

Translation and validation of the Korean Version of the Reflux Symptom Score

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Abstract: Objectives. To assess the validity and reliability of the Korean version of the reflux symptom score (K-RSS).

Materials and Methods. The English version of the RSS was translated into Korean and completed by 77 people (44 and 33 people in the patient group and control group, respectively). They completed the K-RSS (K-RSS-1) and reflux symptom index (RSI) questionnaires and answered questions about age, sex, underlying disease, smoking history, and alcohol and coffee consumption. They completed the K-RSS once more (K-RSS-2) after 1 – 2 weeks. Internal consistency was evaluated using Cronbach's α and test-retest reliability using the intraclass correlation coefficient (ICC). External validity was evaluated using the Spearman rank test between the RSI and K-RSS. The Mann-Whitney U test was used to assess internal validity by comparing the K-RSS-1 scores between the patient and control groups.

Results. The most common symptoms were globus sensation, throat clearing, and throat pain. The K-RSS reported high internal consistency ($\alpha = 0.894$). The ICC for the total score was 0.883, indicating excellent test – retest reliability. According to the Spearman analysis, there was a significant correlation between the total score of the K-RSS and that of the RSI ($r_s = 0.902$; $P < 0.001$), demonstrating strong external validity. Furthermore, the patient group showed significantly higher values than the control group in all K-RSS scores, suggesting high internal validity.

Conclusion. The K-RSS is a patient-reported outcome questionnaire with excellent criterion-referenced validity and ideal reliability.

Key Words: Laryngopharyngeal reflux—Reflux symptom score—Korean version—Reliability—Validity.

INTRODUCTION

Laryngopharyngeal reflux (LPR) is a chronic inflammatory condition of the upper aerodigestive tract and is associated with gastroduodenal content reflux. This can lead to morphological changes in the upper aerodigestive tract.^{1,2} Since gastroduodenal content reflux alone is insufficient to explain the pathophysiology of LPR, indirect effects of neuroreflexive signaling and vagally mediated reflex are considered a possible multifactorial origin of symptoms.^{3,4} LPR-related

symptoms are frequently encountered in the field of otolaryngology, yet it is still difficult to estimate its prevalence owing to the lack of a diagnostic gold standard.⁵ Although tests such as the 24-hour multichannel intraluminal impedance-pH (24h MII–pH) monitoring are available, they are invasive and expensive, so the diagnosis is usually focused on the presenting symptoms. Moreover, a lack of reflux episodes during the 24-hour testing period do not necessarily signify that the patient does not have LPR; it only indicates that there were no reflux episodes during the test period.⁶ Therefore, many clinicians have diagnosed LPR based on their evaluation of symptoms and the patient's responses to empirical treatment with a patient-reported outcome questionnaire (PRO).⁷

The most commonly observed symptoms are throat clearing, globus sensation, voice change, excess throat mucus, and postnasal drip, which are found in at least 75% of patients.^{3,5} The LPR-related symptoms and signs are non-specific because they may be perceived in healthy individuals or in patients with other otolaryngological conditions such as allergies, chronic rhinosinusitis, or laryngeal lesions, making the diagnosis more difficult.⁸ This is also why clinicians need to rate the symptoms of patients through a reliable PRO. The reflux symptom index (RSI) and reflux finding score (RFS) were developed in 2001 by Belafsky et al.^{9,10} Both RSI and RFS are clinical instruments for the assessment of nonspecific symptoms and findings of LPR and are currently used worldwide. However, they do not consider many prevalent LPR symptoms (throat pain,

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halitosis, odynophagia, eructation, or ear pressure) and findings (anterior pillars and posterior pharyngeal wall inflammation, vocal fold erythema, leukoplakia, keratosis, or coated tongue).^{2,11} With regard to the prevalence of non-laryngeal symptoms and the relationship between LPR, gastroesophageal reflux disease (GERD), and some respiratory diseases, the LPR study group consisting of young otolaryngologists from the International Federation of Oto-Rhino-Laryngological Societies developed the reflux symptom score (RSS), which is a validated and reliable PRO that includes the most commonly observed otolaryngological, digestive, and respiratory symptoms.¹²

The RSS is a questionnaire that is helpful in the diagnosis of LPR and evaluation of responses to medication because it also considers quality of life (QoL) as well as various symptoms of LPR. The prevalence of LPR is reported to be quite high in Korea, but RSS has not yet been validated in Koreans.^{13,14} Therefore, we aimed to develop the Korean version of the RSS (K-RSS) and assess its validity and reliability.

MATERIALS AND METHODS

Translation and development of the K-RSS

The RSS is composed of three domains regarding the type of symptoms: ear, nose, and throat (ENT) (domain 1, nine items), digestive (domain 2, 9 items), and respiratory (domain 3, 4 items). The frequency and severity of each symptom were evaluated on a five-point scale, respectively, and the 2 scores were multiplied to obtain a symptom score for each item ranging from 0 to 25 (Figure 1). All symptom scores were summed to calculate the total RSS score. The RSS also evaluates the impact of symptoms on quality of life (QoL) using a five-point scale. The QoL score was calculated by summing all the QoL scores of each item.¹

For cross-cultural adaptation, we translated the English version into Korean over several steps.¹⁵⁻¹⁷ First, 2 Korean/English bilinguals who majored in English language and literature independently translated the English questionnaire into Korean. Then, a qualified professional translator familiar with both Korean and English translated it back into English to check for any misunderstandings in the previous

Reflux Symptom Score

Within the last month, I suffered from one/several of the following symptoms.

Severity: 0 = problem is not severe, 5 = problem very troublesome when it occurs

Frequency: 0 = I haven't had this complaint over the past month, 1;2;3;4 = I had it 1-2;2-3;3-4;4-5 times weekly over the past month, 5 = complaint occurs daily

	Disorder Frequency					Disorder Severity					Total Score	Quality of Life Impact					Total Score			
Ear, Nose and Throat Disorders																				
1. Hoarseness or a voice problem	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5	
2. Throat pain	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5	
3. Pain during swallowing	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5	
4. Difficulty swallowing (pills, liquids or solid foods)	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5	
5. Clearing your throat	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5	
6. Sensation of something sticking in the throat	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5	
7. Excess mucous in the throat or post nasal drip sensation	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5	
8. Ear pressure/pain (daytime or night-time)	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5	
9. Tongue burning	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5	
10. Other:	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5	
Abdominal Disorders																				
1. Heartburn, stomach acid coming up	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5	
2. Regurgitation of liquids, solid foods or burps	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5	
3. Abdominal pain	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5	
4. Diarrheas	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5	
5. Constipation	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5	
6. Indigestion	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5	
7. Abdominal distension and/or flatus	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5	
8. Halitosis	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5	
9. Nausea	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5	
10. Other:	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5	
Chest/respiratory Disorders																				
1. Cough after eating or lying down	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5	
2. Cough (daytime)	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5	
3. Breathing difficulties, breathlessness, or wheezing	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5	
4. Chest pain	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5	
5. Other:	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5	

Do you think that this questionnaire accurately assesses your current complaints? YES – NO RSS total score _____ Quality of Life score _____

FIGURE 1. Reflux Symptom Score, United States/English version.

Reflux Symptom Score

지난 1개월 이내에, 나는 아래와 같은 증상을 한 번 또는 여러 번 겪었다.

심각성 정도 : 0 = 상태가 심각하지 않음, 5 = 증상이 발생할 때 견디기 힘들

발생 빈도 : 0 = 지난 한달 간 나는 이 증상이 없었다, 1 = 1-2회 있었다, 2 = 2-3회 있었다, 3 = 3-4회 있었다, 4 = 4-5회 있었다, 5 = 매일 있었다.

	증상의 심각성					증상 발생 빈도					총점	일상에 미치는 영향					총점		
귀, 코, 목의 증상																			
1. 목이 쉬거나 목소리에 문제가 있음	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5
2. 목의 통증	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5
3. 삼킬 때 아픔	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5
4. 삼킬 때 불편 (알약, 액체나 단단한 음식류)	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5
5. 헛기침 하기	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5
6. 목에 뭔가 걸린 느낌	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5
7. 목 안의 과도한 점액, 또는 코 뒤쪽으로 흐르는 느낌	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5
8. 귀 압박감, 통증 (주간 또는 야간)	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5
9. 혀가 화끈거림	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5
10. 기타:	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5
복부 증상																			
1. 가슴 쓰림, 위산이 올라옴	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5
2. 딱딱한 음식이나 음료가 올라옴, 또는 트림	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5
3. 복통	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5
4. 설사	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5
5. 변비	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5
6. 소화불량	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5
7. 복부 팽창 또는 방귀	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5
8. 입 냄새	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5
9. 메스꺼움	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5
10. 기타:	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5
호흡, 호흡기 증상																			
1. 식후나 누워있을 때 기침	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5
2. 기침 (주간)	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5
3. 호흡곤란, 숨참, 숨가쁨	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5
4. 가슴 통증	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5
5. 기타:	0	1	2	3	4	5	0	1	2	3	4	5		0	1	2	3	4	5

이 설문이 당신의 현재 증상을 잘 측정하고 있다고 생각하십니까? 네/아니요

RSS Total:

QoL Score

FIGURE 2. Reflux Symptom Score, Korean version.

translations. All back-translations were revised by two bilingual (Korean/English) ENT specialists in order to select the best wording from the 2 translations in the previous steps. Finally, the investigators received all products to compare the initial and back-translated versions and decide whether to repeat the translation-back-translation process and to ensure that the translated version is fully comprehensive. The final draft of the manuscript was completed. This final version (Figure 2) was tested in 44 patients with LPR-related symptoms who visited our center (10 male and 34 female patients). Normative data were obtained from 33 individuals without any LPR-related symptoms (14 male and 19 female subjects).

Setting and patients

Patients with LPR-related symptoms who visited the ENT outpatient clinic at our center were included. LPR-related symptoms were defined as symptoms such as globus sensation, throat clearing, throat pain, cough, or hoarseness. Exclusion criteria included age < 19 and > 80 years, patients

with vocal fold lesions (eg, vocal polyps, nodules, and granulomas) on laryngoscopic examination, ongoing pregnancy or neurologic or psychiatric problems, or a history of head and neck malignancy or radiotherapy.

Patients taking anti-reflux medicine (eg, proton pump inhibitor, antacids, and H2-receptor antagonists) were instructed to discontinue them for at least a week prior to K-RSS. All patients answered questions about age, sex, underlying disease, smoking history, alcohol and coffee consumption, and completed the K-RSS and RSI at the first visit (K-RSS-1) and once more (K-RSS-2) within 2 weeks.

The control group comprised 33 people who had no symptoms related to LPR and did not meet the exclusion criteria online through social network services (SNS). We recruited a control group from Kakao Talk, which is a widely used SNS in Korea. They answered the questionnaire through a Google form, and the presence of LPR-related symptoms was evaluated using the RSI score. The first online questionnaire consisted of questions about age, gender, underlying disease, smoking history, alcohol and coffee consumption, and K-RSS and RSI. They conducted a

second online questionnaire consisting of only the K-RSS within 2 weeks. The study protocol was approved by the institutional review board (IRB) of our institution (IRB No. 2021—03—021).

Statistical analysis

The average score of 22 individual items, 4 domains, and the total score and QoL score of the patient group were compared between the K-RSS-1 and K-RSS-2 using the Mann-Whitney U test.

Regarding reliability analysis, test-retest reliability between K-RSS-1 and K-RSS-2 was estimated using the intraclass correlation coefficient (ICC) for each item and the total score in both the patient and control groups. An $r \geq 0.75$ was considered excellent reliability, while an $r \geq 0.60$ was considered good reliability.^{18,19} Internal consistency reliabilities were evaluated by Cronbach's α for symptom scores in three domains as well as the total and QoL scores on K-RSS-1. An $\alpha \geq 0.80$ was considered ideal, and an $\alpha \geq 0.70$ was considered adequate.^{15,18}

External validity was measured through a correlation analysis between the K-RSS-1 and RSI using the Spearman rank test. Internal validity was evaluated by comparing the item score and the total score of K-RSS-1 between the patient and control groups using the Mann-Whitney U test.^{1,15}

All data were analyzed using SPSS ver. 20.0 statistical software (SPSS Inc., Chicago, IL, USA). Results are expressed as mean \pm standard deviation with beta coefficient and 95% confidence interval (CI). Statistical significance was set at $P < 0.05$.

RESULTS

A total of 77 participants completed the evaluation. The patient group consisted of 10 male and 34 female participants aged 17—78 years (mean = 53.6, SD = 14.15), while the control group consisted of 14 male and 19 female patients from 23 to 56 years of age (mean = 31.85, SD = 6.62) (Table 1). The most prevalent symptoms in the patient group were globus sensation (95.45%), throat clearing (72.72%), and throat pain (47.72%). The total RSI score showed a significant difference between the patient and control group (14.20 ± 6.48 versus 2.75 ± 2.67 , $P < 0.001$), and each item also showed a significant difference. The average interval between K-RSS-1 and K-RSS-2 was 12.14 days.

Reliability

The average level of 22 items, 3 domains, and the total score and QoL score were compared between K-RSS-1 and K-RSS-2 (Table 2). There was no significant difference in any item, domain, total score, or QoL score. ICCs were

TABLE 1.
Demographic and Clinical Characteristics of Participants

Demographic and clinical characteristics	Patients ($n = 44$)	Controls ($n = 33$)	<i>P</i> value
Age, years			
Mean \pm SD	53.6 \pm 14.15	31.85 \pm 6.62	
Range	19 – 78	23 – 56	
Sex (Male: Female)	10: 34	14: 19	
Comorbidities			
Diabetes mellitus	4	0	
Hypertension	8	0	
Dyslipidemia	9	0	
Asthma	2	0	
Allergic rhinitis	4	7	
Alcohol	11	27	
Smoking	5	6	
Coffee	22	30	
Reflux Symptom Index (Mean \pm SD)			
Hoarseness or a problem with your voice	1.70 \pm 1.73	0.27 \pm 0.61	<0.001*
Clearing your throat	2.79 \pm 2.07	0.90 \pm 0.99	<0.001*
Excess throat mucus or postnasal drip	1.25 \pm 1.69	0.27 \pm 0.56	0.017*
Difficulty swallowing food, liquids, or pills	0.43 \pm 0.80	0.00 \pm 0.00	0.002*
Coughing after you ate or after lying down	0.79 \pm 1.42	0.03 \pm 0.17	0.004*
Breathing difficulties or choking episodes	0.68 \pm 1.32	0.12 \pm 0.32	0.046*
Troublesome or annoying cough	0.72 \pm 1.01	0.24 \pm 0.49	0.042*
Sensations of something sticking in your throat or a lump in your throat	4.38 \pm 1.19	0.42 \pm 0.81	<0.001*
Heartburn, chest pain, indigestion, or stomach acid coming up	1.43 \pm 1.37	0.48 \pm 0.92	0.001*
Total	14.20 \pm 6.48	2.75 \pm 2.67	<0.001*
Interval between repeat exams	13.31 \pm 8.83	10.60 \pm 2.08	0.092

†Abbreviations: SD, standard deviation.

TABLE 2.
Average Value for Each Item Score and The Total Score Of Patient Group

RSS Items	K-RSS-1 (Mean ± SD)	K-RSS-2 (Mean ± SD)	P value
ENT symptoms			
1. Voice disorder	4.38 ± 6.28	5.90 ± 7.66	0.345
2. Throat pain	6.20 ± 8.53	6.20 ± 8.96	0.953
3. Pain during swallowing	3.02 ± 6.78	3.25 ± 6.89	0.815
4. Dysphagia	1.93 ± 4.33	2.54 ± 5.25	0.479
5. Throat clearing	10.36 ± 10.21	9.06 ± 9.51	0.777
6. Globus sensation	17.34 ± 7.83	16.50 ± 8.56	0.728
7. Excess throat mucus	3.34 ± 6.51	4.00 ± 7.03	0.439
8. Ear pressure/pain	1.61 ± 4.97	2.22 ± 6.03	0.431
9. Tongue burning	0.88 ± 3.46	1.81 ± 5.75	0.481
ENT total score	49.09 ± 32.55	51.65 ± 38.08	0.937
ENT QoL score	12.11 ± 7.60	12.88 ± 8.63	0.904
Digestive symptoms			
1. Heartburn	4.13 ± 6.69	4.11 ± 5.82	0.718
2. Regurgitations or burps	3.59 ± 6.27	2.72 ± 5.06	0.922
3. Abdominal pain	0.70 ± 2.62	1.15 ± 4.41	0.755
4. Diarrhea	0.56 ± 1.94	0.38 ± 0.93	0.804
5. Constipation	0.65 ± 1.52	1.02 ± 3.16	0.668
6. Indigestion	2.65 ± 4.97	3.09 ± 4.62	0.565
7. Abdominal distension/flatus	2.72 ± 5.03	2.43 ± 4.86	0.620
8. Halitosis	2.13 ± 4.80	1.79 ± 3.77	0.818
9. Nausea	1.81 ± 4.91	1.18 ± 4.04	0.570
Digestive total score	19.00 ± 23.75	17.90 ± 25.12	0.694
Digestive QoL score	6.20 ± 6.60	6.13 ± 7.05	0.879
Respiratory symptoms			
1. Cough after eating/lying down	3.15 ± 6.70	3.36 ± 6.95	0.853
2. Cough	2.79 ± 5.18	2.75 ± 5.46	0.989
3. Breathing difficulties	2.25 ± 5.48	1.34 ± 3.92	0.685
4. Chest pain	1.68 ± 4.78	1.47 ± 4.13	0.660
Respiratory total score	10.11 ± 17.44	8.93 ± 14.72	0.889
Respiratory QoL score	3.06 ± 4.10	2.75 ± 3.60	0.786
Total score	78.20 ± 64.95	78.50 ± 65.36	0.890
QoL score	21.38 ± 15.79	21.77 ± 16.58	0.910

†Abbreviations: RSS, reflux symptom score; SD, standard deviation; ENT, ear, nose, throat; QoL, quality of life, * $P < 0.05$

evaluated for test-retest reliability in terms of symptom and QoL scores in each domain, as well as the total score and QoL score (Table 3). Excellent test-retest reliability was obtained for the total RSS score, with an ICC of 0.883. When assessed in each domain, ICCs were excellent for the ENT and respiratory domains, and good for the digestive domain. Some items in the digestive domain, such as heartburn and constipation, showed relatively low correlation coefficients, but still showed fair agreement.

Validity

Cronbach's α of the K-RSS was 0.894 for the total symptom score and 0.910 for the total QoL score, representing high internal consistency (Table 4). Cronbach's α of the symptom and QoL scores in the 3 domains were above 0.700.

To assess the external validity of the K-RSS, Spearman correlation coefficients were measured between the K-RSS

and RSI scores (Table 4). The K-RSS total score and RSI showed a significant correlation ($r = 0.902$; $P < 0.001$), demonstrating high external validity. The QoL score also showed a high level of correlation with RSI ($r_s = 0.919$; $P < 0.001$).

Furthermore, the patient group had significantly higher values than the control group in 22 items, ENT total score (49.09 ± 32.55 vs 1.24 ± 2.59 , $P < 0.001$), digestive total score (19.00 ± 23.75 vs 1.51 ± 2.80 , $P < 0.001$), respiratory total score (10.11 ± 17.44 vs 0.15 ± 0.35 , $P < 0.001$), total score (78.20 ± 64.95 vs 2.90 ± 4.09 , $P < 0.001$) and QoL score (21.38 ± 15.79 vs 1.69 ± 2.41 , $p < 0.001$) (Table 5). This suggests the high internal validity of the K-RSS.

DISCUSSION

LPR is a common disease with a prevalence of approximately 25% in Asia, including Korea.^{13,20} In a study conducted on Asian otolaryngologists, approximately 70% of

TABLE 3.
Test-Retest Reliability (Intraclass Correlation Coefficient) for Each Item Score and The Total Score

RSS Items	ICC	95% CI
ENT symptoms		
1. Voice disorder	0.773	0.645 – 0.856
2. Throat pain	0.899	0.842 – 0.936
3. Pain during swallowing	0.924	0.880 – 0.951
4. Dysphagia	0.883	0.817 – 0.926
5. Throat clearing	0.894	0.834 – 0.933
6. Globus sensation	0.937	0.901 – 0.960
7. Excess throat mucus	0.741	0.593 – 0.835
8. Ear pressure/pain	0.879	0.810 – 0.923
9. Tongue burning	0.722	0.564 – 0.823
ENT total score	0.925	0.883 – 0.953
ENT QoL score	0.945	0.913 – 0.965
Digestive symptoms		
1. Heartburn	0.510	0.254 – 0.699
2. Regurgitations or burps	0.758	0.621 – 0.846
3. Abdominal pain	0.750	0.607 – 0.841
4. Diarrhea	0.638	0.342 – 0.805
5. Constipation	0.561	0.313 – 0.720
6. Indigestion	0.709	0.542 – 0.815
7. Abdominal distension/ flatus	0.932	0.892 – 0.956
8. Halitosis	0.710	0.543 – 0.816
9. Nausea	0.608	0.383 – 0.766
Digestive total score	0.681	0.330 – 0.497
Digestive QoL score	0.713	0.548 – 0.818
Respiratory symptoms		
1. Cough after eating/lying down	0.969	0.951 – 0.980
2. Cough	0.856	0.774 – 0.909
3. Breathing difficulties	0.833	0.738 – 0.894
4. Chest pain	0.630	0.417 – 0.765
Respiratory total score	0.928	0.887 – 0.954
Respiratory QoL score	0.763	0.569 – 0.870
Total score	0.883	0.817 – 0.926
QoL score	0.892	0.830 V 0.931

†Abbreviations: RSS, reflux symptom score; ICC, intraclass correlation coefficient; CI, confidence interval; ENT, ear, nose, throat; QoL, quality of life.

them diagnosed LPR based on an improvement in both symptoms and signs following an empirical therapeutic trial. Furthermore, about 78% had never or very rarely used 24h MII-pH monitoring for diagnosis due to its inconvenience, cost, and lack of meaningfulness.²⁰ Therefore, there is a great need for a tool that can adequately evaluate a patient's symptoms.

The development of the K-RSS, which includes the most prevalent ENT, digestive, and respiratory symptoms, particularly makes sense in Asian countries because many Asian LPR patients experience digestive and respiratory symptoms and not only ENT symptoms as reported in recent studies. Specifically, prevalent LPR-related symptoms in Asia include cough after eating or lying down, throat clearing, globus sensation, chronic cough, stomach acid coming

up, voice problems, heartburn, throat pain, halitosis, odynophagia, swallowing difficulty, tongue burning, chest pain, and breathing difficulties.²⁰ Similar results were found in our study, with globus sensation, throat clearing, and throat pain being the most prevalent symptoms in the patient group. Some of these prevalent symptoms, such as throat pain, are not described in the RSI, a questionnaire that is now widely used. This makes the K-RSS a more complete PRO questionnaire than the RSI. In addition, 97% of the participants answered that the K-RSS adequately expressed their symptoms without the need for additional items. Even in the validation process of the original version of Lechien et al.,¹ 98% of participants answered that their symptoms were all described in the RSS.

In our study, the K-RSS appeared to have strong reliability and validity. The test-retest reliability was high, presenting excellent ICCs in total score (0.883) as well as the ENT (0.925), digestive (0.681), and respiratory domains (0.928). Even when analyzed using the Spearman rank test to compare with the data of the study by Lechien et al.,¹ the correlation coefficient for total symptom score was high at 0.902, whereas that of the study by Lechien et al.¹ was 0.921. The K-RSS is also competitive compared to other PROs translated into various languages. The test-retest reliability of the Spanish (0.987),²¹ Chinese (0.971),²² Italian (0.99),²³ and French versions (0.78)²⁴ of the RSI was comparable to our result. Note that the test-retest reliability was relatively low in the digestive domain, which may be related to confounding factors because some patients may have daily digestive complaints related to clinical conditions other than reflux.

The K-RSS also reported high internal consistency regarding its Cronbach's α coefficient (0.894). The value of the internal consistency of the K-RSS is slightly lower than that of the original version¹ (0.969) but still remains high according to the normative data of validation of the patient-reported outcome questionnaire. A possible explanation for the higher value of the original version of the RSS is the higher number of patients, which may improve the statistical power. Cronbach's α of the Spanish (0.872),²¹ Chinese (0.715),²² Italian (0.99),²³ and French versions (0.85)²⁴ of the RSI was also comparable to our result.

When considering external validity, the total score of the K-RSS showed a higher positive correlation with RSI ($r_s = 0.902$; $p < 0.001$) than that of the original version¹ ($r_s = 0.831$; $P < 0.001$). However, in our study, the digestive and respiratory domains showed a relatively lower coefficient than that of the ENT domain. This is because the RSI is composed of five ENT questions, one digestive question, and two respiratory questions among the nine questions, indicating that the RSI places more emphasis weight on the ENT symptoms.

This is the first Korean version of the RSS, which was translated and verified in Korean through a systematic method with native English professors. When considering the diagnostic instrument for LPR patients, the K-RSS has the strength of considering several common symptoms of LPR, such as throat pain, odynophagia, halitosis, tongue

TABLE 4.
Internal Consistency Reliability (Cronbach's α) for Each Domain and The Total Score and Spearman Correlation Analysis Between the RSS Score and RSI Score

Domain	No. of items	Cronbach's α	r_s
ENT symptom score	9	0.780	0.871 ($P < 0.001^*$)
ENT QoL score	9	0.817	0.895 ($P < 0.001^*$)
Digestive symptom score	9	0.778	0.606 ($P < 0.001^*$)
Digestive QoL score	9	0.826	0.634 ($P < 0.001^*$)
Respiratory symptom score	4	0.811	0.695 ($P < 0.001^*$)
Respiratory QoL score	4	0.792	0.683 ($P < 0.001^*$)
Total score	22	0.894	0.902 ($P < 0.001^*$)
QoL score	22	0.910	0.919 ($P < 0.001^*$)

†Abbreviations: RSS, reflux symptom score; RSI, reflux symptom index; ENT, ear, nose, throat; QoL, quality of life; r_s , Spearman correlation coefficient, * $P < 0.05$

TABLE 5.
Comparison of K-RSS-1 Between Patients with LPR and Asymptomatic Individuals

RSS Items	Clinical RSS			QoL RSS		
	LPR	Controls	P value	LPR	Controls	P value
ENT symptoms						
1. Voice disorder	4.38 \pm 6.28	0.15 \pm 0.70	<0.001*	1.47 \pm 1.72	0.09 \pm 0.37	<0.001*
2. Throat pain	6.20 \pm 8.53	0.15 \pm 0.70	0.001*	1.65 \pm 1.92	0.15 \pm 0.49	<0.001*
3. Pain during swallowing	3.02 \pm 6.78	0.03 \pm 0.17	0.013*	0.68 \pm 1.36	0.03 \pm 0.17	0.013*
4. Dysphagia	1.93 \pm 4.33	0.00 \pm 0.00	0.002*	0.47 \pm 0.98	0.00 \pm 0.00	0.004*
5. Throat clearing	10.36 \pm 10.21	0.33 \pm 1.09	<0.001*	2.54 \pm 2.06	0.06 \pm 0.23	<0.001*
6. Globus sensation	17.34 \pm 7.83	0.48 \pm 1.77	<0.001*	3.77 \pm 1.50	0.12 \pm 0.32	<0.001*
7. Excess throat mucus	3.34 \pm 6.51	0.09 \pm 0.28	0.027*	0.84 \pm 1.60	0.06 \pm 0.23	0.033*
8. Ear pressure/pain	1.61 \pm 4.97	0.00 \pm 0.00	0.017*	0.43 \pm 1.13	0.00 \pm 0.00	0.017*
9. Tongue burning	0.88 \pm 3.46	0.00 \pm 0.00	0.042*	0.22 \pm 0.79	0.00 \pm 0.00	0.049*
ENT Total score	49.09 \pm 32.55	1.24 \pm 2.59	<0.001*	12.11 \pm 7.60	0.51 \pm 1.01	<0.001*
Digestive symptoms						
1. Heartburn	4.13 \pm 6.69	0.36 \pm 0.91	0.003*	1.29 \pm 1.65	0.21 \pm 0.53	0.002*
2. Regurgitations or burps	3.59 \pm 6.27	0.18 \pm 0.71	0.001*	1.13 \pm 1.53	0.06 \pm 0.34	<0.001*
3. Abdominal pain	0.70 \pm 2.62	0.00 \pm 0.00	0.047*	0.31 \pm 0.89	0.03 \pm 0.17	0.048*
4. Diarrhea	0.56 \pm 1.94	0.03 \pm 0.17	0.040*	0.38 \pm 0.85	0.06 \pm 0.23	0.041*
5. Constipation	0.65 \pm 1.52	0.06 \pm 0.23	0.038*	0.27 \pm 0.61	0.03 \pm 0.17	0.024*
6. Indigestion	2.65 \pm 4.97	0.39 \pm 0.98	0.017*	0.81 \pm 1.26	0.24 \pm 0.49	0.037*
7. Abdominal distension/flatus	2.72 \pm 5.03	0.30 \pm 0.45	0.025*	0.90 \pm 1.29	0.24 \pm 0.42	0.030*
8. Halitosis	2.13 \pm 4.80	0.12 \pm 0.32	0.025*	0.63 \pm 1.14	0.09 \pm 0.28	0.013*
9. Nausea	1.81 \pm 4.91	0.03 \pm 0.17	0.013*	0.40 \pm 1.05	0.03 \pm 0.17	0.039*
Digestive Total score	19.00 \pm 23.75	1.51 \pm 2.80	<0.001*	6.20 \pm 6.60	1.00 \pm 1.74	<0.001*
Respiratory symptoms						
1. Cough after eating/lying down	3.15 \pm 6.70	0.06 \pm 0.23	0.004*	0.93 \pm 1.52	0.06 \pm 0.23	0.002*
2. Cough	2.79 \pm 5.18	0.03 \pm 0.17	<0.001*	1.00 \pm 1.36	0.03 \pm 0.17	<0.001*
3. Breathing difficulties	2.25 \pm 5.48	0.06 \pm 0.23	0.035*	0.52 \pm 1.23	0.06 \pm 0.23	0.038*
4. Chest pain	1.68 \pm 4.78	0.00 \pm 0.00	0.017*	0.50 \pm 1.15	0.03 \pm 0.17	0.022*
Respiratory Total score	10.11 \pm 17.44	0.15 \pm 0.35	<0.001*	3.06 \pm 4.10	0.18 \pm 0.45	<0.001*
Total score	78.20 \pm 64.95	2.90 \pm 4.09	<0.001*	21.38 \pm 15.79	1.69 \pm 2.41	<0.001*

†Abbreviations: RSS, reflux symptom score; LPR, laryngopharyngeal reflux; ENT, ear, nose, throat; QoL, quality of life, * $P < 0.05$

burning, and nausea, which had not been included in previous PROs. Another important point is that this questionnaire considers not only the frequency and severity of symptoms, but also the effect of symptoms on QoL through a well-defined rating system.¹

This study has some limitations. First, the number of participants was small. However, although only a moderate number of patients were involved in the study ($n = 77$), our validity and reliability findings are adequate, supporting the use of K-RSS in daily practice in Korea. Second, there was no comparison of the K-RSS scores before and after treatment in the same patient. It may be evaluated in future studies in which Korean otolaryngologists use the K-RSS to monitor empirical therapeutic trials in patients with LPR.

CONCLUSION

The K-RSS is a valid and reliable PRO questionnaire that may be useful in clinical practice for both the diagnosis and follow-up of LPR patients.

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