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Validity and Reliability of the Reflux Sign Assessment-10 (RSA-10)

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Objective: To develop and validate the Reflux Sign Assessment-10 (RSA-10) for documenting the physical findings of laryngopharyngeal reflux disease (LPRD).

Methods: Patients with LPRD at the hypopharyngeal-esophageal multichannel intraluminal impedance-pH monitoring and asymptomatic individuals were consecutively recruited from two European hospitals. Three experienced otolaryngologists rated RSA-10 in patients and controls for assessing internal validity. RSA-10 was rated within a 7-day period to assess test-retest reliability. Internal consistency was measured using Cronbach's α in patients and controls. Convergent validity was evaluated through a correlation analysis between RSA-10 and Reflux Finding Score (RFS). Interrater reliability was evaluated by comparing the RSA-10 evaluations of the three otolaryngologists through Fleiss kappa. Pre- to posttreatment change of RSA-10 was evaluated to assess responsiveness to change. The RSA-10 thresholds were examined by receiver operating characteristic analysis.

Results: Fifty-five patients completed the pre- to posttreatment evaluations from January 2020 to December 2023. A total of 115 asymptomatic individuals completed the study. RSA-10 reported high internal consistency reliability ($\alpha = 0.822$) and test-retest reliability ($r_s = 0.725$). The RSA-10 scores of patients were significantly higher than those of controls ($p = 0.001$), suggesting high internal validity. RSA-10 was significantly correlated with the RFS ($r_s = 0.771$). The interrater reliability was adequate for sub- and total RSA-10 scores ($k = 0.708$). RSA-10 significantly improved from baseline to 3-month posttreatment ($p = 0.001$). An RSA-10 > 13 may be suggestive of LPRD. Both RSA-10 > 13 and Reflux Symptom Score-12 > 11 were associated with a sensitivity of 92.7% and a specificity of 97.3%.

Conclusion: The RSA-10 is a reliable and valid clinical instrument for documenting the most prevalent laryngeal and extra-laryngeal findings associated with LPRD.

Key Words: finding, laryngitis, laryngology, laryngopharyngeal, otolaryngology, reflux, score, sign.

Level of Evidence: 3

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INTRODUCTION

Laryngopharyngeal reflux disease (LPRD) is an upper aerodigestive tract condition resulting from the direct and/or indirect effects of gastroduodenal content reflux, inducing morphological and/or neurological changes in the upper aerodigestive tract.[1] The clinical diagnosis of LPRD remains challenging because LPRD is associated with recognized nonspecific laryngeal and extra-laryngeal symptoms and signs that can be found in many other otolaryngological conditions.[2,3] Thus, the use of patient-reported outcome questionnaires and clinical instruments documenting laryngeal and extra-laryngeal signs is recommended to improve the LPRD management in otolaryngological practice.[1,4,5] Reflux Symptom Score (RSS), Reflux Symptom Index (RSI), and Reflux Symptom Score-12 (RSS-12) are the mostly used patient-reported outcome questionnaires and can be used with clinical instruments to screen patients with LPRD symptoms before objective diagnostic testing or empirical treatments.[1,3] To date, only Reflux Finding Score (RFS)[6] and Reflux Sign Assessment (RSA)[7] reported moderate-to-high validity and reliability for evaluating common findings associated with LPRD. However, RFS and RSA reported some important limitations. RFS does not consider extra-laryngeal signs, and studies suggested poor interrater reliability.[8,9] Moreover, RFS was tested on patients with acid reflux event only, and treated with acid suppression, while most LPRD patients have weakly acid or alkaline reflux events.[1] Concerning RSA, despite better reliability than RFS,[7,10] the full version of RSA is still time-consuming with 17 items.[7]

The aim of this study was to develop and validate the Reflux Sign Assessment-10 (RSA-10), a shortened version of RSA focusing on the most common laryngeal and extra-laryngeal findings associated with LPRD.

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METHODS

Reflux Sign Assessment-10 Development

The development of the RSA-10 was based on the recent data reporting the most prevalent RSA findings associated with LPRD.[11] Some closest items reporting significant associations were merged into one item to reduce the number of findings (e.g., posterior commissure hypertrophy and retrocricoid edema). The authors aimed to propose a revised RSA version that could be completed in less than one minute for diagnosing and following up with LPRD patients. The three experts, experienced in using RSA, were involved in several past studies that included RSA data of LPRD patients.[12,13] The RSA-10 items are rated using a scoring system designed to minimize subjective ratings, such as "mild," "moderate," or "severe" signs. RSA-10 uses scoring systems that aim to be as descriptive as possible. The weight assignment of each finding was based on the prevalence of the related finding in previous studies.[7,11] The RSA-10 is presented in Figure 1. Examples of clinical findings of RSA-10 are illustrated in Figure 2. The RSA-10 is subdivided into oral cavity, pharyngeal, and laryngeal subscores. Given that LPRD has recently been associated with atypical signs in some cases,[14,15] RSA-10 allows for the inclusion of additional signs, such as rhinopharyngeal erythema,[15] mulberry inferior turbinate,[14] or nasal crusts.[15] The total RSA-10 score ranges from 0 to 40. The current study was conducted according to a checklist of recommendations designed to obtain valid and reliable clinical instruments (Appendix 1).[5]

Subjects and Setting

Patients with LPRD symptoms and findings were consecutively recruited from January 2020 to December 2023 from the Departments of Otolaryngology-Head and Neck Surgery from two European hospitals (CHU Saint-Pierre, Brussels, Belgium) and the Elsan Polyclinique of Poitiers (Poitiers, France). The LPRD diagnosis was based on the occurrence of more than one pharyngeal reflux events at the 24-h hypopharyngeal-esophageal multichannel intraluminal impedance-pH monitoring (HEMII-pH), which consisted of the Dubai criteria.[1] Gastrointestinal (GI) endoscopy was performed in patients with gastroesophageal reflux disease (GERD) symptoms or GERD complication history. A control group of sex-

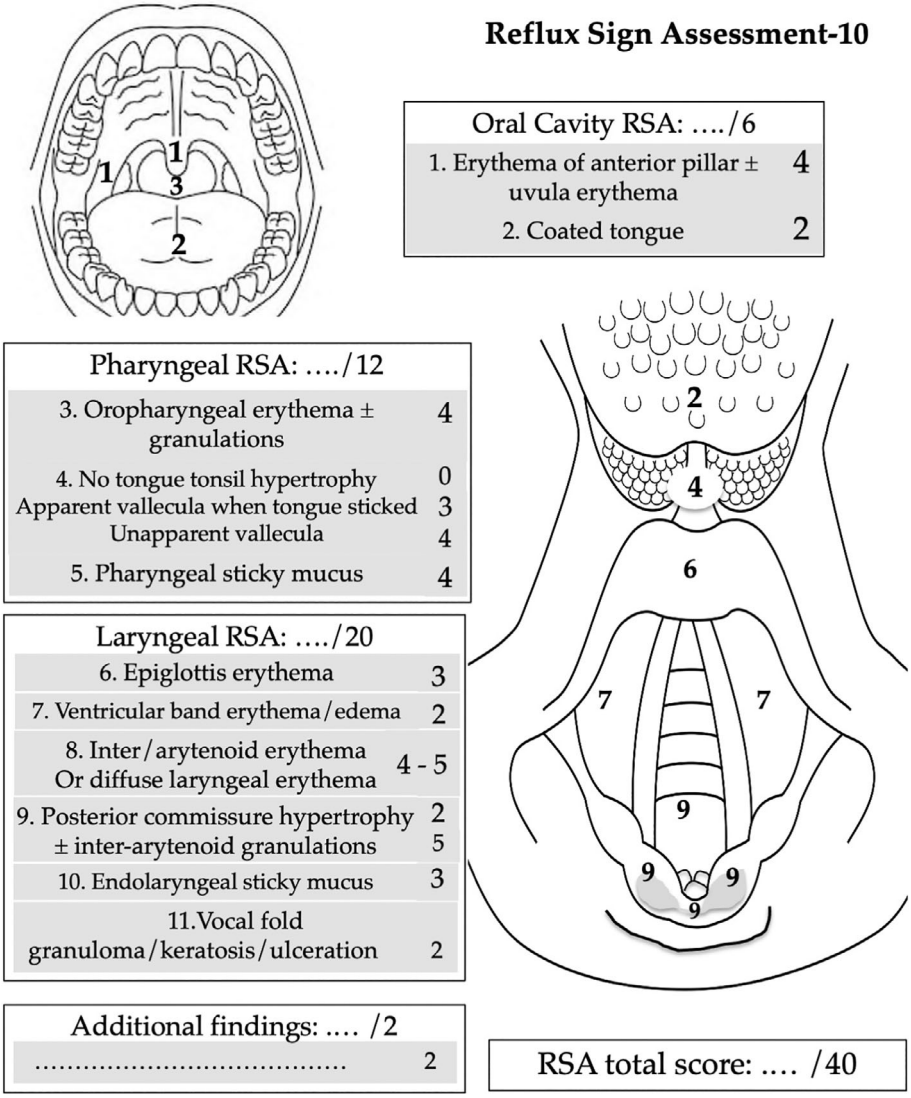


Fig. 1. Reflux Sign Assessment-10. RSA-10 includes common oral, pharyngeal and laryngeal signs associated with LPRD. Additional signs (uncommon) may be added, including nasal findings.

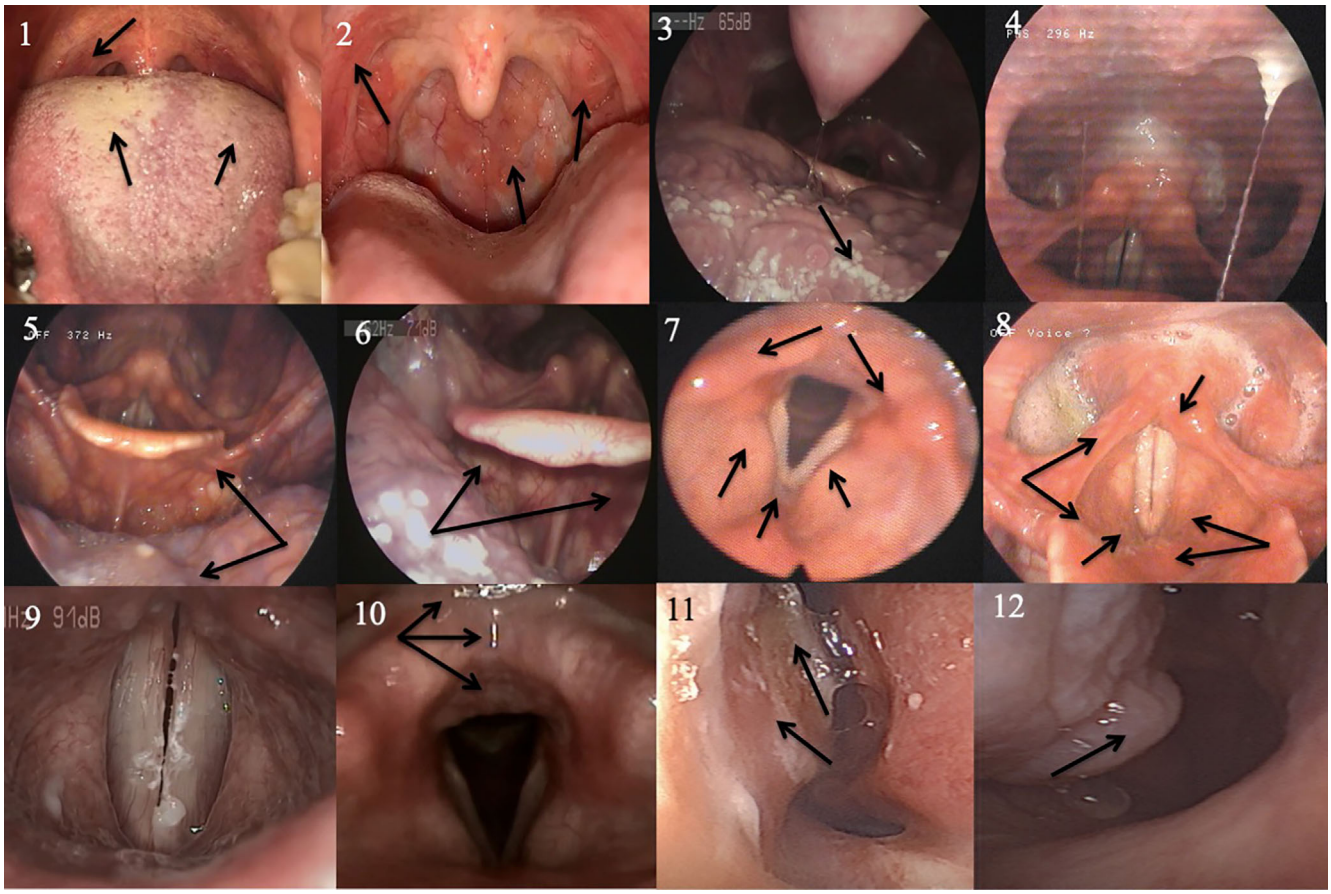


Fig. 2. Common and uncommon findings associated with laryngopharyngeal reflux. The oral signs include anterior pillar erythema (1, 2), and anterior or posterior coated tongue (1, 3). Pharyngeal signs include oropharyngeal erythema or granulation of the posterior wall (2) and the evaluation of throat sticky mucus (4). The tongue tonsil hypertrophy may be absent (apparent vallecula at a rest position of the tongue, 5); mild-to-moderate when the vallecula are apparent only when the tongue is sticked (6); or unapparent (3). Laryngeal signs include erythema at the epiglottic petiole (7) or extended to the larynx (8), hypertrophy with (8) or without (7) erythema of the ventricles, posterior commissure hypertrophy (7), and endolaryngeal mucus (9). The granulation of the posterior commissure, the retrocricoid edema, and the posterior commissure hypertrophy were merged into one item (10). Nasal crusts 11), and Mulberry inferior turbinate (12) are atypical findings. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

and age-matched asymptomatic individuals without LPRD or GERD symptoms was recruited from the University of Mons (Mons, Belgium). Symptoms of patients and asymptomatic individuals were assessed with the French version of the RSS.[16] Only patients who completed pre- to 3-month posttreatment evaluations were included. The exclusion criteria of LPRD and asymptomatic individuals included smoking, alcohol dependence, upper respiratory tract infection within the last month, asthma, current use of anti-reflux treatment or inhaled corticosteroids, neurological or psychiatric conditions, previous history of neck surgery or trauma, malignancy, history of head and neck radiotherapy, and active seasonal allergies. The local ethics committee approved the study protocol (n°BE076201837630).

Hypopharyngeal-Esophageal Multichannel Intraluminal Impedance-pH Monitoring

Practitioners transnasally introduced the catheter (Versaflex Z®, Digitrapper pH-Z testing System, Medtronic, Europe) in the morning before breakfast. Note that patients were off of proton pump inhibitors (PPIs), H2 receptor blockers, or alginate 14 days before and during the HEMII-pH testing. The probe was composed of eight impedance segments and two pH electrodes. Six impedance segments were placed along the esophagus zones (Z1 to Z6) at 19, 17, 11, 9, 7, and 5 cm above the lower esophageal sphincter (LES). The hypopharyngeal sensors were placed 1 and 2 cm above the cricopharyngeal sphincter in the hypopharynx. The pH electrodes were placed 2 cm above LES and 1-to-2 cm below cricopharyngeal sphincter, respectively. The LPRD diagnosis was based on the occurrence of >1 acid (pH < 4.0), weakly acid (pH = 4.0–7.0), or nonacid (pH > 7.0) pharyngeal reflux event.[1,17] The definition and criteria of GERD diagnosis were based on the Lyon consensus, which defines GERD when patients report the following findings: Los Angeles grade C and D esophagitis; long segment Barrett's mucosa; peptic esophageal stricture; or distal acid exposure time >6%.[18] Patients were instructed to maintain usual daily diet and activities during the 24-hour recording.

Treatments

The therapeutic algorithm was based on HEMII-pH features, that is, the time/position at which episodes occurred (upright and daytime/recumbent and nighttime), the pH of events (acid, weakly acid, alkaline), and the presence of GERD.[19] Patients were recommended to adhere to a standardized diet,[20] and to reduce stress and anxiety as much as possible throughout the 3-month

therapeutic period, given the impact of autonomic nerve dysfunction on LPRD physiology.[1] Patients with acid LPRD or GERD were treated with PPIs (pantoprazole, 20 mg once or twice daily), and post-meal alginate (Gaviscon). Patients with weakly acid or alkaline LPRD were treated with post-meal Gaviscon only.[19]

STATISTICAL METHODS

The RSA-10 was evaluated by three board-certified otolaryngologists through videolaryngostroboscopies and oral cavity photos of patients and asymptomatic individuals. Video and photos were stored in a database without information about the time of the recording (baseline vs. posttreatment).

Reliability

Cronbach's alpha was used for assessing internal consistency. Intrarater reliability was evaluated through blinded test-retest evaluations at 7-day intervals (Pearson analysis). According to recommendations, the correlation coefficient (r_s) was considered as ideal and adequate for $r_s \geq 0.80$ and $r_s \geq 0.70$, respectively.[5]

The interrater reliability (concordance analysis) between the three otolaryngologists was assessed with Fleiss kappa (coefficient of concordance). Importantly, because the assessment of findings may be tiring and time-consuming (2–4 min to rate RSA-10 and RFS on the photo and video recordings), the number of patients and asymptomatic individuals was limited to 55 and 115, respectively.

Validity and Responsiveness to Change

The RSA-10 scores of patients and asymptomatic individuals were compared to assess the internal validity (Mann–Whitney *U* test). The prevalence of signs in LPRD and asymptomatic individuals was compared with Chi-square. Convergent validity was evaluated through a Pearson correlation analysis between the RSA-10 and RFS. The pre- to 3-month posttreatment changes of RSA-10 were used for measuring responsiveness to change (Wilcoxon signed-rank test).

Normative Data

The receiver operating characteristic (ROC) analysis of RSA-10 and RFS was used to investigate the RSA-10 threshold for determining the presence and absence of LPRD. The area under the curve (AUC) was calculated for RSA-10 and RFS. Sensitivity, specificity, positive and negative predictive values were evaluated for the association of symptoms (RSS > 13 and RSS-12 > 11[21]) and signs (RSA-10 cutoff). The RSS-12 score was calculated a posterior from the RSS.

Statistical analyses were performed using the Statistical Package for the Social Sciences for Windows (SPSS version 29,0; IBM Corp, Armonk, NY, USA). Multiple linear regression was used to identify potential relationships between patient characteristics, relevant GI findings, symptoms, and findings. A level of significance of $p < 0.05$ was used.

RESULTS

Fifty-five patients completed the evaluations accounting for 21 (38%), 11 (20%), and 23 (42%) mild, moderate, and severe LPRD,[22] respectively (Table I). There were 33 (60%) females. The mean age was 49.2 ± 15.2 years. Gastrointestinal endoscopy was performed in 46 patients, including 23 (50%) LES insufficiency and 20 (43%) esophagitis. The HEMII-pH features are described in Table I. Most patients had weakly acid upright and daytime LPRD. Based on Lyon criteria, 11 (20%) patients had both LPRD and GERD. A total of 115 asymptomatic individuals were recruited from a public call of the University of Mons. The mean BMI (24.4 ± 7.4) and mean age (47.8 ± 17.9) of asymptomatic individuals were comparable to LPRD patients.

TABLE I.
Demographics.

Characteristics	Patients (*N* = 55)
Mean age (range, years)	49.2 ± 15.2
Body mass index (mean, SD)	26.4 ± 6.5
Gender (*N*, %)	
Male	22 (40)
Female	33 (60)
Severity of reflux (RSS-QoL)	
Mild reflux (6-25)	21 (38)
Moderate reflux (26-38)	11 (20)
Severe reflux (>38)	23 (42)
Gastrointestinal endoscopy	*N* = 46
Normal	7 (15)
Esophagitis	20 (43)
Hiatal hernia	10 (22)
LES insufficiency	23 (50)
Gastritis	19 (41)
Helicobacter Pylori infection	4 (9)
HEMII-pH feature (mean, SD)	
Pharyngeal events	
Pharyngeal acid reflux events	17.7 ± 17.3
Pharyngeal nonacid reflux events	11.6 ± 8.9
Total number of pharyngeal events	34.1 ± 50.2
Position events	
Pharyngeal event upright	26.7 ± 30.0
Pharyngeal event supine	6.5 ± 21.9
GERD	
Number of patients (%)	11 (20)
Percentage of time with distal pH < 4	2.3 ± 3.8
Reflux Symptom Score	123.0 ± 75.5
Reflux Symptom Score—QoL	35.4 ± 19.5
Reflux Symptom Score-12	64.7 ± 38.8

GERD = gastroesophageal reflux disease; HEMII-pH = hypopharyngeal-esophageal multichannel intraluminal impedance-pH monitoring; LES = lower esophageal sphincter; QoL = quality of life; RSS = reflux symptom score; SD = standard deviation.

Clinical Findings

The mean RSS of LPRD patients and asymptomatic individuals were 123.0 ± 75.5 and 3.18 ± 7.11, respectively ($p = 0.001$). The mean RSS-12 of LPRD patients and asymptomatic individuals were 64.7 ± 38.8 and 0.9 ± 1.4, respectively ($p = 0.001$).

RSA-10 signs were significantly more prevalent in LPRD patients compared to asymptomatic individuals (Appendix 2). The mean RSA-10 scores of LPRD patients and asymptomatic individuals are reported in Table II. The RSA-10 pharyngeal, laryngeal, and total scores were significantly higher in LPRD patients compared to asymptomatic individuals, which suggests a high internal validity. The Cronbach's alpha suggested an adequate RSA-10 internal consistency reliability ($\alpha = 0.822$). The test-retest reliability was high for sub- and total RSA-10 scores ($r_s = 0.725$; Table III). Convergent validity was adequate according to the significant association between RSA-10 and RFS ($r_s = 0.771$; $p = 0.001$). The Fleiss kappa analysis supported an adequate interrater reliability for sub- and total RSA-10 scores ($k = 0.708$; $p = 0.001$; Table IV). The interrater reliability of RSA-10 ($k = 0.708$) was higher compared to RFS ($k = 0.603$). RSA-10 significantly improved from baseline to 3-month posttreatment (Table V). The area under the curve of ROC analysis for RSA-10 and RFS was 0.906 and 0.838, respectively (Fig. 3). RSA-10 > 13 is suggestive of LPRD. Considering the association of symptoms and signs, the sensitivity, specificity, positive and negative predictive values of RSA-10 > 13 and RSS > 13 were 83.6, 97.3, 93.9, and 92.9, respectively. Using RSS-12, the sensitivity, specificity, positive and negative predictive values of RSA-10 > 13 and RSS-12 > 11 were 92.7, 97.3, 94.4, and 96.5, respectively.

The multivariate analysis did not reveal significant associations between HEMII-pH, RSA-10, RSS-12, and RSS.

DISCUSSION

The most objective diagnostic approach for LPRD is the 24-hour HEMII-pH. However, this approach can be

TABLE III.
Test-Retest Reliability.

Reflux Sign Assessment-10 items	r_s
1. Anterior pillar ± uvula erythema	0.866
2. Coated tongue	0.575
Oral cavity subscore	0.437
1. Posterior oropharyngeal wall erythema ± granulation	0.068
2. Tongue tonsil hypertrophy	0.808
3. Pharyngeal sticky mucus	0.603
Pharyngeal cavity subscore	0.476
1. Epiglottis erythema	0.630
2. Ventricular band erythema ± edema	0.514
3. Arytenoid, posterior commissure erythema	0.096
4. Posterior commissure or retrocricoid hypertrophy ± granulation	0.620
5. Endolaryngeal sticky mucus	0.892
6. Vocal cord granuloma, keratosis, or ulceration	0.990
Laryngeal subscore	0.678
RSA-10 Total score	0.725

The data consist of correlation coefficients (Pearson analysis). There were only 2 patients with granuloma in the cohort.
RSA-10 = reflux sign assessment-10.

TABLE II.
Internal Validity.

Reflux Sign Assessment-10 items	LPRD	Controls	*p*-value
1. Anterior pillar ± uvula erythema	2.86 ± 1.24	2.57 ± 1.92	NS
2. Coated tongue	1.27 ± 0.66	0.82 ± 0.98	0.001
Oral cavity subscore	4.13 ± 1.59	3.38 ± 2.39	NS
1. Posterior oropharyngeal wall erythema ± granulation	2.18 ± 1.10	0.19 ± 0.84	0.001
2. Tongue tonsil hypertrophy	2.20 ± 1.61	2.00 ± 1.36	NS
3. Pharyngeal sticky mucus	1.75 ± 1.35	0.38 ± 1.17	0.001
Pharyngeal cavity subscore	5.90 ± 2.47	2.78 ± 2.04	0.001
1. Epiglottis erythema	1.04 ± 1.11	0.30 ± 0.90	0.001
2. Ventricular band erythema ± edema	0.74 ± 10.49	0.03 ± 0.26	0.001
3. Arytenoid, posterior commissure erythema	3.07 ± 1.60	0.71 ± 1.60	0.001
4. Posterior commissure or retrocricoid hypertrophy ± granulation	3.12 ± 1.61	1.67 ± 2.37	0.001
5. Endolaryngeal sticky mucus	0.91 ± 0.87	0.33 ± 0.93	0.001
6. Vocal cord granuloma, keratosis, or ulceration	0.04 ± 0.27	0.00 ± 0.00	0.001
Laryngeal subscore	8.92 ± 3.74	3.03 ± 3.27	0.001
RSA-10 Total score	19.00 ± 5.67	9.19 ± 4.78	0.001

LPRD = laryngopharyngeal reflux; NS = non-significant; RSA-10 = reflux sign assessment-10.

TABLE IV.
Interrater Reliability.

Reflux Sign Assessment-10 items	Fleiss kappa	*p*-value
1. Anterior pillar ± uvula erythema	0.509	0.001
2. Coated tongue	0.550	0.001
Oral cavity subscore	0.600	0.001
1. Posterior oropharyngeal wall erythema ± granulation	0.232	0.006
2. Tongue tonsil hypertrophy	0.663	0.001
3. Pharyngeal sticky mucus	0.524	0.001
Pharyngeal cavity subscore	0.558	0.001
1. Epiglottis erythema	0.585	0.001
2. Ventricular band erythema ± edema	0.249	0.001
3. Arytenoid, posterior commissure erythema	0.520	0.001
4. Posterior commissure or retrocricoid hypertrophy ± granulation	0.469	0.001
5. Endolaryngeal sticky mucus	0.516	0.001
6. Vocal fold granuloma, keratosis, or ulceration	0.990	0.001
Laryngeal subscore	0.633	0.001
RSA-10 Total score	0.708	0.001
RFS total score	0.630	0.001

NS = non-significant; RFS = reflux finding score; RSA-10 = reflux sign assessment-10.

costly, time-consuming, and is primarily available in Western countries, while otolaryngologists may still be unaware of its usefulness.[23] Therefore, the empirical therapeutic trial remains the most common approach for managing LPRD patients.[23] In 2019, our team developed the RSA.[7] RSA was the first clinical instrument to consider LPRD-related extra-laryngeal signs, which, though as prevalent as laryngeal signs, were seldom considered in previous clinical instruments.[7,11] RSA has been reported to possess high validity and reliability, however, completing the RSA can be time-consuming in otolaryngological practice. Using RSA in large cohort studies over the past few years has enabled us to identify the most prevalent LPRD-related signs, leading to the development of RSA-10.

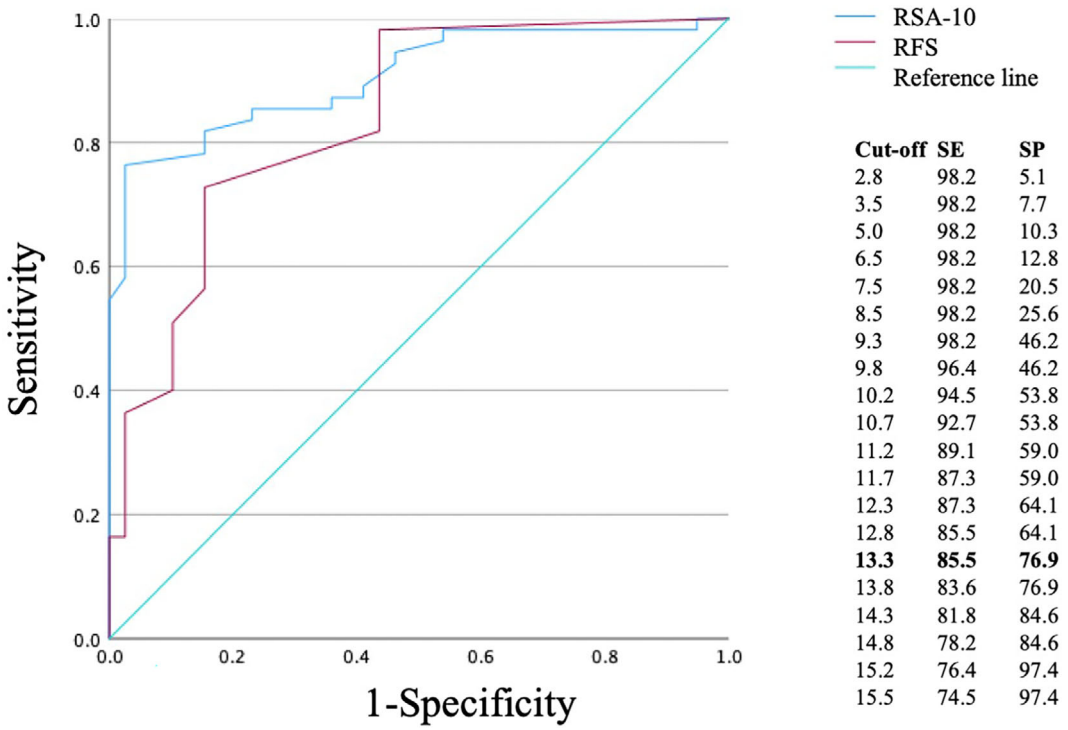
RSA-10 reports high internal consistency and test-retest reliability. Cronbach's alpha of RSA-10 and RSA were comparable (0.822 and 0.821). Notably, internal consistency has not been evaluated in previous clinical instruments, such as RFS,[6] Chronic Posterior Laryngitis Index (CPLI),[24] Laryngoscopic Grading Scale (LGS),[25] Laryngeal Reflux Grade (LRG),[26] and Laryngopharyngeal Reflux Disease Index (LRDI; Appendix 3).[27] The test-retest reliability of the RSA-10 total score was higher than that of some other clinical instruments,[27,28] and was comparable to or lower than that of RFS,[6] LRG,[26] and RSA.[7]

The internal validity of RSA-10 sub- and total scores was high, which corroborates the findings of RFS,[6] RSA,[7] and LRDI.[27] Other studies did not evaluate internal validity by comparing LPRD with asymptomatic subjects.[24–26] Interestingly, certain findings, such as anterior pillar erythema and tongue tonsil hypertrophy, showed a significantly higher prevalence in LPRD patients than in controls, yet their mean RSA-10 item scores did not differ between the groups. Two hypotheses might explain this observation. First, certain inflammatory findings, like erythema of the anterior pillar, may require more than 3 months of treatment to resolve. Second, despite a higher prevalence in LPRD patients than in controls, some signs may have multifactorial origins, such as tobacco-induced pharyngitis, allergy, postnasal drip related to rhinitis, and may present with few

TABLE V.
Responsiveness to Change Findings.

Reflux Sign Assessment-10 items	Baseline	3 mo	*p*-value
1. Anterior pillar ± uvula erythema	2.86 ± 1.24	1.84 ± 1.24	0.001
2. Coated tongue	1.27 ± 0.66	1.33 ± 0.71	NS
Oral cavity subscore	4.13 ± 1.59	4.04 ± 1.55	NS
1. Posterior oropharyngeal wall erythema ± granulation	2.18 ± 1.10	1.84 ± 1.24	NS
2. Tongue tonsil hypertrophy	2.00 ± 1.36	1.67 ± 1.30	0.049
3. Pharyngeal sticky mucus	1.75 ± 1.35	1.48 ± 1.37	NS
Pharyngeal cavity subscore	5.90 ± 2.47	4.99 ± 2.61	0.026
1. Epiglottis erythema	1.04 ± 1.11	0.49 ± 0.72	0.001
2. Ventricular band erythema ± edema	0.74 ± 10.49	0.56 ± 0.56	0.007
3. Arytenoid, posterior commissure erythema	3.07 ± 1.60	2.31 ± 1.56	0.019
4. Posterior commissure or retrocricoid hypertrophy ± granulation	3.12 ± 1.61	2.42 ± 1.75	0.011
5. Endolaryngeal sticky mucus	0.91 ± 0.87	0.73 ± 0.89	NS
6. Vocal fold granuloma, keratosis, or ulceration	0.04 ± 0.27	0.04 ± 0.27	NS
Laryngeal subscore	8.92 ± 3.74	6.55 ± 3.62	0.001
RSA-10 Total score	19.00 ± 5.67	15.56 ± 5.85	0.001
RFS total score	4.88 ± 2.37	3.75 ± 2.39	0.002

mo = month; NS = non-significant; RFS = reflux finding score; RSA-10 = reflux sign assessment-10.



Cut-off	SE	SP
2.8	98.2	5.1
3.5	98.2	7.7
5.0	98.2	10.3
6.5	98.2	12.8
7.5	98.2	20.5
8.5	98.2	25.6
9.3	98.2	46.2
9.8	96.4	46.2
10.2	94.5	53.8
10.7	92.7	53.8
11.2	89.1	59.0
11.7	87.3	59.0
12.3	87.3	64.1
12.8	85.5	64.1
13.3	**85.5**	**76.9**
13.8	83.6	76.9
14.3	81.8	84.6
14.8	78.2	84.6
15.2	76.4	97.4
15.5	74.5	97.4

Fig. 3. Receiver operating characteristics (ROC) curve of RSA-10. The area under the curve of ROC analysis for RSA-10 and RFS was 0.906, and 0.838, respectively. Abbreviations: RFS=reflux finding score; RSA-10=reflux sign assessment-10. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

symptoms or go undetected in healthy individuals. This emphasizes the importance of considering oral, laryngeal, and pharyngeal subscores rather than isolated and nonspecific signs when assessing changes in findings over time.

RSA-10 was significantly correlated with RFS, which suggests a high convergent validity. The convergent validity of RSA-10 was higher than that of RSA ($r_s = 0.771$ vs. 0.668),[7] with no data available for other instruments.[6,24–27] The interrater reliability (concordance) of RSA-10 was high ($k = 0.708$), corroborating the results of LGS,[25] and RSA[7] studies. Concordance is crucial in clinical practice, as patients may be evaluated by different practitioners over time using the same clinical instrument for follow-up. The higher concordance of RSA-10 over RSA is related to the use of scoring as descriptive as possible and the association of some close RSA items. Indeed, we observed that practitioners often had difficulty distinguishing closely related findings, such as posterior commissure hypertrophy and retrocricoid edema, leading us to combine these items. The low interrater reliability of some clinical instruments[9,10,26–28] is probably related to the use of subjective scoring systems (e.g., "mild," "moderate," or "severe"), which are based on the experience of practitioners, and, consequently, subjective. It has been demonstrated that some LPRD findings require more than 3 months of treatment to improve.[29] In this study, only the RSA-10 pharyngeal subscore, laryngeal subscore, and total score showed significant improvement after 3 months of treatment, suggesting adequate responsiveness to change. The oral finding score of RSA-10 did not change from pre- to posttreatment evaluations, while the oral subscore of RSA reported significant improvement after 3 months of treatment.[7,29] Statistically, combining the anterior pillar erythema and uvula erythema items may explain the observed lack of improvement due to the reduction of items and the maximum oral score, leading to a decreased score difference between baseline and posttreatment. However, we maintain that combining these two items was crucial for simplifying the assessment of findings in clinical practice. It is noteworthy that other LPRD-clinical instruments have shown a level of responsiveness to change comparable to that of RSA-10.[6,24–28]

The primary strengths of the present study are the consideration of patients with a demonstrated diagnosis of LPRD at the HEMII-pH and the development of a clinical instrument, which was based on findings from large cohort studies.[11] Thus, the validation of RSA-10 may be considered as the final step of a long work of several years, which started with the identification of the most prevalent LPRD signs,[30] the development and the application of the full version of RSA in several studies.[7,11] The use of HEMII-pH is a strength because LPRD symptoms and findings are nonspecific, and the inclusion of patients with a suspected LPRD diagnosis may bias the validity and reliability studies. Indeed, the pre- to posttreatment clinical evolution of patients with similar LPRD symptoms and findings but no LPRD may be insignificant, while the differences between suspected patients

and controls may be scarce. RSA-10 also proposed the possibility to include atypical signs associated with LPRD. Because LPRD may be atypical and involved in nasal or tear disorders, for example,[14,15,31,32] the practitioners may include atypical items to evaluate their changes over time. In the present study and because HEMII-pH may not be available in all hospitals, we reported that the association of RSS > 13 and RSA-10 > 13 may be used in an empirical therapeutic fashion for selecting patients with potential LPRD. Future studies could use RSS-12 in place of RSS to be more time-effective in clinical practice. Because of inconvenience and cost, the HEMII-pH was not performed in asymptomatic individuals, which is the primary limitation of the present study.

CONCLUSION

The RSA-10 is a reliable and valid clinical instrument for documenting the most prevalent laryngeal and extra-laryngeal findings associated with LPRD. An RSA-10 > 13 may be suggestive of LPRD, while RSA-10 > 13 and RSS > 13 report high sensitivity and specificity for the clinical diagnosis of LPRD.

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