (Cronbach's coefficient of 0.6). Although they evaluated patients with bronchiectasis, we focused on patients with COPD. The American version of the SGRQ in COPD patients also reported a Cronbach's coefficient>0.7 for all dimensions, except symptoms (16). These results may suggest that although the COPD-specific questionnaire has acceptable reliability in UK/English and is similar to the original version (27), the translations in different languages do not have the same high reliability. The reasons for these differences could be due to the disease characteristics in different nations, which also can vary based on social and cultural contexts, gender, ethnicity, lifestyle, education levels, professional skills, and knowledge disparities among COPD patients (28, 29).

The results of the second phase of the present study indicated that the current health status of participants was very good in about 8%, good in 22%, fair in 45%, poor in 23%, and very poor in 2.5% of the participants. The mean±SD scores calculated for a symptom, activity, impact, and the total score were 54.216±23.725, 48.45±27.22, 37.48±26.39, and 43.89±23.62, respectively. Although the majority of participants had marked their current health status as not poor or very poor, the reported scores indicated inappropriate HRQOL in the studied patients. It might be due to the lack of knowledge of the patients about

the different dimensions of their disease. Ferrer et al. (20) reported the mean SGRQ scores in normal subjects in a general Spanish population and reported the normal scores of participants without COPD at 12, 9, 2, and 6, for symptom, activity, impact, and total scores, respectively. They reported variations in these scores according to patients' age, sex, educational level, and concomitant diseases like asthma, and smoking status. In another similar study on 1817 patients with COPD, Jones et al. (6) reported a mean total SGRQ score of 44.7±19.4 and interpreted it as a marked impairment of HRQL. They declared that the total scores varied from about 40 to 50 according to the studied countries (6). In addition, Tashkin et al. (30) reported a mean total score of about 46 on about 6000 patients. Rutten-van Mólken et al. (31) found a total mean score of 48-50 in different drug groups. In a study on 37 COPD patients in Iran by Mirdamadi et al. (32), the total SGRQ score was 44.5±22.1 and negatively correlated with FEV<sub>1</sub>.

Although the total score reported in the present study was much higher than (6, 30, 31), the mean score of symptom dimension (54.2) was lower than the Jones' study (6) and even in patients at the first stage of COPD (56.2). It was similar to Rutten-van Mólken's study (31) in the placebo group (54.4) and in the salmeterol+ipratropium bromide group (54.0). Also, the mean activity score in the present study was 48.45, which was less than the above-mentioned studies, even in patients in the first stage of COPD (47.6). It was much less than that of Rutten-van Mólken's study (64-65 in different groups) (31). Furthermore, the mean impact score of the present study (37.4) was similar to the salmeterol+ipratropium bromide group in the study by Rutten-van Mólken et al. (31). At the same time, it was much higher than that in Jones' study, reporting the mean impact score at different disease stages ranging from 27.8 to 33 (6). These variations can be attributable to different patients and disease characteristics between studies. Considering that the minimum clinically significant difference in SGRQ is set at four units (33), paying attention to these values is of great importance. In view of the inappropriate health status of the studied

patients, it is necessary to implement effective measures for improving the HRQOL of patients with COPD at this center.

One of the crucial issues in assessing the HRQOL of patients with COPD is the different variables affecting it (28). A study in Iran has suggested that patients' socioeconomic status and income are essential predictors of HRQOL in COPD patients (34). In addition, the disease severity, the presence, and the number of concomitant comorbidities are considered essential predictors of HRQOL in patients with COPD (6, 35). Therefore, differences between the studies worldwide may not specifically be attributed to the difference in the patient's HRQOL but may be due to the differences in patients' characteristics, disease features, and socioeconomic status, as explained above.

The limitation of the present study was the selection of samples from a single center that might not be representative of the general population limiting the generalizability of the results. However the study contained all of the patients with stable COPD followed in the hospital during their illness period with different severity of disease, the response rate was good, and patients consented and wanted to complete the questionnaire.

## Conclusion

The present study results showed that the Persian version of SGRQ-C had acceptable reliability and validity and could be used in Iranian patients with COPD. The results of assessing the health status of 158 patients with COPD showed that only about 25% of them had poor or very poor current health status. The majority (75%) considered their current health status desirable. However, the scores of three dimensions, including symptom, activity, and impact, were relatively high. The total score was inappropriate as well, which indicated impaired HRQOL in these patients and called for greater attention to the health status of these patients and implementing the necessary measures for better management and patient care at the study center. Future multicentric studies can investigate Iranian patients from different cities and ethnicities to examine the differences and predictors of the health status of patients with COPD across the country.

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## Conflict of Interest

The present study's authors declare that they have no conflicts of interest.

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