

## Original Article



# Rhinosinusitis Quality-of-Life Assessment: A Persian Adaptation and Validation

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## Abstract

**Background:** Rhinosinusitis involves inflammation within the paranasal sinuses and the nasal mucosa. It is a very common chronic health condition. This paper performs a validation process on the Persian translation of the rhinosinusitis quality-of-life questionnaire (RhinoQOL), for use in clinical assessment of chronic rhinosinusitis (CRS) patients. The Lund-Mackay score is also used widely in assessing CRS, and this study aims to describe its relationship to RhinoQOL.

**Methods:** The Persian RhinoQOL adaptation was carried out on 110 CRS patients. A follow-up questionnaire was completed two weeks later. Psychometric properties were determined by statistical analysis (reliability, reproducibility, validity, responsiveness). A total of 45 patients were included for radiologic score calculation. The Spearman's test was used for assessing the correlation between the RhinoQOL scores and Lund-Mackay score.

**Results:** Internal reliability was excellent for the impact scale (Cronbach's alpha=0.92). Cronbach's alpha was 0.63 and 0.55 for frequency and irritation scales, which reflects lower internal consistency values. Temporal stability or Test-retest reliability was excellent across all three scales. ICC was 0.96, 0.97, and 0.99 for RhinoQOL frequency, irritation, and impact scales. No significant correlation was observed between the Lund-Mackay score and RhinoQOL scores in terms of frequency, irritation and impact scales.

**Conclusion:** The Persian version of RhinoQOL appears to be as reliable, valid, and sensitive to change as the English version.

**Keywords:** Lund-Mackay scoring, Quality of life, Questionnaires, RhinoQOL, Sinusitis

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## Introduction

Rhinosinusitis, which involves paranasal sinus inflammation and nasal mucosa inflammation, can be classified by duration as acute (symptoms less than 4 weeks) or chronic (symptoms more than 12 weeks).<sup>1</sup> Chronic rhinosinusitis (CRS) is a very common chronic health condition. According to the 2008 National Health Interview Survey data, CRS affects 1 in 7 adults in the United States.<sup>2</sup> A European multi-center study showed an overall prevalence of 10.9%, based on self-reported criteria.<sup>3</sup> Several studies have estimated the total direct annual cost of CRS within the US healthcare system to range between \$6.9 and \$9.9 billion in 2014 (in comparison with the total 2014 US healthcare spending of \$831 billion). The total indirect annual cost was estimated at \$13 billion in 2014, which represents a significant loss of productivity associated with this health condition.<sup>4</sup>

Various instruments have been proposed to subjectively measure health-related quality of life (HRQOL). Some of these instruments measure general health (generic measures), while others are designed for use in special health conditions. These instruments, typically questionnaires, allow comparison between conditions or treatments, and thus help in assessing the relative cost utility of interventions.<sup>5</sup>

Since 1995, numerous sinusitis-specific HRQOL

measures have been developed, including: Chronic Sinusitis Survey<sup>6</sup>; Sinonasal Outcome Tests (SNOT20, SNOT22), which are modified versions of the Rhinosinusitis Outcome Measure (RSOM-31)<sup>7-9</sup>; the Rhinosinusitis Disability Index (RSDI)<sup>10</sup>; and the Rhinosinusitis Quality of Life Survey (RhinoQOL). RhinoQOL is one of the most recently developed and frequently used instruments. The English version of RhinoQOL was developed in 2005 by Atlas et al. Its validity has been demonstrated in English-speaking patients with both acute and chronic sinusitis.<sup>11</sup> Since then, it has been cross-culturally adapted to French, Portuguese and Moroccan,<sup>12-14</sup> but as yet, it is not available in Persian. The aim of this paper is to adapt the RhinoQOL culturally into Persian for use with Persian-speaking individuals. Psychometric evaluation was then performed for the Persian version of RhinoQOL.

## Materials and Methods

### Translation of RhinoQOL

RhinoQOL is a 17-item questionnaire with three scales: symptom frequency (Q1 to Q5: 5 items); symptom impact (Q6 to Q14: 9 items) (both of which use a 5-point grading score ranging from 0 to 4); and symptom irritation (Q1a to Q3a: 3 items), which uses an 11-point rating scale ranging from 0 to 10. Results in each domain are transformed onto a 0-100 scale for reporting purposes. Lower scores

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indicate poorer health status and higher symptom impact. The corresponding author of the original article was first contacted and asked for permission. Translation and cross-cultural adaptation was performed following standard procedures.<sup>15,16</sup> At first, forward translation from the original language to Persian was performed separately by two translators, one of whom was aware of medical concepts and one with no medical background. Next, the two translations were synthesized in the presence of the two translators by choosing the optimal wording for each item. Then, a final consensus version was translated back to English independently by two professional translators who were unaware of the original questionnaire, as validity check.<sup>15</sup> Finally, all translation reports were reviewed by a committee consisting of an otolaryngologist, a methodologist familiar with the adaptation process, and the translators. They reached consensus on any discrepancies and produced the final version of the survey.

### **Participants and Study Design**

The study was conducted at Amir Alam hospital, a tertiary care hospital. For the psychometric evaluation, 110 patients diagnosed with CRS were included in the study. Diagnostic criteria were defined by the American Academy of Otorhinolaryngology - Head and Neck Surgery. Patients presented with two or more of the following symptoms for a minimum of 12 weeks: mucopurulent drainage; nasal obstruction; facial pain-pressure-fullness; decreased sense of smell; and inflammation. The latter was diagnosed by either nasal endoscopy (purulent mucus or edema in the middle meatus/anterior ethmoid region, or by finding polyps within the nasal cavity or the middle meatus), or by computed tomography (CT) scans of the paranasal sinuses. Other inclusion criteria were: age  $\geq$  18 years, native Persian speaker, and available to repeat the questionnaire within 2 weeks. The exclusion criteria were: sinonasal malignancy, invasive fungal sinusitis, sarcoidosis, Wegener's granulomatosis, and recent trauma. Individuals in the CRS group completed the questionnaire during the first visit, after the diagnosis was confirmed. They were also asked to answer the questions again after approximately 2 weeks. A control group of 100 healthy volunteers who had no history or current nasal sinus disease were included.

### **Radiologic Score**

The diagnosis was confirmed by either CT scan or nasal endoscopy. To assess the correlation between quality of life measurements and radiologic disease severity measures, CT scans were staged with reference to the Lund-Mackay system, whereby each sinus group is scored as follows: 0=no abnormality; 1=partial opacification; and 2=total opacification. The ostiomeatal complex is scored as 0=not obstructed or 2=obstructed. To ensure that the two measurements are made in the same conditions, the radiologic score is evaluated only if they were less than one week apart. A total of 45 patients were included for

radiologic score calculation.

### **Statistical Procedure**

Statistical analysis was conducted using SPSS version 22 (SPSS, Inc., Chicago, IL, USA). All data analyses were performed separately for the three domains. Internal consistency and reliability were assessed using Cronbach's alpha coefficient upon each scale. The intraclass correlation coefficient (ICC) was evaluated to determine the test-retest reliability for each scale; the RhinoQOL was administered twice to the patients with CRS (baseline and retesting responses). The unpaired Mann-Whitney U test was implemented to assess discriminant validity, showing the ability of RhinoQOL to differentiate between CRS patients and healthy volunteers. The correlation between radiologic score and quality of life scores was calculated separately in three subscales of the RhinoQOL instrument using the Spearman's test.

## **Results**

### **Participant Characteristics**

A total of 115 patients diagnosed with CRS were recruited, and 5 patients were excluded due to inability to follow-up. Of these, 79 participants (71.8%) were male. The mean age in the CRS group was 37.08 (SD 10.89). The control group comprised 100 healthy volunteers, of whom 71 (71%) were male. The mean age in this group was 36.13 (SD 10.45). There were no significant differences between the groups in terms of age and gender.

### **Reliability Assessment**

Internal reliability was excellent for the 9-item impact scale (Cronbach's alpha was 0.92, CI: 0.89–0.94), which shows that items in this scale excellently measured a single concept. Cronbach's alpha was 0.63 (CI: 0.51–0.73) and 0.55 (CI: 0.39–0.68) for the frequency and irritation scales, which reflects lower internal consistency values. The item to total correlation coefficients for each subscale are displayed in [Table 1](#).

This coefficient compares the correlation of the score of each item in a scale to the total score of that scale. Temporal stability or Test-retest reliability was excellent across the three scales. ICC values were 0.96 (CI: 0.952–0.977), 0.97 (CI: 0.956–0.979) and 0.99 (CI: 0.992–0.996) for the frequency, irritation, and impact scales of RhinoQOL, respectively.

### **Validity Assessment**

The questionnaire discriminant validity was evaluated by comparing the RhinoQOL scores in each scale between CRS participants and healthy controls. The results are displayed in [Table 2](#). The results demonstrated that the questionnaire had an excellent ability to discriminate between the groups.

The correlation between RhinoQOL scores and Lund-Mackay score was assessed using the Spearman's test, as shown in [Table 3](#). No significant correlation was seen

between the Lund-Mackay score calculated based on paranasal CT scan and RhinoQOL scores, in terms of frequency, irritation and impact scales.

### Discussion

Rhinitis and rhinosinusitis include multiple chronic conditions with high incidence rates. Rhinosinusitis has been defined as nasal and paranasal sinus inflammation. It is characterized by two or more symptoms, including nasal blockage/obstruction/congestion or nasal discharge; and/or endoscopic evidence of polyps; and/or mucopurulent discharge; and/or CT scans demonstrating mucosal changes within the ostiomeatal complex and/or sinuses.<sup>17</sup>

**Table 1.** Item to Total Correlation Coefficients for Each Subscale

Items	Item to Total Correlation Coefficient
<b>Frequency Scale</b>	
Q1. Sinus headaches, facial pain or facial pressure	0.26
Q2. Blocked or stuffy nose	0.51
Q3. Post-nasal drip	0.27
Q4. Thick nasal discharge	0.57
Q5. Runny nose	0.34
<b>Irritation Scale</b>	
Q1a. Sinus headaches, facial pain, or facial pressure	0.36
Q2a. Blocked or stuffy nose	0.40
Q3a. Post-nasal drip	0.32
<b>Impact Scale</b>	
Q6. Tired or fatigued	0.59
Q7. Trouble sleeping	0.76
Q8. Harder to concentrate	0.68
Q9. Harder to do the things you normally do	0.66
Q10. Embarrassed	0.68
Q11. Frustrated	0.81
Q12. Irritable	0.72
Q13. Sad or depressed	0.77
Q14. Think about	0.75

**Table 2.** Discriminant Validity of the RhinoQOL Questionnaire

Score	Group	N	Mean	P value
Frequency	CRS	110	48.18 (19.05)	<0.001
	Control	100	97.0 (4.26)	
Bothersomeness	CRS	110	45.30 (22.50)	<0.001
	Control	100	97.73 (4.26)	
Impact	CRS	110	52.07 (27.53)	<0.001
	Control	100	98.25 (4.26)	

CRS, chronic rhinosinusitis

**Table 3.** The Correlation between RhinoQOL Scores and Lund-Mackay Score

	Frequency		Bothersomeness		Impact	
	Spearman Correlation Coefficient	P Value	Spearman Correlation Coefficient	P Value	Spearman Correlation Coefficient	P Value
Lund-Mackay score	0.016	0.917	0.115	0.454	0.116	0.450

RhinoQOL, rhinosinusitis quality-of-life questionnaire.

These symptoms are not life-threatening, but a range of studies have associated the conditions with lower quality of life scores (QOL).<sup>6</sup>

Moreover, using disease-specific questionnaires increases medical knowledge. More than 15 disease-specific questionnaires are known to exist in English. In this study, the goal of creating a Persian version of the RhinoQOL questionnaire<sup>11</sup> was achieved, matching it to a Persian cultural and medical context and thus addressing the lack of such a standardized assessment tool.

Translation and cross-cultural adaptation were performed following standard procedures, in the following order: forward translation from the original language to Persian; synthesizing the optimal translation for each item; validity checking the final consensus version by translating back to English independently by two professional translators; reviewing translation by a committee consisting of an otolaryngologist, a methodologist familiar with the adaptation process, and the translators.

The results of this cross-sectional study indicate that the reliability of the RhinoQOL questionnaire was excellent in all subgroups. Compared with previous studies, the ICC in our study is more compatible with the Moroccan version. As for the RhinoQOL, the ICC was 0.57, 0.66, and 0.67 for the frequency, irritation and impact scores in the English version, respectively. These were 0.96, 0.97, and 0.99 in the present paper. An excellent internal reliability was demonstrated for the 9-item impact scale (Cronbach's alpha 0.92), which shows that items in this scale excellently measure a single concept. Cronbach's alpha was 0.63 and 0.55 for the frequency and irritation scales, respectively, which suggests lower internal consistency. The discriminant validity was evaluated by comparing the RhinoQOL scores in each scale between CRS participants and healthy individuals in the control group. The results revealed that the questionnaire was also able to discriminate between the groups significantly.

In this study, we also observed that the radiological scale of disease severity is not related to any of the subscales of the RhinoQOL. As previously mentioned, in numerous studies on the relevance of radiologic findings by CT scan (characterized by symptoms and measures of quality of life), the majority of studies show a lack of connection between these two. However, the Moroccan version of the questionnaire revealed a significant relationship between the Lund-Mackay criterion and each subscale.<sup>14</sup>

In conclusion, the Persian version of RhinoQOL appears to be as reliable, valid, and sensitive to change as the English version. Even with lower internal consistency found in irritation and impact subscales as it is a scale

sensitive to reported changes, it could be used adequately to follow up and evaluate treatment response. Further studies are suggested to evaluate the susceptibility and variability of the questionnaire and its effectiveness in follow-up and treatment in Iranian society. Some of the cases did not have cross-sectional imaging within a week before or after completing the RhinoQOL instrument, so they were excluded from the study. Due to this, there was a smaller sample size in terms of evaluating radiologic scores.

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#### Authors' Contribution

BMA designed the article and collated information. SB and KA contributed to collecting patients. HA and MM analyzed the data. HA contribute to drafting manuscript. The study was conducted under supervision of NY. All authors have read and approved the manuscript.

#### Conflict of Interest Disclosures

The authors declare no conflicts of interest

#### Ethical Statement

All procedures involving human participants were conducted in accordance with the 1964 Helsinki declaration, as well as those of the institutional research ethical standards committee.

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