

## Usefulness of Reflux Symptom Index and Reflux Finding Score in the diagnosis of Laryngopharyngeal Reflux Disease

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### Abstract

#### Introduction:

Laryngopharyngeal reflux disease (LPRD) is a common condition with an estimated prevalence between 8-30% in the general population. The complaints of LPRD are non-specific and may overlap with many other common conditions leading to misdiagnosis. Reflux Symptom Index (RSI) is a 9-item patient response based questionnaire developed to diagnose LPRD. Similarly, Reflux Finding Score (RFS) is an 8-item based scoring system created to diagnose LPRD based on endoscopic findings during laryngoscopy. The aim of our study was to evaluate the usefulness of the two scoring systems in identifying patients with LPRD.

#### Materials and Methods:

Patients with features suggestive of LPRD were considered for participation as per strict inclusion and exclusion criteria. The RSI and RFS was calculated in each case and result was analyzed for statistical significance.

#### Results:

Total of 150 patients were identified with 37.38 years as mean age of presentation. M:F ratio was 1:1.88. 111 cases (74%) had RSI score above 13 suggestive of LPRD with mean RSI of 19.58. 84 cases (56%) had RFS above 7 suggestive of LPRD with mean RFS of 7.29. There was a positive correlation between RSI score and RFS.

#### Conclusion:

There was positive correlation between RSI score and RFS in our study ( $p < 0.0001$ ) and the correlation was stronger with RSI scores above 13. This corroborates with the findings of most studies although some authors have inferred otherwise. Using both RSI score and RFS may be useful and complimentary to each other for the correct diagnosis of LPRD.

**Keywords:** Laryngopharyngeal reflux disease (LPRD); Reflux Symptom Index (RSI); Reflux Finding Score (RFS)

Received date: 20 Dec 2025

Accepted date: 04 Jul 2026

**\*Please cite this article;** Chatterji P, Mukherjee Y. Usefulness of Reflux Symptom Index and Reflux Finding Score in the diagnosis of Laryngopharyngeal Reflux Disease. *Iran J Otorhinolaryngol*. 2026;38(5): 333-340.  
Doi: 10.22038/ijorl.2026.93713.4111

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## Introduction

Laryngopharyngeal reflux disease (LPRD) is frequently encountered in clinical practice, with a wide-ranging prevalence from 8% up to 30% in the community (1,2).

It is primarily caused by chronic exposure of the mucosal lining of the pharynx, larynx and rest of the airway to the regurgitated gastric & duodenal contents (1). This results in the inflammation of the mucosal lining and its subsequent signs and symptoms.

Frequently encountered symptoms include a persistent sensation of a “lump” in the throat, dysphagia, voice changes, throat pain, and recurrent spells of coughing, along with a range of other associated complaints (3). In long-standing cases, the refluxate may even reach as high as the oropharynx and nasopharynx and result in altered middle ear physiology due to chronic Eustachian tube dysfunction (4).

The clinical presentation of LPRD is, however, very much non-specific and overlaps with many other common conditions. This may lead to a wrong diagnosis if the subjects are not assessed in a meticulous manner (5).

Thus, researchers have grappled with the idea of creating a standard and reproducible protocol for the diagnosis of LPRD so that the condition may be identified and reported accurately.

As the initial suspicion of LPRD is largely based on the subjective complaints of the patient, Belafsky and colleagues developed a standardized screening tool in the form of a nine-item self-assessment questionnaire. Each parameter is graded on a scale of 0 to 5, ranging from no symptoms to severe symptoms, yielding a maximum possible score of 45. The cumulative score is reported as the Reflux Symptom Index (RSI), with a value exceeding thirteen considered indicative of LPRD (6).

Endoscopic laryngeal examination has also become an essential part of the ENT specialist's armamentarium for assessing the throat. However, the reporting of findings may vary widely from one specialist to another as the assessment is subjective in nature. To ensure uniform documentation and interpretation of laryngoscopy findings, the Reflux Finding Score (RFS) was developed. This clinician-based grading tool evaluates eight distinct endoscopic features of the larynx, with scores assigned according to the extent of observed abnormalities. The maximum attainable score is

26, out of which Belafsky considered a score >7 as significant and highly indicative of LPRD. In addition to aiding diagnosis, the scoring system also serves as a valuable method for assessing therapeutic response to treatment and tracking disease progression over time (7). As is evident, the RSI depends on patient response, while RFS is dependent on observer interpretation of endoscopic findings. We undertook a study to assess the usefulness of the two scoring systems in the assessment of subjects with LPRD.

## Materials and Methods

The goal of the study was to evaluate the usefulness of RSI and RFS in assessing subjects with LPRD. Permission was received from the Institutional Ethics Committee of our Institute before the commencement of the research. An outpatient department-based observational study was carried out over a 12-month period. All patients presenting with features suggestive of LPRD were enrolled for participation. The inclusion & exclusion criteria for patient enrolment were as follows:

### Inclusion Criteria

- Subjects over the age of 18 years with symptoms suggestive of LPRD for at least 3 months duration
- Voluntary participation

### Exclusion Criteria

- Presence of any other laryngeal pathologies like vocal cord polyps, nodules and neoplasms identified during laryngeal endoscopy.
- Patients already taking Proton Pump Inhibitors for treatment of LPRD.
- Smokers were also excluded as it is a common cause of chronic laryngitis.

Consent was taken from all the participants, and a meticulous history was taken regarding the presenting complaints, followed by a complete ENT clinical examination.

The patients were then asked to fill out the RSI questionnaire to record their individual complaints. The questionnaire was printed in both English and Hindi (validated version), and it was given to the patients as per their choice.

All findings were recorded in a standard format. This was followed by laryngoscopy on an out-patient basis. It was done under topical anaesthesia using a 70° rigid endoscope. All procedures were carried out using established aseptic protocols, and the endoscope was appropriately sterilized prior to use with 2%

Glutaraldehyde solution for 30 minutes. All cases were assessed by one clinician to prevent inter-observer variability. The RFS for each patient was calculated based on the endoscopic assessment and subsequently recorded in an independent proforma. Finally, all the data was analyzed and checked for statistical significance. Statistical methods: All the data was compiled and the applicable statistical analysis was done using Statistical Package of Social Sciences V23.0 and Microsoft Excel 2019. McNemar test on paired proportions was applied for testing any association between RSI and RFS. p-value < 0.05 was considered to be significant in each case.

## Results

In the present study, we recruited 150 subjects who fulfilled the inclusion criteria. Of the total subjects enrolled, 98 were women and 52 were men, representing 65.3% and 34.7% of the cohort, respectively.

The gender distribution translated to a female-to-male ratio of 1.88:1.

Patients in the fourth decade of life were most frequently represented in the study cohort, with 47 cases (31.3%). The second most common age group were those in the third decade, comprising 43 patients (28.6%) (Table. 1). The overall mean age of the participants was found to be 37.38 years.

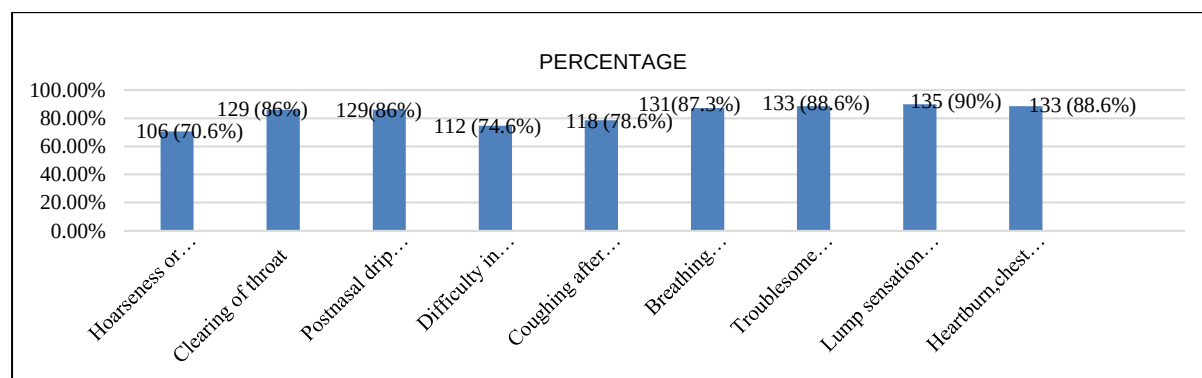
**Table 1.** Age distribution of patients

| Age of the patients | Men | Women | Cumulative | p-value                  |
|---------------------|-----|-------|------------|--------------------------|
| 21 years-30 years   | 16  | 27    | 43 (28.6%) | 0.3549 (not significant) |
| 31 years-40 years   | 17  | 30    | 47 (31.3%) |                          |
| 41 years-50 years   | 6   | 20    | 26 (17.3%) |                          |
| 51 years-60 years   | 8   | 16    | 24 (16%)   |                          |
| 61years -70 years   | 5   | 3     | 7 (4.6%)   |                          |
| 71 years -80 years  | 0   | 2     | 2 (1.3)    |                          |
| Total               | 52  | 98    | 150 (100%) |                          |

Symptom analysis demonstrated that the overwhelming majority of participants experienced a globus-like sensation, with 135 individuals (90%) reporting a feeling of something being lodged in the throat. Respiratory and reflux-related manifestations were also highly prevalent. Both persistent cough and heartburn were documented in 133 patients (88.6%), whereas choking spells or episodes of breathing discomfort were recorded in 131 patients (87.3%). Complaints related to throat secretions were similarly common, with excess mucus production and repeated throat clearing each affecting 129 subjects (86%). Postprandial cough especially after lying down

was present in 118 patients (78.6%). Swallowing discomfort was reported by 112 individuals (74.6%), while disturbances in vocal quality, including hoarseness, were noted in 106 patients (70.6%) (Fig.1). The statistical analysis of the findings suggests that presenting complaints varied with every patient and p-value obtained was not significant (0.5374).

When symptom severity was quantified using the RSI, only about one-quarter of the subjects (n = 39, 26%) achieved scores of 13 or less. On the contrary, 111 cases (74%) had a score >13 which was indicative of LPRD. (p-value <0.0001) (Figure. 1) The mean value of RSI was 19.58 with SD 7.04.



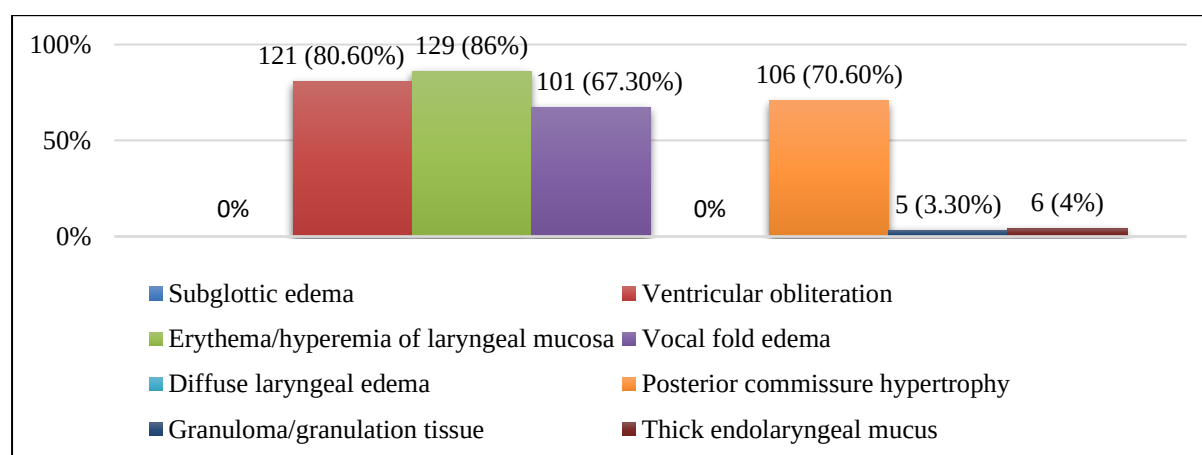
**Fig.1.** Bar chart depicting various complaints of patients suggestive of LPRD

**Table 2.** RSI score findings

| Reflux Symptom Index (RSI) score             | Number of subjects | %    | p-value                                            |
|----------------------------------------------|--------------------|------|----------------------------------------------------|
| RSI score $\leq 13$ (not indicative of LPRD) | 39                 | 26%  | <0.0001 and hence was considered to be significant |
| RSI score $>13$ (indicative of LPRD)         | 111                | 74%  |                                                    |
| Cumulative                                   | 150                | 100% |                                                    |

The 8-parameter based laryngoscopy findings for assessment of RFS was done in all cases by one clinician only (to prevent inter-observer variations in reporting) and it showed that maximum number of patients i.e. 129 (86%) had feature of erythema/hyperaemia of the laryngeal mucosa followed by ventricular obliteration in 121 cases (80.6%), posterior

commissure hypertrophy in 106 cases (70.6%) and vocal fold oedema in 101 cases (67.3%). Only 5 (3.3%) and 6 (4%) cases had features of granulation tissue and thick endolaryngeal mucus, respectively, while none had subglottic oedema or diffuse laryngeal oedema. (p-value < 0.0001) (Figure. 2)

**Fig. 2.** Bar chart depicting laryngeal findings during assessment of RFS

When endoscopic abnormalities were quantified using the Reflux Finding Score, 66 participants (44%) were found to have values  $\leq 7$  suggesting that these patients did not exhibit features of laryngopharyngeal reflux.

On the contrary, 84 cases (56%) had a score  $>7$  indicating features of LPRD. (p-value 0.1416) (Table. 3) The mean value of RFS was 7.29 with SD 3.24.

**Table 3.** RFS findings

| Reflux Finding Score (RFS)            | Number of subjects | %    | p-value                  |
|---------------------------------------|--------------------|------|--------------------------|
| RFS $\leq 7$ (not indicative of LPRD) | 66                 | 44%  | 0.1416 (not significant) |
| RFS $>7$ (indicative of LPRD)         | 84                 | 56%  |                          |
| Total                                 | 150                | 100% |                          |

To determine whether patient-reported symptom severity reflected objective laryngeal findings, a correlation analysis was performed between RSI and RFS scores. The results demonstrated a significant positive correlation,

suggesting concordance between the two measures. This relationship was highly significant ( $p < 0.0001$ ) and became stronger when RSI scores exceeded the diagnostic threshold of 13 (Table. 4).

**Table 4.** Showing McNemar test on paired proportions

|            | RSI >13 | RSI ≤13 | Total | p-value |
|------------|---------|---------|-------|---------|
| RFS >7     | 78      | 6       | 84    | <0.0001 |
| RFS ≤7     | 33      | 33      | 66    |         |
| Cumulative | 111     | 39      | 150   |         |

(95% Confidence Interval has values between 10.37% and 25.63%; Difference of 18.00%;)

## Discussion

From a historical perspective, LPRD has been identified as a specific pathological condition only in the last three decades or so. The credit for that goes to J.A Koufman who did pioneering research on this subject and whose landmark thesis on it was published about 35 years ago in 1991 (8).

Considering the high prevalence of this condition, some researchers have estimated that 15 - 20% of cases attending the otolaryngology clinic with non-specific complaints like chronic cough, sore throat, voice change and globus sensation may be due to LPRD or various other causes (9). Fraser and colleagues have suggested that LPRD may be diagnosed in approximately 10% of patients attending the outpatient department of our speciality and the figure may be as high as 50% in cases presenting with voice complaints (10). Unlike the oesophagus, which is adapted to withstand considerable chemical and mechanical stress, the larynx is covered by relatively fragile squamous and respiratory epithelial layers that are more susceptible to damage. When the regurgitated gastric contents reach the larynx, they cause local tissue injury that is most likely caused by the activated pepsin. The affected tissue demonstrates considerable vulnerability,

with pathological changes reported following exposures as short as half a minute when repeated three times weekly (1).

There are a number of methods available for the diagnosis of LPRD of which oesophageal pH monitoring and oesophageal manometry are the gold standard (11). Unfortunately, they are expensive, time consuming and not available universally. Similarly, identification of pepsin in the saliva (salivary pepsin test) which is an immunological in-vitro test, was initially thought to be a very easy and useful tool to identify patients with LPRD, but a meta-analysis done in 2018 concluded that it has only limited diagnostic value and it is not as useful as it was previously thought (12). Therefore, researchers have been attempting to identify a cheap, user friendly and reliable method of diagnosis of LPRD for a long time. That is where the role of RSI and RFS comes in to the picture. The mean age of subjects in the current study (37.38 years) correlates well with the findings of Soni et al (39 years) (13).

The most common presenting complaints of LPRD in our study are compared with findings of some other studies in the table below (14, 15). It is quite evident that the figures vary widely from parameter to parameter from study to study.

**Table 5.** Comparison of subjective complaints of patients with other studies

| Variable                            | Present study | Bhargava et al <sup>14</sup> | Satish et al <sup>15</sup> |
|-------------------------------------|---------------|------------------------------|----------------------------|
| Foreign body sensation in throat    | 135 (90%)     | 66 (55%)                     | 55 (71.6%)                 |
| Cough                               | 133 (88.6%)   | 61 (51%)                     | 22 (28.57%)                |
| Heart burn/ Chest pain              | 133 (88.6%)   | 34 (28.3%)                   | 61 (79.2%)                 |
| Difficulty in swallowing            | 112 (74.6%)   | 28 (23.3%)                   | 27 (35%)                   |
| Hoarseness                          | 106 (70.6%)   | 48 (40%)                     | 30 (38.96%)                |
| Excess throat mucus                 | 129 (86%)     | 30 (25%)                     | 44 (57.14%)                |
| Coughing after eating or lying down | 118 (78.6%)   | 25 (20.8%)                   | 22 (28.57%)                |
| Breathing difficulties              | 131 (87.3%)   | 21 (17.5%)                   | 21 (27.27%)                |

The present study revealed that 111 cases (74%) had a score >13 which was indicative of typical presentation of LPRD while only 39 subjects (26%) out of 150 had a score of 13 or below. The values match the findings of Karakaya where 68% had scores above 13 and

32% had score 13 or below (16). The comparison of assessment by laryngoscopy with findings of other studies are shown in the table below. The parameters vary widely from study to study.

**Table 6.** Comparison of laryngeal findings with other studies

| Variable                                | Present study | Bhargava et al <sup>14</sup> | Satish et al <sup>15</sup> | Karakaya et al <sup>16</sup> |
|-----------------------------------------|---------------|------------------------------|----------------------------|------------------------------|
| Erythema/hyperaemia of laryngeal mucosa | 129 (86%)     | 86 (71.6%)                   | 57 (74%)                   | 53 (98.2%)                   |
| Post. commissure hypertrophy            | 106 (70.6%)   | 74 (61.6%)                   | 7 (9%)                     | 54 (100%)                    |
| Ventricular obliteration                | 121 (80.6%)   | 68 (56.6%)                   | 6 (7.79%)                  | 37 (71.3%)                   |
| Vocal fold oedema                       | 101 (67.3%)   | 26 (21.6%)                   | 15 (19.4%)                 | 54 (100%)                    |
| Diffuse laryngeal oedema                | 0             | 26 (21.6%)                   | 12 (15.58%)                | 53 (98.2%)                   |
| Granuloma/granulation tissue            | 5 (3.3%)      | 48 (40%)                     | 4 (5.19%)                  | 0                            |
| Thick endo-laryngeal mucus              | 6 (4%)        | 65 (54.1%)                   | 2 (2.59%)                  | 11 (18.2%)                   |
| Subglottic oedema                       | 0             | 18 (15%)                     | 12 (15.58%)                | 20 (36.2%)                   |

We also compared the mean values of RSI and RFS of our study with results of some

other studies as depicted below in Table 7 (16,17,18).

**Table 7.** Comparison of mean values of RSI and RFS with the other studies

| Variable | Present study | Karakaya et al <sup>16</sup> | Nunes et al <sup>17</sup> | Sirajuddin et al <sup>18</sup> |
|----------|---------------|------------------------------|---------------------------|--------------------------------|
| RSI mean | 19.58±7.04    | 18.6±4.4                     | 20.7±6.67                 | 15.45±7.85                     |
| RFS mean | 7.29±3.24     | 14.2±4.6                     | 9.53±2.64                 | 9.33±2.44                      |

The present study demonstrated a significant direct relationship between symptom severity, as measured by the Reflux Symptom Index, and laryngoscopy abnormalities quantified using the Reflux Finding Score. The strength of this association increased among patients with RSI values exceeding 13, and the observed correlation was highly significant statistically ( $p < 0.0001$ ). These observations are in agreement with the findings of Messalam, who reported a similarly strong correlation between RSI and RFS with a highly significant p-value ( $<0.0001$ ) (9). Comparable results were also described by Nunes, who noted a robust association between the two indices in the majority of evaluated patients and emphasized the utility of RSI as a valuable aid in the assessment of suspected LPRD (17). Furthermore, Karakaya demonstrated significant positive relationships between RSI and nearly all individual RFS components, with

the exception of posterior commissure hypertrophy (16). Their study likewise identified a statistically significant correlation between the overall RSI and RFS scores ( $r = 0.696$ ,  $p = 0.0001$ ). Based on these findings, the authors regarded RFS as a reliable and reproducible clinical instrument capable of maintaining consistency across diverse practice environments. They further suggested that an RFS value greater than 7 is associated with an estimated 94% likelihood of LPRD.

The sensitivity and specificity of RFS was found to be 87.8% and 37.5% respectively, whereas that for RSI was 79.1% and 83.7% respectively as per some studies (11,19).

Some other studies have however concluded otherwise. Satish failed to demonstrate a significant relationship between RSI and RFS, observing a negligible correlation coefficient ( $r = 0.078$ ) that did not achieve statistical significance ( $P = 0.501$ ). Furthermore, the

absence of correlation persisted even after therapeutic intervention, suggesting that symptom-based and laryngoscopy assessments may not always exhibit concordance (15). A similar conclusion has been drawn by Soni et al. (13) But the main drawback of both the studies was a relatively small sample size (77 and 49 subjects respectively) compared to the previously mentioned studies where the study population was much larger including the present study. Branski and colleagues raised queries regarding the routine use of laryngeal endoscopy in the evaluation of subjects with LPRD (19). Through a blinded prospective randomized study design, the researchers evaluated the reproducibility of observations by laryngoscopy. The degree of agreement among examiners, as well as repeated assessments by the same examiner, was found to be unsatisfactory. In view of this lack of consistency, they argued against using laryngeal endoscopic findings as the sole basis for diagnosing suspected LPRD.

#### **Limitations of RSI and RFS:**

While RSI offers a structured method for quantifying symptoms of suspected LPRD, it is fundamentally dependent on self-assessment by the patient. As a result, the accuracy of the score is influenced by the respondent's ability to understand, recall, and evaluate their own symptoms. Individual differences in educational status, awareness of health-related issues, and subjective symptom appraisal may therefore affect the reliability of the obtained score. Despite being regarded as a relatively objective tool, RFS is associated with several operational and methodological constraints. Its application necessitates laryngeal endoscopy, a procedure that requires dedicated equipment, additional clinical time, and increased expenditure, thereby imposing a greater financial burden on patients. Such factors assume greater importance in developing nations, where treatment costs frequently influence medical decision-making. Other factors that need consideration include equipment sterilisation between successive procedures and access to personnel skilled in performing and interpreting the examination. The reliability of the score may also be affected by differences in observer judgement, as variation in the assessment of laryngoscopy findings can occur between examiners.

#### **Conclusion**

A significant concordance was observed between patient-reported symptom scores and endoscopy findings, as evidenced by the positive correlation between RSI and RFS ( $p < 0.0001$ ). The strength of this relationship was greater in subjects with RSI scores above 13, suggesting improved predictive value of symptom assessment at higher RSI levels. This tends to corroborate with the findings of most studies although some studies conclude otherwise. Till the debate is settled conclusively, using of both RSI score and RFS may be highly useful and complimentary to each other for the correct diagnosis of LPRD as well as for the follow up of these cases for response to treatment.

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