



Original Article

## A Study to Correlate Reflux Symptom Index with Reflux Finding Score in Suspected Cases of Laryngopharyngeal Reflux Disease

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### ABSTRACT

Despite increasing prevalence of Laryngopharyngeal reflux disease (LPRD), it is often misdiagnosed and undertreated. Patients often present with vague and nonspecific symptoms leading to diagnostic dilemma. Combination of objective and subjective, when used together as a combination of symptoms and signs are a strong indicator of Reflux. The present study evaluated the correlation between Reflux Symptom Index (RSI) and Reflux Finding Score (RFS). A total of 85 patients aged between 18 to 64 years with symptoms suggestive of LPRD were included in the study. Patients with chronic debilitating disorders, Chronic NSAIDS users and Patients who have already received treatment for LPRD were excluded. Patients having RSI score of 13 or more were selected and further subjected to endoscopic examination for RFS assessment. Mean age of patients in this study was 35.7±12.2 years. Most commonly reported symptom based on RSI index was excessive throat clearing (96.5%) followed by heart burn (95.3%). The most common sign noted based on RFS was erythema (100%) followed by Posterior commissure hypertrophy (95.3%). Significant associations were noted between Throat mucus/postnasal drip and vocal fold edema; Difficulty in swallowing and ventricular obliteration, posterior commissure hypertrophy, and thick endolaryngeal mucus; Cough following eating/lying down and diffuse laryngeal edema and; Globus sensation and vocal fold edema ( $p < 0.05$ ). Based on Pearson's correlation test, significant positive correlation was observed between RSI and RFS scores with  $r = 0.6$  and  $p < 0.001$ . RSI questionnaire followed by RFS assessment should be implemented as a routine screening measure for the diagnosis of LPRD in ENT outpatient clinics.

**Keywords:** Laryngopharyngeal reflux disease, Reflux Finding Score, Reflux Symptom Index.

### AIM & BACKGROUND

Laryngopharyngeal reflux (LPR) is a form of extra esophageal reflux, which occurs secondary to reflux of gastric contents in the upper aero digestive tract resulting in laryngeal symptoms including throat clearing, hoarseness, pain, globus sensation, cough, excess mucus in the throat, and dysphonia<sup>1</sup>. Laryngopharyngeal reflux disease (LPRD) is a growing epidemic specially affecting the younger generation due to lifestyle and stress factors accounting for 10-30% of patients consulting Ear Nose and throat (ENT) specialists, however the exact prevalence is not known<sup>2</sup>. It is among one of the under diagnosed diseases and affects the overall quality of life, results in work impairment, financial losses; therefore, is of public health importance<sup>3</sup>. Previous studies have reported an association between LPRD and host laryngeal conditions such as muscle tension, dysphonia, spasm and stenosis<sup>4</sup>. Further, LPRD is considered as a risk factor for laryngeal squamous cell carcinoma of arytenoids and adenocarcinoma of distal esophagus<sup>5</sup>. LPRD is often misdiagnosed and undertreated. It is usually clinically diagnosed by clinical history and laryngoscope examination. Patients often present with vague and nonspecific symptoms such as foreign body sensation in throat, persistent dry

cough, frequent throat clearing, voice change, sore throat, thick mucus, feeling of lump in the throat and postnasal discharge adding to ambiguity of the diagnosis<sup>6</sup>. Due to lack of gold standard diagnostic methods and testing methods with lack of sensitivity or specificity further results in diagnostic dilemma. This further leads to unwanted treatment in such patients including repeated antibiotic courses, tonsillectomies, middle meatal antrotomy among others. Consequently, there is increased hospital visits by patients in chase of a diagnostic accuracy or improvement in symptoms leading to increased healthcare cost and resource utilization<sup>7,8</sup>.

Based on previous studies, ambulatory 24-hour pH dual/triple probe monitoring is considered standard for diagnosis of LPRD<sup>9</sup>. However, due to its invasive nature, increased error rate and cost, it is not often used routinely. Belafsky et al<sup>10</sup> developed Reflux Symptom Index (RSI), a self-administered 9-item questionnaire to assess symptoms related to LPR. A score of at least 13 was considered abnormal and indicative of LPRD. The diagnostic value of RSI is similar to pH monitoring<sup>11</sup>. Other newer clinical scales developed to diagnose LPR include Reflux Finding Score (RFS)<sup>12</sup>, Carlsson-Dent<sup>13</sup>, ReQuest<sup>14</sup>, and GerdQ<sup>15</sup>. These scales are simple, economical and minimally invasive diagnostic tools which use either clinical symptoms or laryngoscopic findings to diagnose LPR and aid in earlier initiation of treatment. Combination of objective and subjective assessment (RFS and RSI, respectively), when used together as a combination of symptoms and signs are a strong indicator of Reflux. These simple assessments when included in the outpatient setting as a diagnostic tool can aid in early diagnosis of the disease. Therefore, clinical correlation of these indices among patients with suspected LPRD is critical. In view of this the present study was undertaken to evaluate the relationship between RSI and RFS score in patients with suspected LPRD.

### AIM

The study aimed to understand the relationship between reflex symptom index and reflux finding score in patients with suspected laryngopharyngeal reflux disease.

### OBJECTIVES

- To identify the symptoms of laryngopharyngeal reflux using reflex symptom index score.
- To clinically assess the laryngopharyngeal reflex changes using 70-degree (4mm\*175mm) endoscope via reflex finding score.
- To clinically evaluate the correlation between the reflex symptom index and reflex finding score among patients with suspected laryngopharyngeal reflux disease.

### METHODS & MATERIALS

The present study was conducted among patients attending the outpatient department of ENT at Karnataka Institute of Medical Sciences, Hubballi.

Study design

Cross-sectional study

Study period

One year, from May 2023 to April 2024

Place of study

Department of ENT, Karnataka Institute of Medical Sciences, Hubballi.

Sampling method

Convenient/ Random Sampling method

Sample size calculation

In a previous study by Powell J et al<sup>16</sup> prevalence of symptoms of LPRD was 29.8%, with a confidence interval of 95%.

Based on this the sample size of current study was calculated using the formula:

$$N=4pq/d^2$$

Where, p=prevalence (29.8%),

q=100-p (70.2),

d=precision (10),

Sample size (n)=83.67.

Sample size was rounded-off to 85.

Selection criteria:

Inclusion criteria

- Patients above 18 years of age
- Patients presenting with the symptoms suggestive of LPR disease.

#### Exclusion criteria

- Patients with chronic debilitating disorder
- Chronic NSAID users
- Patients who have already received treatment for LPR disease
- Patients who do not provide consent to participate in the study.

#### Study methodology

Following the clearance and approval from the institutional ethics committee, all patients fulfilling the inclusion criteria and willing to participate in the study by signing the informed consent were included in the study. Detailed history followed by complete general physical examination and complete otorhinolaryngological examination was carried out and details were entered in a case history proforma designed specifically for the study. The patients underwent the following tests:

- Reflex symptoms index score card
- 70-degree endoscopic examination of larynx

Those patients who fulfilled the inclusion and exclusion criteria were enrolled and subjected to endoscopic examination.

Patients were evaluated using Reflux Symptom Index, a set of nine self-assessment questions that are graded from 0 to 5 (with a total score of 0 – 45) according to severity and those who were having a score of 13 or more in symptom scores were selected for endoscopic examination for the assessment of reflux finding score after getting consent.

Xylocaine viscous 10 ml was administered orally to the patient. The patient was advised not to swallow and retain the preparation for 2 minutes to anaesthetize the throat. 70-degree Hopkins Endoscope was introduced with proper lubrication through oral cavity and guided to the laryngopharynx and the larynx was assessed. Patient's Reflux finding scores were assessed. Endoscopic examination was done by the study investigator and confirmed by an expert who was not below the post of an Assistant professor. We recorded the Reflux Symptom Index and Reflux Finding Score on the proforma along with a set of questions regarding their dietary, history and habits.

#### Reflux symptom index

Reflux Symptom Index was obtained from all the patients included in the study. Reflux Finding Score was evaluated with 70° endoscope. Patients with Reflux Symptom Index score  $\geq 13$  and Reflux Finding Score  $\geq 7$  was considered as positive for Laryngopharyngeal Reflux diseases.

In order to reduce the observation bias, RSI and RFS questionnaires were assessed by independent examiners. RSI was translated to local language and was administered by a first examiner. 70° Endoscopic Examination of Larynx was carried out by the 2nd examiner who was blinded to the RSI findings. The RFS findings were further confirmed by a 3rd expert examiner with ample experience in the field.

#### Ethical consideration

Institutional ethical clearance was obtained prior to initiation of the study. The details of the study were explained to the patients and an informed consent was obtained from all patients.

#### Statistical analysis

The data collected was entered into excel sheet and was analyzed using SPSS ver. 21.0. Continuous variables were presented using mean, standard deviation, median, maximum and minimum values. Categorical variables are presented as frequency and percentages. Overall total RSI and RFS score were calculated and described using descriptive statistics. Severity of individual signs and symptoms were assessed based on scoring. Association between signs and symptoms was carried out using fisher exact test. Correlation between RSI and RFS was carried using Pearson correlation analysis. P value of  $<0.05$  was considered statistically significant.

## RESULTS

#### Age and Gender

A total of 85 patients were included in the study. The mean age of the study participants was  $35.7 \pm 12.2$  years and the median age was 35 years. Majority of the patients were between the age group of 21-30 years ( $n=24$ , 28.2%), followed by 31-40 years ( $n=23$ , 27.1%). Majority of the study participants were females (Male- $n=39$ , 45.9% and Female- $n=46$ , 54.1%).

### Education and Occupation

Most patients were either completed graduation or studying (n=26, 30.6%) followed by PUC and secondary education until 10th standard (n=24, 28.2%, each). Most patients in the study were homemakers (n=26, 30.6%) followed by students who weren't working (n=14, 16.5%) and agriculture (n=13, 15.3%).

### Personal habits

Among the study participants, 34.1% (n=29) had history of smoking, 21.2% (n=18) had history of tobacco consumption and 10.6% (n=9) had history of alcohol consumption.

### Body mass index (BMI)

The mean BMI of the study participants was  $23.8 \pm 3.8$  Kg/m<sup>2</sup> and median BMI was 22.9 Kg/m<sup>2</sup>. The minimum and maximum BMI among the study participants was 16.3 and 36.2 Kg/m<sup>2</sup>. Majority of the study participants were overweight (n=22, 25.9%).

### Signs and Symptoms

Most patients complained of foreign body sensation in throat (n=23, 27.1%) followed by change in voice (n=14, 16.5%). In the study population, most commonly reported symptom based on RSI index was excessive throat clearing (n=83, 96.5%) followed by heart burn (n=81, 95.3%) and globus sensation (n=79, 92.9%).

The most common sign noted based on RFS was erythema (n=85, 100%) followed by PC hypertrophy (n=81, 95.3%) and diffuse laryngeal edema (n=80, 94.1%).

### RSI and RFS

**Table 1: Correlation between RSI and RFS**

RFS/ RSI	13-17	18-22	23-27	28-32	P value
7-11	50	11	2	3	0.000*
12-16	2	4	10	0	
17-21	0	0	0	3	

\*-Correlation significant at the 0.01 level

The RSI score ranged from 13-30 with a mean  $\pm$  SD of  $17.4 \pm 4.7$  and a median of 15. Overall, total score of most patients was 13-17 (n=52, 61.2%) followed by 18-22 (17.6%).

The RFS score ranged from 7 to 17 with a mean  $\pm$  SD of  $9.6 \pm 2.6$  and a median of 9. Overall, total score of most patients ranged between 7 and 11 (n=66, 77.6%) followed by 12-16 (n=16, 18.8%).

Subglottic edema was absent in all patients (n=85, 100%).

Ventricular obliteration was noted in 41 (48.2%) patients, all cases had partial obliteration.

Erythema was noted in all patients; 11(12.9%) had only in the arytenoid while 74 (87.1%) had diffuse erythema.

Vocal cord edema was mild, moderate and severe among 54 (63.5%), 16(18.8%) and 3 (3.5%), respectively.

Diffuse laryngeal edema was mild, moderate and severe among 40 (47.1%), 29 (34.1%) and 11 (12.9%), respectively.

Posterior commissure hypertrophy was mild, moderate and severe among 32 (37.6%), 26 (30.6%) and 23 (27.1%), respectively.

Granuloma/granulation tissue was present in 2 (2.4%) of patients and thick Endolaryngeal Mucus was present in 11 (12.9%) of patients.

Presence of erythema was common for all symptoms. Vocal fold edema, Diffuse Laryngeal edema, PC Hypertrophy was seen in over 80% of patients with any reported symptoms. Significant association was seen between throat mucus/postnasal drip with vocal fold edema; Difficulty in swallowing with ventricular obliteration, PC hypertrophy and thick Endo laryngeal Mucus; Cough following eating /lying down with Diffuse Laryngeal edema and Globus sensation with vocal fold edema.

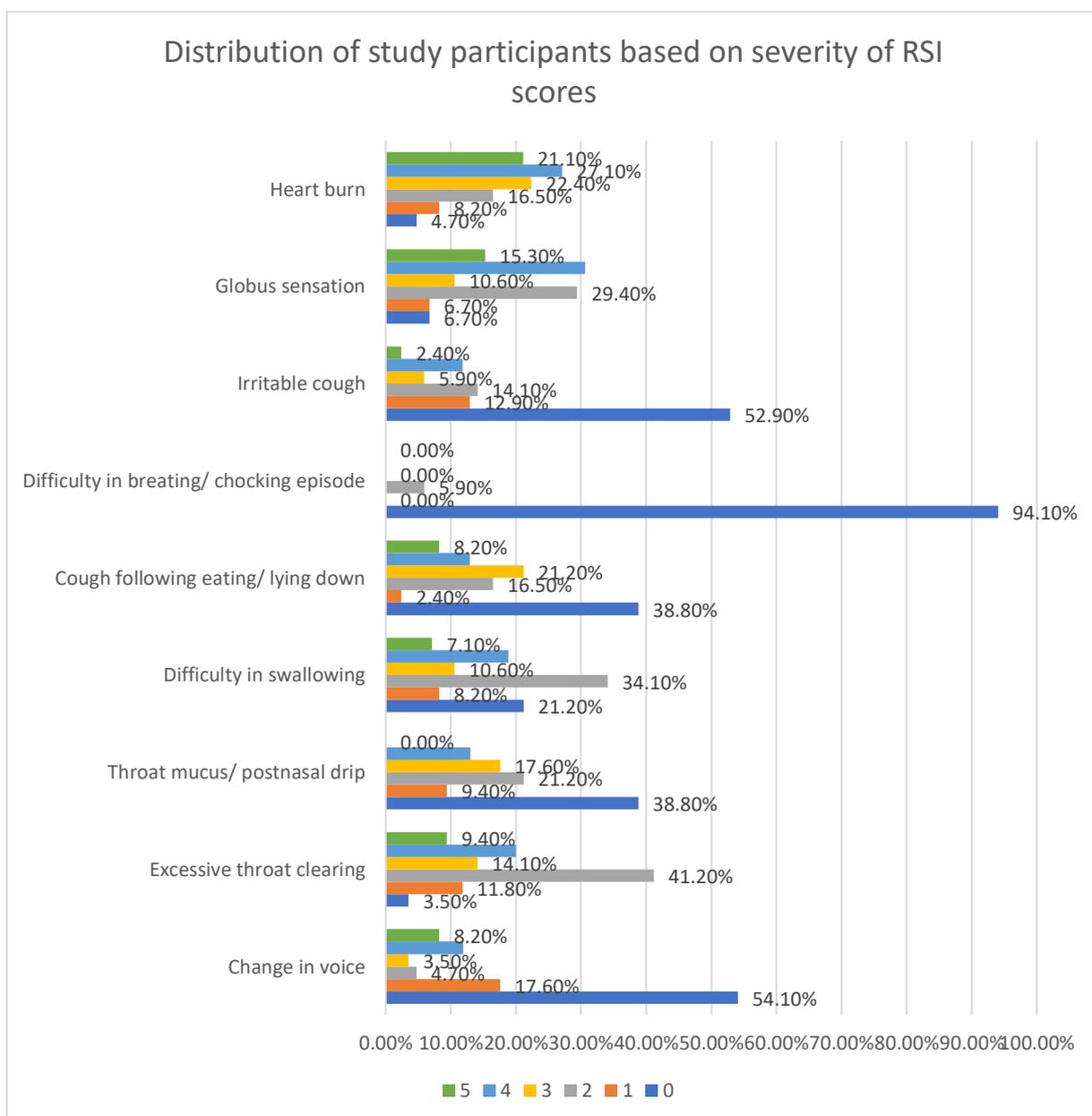
### DISCUSSION

A total of 85 adult patients presenting with symptoms suggestive of LPR were included in this study. The mean age of the patients was  $35.7 \pm 12.2$  years, with a median age of 35 years. The lower age distribution in our study aligns with findings from Lechien JR et al<sup>17</sup>. who studied the impact of age on LPR. Despite experiencing similar LPR symptoms, older patients tend to report fewer complaints compared to younger patients. This suggests that age may diminish the subjective perception of LPR symptoms, resulting in lower rates of hospital reporting and diagnosis.

Previous studies have reported differences in reflux characteristics. Liu Z et al<sup>18</sup>. noted a higher incidence of LPR positivity and a higher symptom score among women compared to men. Similarly, in our study, 39 patients were male (45.9%) and 46 patients (54.1%) were female, suggesting a slightly higher frequency of LPRD among women.

Smoking, tobacco use, alcohol consumption, and increased coffee intake are known to increase the risk of LPR<sup>19,20</sup>. Additionally, patients with these habits tend to have higher symptom scores. However, our study found no significant association between smoking and alcohol consumption in relation to LPR. Interestingly, BMI showed a negative correlation with LPR, with higher BMI associated with lower odds of LPR. Prevalence of smoking, tobacco use and alcohol in the present study was 34.1%, 21.2% and 10.6% respectively. While the association remains controversial based on previous studies, clinicians should educate patients about the impact of smoking, tobacco, alcohol consumption, and weight gain on the development of LPR. They should also provide guidance on smoking cessation, reduction of alcohol intake, and lifestyle modifications.

The most common complaints among LPR patients include coughing, hoarseness, dysphagia, globus sensation, and sore throat, among others. In our study, the predominant complaint was foreign body sensation in the throat (n=23, 27.1%), followed by voice changes (n=14, 16.5%). This finding is consistent with a study by Fathima A et al<sup>21</sup>., where foreign body sensation in the throat was reported by 52% of patients.



**Figure 1: Distribution of study participants based on severity of RSI scores**

Most commonly reported symptoms based on the RSI were excessive throat clearing (n=83, 96.5%), heartburn (n=81, 95.3%), and globus sensation (n=79, 92.9%). The least reported symptom was difficulty in breathing or choking episodes (n=5, 5.9%). These symptom profiles differ slightly from those reported by Nunes HS et al.<sup>22</sup>, where cough (40%), globus sensation (21%), dysphonia (20%), throat clearing (16%), postnasal drip (3%), and other symptoms were common among their study participants.

All patients in our study had an RSI score of 13 or higher, indicative of LPRD. The mean  $\pm$  SD RSI score was  $17.4 \pm 4.7$ , with a median RSI score of 15. This mean score is lower than the 20.7 reported by Nunes HS et al.<sup>22</sup>. Overall, the majority of patients had total RSI scores ranging from 13 to 17 (n=52, 61.2%), followed by scores of 18 to 22 (n=15, 17.6%). Only 6 patients (7.1%) had scores between 28 and 32, suggestive of severe disease. This suggests that LPRD was less severe among the study population.

**Table 2: Signs**

SIGNS	Number (%)
Subglottic edema	85 (100%)
Ventricular obliteration	
Absent	44 (51.8%)
Partial	41 (48.2%)
Complete	0 (0%)
Erythema/ hyperemia	
Absent	0 (0%)
Only in arytenoid	11 (12.9%)
Diffuse	74 (87.1%)
Vocal fold edema	
Absent	12 (14.1%)
Mild	54 (63.5%)
Moderate	16 (18.8%)
Severe	3 (3.5%)
Polypoid	0 (0%)
Diffuse laryngeal edema	
Absent	5 (5.9%)
Mild	40 (47.1%)
Moderate	29 (34.1%)
Severe	11 (12.9%)
Obstruction	0 (0%)
Posterior commissure hypertrophy	
Absent	4 (4.7%)
Mild	32 (37.6%)
Moderate	26 (30.6%)
Severe	23 (27.1%)
Obstruction	0 (0%)
Granuloma/ Granulation tissue	2 (2.4%)
Thick endo laryngeal mucus	11 (12.9%)

Based on RFS assessment in our study, the most common sign was erythema (n=85, 100%). None of the patients exhibited subglottic edema, and only 2 patients had granuloma (n=2, 2.4%). These findings align with those of Fathima A et al<sup>21</sup>, who reported hyperemia/erythema of laryngeal tissue, particularly bilateral arytenoids, as the most common sign observed.

All patients in our study had an RFS score of 7 or higher, indicating LPRD. The mean  $\pm$  SD RFS score was  $9.6 \pm 2.6$ , with a median score of 9, consistent with the 9.5 reported by Nunes HS et al.<sup>22</sup>.

Our study also found a significant positive correlation between RSI and RFS scores. These findings are consistent with previous studies by Mesallam TA et al.<sup>23</sup>, which reported significant correlations between RSI and RFS, and positive correlations between hoarseness, vocal fold edema, and thick laryngeal mucus, as well as between excessive throat clearing and thick endo-laryngeal mucus. Studies by Jawad J et al<sup>24</sup> and Geraldi M et al.<sup>25</sup> similarly reported significant correlations between RSI and RFS among patients diagnosed with LPRD.

Screening for LPRD using RSI and RFS may introduce bias if assessed by a single examiner. Additionally, interobserver bias can occur since RFS findings are subjective. Vance D et al.<sup>26</sup> previously reported fair to substantial interrater reliability and modest intra-rater reliability in RFS assessment when four observers were involved. In our study, to mitigate observation bias, RSI and RFS were independently evaluated by different examiners. Furthermore, RFS findings were validated by an expert to ensure accuracy. Implementing a blinded approach, where the clinician performing laryngeal endoscopy for RFS assessment is unaware of the patient's RSI results, should be standard practice across healthcare settings to minimize observer bias.

In clinical practice, due to the challenge of "silent reflux" and inadequate diagnostic and therapeutic protocols, LPRD is frequently misdiagnosed, leading to treatment delays, increased morbidity, more hospital visits, decreased quality of life, and greater healthcare resource utilization. Early diagnosis using reliable screening measures such as RSI in outpatient settings, and correlating these findings with RFS, can facilitate early detection of LPRD. Our study identified a significant correlation between RFS and RSI, suggesting that these tools can be effectively utilized in routine ENT outpatient settings as screening measures for diagnosing LPRD.

#### Strengths and Limitations

Correlation of RSI and RFS was assessed among patients who had definitive LPRD in RSI ( $\geq 13$ ). There are few limitations in the present study which includes small sample size, single-center study, and Only patients with symptoms suggestive of LPRD ( $\geq 13$ ) were included in the study.

#### CONCLUSION

RSI questionnaire followed by RFS assessment should be implemented as a routine screening measure for the diagnosis of LPRD in ENT outpatient clinics. RSI and RFS questionnaires to be tested in routine outpatient settings in larger multicenter clinical settings with diverse populations among all patients who present with complaints suggestive of LPRD to assess the real-world benefit of RSI and RFS questionnaires.

#### Clinical Significance

- Occurrence of LPRD predominant in younger age group and women.
- Excessive throat clearing, heartburn, and globus sensation are commonly reported symptoms.
- Erythema, PC hypertrophy, and diffuse laryngeal edema are commonly observed signs.
- The RSI questionnaire and RFS assessment with an endoscope are simple, economical, and minimally invasive diagnostic methods.
- These subjective and objective measures of LPRD assessment should be implemented as routine screening measures for the diagnosis of LPRD in ENT outpatient clinics.

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