

The Persian Version of Reflux Sign Assessment Scale: Validity and Reliability for the Examination of Patients with Laryngopharyngeal Reflux Disease

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Abstract: Objectives/Hypothesis. The non-specificity of signs associated with laryngopharyngeal reflux disease (LPRD) makes the diagnosis challenging. This study aimed to evaluate the psychometric properties of the Persian version of reflux sign assessment (RSAP) in LPRD.

Study Design. This was a methodological study.

Methods. The prefinal version of RSAP was developed in a forward and backward translation protocol. It was completed by a speech-language pathologist (SLP) and an otolaryngologist for 20 LPRD patients to provide a final version. The final version was completed by a SLP (rater 1) for 42 LPRD patients and 42 healthy people. To study intra and inter-rater reliability, the RSAP was recompleted after 21 days by rater 1 and another SLP (rater 2), respectively. For construct validity, the reflux finding score and reflux symptom index was completed in the patients.

Results. There were significant differences in the subscales and total scores of RSAP between the patient and healthy groups ($P < 0.001$). The Cronbach's alpha of the total score was 0.76 and 0.72 for rater 1 and 2, respectively. Concordance correlation coefficient and intraclass correlation coefficient values for all scores showed excellent intra and inter-rater reliability. The total score had a significant positive correlation with the scores of reflux finding score and reflux symptom index ($r_p = 0.813$, $P < 0.001$ and $r_p = 0.811$, $P < 0.001$ respectively).

Conclusions. The current study indicated the RSAP is a valid and reliable scale for the examination of the vocal tract in LPRD. The RSAP can be used as a useful tool in clinical and research settings for Persian LPRD patients.

Key Words: Laryngopharyngeal–Reflux–Sign–Validity–Reliability–Persian.

INTRODUCTION

Gastroesophageal reflux disease⁵ (GERD) is one of the most common disorders of the digestive tract. GERD can be introduced as an acute disorder that occurs when contents in the stomach flow back into the esophagus or adjacent to it, and as a result, it causes a variety of supraesophageal and esophageal signs.¹ The prevalence of

GERD is increasing and its prevalence is higher in the Asian continent.² In Iran, the prevalence of GERD is relatively high and lifestyle has been known as a critical risk factor.^{3,4} Several reports indicate that more than 60% of GERD patients suffer from laryngopharyngeal reflux disease⁶ (LPRD).⁵ The retrograde flow of stomach contents back into the esophagus is known as GERD, while LPRD is the flow of stomach contents back into the upper respiratory-digestive system. The difference between GERD and LPRD lies in how they occur. In fact, heartburn and retrograde of food are common symptoms of GERD. However, such symptoms are not mostly observed in LPRD.^{6–8} Symptoms of LPRD include muscle tension dysphonia,⁷ laryngospasm, hoarseness, vocal fatigue, excessive throat clearing, globus pharyngeus, chronic cough, postnasal drip, and dysphagia. The cause of many laryngeal diseases including reflux laryngitis, subglottic stenosis, laryngeal carcinoma, granulomas, contact ulcers, vocal nodules, and arytenoid fixation can also be LPRD.⁶ LPRD is the cause of about 10% of the referrals to otolaryngologists.⁹

LPRD is often difficult to diagnose; it is likely misdiagnosed with other laryngeal diseases.¹⁰ LPRD is usually diagnosed by ear, nose, and throat physicians, lung

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⁵ gastroesophageal reflux disease.

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⁶ laryngopharyngeal reflux disease.

⁷ muscle tension dysphonia.

specialists, or general physicians.¹¹ To diagnose LPRD, the clinicians utilize different methods including ambulatory 24-hour double probe pH monitoring, upper gastrointestinal endoscopy, laryngoscopy, and self-assessment.¹² Each of these diagnostic methods has its own advantages and disadvantages. Although among them, the pH probe is considered the golden standard, it can lead to false-negative or false-positive diagnosis due to the change in the position or movement of the probe during the examination. Additionally, the evidence shows that intermittent reflux cannot happen during pH probe monitoring, which can also lead to errors in the diagnosis.¹³ Furthermore, this technique is very expensive, and using it as a common method is practically not possible, especially in developing countries. On the other hand, considering that the pH probe is classified as an invasive assessment method, it is difficult for many patients to tolerate it.¹⁴ Upper gastrointestinal endoscopy also has a low sensitivity for the diagnosis of LPRD. Many patients with LPRD do not have esophagitis or any other signs of lower esophageal sphincter weakness. Considering all limitations of the above diagnostic methods, it is suggested to diagnose LPRD based on the laryngoscopic examination and self-assessment.¹³

Today, laryngoscopy is known as a common clinical assessment method to diagnose and evaluation of patients with LPRD.¹³ Since the interpretation of the results of laryngoscopy is abstract and depends on expert judgment, researchers recently have tried to take effective steps in preparing LPRD evaluation tools based on the laryngoscopic findings to objectify these findings as much as possible. Toward this way, Belafsky et al (2001) developed a valid and reliable questionnaire scoring system called reflux finding score⁸ (RFS) that can help clinicians to diagnose LPRD based on the endolaryngeal inflammatory findings. According to the RFS, the probability of LPRD with a score higher than seven is 94%.¹⁵ However, the RFS has some disadvantages that limit its application. This questionnaire does not have the necessary sensitivity to the diagnosis of LPRD. The RFS is overly dependent on laryngeal signs, while according to the clinical reports, LPRD patients have some oral and pharyngeal signs in addition to the laryngeal signs that are not considered in this questionnaire.¹⁶ The mentioned issues made the researchers look for a more comprehensive questionnaire in order to overcome the existing limitations. In this regard, a questionnaire called reflux sign assessment⁹ (RSA) has been recently developed. The RSA addresses a wider range of signs related to LPRD in the vocal tract based on the clinical findings. In the RSA, the signs of LPRD are examined in the oral, pharyngeal, and laryngeal cavities separately and an individual score is documented for each. In

addition, a total score is reported for the scale which is a combination of these three scores.¹⁶

Considering the non-specificity of LPRD signs and the difficulty to perform the diagnosis, the preparation of the Persian version of RSA can make the role of laryngoscopy more documented and accurate in the clinical examination and diagnosis of LPRD. Eventually, it helps various specialists, especially in our country where the use of the golden standard faces many problems especially due to economic limitations. Therefore, the present study aimed to investigate the validity and reliability of the Persian version of reflux sign assessment¹⁰ (RSAp) for the examination of patients with LPRD.

MATERIAL AND METHODS

Study Design

The present study had two phases of adaptation and validation of the RSA. The first phase was a cross-sectional study designed for the cross-cultural adaptation of the RSA into the Persian language. The second phase followed a methodological study that was conducted to investigate the psychometric properties of RSAp. The present study was approved by the Ethics Committee of the School of Nursing, Midwifery, and Rehabilitation, Research Vice-Chancellor, Tehran University of Medical Sciences (Code number: IR.TUMS.VCR.REC.1398.882). Before study initiation, all subjects declared their consent to participate in the study.

Procedure

First Phase: Cross-Cultural Adaptation of the RSA Into the Persian Language

First, permission was obtained from the developer of the original version of RSA, Jerome R. Lechien, for cultural adaptation of the English version into the Persian language. Then, the process of cross-cultural adaptation was conducted based on the protocol proposed by Kristjansson et al¹⁷ For this purpose, the English version of RSA was first translated into Persian by one Persian-speaking speech-language pathologist¹¹ (SLP) and three Persian-speaking otolaryngologists who were fluent in English. Then, the translated Persian versions were integrated by a multidisciplinary expert team including two SLPs and an otorhinolaryngologist. The integrated Persian version of the scale was given to an expert team including one other SLP and three other otolaryngologists who were fluent in both Persian and English to translate it to English, separately. Finally, the prefinal version of RSAp was provided according to the versions translated into English and based on the opinion of the multidisciplinary expert team, in-

⁸ reflux finding score.

⁹ reflux sign assessment.

¹⁰ the Persian version of reflux sign assessment.

¹¹ speech-language pathologist.

cluding the developer of the original RSA. To evaluate the face validity and develop the final version of RSAP, the pre-final version was given to one SLP and an otolaryngologist who were experienced in the field of laryngoscopy to complete it on 20 patients diagnosed with LPRD. Therefore, the questionnaire was completed by these two clinical experts based on the information obtained from the examination of the oral cavity and pharyngeal cavity with a flashlight and the examination of the larynx with laryngoscopy examination. The SLP and otolaryngologist were asked to state if they had problems with understanding the concepts and terms used in the questionnaire or its wording to make necessary changes in the questionnaire based on their suggestions and in consultation with the multi-disciplinary expert team. Eventually, the final version of RSAP was produced (Appendix 1).

Second Phase: Study of Psychometric Properties of the RSAP

To investigate the psychometric properties of RSAP, the questionnaire was completed on two groups of participants including patients with LPRD ($n = 42$) and healthy people ($n = 42$), who were selected through convenience sampling. The Patients were selected by two SLPs who were experienced in the evaluation of voice disorders from a referral pool to a voice clinic in Karaj, Alborz, Iran. These patients were referred by otorhinolaryngologists for imaging of the larynx to the voice clinic between May 2020 to September 2021. Inclusion criteria for the patient group included 1) ages between 18 and 70 years; 2) having common symptoms of LPRD such as foreign body sensation in the throat, throat clearing, and altered voice quality; 3) a positive diagnosis of LPRD based on the RFS and the reflux symptom index¹² (RSI) ($RFS > 7$ and $RSI > 13$)^{15,18}; and 4) being able to read and write in the Persian language. The healthy group was selected from men and women volunteers who met the inclusion criteria. The inclusion criteria for the healthy group were 1) ages between 18 and 70 years; 2) lacking the common symptoms of LPRD such as foreign body sensation in the throat, throat clearing, and altered voice quality; 3) getting scores seven or less than seven and scores 13 and less than 13 in the RFS and RSI, respectively.^{15,18,19} Being able to read and write in the Persian language. Exclusion criteria in both patient and healthy groups were having a history of benign and malignant laryngeal lesions, heart problems, neurological or psychiatric disorders, pregnancy, smoking, and alcohol consumption, active seasonal allergies or asthma, head and neck surgery, trauma, or radiotherapy, surgery for digestive problems, upper respiratory tract infection within the last month, and current use of antireflux treatment (ie, proton pump inhibitors, H2 blockers, alginate, and/or magaldrate) based on the results of self-reporting and

history taking. In addition, people who were unable to tolerate laryngeal examination through videolaryngoscopy were excluded from the study. Healthy people were matched with the patient group in terms of age.¹⁶

To study discriminant validity, the scale was completed by a SLP (the first author, rater 1) who had experience in the field of assessment and treatment of voice disorders after examination of the oral cavity and performing laryngoscopy on the patients with LPRD and healthy people who met the eligible criteria. In addition, inter-rater and intra-rater reliability were examined. To evaluate intra-rater reliability, the rater 1 scored the RSAP again after 3 weeks (21 days) by reviewing the previously recorded videos and images. The RSAP was also recompleted blindly by another SLP (rater 2) experienced in the field of laryngoscopy to investigate inter-rater reliability. Finally, to evaluate construct validity, the correlation between the RSAP with the RFS and RSI was calculated for the patient group.¹⁶

The tools and instruments that were used in different stages of the study to select the participants and evaluate them have been described below:

History Taking Questionnaire. It was a researcher-made and paper-pencil questionnaire containing 18 qualitative items and data collection was based on the self-reporting. It examined the medical history and possible causes of LPRD symptoms, such as a history of smoking and alcohol consumption, benign and malignant larynx problems (polyps, nodules, etc.), neurological disorders (Parkinson's, tics, etc), psychiatric disorders (severe depression, obsessive-compulsive disorder, etc), cardiovascular diseases, head and neck surgery/trauma/radiotherapy, surgery related to digestive diseases, respiratory problems, and pregnancy. On the other hand, this questionnaire was used to evaluate the inclusion and exclusion criteria for the participants.

Reflux Finding Score (RFS). The RFS is an 8-item scale that is completed by an expert based on the expert's visual-perceptual judgment during laryngoscopy. The items are scored in a stepwise method according to the question asked so that the scores and findings vary from no abnormal findings (score 0) to the worst possible findings (score 26). Therefore, the score ranges from 0 to 26. A score higher than seven indicates LPRD.¹⁵ In this study, the RFS was used to select the participants in the patient and healthy groups. Moreover, it was utilized for investigating construct validity of the RSAP.

Reflux Symptom Index (RSI). The RSI is a 9-item self-reported questionnaire for the assessment of symptoms in patients with LPRD. It is scored based on a 5-point Likert scale so that 0 is considered for no problem and five for the severe problem. The score of RSI ranges from 0 and 45. A score higher than 13 indicates the presence of LPRD.¹⁸ In the present study, the Persian version of RSI was used to

¹² reflux symptom index.

select the participants and also to study construct validity of the RSAP.²⁰

Medical Flashlight. A medical flashlight was applied to examine the oral cavity and to complete the oral subscale of the RSAP.

Video Laryngoscopy. A video laryngoscope (STORZ, Lxstrobe, laryngograph), Light source (xe 180stb), Camera (Promis, ecs111fhd) with rigid endoscope (STORZ, 70 degree, 10 mm) was used to investigate the inflammatory symptoms caused by LPRD in the pharynx and larynx. So, it was utilized to complete the RFS and the pharyngeal and laryngeal subscales of the RSAP.

Statistical Analysis

The mean score of the oral cavity, pharyngeal cavity, and laryngeal cavity subscales as well as the total score were calculated and compared between the patients with LPRD and healthy people using the independent *t*-test to evaluate the discriminant validity of RSAP. To measure internal consistency, the Cronbach's alpha was calculated. The Cronbach's alpha greater than 0.7 indicates good internal reliability. The Cronbach's alpha of 0.7–0.8 is considered acceptable, 0.8–0.9 is good, and 0.9–1 is excellent.^{21,22} The inter-rater and intra-rater reliability were calculated to measure the external reliability of RSAP. For this purpose, the degree of agreement between the mean score of the oral cavity, pharyngeal cavity, and laryngeal cavity subscales and the total RSAP score were measured using a 45-degree line (equality line), the concordance correlation coefficient¹³ (CCC), the intraclass correlation coefficient¹⁴ (ICC), and the Bland-Altman plot in two examinations by the rater one and the examination by the rater two.²³ The values of CCC/ICC which are more than 0.75 indicate excellent intra-rater and inter-rater reliability, those from 0.4 to 0.75 are fair to good and those less than 0.4 are poor.²⁴ To investigate the convergent validity, the correlation between the total score of RSAP and the results of RFS and RSI were calculated using the Pearson's correlation coefficient.¹⁶ This coefficient can demonstrate a very weak and insignificant correlation ($r > 0.2$), weak correlation ($0.4 > r > 0.2$), moderate correlation ($0.6 > r > 0.4$), strong correlation ($0.8 > r > 0.6$), and very strong correlation (0.8).²⁵ The data were analyzed by the SPSS software version 22.0 (SPSS, Inc, Chicago, IL) and $P < 0.05$ was considered significant.

RESULTS

Characteristics of Participants

In the current study, 42 patients with LPRD (21 men and 21 women; with average age of 41.38 years) and 42 healthy

people (12 men and 30 women; with average age of 41.55 years) participated. The independent *t*-test was used to compare the average age between the patient and healthy groups and also to evaluate age homogeneity. The results showed that there was no significant difference between two groups in terms of age ($P = 0.95$).

Face Validity

According to the opinions of the SLP and otolaryngologist, there was no problem in understanding the concepts and terms used in the RSAP or its wording. These findings demonstrated the RSAP had face validity.

Discriminant Validity

The comparison of the mean score of the oral cavity, pharyngeal cavity, and laryngeal cavity subscales as well as the total score of RSAP using the independent *t*-test showed that there was a statistically significant difference between the patients with LPRD and healthy people ($P < 0.001$) (Table 1).

Internal Reliability

The Cronbach alpha measured by the rater one for the scores of oral cavity, pharyngeal cavity, and laryngeal cavity subscales in addition to the total score of the RSAP were equal to 0.71, 0.63, 0.49, and 0.76, respectively. Based on the reports of the rater two, the values of Cronbach alpha for the scores of oral, pharyngeal, and laryngeal cavities subscales and the total score of the RSAP were equal to 0.73, 0.53, 0.41, and 0.73, respectively.

External Reliability

Intra-rater Reliability

The distribution of the subscales and total scores of RSAP measured by the rater one along with the 45-degree line (line of equality) has been shown in Figure 1. The total score of RSAP was almost on a 45-degree line. A relatively similar trend was also observed for the scores of the oral cavity, pharyngeal cavity, and laryngeal cavity subscales.

In Table 2, the values of CCC and ICC have been demonstrated to determine intra-rater agreement of the RSAP. All CCC and ICC values for the subscales and total scores of RSAP were higher than 0.9. The highest correlation value was related to the oral cavity subscale and the lowest one was related to the laryngeal cavity subscale. The results obtained regarding the intra-rater agreement were also visually examined through the Bland-Altman plot (Figure 2). Regarding the total score, all points except two points (2.4%) were within the upper and lower limits of agreement. Additionally, no significant trend was seen in the distribution of points in this plot. A relatively similar trend was also observed for all subscales. For the oral cavity, pharyngeal cavity, and laryngeal cavity subscales, four points (4.8%), 13 points (15.5%), and two points (2.4%) were outside the upper and lower limits of agreement, respectively.

¹³ concordance correlation coefficient.

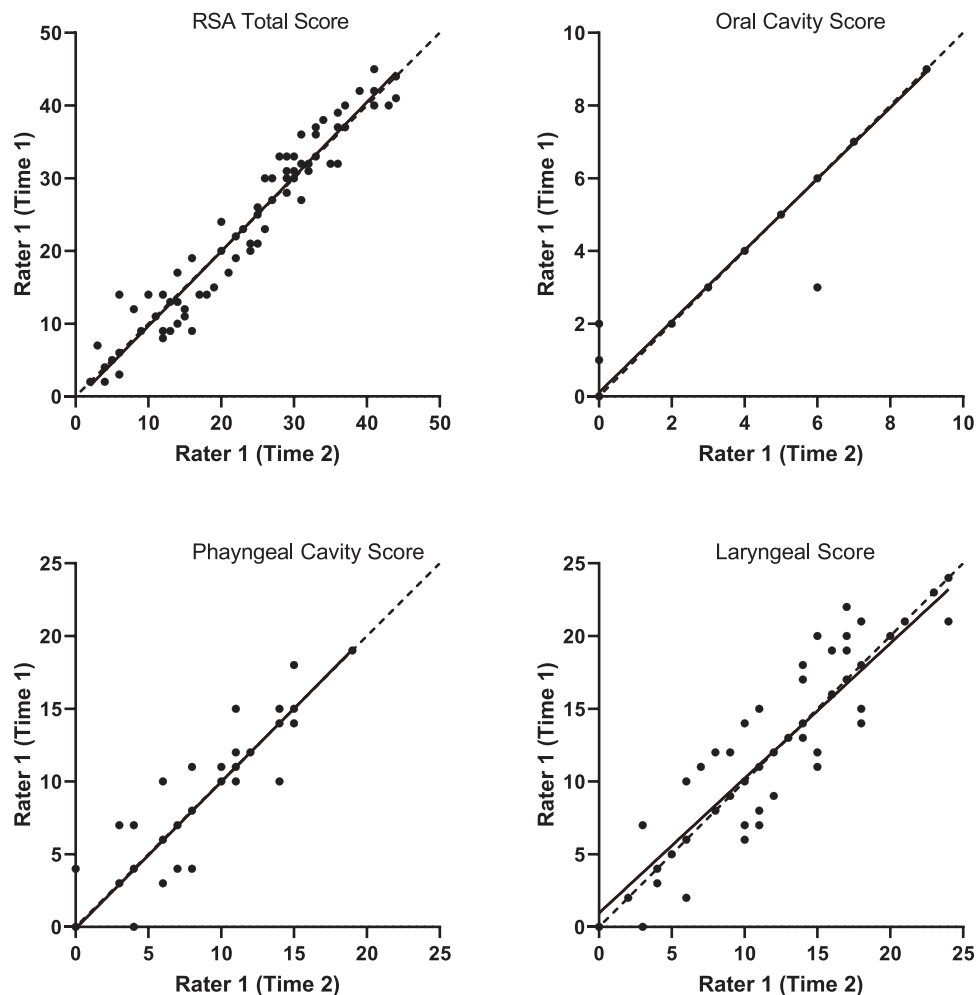
¹⁴ intraclass correlation coefficient.

TABLE 1.
Comparison of the Subscales and Total Mean Score of RSAp between the Patients with LPRD and Healthy People (n = 84)

The RSAp score	Mean score (Standard deviation)		$t_{(82)}^{\dagger}$	<i>P</i>	Effect size (<i>d</i>)
	Patients with LPRD (n = 42)	Healthy people (n = 42)			
Oral cavity subscale	7.14 (2.028)	1.98 (2.72)	9.44	<0.001*	2.06
Pharyngeal cavity subscale	9.60 (4.36)	2.86 (3.66)	7.67	<0.001*	1.67
Laryngeal cavity subscale	16.38 (3.90)	8.14 (4.13)	9.40	<0.001*	2.05
Total	33.12 (5.59)	12.98 (6.59)	14.70	<0.001*	3.21

RSA_p, the Persian version of reflux sign assessment; LPRD, laryngopharyngeal reflux disease.

* Independent *t*-test; Statistical significance at *P* < 0.05.

**FIGURE 1.** Distribution of the RSAp scores measured by the rater one in the first and second examinations with an interval of 21 days in the patients with LPRD and healthy people (n = 84).

Inter-rater Reliability

Figure 3 shows the distribution of the subscales and total scores of RSAp measured by the rater two along with the 45-degree line (line of equality). The total score of RSAp was almost on a 45-degree line and a relatively similar trend was observed for three subscales.

For the inter-rater agreement of the RSAp, the values of CCC and ICC have been shown in Table 3. All correlation values were higher than 0.91. The highest correlation value

was assigned to the oral cavity subscale and the lowest one was belonged to the subscale of laryngeal cavity. Figure 4 demonstrates the inter-rater agreement through the Bland-Altman plot. All points related to the total score, except for three points (3.6%), were in the upper and lower limits of agreement. There was no significant trend in the distribution of points. For the oral, pharyngeal, and laryngeal cavities subscales, four points (4.8%), 11 points (13.1%), and one point (1.2%) were outside the upper and lower

TABLE 2.
Intra-rater Agreement of the RSAP in the Patients with LPRD and Healthy People (n = 84)

The RSAP score	CCC (95% CI)	ICC (95% CI)
Oral cavity subscale	0.99 (0.98–0.99)	0.99 (0.99–0.97)
Pharyngeal cavity subscale	0.94 (0.90–0.96)	0.94 (0.90–0.96)
Laryngeal cavity subscale	0.90 (0.85–0.93)	0.90 (0.85–0.94)
Total	0.94 (0.94–0.98)	0.96 (0.94–0.98)

RSAP, the Persian version of reflux sign assessment; LPRD, laryngopharyngeal reflux disease; CCC, concordance correlation coefficient; CI, confidence interval; ICC, intraclass correlation coefficient.

limits of agreement, respectively. These results were approximately similar to the trend observed for the total score of RSAP.

Convergent Validity

The correlation analysis using the Pearson correlation coefficient showed a significant positive correlation between the total score of the RSAP with the score of the RFS ($r_p = 0.813$; $P < 0.001$) and RSI ($r_p = 0.811$; $P < 0.001$).

DISCUSSION

The purpose of present study was to investigate the psychometric properties of the RSAP for the assessment of patients with LPRD. The patients with LPRD obtained remarkably high scores in all three subscales of oral cavity, pharyngeal cavity, and laryngeal cavity as well as in the total score of RSAP compared to healthy people, indicating the discriminative validity of RSAP. The internal consistency of oral cavity subscale and total score of the RSAP were acceptable. The intra-rater and inter-rater reliability findings demonstrated that all subscales and total score of the RSAP have excellent agreement in several examinations. Moreover, the RSAP scale had an acceptable convergent validity based on the results of RFS and RSI. So far, the psychometric properties of RSA scale have only been studied for the original English version.¹⁶ However, the psychometric properties of the RFS, another tool suggested for the laryngoscopic findings of LPRD, have been studied in Brazilian and Polish languages in addition to the original version.^{13,15,26}

Firstly, translation and cross-cultural adaptation of the RSAP were conducted without any problems by the clinicians, revealing face validity of the RSAP. The current study indicated that the scores of oral cavity, pharyngeal cavity, and laryngeal cavity subscales and the total score of RSAP were higher in the patients with LPRD rather than the healthy

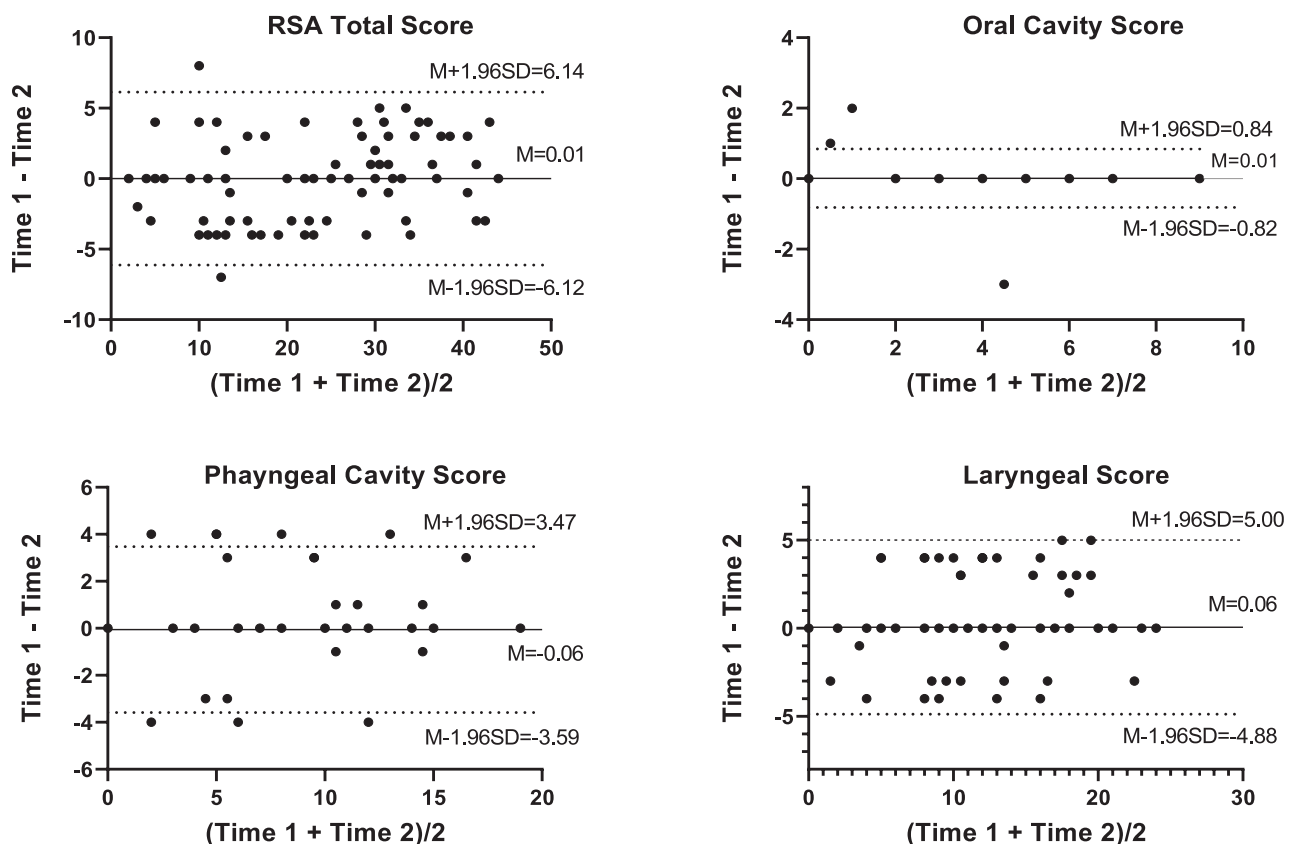


FIGURE 2. The Bland-Altman plot of RSAP scores measured by the rater one in the first and second examinations with an interval of 21 days in the patients with LPRD and healthy people (n = 84).

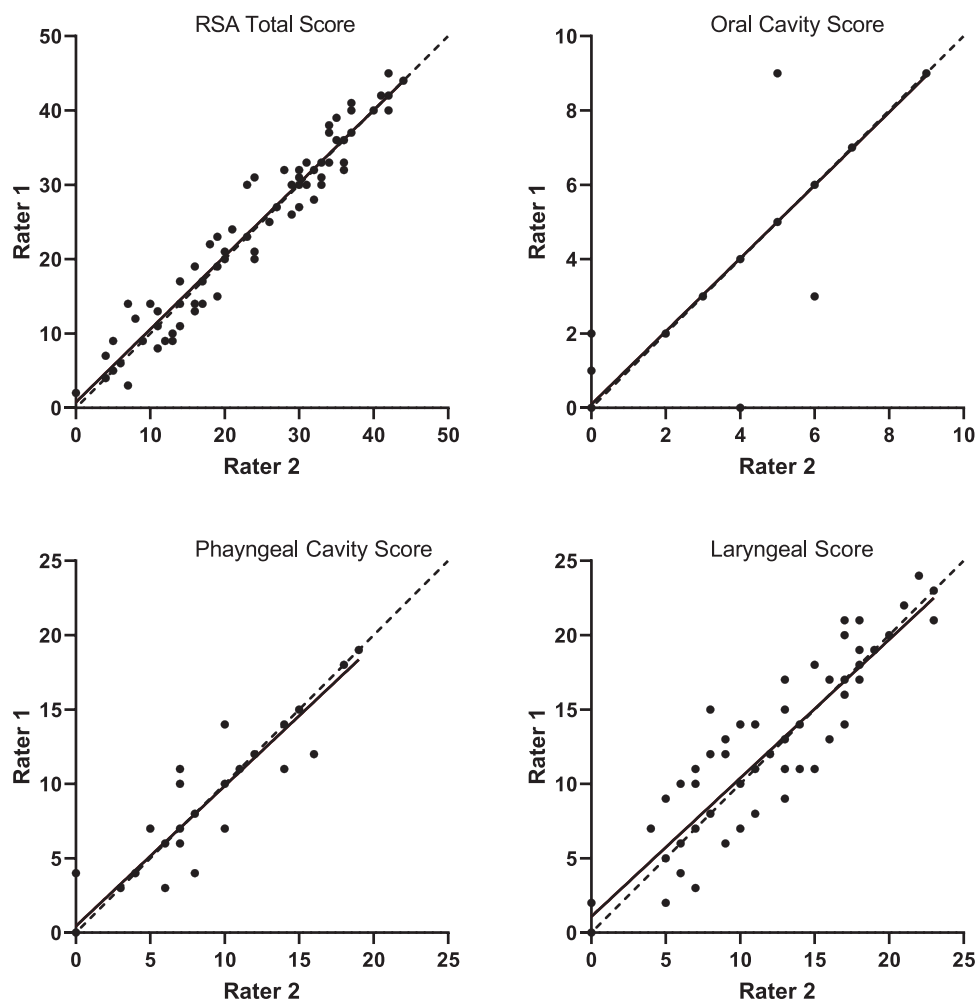


FIGURE 3. Distribution of the RSAp scores measured by the rater two in the first and second examinations in the patients with LPRD and healthy people ($n = 84$).

TABLE 3.
Inter-rater Agreement of the RSAp in the Patients with LPRD and Healthy People ($n = 84$)

The RSAp score	CCC (95% CI)	ICC (95% CI)
Oral cavity subscale	0.98 (0.97–0.99)	0.98 (0.97–0.99)
Pharyngeal cavity subscale	0.97 (0.95–0.98)	0.97 (0.95–0.98)
Laryngeal cavity subscale	0.91 (0.86–0.94)	0.91 (0.86–0.94)
Total	0.97 (0.95–0.98)	0.97 (0.96–0.98)

RSA_p, the Persian version of reflux sign assessment; LPRD, laryngopharyngeal reflux disease; CCC, concordance correlation coefficient; CI, confidence interval; ICC, intraclass correlation coefficient.

group, and this difference was remarkable. That is why the present study strongly confirms the discriminative validity of RSAp. These findings are consistent with the results of the original version of RSA, the English version of RFS, and the

Polish version of RFS, indicating the capability of RSAp in differentiating patients with LPRD from healthy people.^{15,26} The internal consistency of RSAp with Cronbach's alpha, which was greater than 0.7 for the score of oral cavity subscale and the total score, was sufficient and satisfactory.^{21,22} The findings related to the internal consistency of the RSAp are a line with the original version of RSA. In the original version of RSA, Cronbach's alpha for LPRD patients and controls was 0.82, which indicates good internal consistency.¹⁶ However, we found the Cronbach's alpha was less than 0.7 (minimum 0.41 and maximum 0.63) for the pharyngeal cavity and laryngeal cavity subscales that means the internal consistency was low.^{21,22} It was interesting to note that the results of internal consistency done by both raters were approximately similar; both raters showed lower internal consistency for the subscales of pharyngeal and laryngeal cavities. It should be noted that decreasing internal consistency for the pharyngeal cavity and laryngeal cavity subscales is expectable regarding to diverse options utilized for documentation of scores in some items of these two subscales of the RSA compared to the oral cavity subscale in which all items have been scored by only two

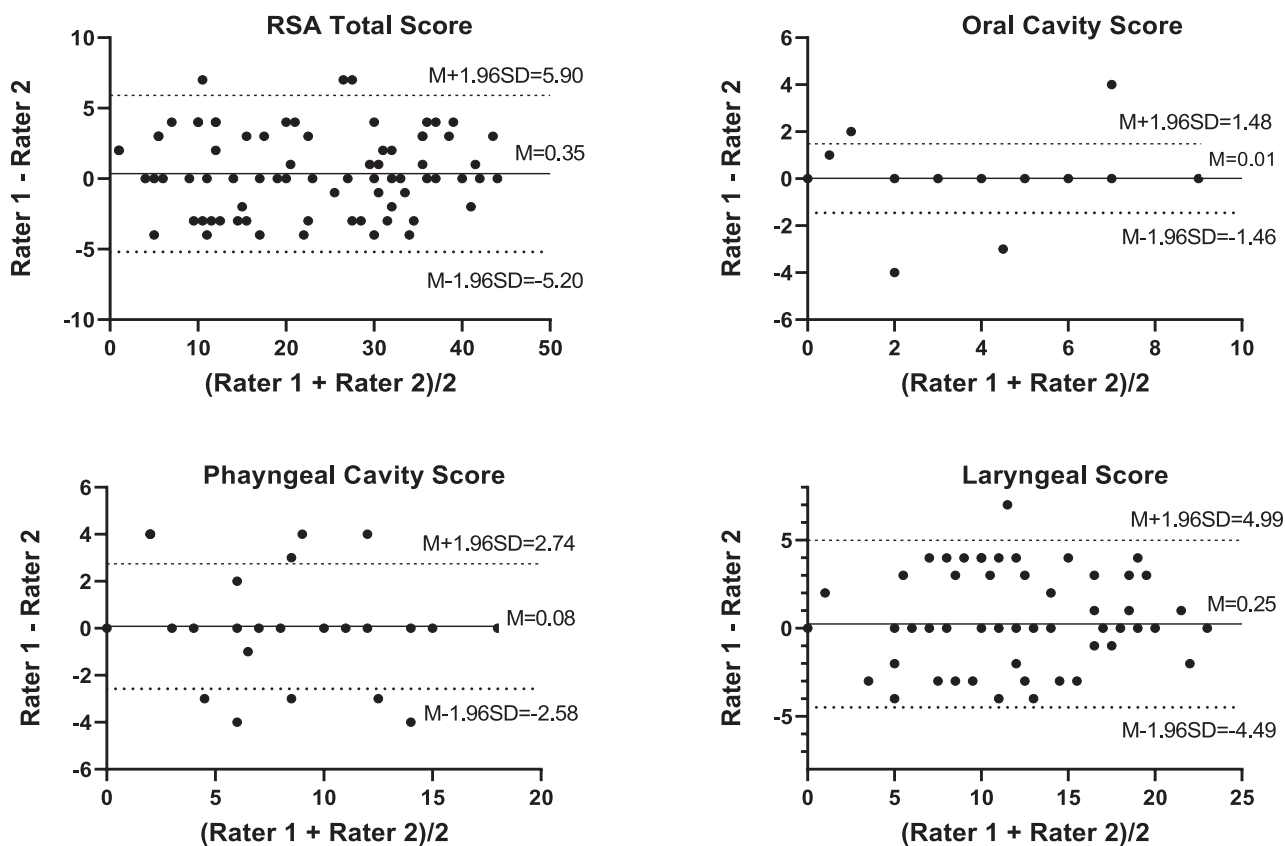


FIGURE 4. The Bland-Altman plot of RSAP scores measured by the rater two in the first and second examinations with an interval of 21 days in the patients with LPRD and healthy people ($n = 84$).

options. Considering that the RSA is completed based on visual-perceptual judgment, the raters' reliability was used to investigate the external reliability in the present study. The values of CCC and ICC for the scores documented by the rater one in the first and second evaluation were greater than 0.7, indicating there was excellent agreement between different evaluations performed by the same rater for all subscales and total score of the RSAP. These findings demonstrated the acceptable intra-rater reliability of the RSAP.²⁵ The results obtained from the investigation of intra-rater reliability are in line with the results of original English version of RSA and the Brazilian version of RFS.^{13,16} Similar findings were obtained for the evaluations conducted by the rater one and the rater two. This means that CCC and ICC values of inter-rater reliability indicated excellent agreement between both raters in all subscales and the total score of RSAP.²⁵ The results of inter-rater reliability of RSAP were consistent with the results obtained for the original versions of RSA and RFS.^{15,18} Additionally, the Bland-Altman plot and the 45-degree line confirmed high external reliability of the RSAP. The convergent validity was proved by the significant correlation between the RSAP and the results of RFS and RSI. The results of convergent validity of RSAP were in agreement with the English version of RSA. The convergent validity of original

RSA was assessed through a study of the similarity of the results of RSA and RFS before and after treatment in LPRD revealed the English version of RSA had good construct validity.¹⁶

As previously mentioned, the diagnosis of LPRD is usually challenging.¹⁰ Although different medical methods have been introduced to diagnose LPRD, they are rarely used due to several weaknesses such as invasiveness, contradictory results, and high cost. This issue is felt more obviously in developing countries due to economic and social problems. Consequently, self-assessment questionnaires in addition to laryngoscopy for investigating clinical symptoms and laryngoscopic signs have been considered in recent decades by researchers and clinicians for the assessment, diagnosis, and document treatment outcomes of LPRD in research and clinical settings.²⁷

Currently, there are very few standardized assessment tools in Persian-speaking countries.²⁸ Therefore, it is clearly needed to provide valid and reliable scales that help experts to document the symptoms and signs of diseases more accurately and comprehensively. The RSAP examines a wide range of LPRD signs in the oral, pharyngeal, and laryngeal cavities and as far as we know

its English version is only available. Compared to the RFS, the RSA can be a valuable and useful tool for the assessment and document treatment outcomes in patients with LPRD in a structured way based on a wider range of clinical manifestations caused in the vocal tract by LPRD. In the current study, the steps of translation and cultural adaptation of the RSAP were done without any problems and the raters completed all subscales, indicating the face validity, acceptability, and clinical use of this scale. The RSAP can be used as a useful tool for research purposes and in clinical settings among the Persian-speaking population.

The present study faced some limitations. The first limitation was the method of diagnosing LPRD. Due to the economic problems and the lack of import of equipment related to pH probe monitoring in our country, it was not possible to use this technique. Therefore, people who showed symptoms similar to LPRD due to other pathologies or individual life conditions were excluded from the study based on the results of history taking. Next, the results of self-assessment and laryngoscopy were used to diagnose LPRD. Another practical limitation of the present study was the coronavirus pandemic, the requirement to comply with the health guidelines for managing the coronavirus outbreak, and the samples' fear of being infected by coronavirus during the examination of vocal tract. These conditions made the sampling process prolonged; even it was stopped in different periods during data gathering because of lock down following epidemic. The above conditions made access to study samples, especially healthy people, so difficult. Consequently, we encountered a large number of patients who had a variety of laryngitis symptoms due to coronavirus disease or after the recovery period; however, they were excluded from the study.

CONCLUSIONS

The Persian version of RSA is associated with consistent intra- and inter-rater reliability and is a valid clinical instrument in daily practice. Further research is recommended to study sensitivity/specificity as well as responsiveness of the RSAP in response to various medical and behavioral treatments in patients with LPRD.

The current study declared that more standardized assessment tools are needed in Persian speaking countries for assessment and document outcomes in patients with LPRD.

CRedit authorship contribution statement

Hadi Rezaei Fard: Sampling, Examination of subjects as a rater one, writing the article, and interpreting the results; **Seyyede Maryam Khoddami:** Designing the project, writing the article, interpreting the laryngoscopic findings, and interpreting the results; **Jerome R. Lechien:** Designing the project, interpreting the laryngoscopic findings, and writing the article; **Payman Dabirmoghaddam:** Diagnosis of LPRD, interpretation the laryngoscopic findings.

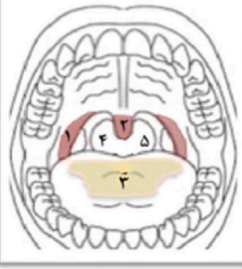
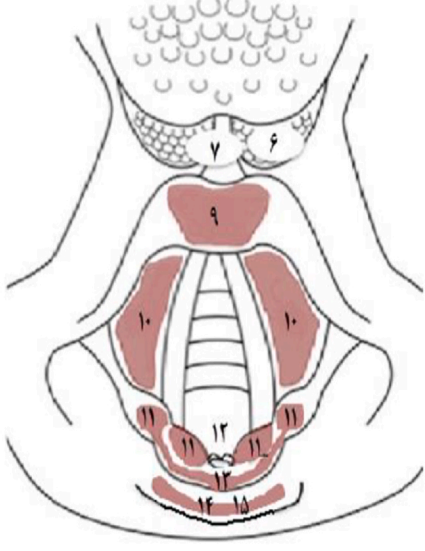
DECLARATION OF COMPETING INTEREST

We wish to confirm that there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome. No funding was received for this work. We further confirm that any aspect of the work covered in this manuscript that has involved human patients has been conducted with the ethical approval of all relevant bodies and that such approvals are acknowledged within the manuscript. All authors had substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work and drafting the work or revising it critically for important intellectual content.

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Appendix 1

حفره حلقی RSAP: ۱۹/...		اریتم هایپوفارنژیال / حلقی دهانی ۰ ندارد ۴ دارد	۴
مخاط چسبناک حلقی ۰ ندارد ۴ دارد	۷	گراتولوم شدن هایپوفارنژیال / حلقی دهانی ۰ ندارد ۲ دارد	۵
تماس اپی گلوت با قاعده زبان ۰ ندارد ۴ دارد	۸	هایپرتروفی لوزه زبانی ۴ شدید ۳ خفیف / متوسط ۰ ندارد	۶
			
حفره دهانی RSAP: ۱۹/...		اریتم چین قدامی ۰ ندارد ۴ دارد	۱
		ادم قرمزی زبان کوچک ۰ ندارد ۳ دارد	۲
		زبان جرم دار ۰ ندارد ۲ دارد	۳
			
نمره کل RSAP: ۱۹/...		ادم / اریتم اپی گلوت ۰ ندارد ۳ دارد	۹
		ادم / اریتم بعد و تریکولار ۰ ندارد ۲ دارد	۱۰
		اریتم حنجره‌ای ۴ محدود به آری تنوئیدها ۵ منتشر	۱۱
		گراتولوم شدن های انتهایی بین آری تنوئیدها ۰ ندارد ۲ دارد	۱۲
		هایپرتروفی پیوستگاه حلقی ۰ ندارد ۵ دارد	۱۳
		اریتم پشت کریکونئید ۰ ندارد ۳ دارد	۱۴
		ادم پشت کریکونئید ۰ بدون تماس با دیواره هایپوفارنژیال (گلوت باز) ۴ تماس با دیواره هایپوفارنژیال (گلوت باز)	۱۵
		مخاط چسبناک داخل حنجره‌ای ۰ ندارد ۳ دارد	۱۶
		گراتولوم چین صوتی ۰ ندارد ۲ دارد	۱۷
		کراتوسیس حنجره‌ای ۰ ندارد ۲ دارد	
		زخم چین صوتی ۰ ندارد ۲ دارد	
حفره حنجره‌ای RSAP: ۲۳/...			

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