



# Role of Reflux Symptom Index and Reflux Finding Score in Evaluation of Treatment Outcome in Patients with Laryngopharyngeal Reflux

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## ABSTRACT

**Introduction:** Laryngopharyngeal reflux (LPR) is defined as the reflux of gastric content into the larynx and pharynx with symptoms like foreign body sensation in the throat, cough, heartburn, chest pain, difficulty in swallowing, and hoarseness.

**Study design:** Prospective study.

**Study duration:** April 2015 to March 2016.

**Materials and methods:** Patients with suspected LPR were evaluated using reflux symptom index (RSI) and reflux finding score (RFS) and treated with proton pump inhibitors (PPIs). Pre- and posttherapeutic RSI and RFS were compared.

**Results:** A total of 120 patients were included over a period of 12 months. Median total score of RSI and RFS before therapy was  $23.37 \pm 7.26$  and  $10.36 \pm 3.11$  respectively, and had reduced to (RSI and RFS)  $5.24 \pm 2.51$  and  $4.31 \pm 2.00$  ( $p < 0.001$ ) respectively.

**Conclusion:** Implementation of RFS and RSI in daily use may reduce cost-intensive and time consuming examination, thus helping in early diagnosis of LPR and reducing serious complications of LPR.

**Keywords:** Gastroesophageal reflux disease, Laryngopharyngeal reflux, Reflux finding score, Reflux laryngitis, Reflux symptom index.

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## INTRODUCTION

The term “reflux” literally means backflow (Latin, re—back + fluere—to flow). Laryngopharyngeal reflux is defined as the reflux of gastric content into the larynx and pharynx.<sup>1</sup> The term LPR was coined by James in 1980.<sup>2</sup> In 1996, Koufman proposed the term to designate LPR symptoms, signs, or tissue damage resulting from the aggression of the gastrointestinal contents in the upper aerodigestive tract.<sup>3</sup>

Various terms for LPR have been used in the medical literature: Supraesophageal reflux, extraesophageal reflux, reflux laryngitis, laryngeal reflux, gastropharyngeal reflux, pharyngoesophageal reflux, and atypical reflux.<sup>4</sup> Patients presenting with extraesophageal reflux-related signs and symptoms may account for up to 10% of an otolaryngologist’s practice.<sup>2</sup> The LPR may be manifested as laryngeal symptoms, such as cough, sore throat, hoarseness, dysphonia, and globus, as well as signs of laryngeal irritation at laryngoscopy.<sup>5</sup>

Laryngopharyngeal symptoms are increasingly recognized by general physicians, lung specialists, and ear, nose, and throat (ENT) surgeons.<sup>6</sup> The LPR is considered a different disease from classic reflux or gastroesophageal reflux disease (GERD). It is believed that the primary defect in LPR might be upper esophageal sphincter dysfunction in less than half of LPR patients with GERD.<sup>2</sup> For the larynx, as few as three episodes a week have been shown to be associated with the development of significant disease.<sup>2</sup>

A diagnosis of LPR may be established by interviewing patients and questioning about specific symptoms, videolaryngoscopic evaluation of the larynx, or double probe pH monitoring.<sup>7-9</sup> Ambulatory 24-hour double probe (pharyngeal and esophageal) pH monitoring is highly sensitive and specific for the diagnosis of LPR.<sup>10</sup> While pH monitoring is not widely available in clinical practice due to its inconvenience and cost, video laryngoscopic examination is more easily accessible.

Belafsky et al<sup>7</sup> developed simple noninvasive, economical instruments, which they named RSI and RFS.<sup>9</sup>

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**Table 1:** Reflux symptom index

<i>Within the last month, how did the following problems affect you?</i>	<i>0 = no problem 5 = severe problem</i>					
Hoarseness or a problem with your voice	0	1	2	3	4	5
Clearing your throat	0	1	2	3	4	5
Excess throat mucus or postnasal drip	0	1	2	3	4	5
Difficulty swallowing food, liquids, or pills	0	1	2	3	4	5
Coughing after you ate or after lying down	0	1	2	3	4	5
Breathing difficulties or choking episodes	0	1	2	3	4	5
Troublesome or annoying cough	0	1	2	3	4	5
Sensations of something sticking in your throat or a lump in your throat	0	1	2	3	4	5
Heartburn, chest pain, indigestion, or stomach acid coming up	0	1	2	3	4	5
<b>Total</b>						

**Table 2:** Reflux finding score

<i>Finding</i>	<i>Score</i>
Subglottic edema	2 = present 0 = absent
Ventricular obliteration	2 = partial 4 = complete
Erythema/hyperemia	2 = arytenoids only 4 = diffuse
Vocal cord edema	1 = mild 2 = moderate 3 = severe 4 = polypoid
Diffuse laryngeal edema	1 = mild 2 = moderate 3 = severe 4 = obstructing
Posterior commissure hypertrophy	1 = mild 2 = moderate 3 = severe 4 = obstructing
Granuloma/granulation	2 = present 0 = absent
Thick endolaryngeal mucus/ other	2 = present 0 = absent
<b>Total</b>	

The videolaryngoscopic examination was the primary procedure for diagnosing LPR. Feng et al<sup>11</sup> have found that laryngopharyngeal pH monitoring and RSI scoring have the same value in diagnosing LPR disease.

Reflux symptom index<sup>7</sup> is a 9-item self-administered outcome instrument. It has been stated that it accurately documents symptoms of patients with LPR. This index appears to be valid and is highly reproducible. An RSI of more than 13 is considered to indicate LPR. It ranges from 0 to 45 (worst possible score). Reflux finding score,<sup>9</sup> on the contrary, is an 8-item clinical severity rating scale based on endoscopic findings. The scale includes most common laryngeal findings related to LPR. It has been concluded that any individual with RFS greater than 7 has more than 95% probability of having LPR.<sup>9</sup> Belafsky et al concluded that RFS accurately documents treatment efficacy in patients with LPR. It ranges from 0 to 26. This study was undertaken to evaluate the clinical characteristics of LPR and the roles of RSI and RFS in assessing the treatment outcomes in patients with LPR disease.

**MATERIALS AND METHODS**

This is a prospective study conducted in the Department of ENT at Era’s Lucknow Medical College and Hospital, Lucknow, Uttar Pradesh, India, after obtaining clearance from the Institutional Ethical Committee.

Study was conducted from April 2015 to March 2016. *Sample size:* 120 patients

**Inclusion Criteria**

Patients were enrolled based on RSI and RFS. Patients included were of the age group 18 to 65 years with symptoms of LPR for the last 1 month having RSI greater than 13 (Table 1)<sup>7</sup> and RFS greater than 7 (Table 2).<sup>9</sup>

**Exclusion Criteria**

Patients with some other obvious causes of symptoms and signs, such as infection, malignancy, and chronic diseases were excluded.

All patients meeting the inclusion criteria completed a questionnaire at the start of the study. The questionnaire consisted of demographic status, socioeconomic status, educational qualification, tobacco use, smoking and alcohol use, and presence of symptoms according to RSI. Patients were asked to report on the presence or absence of symptoms, such as hoarseness, throat clearing, cough, lump in throat, heartburn, regurgitation, problem swallowing, chest pain, and excess throat mucus. Also, they were asked to score the severity using a scale of 0 to 5 [0 (no problem) to 5 (severe problem)].

Each patient underwent a complete ENT examination followed by laryngeal endoscopy. The diagnosis of LPR was made based on RSI and RFS. Patients with RSI greater than 13 and RFS greater than 7 were given PPIs, i.e., omeprazole 20 mg twice daily for 8 weeks. Laryngeal endoscopy was repeated after 8 weeks and RSI and RFS were calculated again. Even after 8 weeks, patients were on monthly follow-up with counseling for lifestyle modification and treatment, if required.

**RESULTS**

A total of 120 patients (male 64, female 56; mean age 34.3 and rural to urban ratio being 11:4; Table 3) with symptoms and signs of LPR were enrolled. The socioeconomic group

**Table 3:** Demographic data

<i>Variable</i>	<i>Mean ± SD</i>
Age (years)	34.3 ± 12.15
Sex (male:female)	8:7
Zone (rural:urban)	11:4

SD: Standard deviation



**Table 4:** Socioeconomic status

Variable	Number (%)
Lower	39 (32.5)
Lower middle	47 (39)
Upper lower	12 (10)
Upper middle	22 (18.3)

**Table 5:** Personal history

Variable	Number (%)
Tobacco	27 (22.5)
Smoking	15 (12.5)
Alcohol	12 (10)

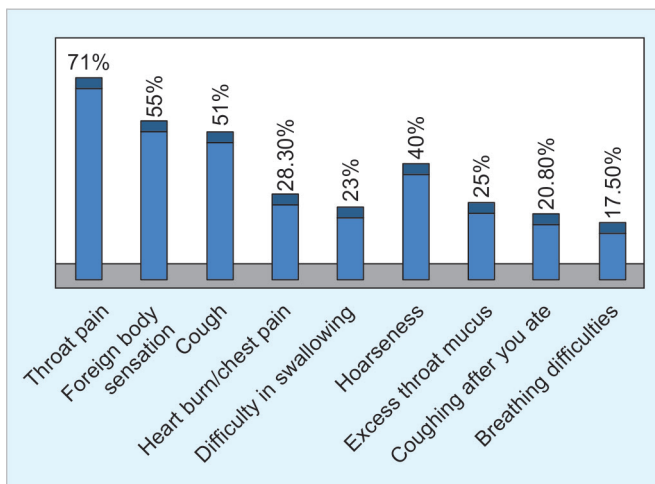
with the highest percentage was of the lower middle class (39%) (Table 4 and Graph 1). There was history of tobacco chewing in 22.5%, alcohol (10%), and smoking (12%) of the patients (Table 5).

**Reflux Symptom Index**

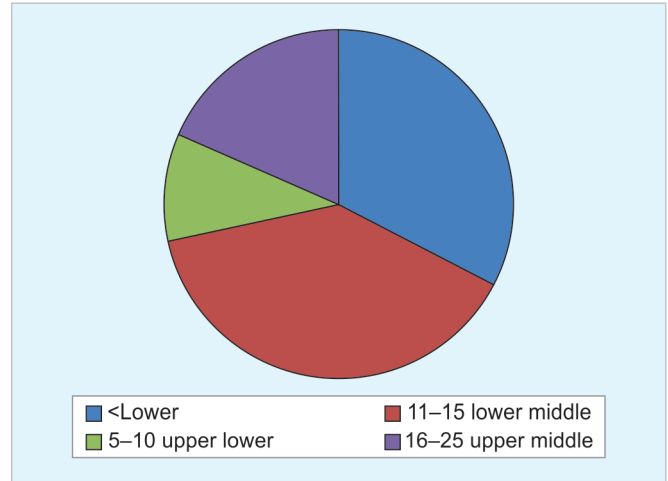
Presenting symptoms (average symptom severity score on scale 0–5) included frequent clearing of the throat (71%), foreign body sensation in the throat (55%), cough (51%), heartburn/chest pain (28%), difficulty in swallowing (23.5%), hoarseness (40%), excess throat mucus (25%), coughing after eating or after lying down (21%), and breathing difficulties (17%) (Table 6 and Graph 2).

**Table 6:** Chief symptoms

Variable	Number (%)
Throat pain	85 (71)
Foreign body sensation in throat	66 (55)
Cough	61 (51)
Heartburn/chest pain	34 (28.3)
Difficulty in swallowing	28 (23.3)
Hoarseness	48 (40)
Excess throat mucus	30 (25)
Coughing after eating or after lying down	25 (20.8)
Breathing difficulties	21 (17.5)



**Graph 2:** Chief symptoms



**Graph 1:** Socioeconomic status (in percentage)

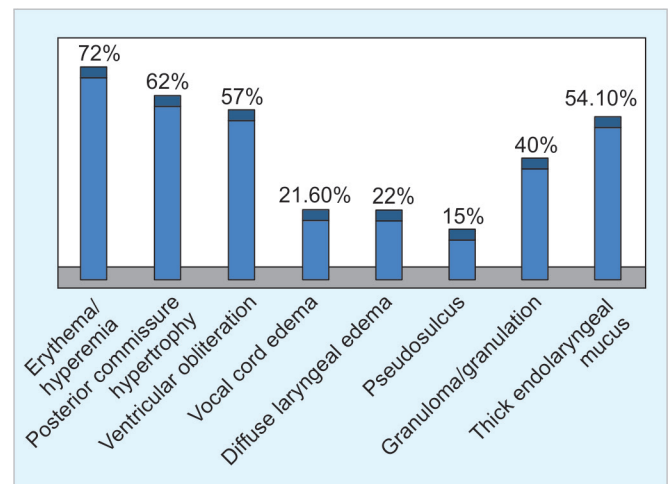
**Reflux Finding Score**

Table 7 and Graph 3 lists scores for erythema/hyperemia (72%), posterior commissure hypertrophy (62%), ventricular obliteration (57%), vocal cord edema (22%), diffuse laryngeal edema (22%), pseudosulcus (15%), granuloma/granulation (40%), thick endolaryngeal mucus (54%).

We found statistically significant differences in RSI and RFS between pre- and posttreatment with PPI. Median total score of RSI and RFS before therapy was

**Table 7:** Reflux finding score

Variable	Number (%)
Erythema/hyperemia	86 (71.6)
Posterior commissure hypertrophy	74 (61.6)
Ventricular obliteration	68 (56.6)
Vocal cord edema	26 (21.6)
Diffuse laryngeal edema	26 (21.6)
Pseudosulcus	18 (15)
Granuloma/granulation	48 (40)
Thick endolaryngeal mucus	65 (54.1)



**Graph 3:** Reflux finding score

23.37 ± 7.26 and 10.36 ± 3.11 respectively, and had reduced to (RSI and RFS) 5.24 ± 2.51 and 4.31 ± 2.00 ( $p < 0.001$ ) respectively.

## DISCUSSION

The LPR has become a frequent disease in the otorhinolaryngologist's office. A large number of studies have been published in the medical literature over the last few years, but LPR still is a dilemma.<sup>12</sup> The combination of symptoms and characteristic laryngoscopic findings may be more suggestive of LPR. Unlike with GERD, response to PPI therapy in patients with LPR has been described as highly variable.<sup>13</sup> This is in part because LPR requires more aggressive and prolonged therapy than GERD.<sup>14</sup> Kamani T et al have found alcohol not to be a risk factor for LPR-related symptoms.<sup>15</sup> Controversy regarding the effect of alcohol exists not only for LPR, but also for GERD, as the results of different studies are diverse and contradictory. Despite the controversies regarding the effect of smoking and drinking on LPR, the recommendations of lifestyle modifications for the treatment of LPR include smoking cessation and limiting alcohol intake.<sup>16</sup> In our study, we found 27 (22.5%) tobacco chewers, 15 (12.5%) smokers, and 12 (10%) alcoholics. Our study comprised a greater population from the rural sector, with a higher percentage from the lower middle socioeconomic group. We emphasize on increasing the awareness for the subtle symptoms of LPR and diagnosis by RFS and RSI to achieve early diagnosis at a primary level. There are four categories of drugs used in treating LPR: PPIs, H<sub>2</sub>-receptor antagonists, prokinetic agents, and mucosal cytoprotectants. Proton pump inhibitors are considered the mainstay of medical treatment.<sup>17</sup> Empirical treatment with PPIs for 2 to 3 months continues to be recommended in the medical literature as also as a cost-effective and useful therapy for the initial diagnosis of LPR.<sup>18</sup> The recommendation is that empirical therapy should use the full dose of PPIs for a minimum period of 2 to 3 months.<sup>18,19</sup> The PPIs are commonly given before meals in most of the studies. Twice-daily dosing is usually employed to better control both nocturnal and daytime esophageal acid exposure. In our study, we used PPI administered twice daily for 2 months<sup>20</sup> and there has been a significant decrease in the symptoms and signs of the LPR. After the treatment with PPI for two months, RFS and RSI was significantly reduced. Weber<sup>21</sup> who demonstrated complete (100%) symptom-free healing of LPR after a 4-week treatment with 40 mg omeprazole per day was also demonstrated in our study; Kamel and Hanson<sup>22</sup> found a 92% response rate; Wo and Hunter;<sup>23</sup> Hanson et al;<sup>24</sup> Pieter Noordzij and Khidir;<sup>25</sup> Tauber and Gross;<sup>26</sup> and Williams and Szczesniak<sup>27</sup> reported 47 and 63% response rates at 6 and

12 weeks respectively, with omeprazole; Delgaudio and Waring;<sup>28</sup> Issing and Karkos;<sup>29</sup> Bilgem and Ogut;<sup>30</sup> Toros and Toros;<sup>31</sup> Zelenik et al.<sup>32</sup> To minimize the subjectivity of these evaluations, a group of researchers proposed a scoring system, the RFS, based on the endolaryngeal inflammatory findings supposedly suggestive of reflux. This index has been validated in English in 2001 by Belafsky et al and has been widely used in the literature as a diagnosis parameter of LPR. The rating score allocates intensity degrees of inflammatory signs and the presence or absence of lesions suggestive of the disease. The RFS has demonstrated high reproducibility and reliability, and a patient with scores above 7 points has 94% probability of presenting with LPR. This instrument has also been used to monitor the disease evolution and response to the treatment.<sup>33</sup> In most patients, the RSI and RFS were positive. This shows that the RSI is an important clinical parameter to be considered in the diagnosis. Physicians can evaluate it independently, and it indicates whether or not to proceed with other tests, given the significant correlation between such symptomatic and endoscopic parameters.<sup>7,9,33</sup>

## CONCLUSION

The LPR disease is becoming a commonly diagnosed condition among the pharyngeal and voice disorders. It is a chronic intermittent disease, and diagnosis depends upon detailed history and clinical examination followed by laryngeal endoscopy. By implementation of RFS and RSI in daily use, most patients may not need time-consuming and cost-intensive examinations, which could also help us in achieving an early diagnosis of LPR, and, thereby, reducing serious complications of LPR, such as laryngeal granuloma, subglottic stenosis, laryngospasm, and laryngeal carcinoma. Increasing the awareness of these tools can help in the early diagnosis and treatment follow-up, thus minimizing the consequences of LPR.

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