#### **ORIGINAL ARTICLE**

# Revisiting the Clinical Practices in Laryngopharyngeal Reflux Disease; Measures that Decrease the Duration of Treatment

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#### **A**BSTRACT

Introduction: Laryngopharyngeal reflux (LPR) is a very common disease seen in the ENT outpatient department. Reflux symptom index (RSI) and Reflux findings score (RFS) are used to diagnose LPR clinically. The treatment of LPR includes dietary and behavioral modifications for all patients in addition to pharmacotherapy. This study aims to revisit the clinical practices followed in the treatment of LPR and to find out measures that decrease the duration of treatment.

Materials and methods: An interventional study was conducted on 50 patients who presented with reflux symptoms. Reflux symptom index and RFS were used to diagnose LPR. Patients started on treatment with the tablet rabeprazole 20 mg twice daily for 6 weeks along with proper counseling regarding lifestyle modification (LSM). Patients were asked to review after 3 weeks and divided into two groups. They were reviewed again at the end of 6 weeks and treatment response was assessed. Patients were divided into two groups with group A having patients who followed the pharmacotherapy and LSM advice without deviation, group B having patients with poor treatment compliance by not following LSM measures. Treatment response was assessed using RSI and RFS. An independent sample *t*-test was applied to compare the pretreatment and posttreatment RSI and RFS and the results were tabulated.

Results: The mean RSI was found to be 12.23 in group A and 12.41 in group B before starting treatment. The mean posttreatment RSI was found to be 6.27 in group A and 8.36 in group B. The mean difference in RSI between the pretreatment and posttreatment values was found to be 5.95 in group A and 4.05 in group B. Independent *t*-test was applied for the mean difference in RSI and the *p*-value was found to be 0.002. The mean RFS was 6.73 in group A and 6.77 in group B before starting treatment. The mean posttreatment RFS was 4.09 in group A and 4.55 in group B. The mean difference in RFS was found to be 2.64 in group A and 2.23 in group B. Independent sample *t*-test was applied for the mean difference in RFS and the *p*-value was found to be 0.372.

Conclusion: Reflux symptom index is found to be a sensitive index of prognosis of LPR and it can be used in monitoring the prognosis of patients undergoing treatment in the outpatient clinic. From our study, we have observed that patients who followed LSM measures effectively had a significant improvement in reflux symptoms sooner than patients who did not follow LSM measures. Lifestyle modifications alone do not suffice in the treatment of LPR. A combination of both, with effective counseling, is needed for the successful treatment of LPR.

Keywords: Gastroesophageal reflux disease, Laryngoscopy, Laryngopharyngeal reflux.

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#### INTRODUCTION

Laryngopharyngeal reflux (LPR) is a frequently encountered disease in ENT outpatient department (OPD) and its diagnosis is challenging for ENT surgeons. Patients usually present with laryngeal symptoms. The common symptoms of LPR include cough, hoarseness, sore throat, and globus. The laryngoscopy reveals erythema and edema in the larynx. Reflux symptom index (RSI) and reflux findings score (RFS) are used to diagnose LPR clinically.

Treatment of LPR includes dietary and behavioral modifications in addition to medical treatment with proton pump inhibitors (PPIs). Dietary and lifestyle modification (LSM) measures are effective in the management of LPR. The main dietary changes include avoidance of fatty food, fizzy drinks, and preserved fruit juices in addition to a timely diet at regular intervals.

Smoking and alcohol consumption should be avoided. Patients who present with supine reflux will benefit from using extra pillows or propping up the head end of the bed. Obesity and tight clothing also worsen it. The treatment of LPR has been mainly PPIs. However, studies have shown that even after PPI treatment, more than 30%

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of patients fail to respond.<sup>4</sup> Due to multifactorial etiology and non-specific therapeutic interventions, recurrence of symptoms is common in LPR. Since there has been adverse change in our dietary habits over the recent years, LPR patients and sometimes even practitioners are also not aware of the significance of avoiding

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**Table 1:** Reflux symptom index (Maximum score 45)

How did the problems listed below affect you since last month? Please circle the appropriate answer	0 = no problem			5 = severe		
1 Hoarseness or voice problems	0	1	2	3	4	5
2 Throat clearing	0	1	2	3	4	5
3 Excess mucus or postnasal drip (descends behind the nose to the throat)	0	1	2	3	4	5
4 Difficulty in swallowing solids, fluids or tablets	0	1	2	3	4	5
5 Coughing after eating or lying down	0	1	2	3	4	5
6 Breathing difficulty or choking episodes	0	1	2	3	4	5
7 Annoying cough	0	1	2	3	4	5
8 Sensations of a lump or foreign body in the throat	0	1	2	3	4	5
9 Burning, heartburn, chest pain, indigestion, or sensation of stomach acid coming up (reflux)	0	1	2	3	4	5
Total						

these factors in the management of LPR. Hence counseling becomes a significant part of the successful management of LPR symptoms. This study aims to revisit the clinical practices followed in the treatment of LPR and to find out measures that decrease the duration of treatment.

#### MATERIALS AND METHODS

This is an Interventional study, with a sample size of 50 patients conducted in the Department of Otorhinolaryngology in a Tertiary Hospital in Southern India for a period of 1 year between 2018 and 2019.

Patients aged between 18 and 60 years who were diagnosed to have LPR were included in this study.

Patients with known allergies to PPIs, patients on medication for chronic disorders like diabetes, hypertension, chronic arthritis or on long-term oral corticosteroids, pregnancy, lactating mothers, patients diagnosed to have pharyngoesophageal disorders like achalasia cardia, hiatus hernia, and malignancies, patients who have undergone abdominal and cardiothoracic surgeries, patients with poor comprehending capacity or who are unwilling to participate in the study were excluded from the study.

Approval from the Institutional Scientific and Research Committee and Institutional Ethics Committee was obtained. Written consent was taken from all patients enrolled in this study. Patients who presented to ENT OPD with complaints of cough, sore throat, hoarseness, dysphonia, and Globus were subjected to detailed history taking and examination including video laryngoscopy. Reflux symptom index (Table 1) and RFS (Table 2) were recorded. Reflux symptom index scores more than or equal to 13 or RFS more than or equal to 7 were considered significant to diagnose LPR.<sup>5</sup> These patients were started on oral tablet rabeprazole, 20 mg twice daily 1 hour before food.

All patients underwent detailed counseling individually by the principal investigator about the 13 enlisted LSM. Pamphlets (Annexure 1) were issued on the day of diagnosis. Patients were reassessed 3 weeks after commencement of treatment. Patients who follow pharmacotherapy and lifestyle modification advice without deviation were included in group A. Patients with poor treatment compliance in the form of irregular LSM measures were included in group B. These patients were followed up again at the end of 6 weeks of treatment and the RSI and RFS were documented. The results were tabulated; statistical analysis was carried out using SPSS software. An independent sample *t*-test was

Table 2: Reflux findings score (Maximum score 26)

<b>Table 2:</b> Reflux findings score (Maximum	score 26)
Pseudosulcus (infraglottic edema)	0 = Absent 2 = Present
Ventricular obliteration	0 = None 2 = Partial 4 = Complete
Erythema/hyperemia	0 = None 2 = Arytenoids only 4 = Diffuse
Vocal fold edema	0 = None 1 = Mild 2 = Moderate 3 = Severe 4 = Polypoid
Diffuse laryngeal edema	0 = None 1 = Mild 2 = Moderate 3 = Severe 4 = Obstructing
Posterior commissure hypertrophy	0 = None 1 = Mild 2 = Moderate 3 = Severe 4 = Obstructing
Granuloma/granulation	0 = Absent 2 = Present
Thick endolaryngeal mucus	0 = Absent 2 = Present
Total	

applied and a p-value less than 0.05 was considered a significant result.

#### RESULTS

A total of 50 patients were originally included in this study. However, during the course of the study, 4 patients in group A and 2 patients in group B dropped out. The data of the remaining 44 patients has been used for analysis. These patients were divided into group A and group B as described earlier. Each group had 22 patients. The commonest age-group in our study was between 31 and 40 years (38.63%) (Table 3). The Male-to-female ratio was 1:1 in our study. The personal habits of the included patients were noted down (Table 4). It was found that alcohol intake was the most common habit in



group B (36.36%). Antacid use was equally common in group A and group B (31.81%) and it was found to be the commonest personal habit among the patients in group A.

The RSI and RFS recorded on the day of first consultation and then after 6 weeks following treatment were tabulated and statistical analysis was carried out.

The mean RSI was found to be 12.23 in group A and 12.41 in group B before starting treatment. The mean posttreatment RSI was found to be 6.27 in group A and 8.36 in group B. The mean difference in RSI between the pretreatment and posttreatment values was found to be 5.95 in group A and 4.05 in group B. Independent *t*-test was applied for the mean difference in RSI and the *p*-value was found to be 0.002. This is a significant difference in the mean difference in RSI with patients in group A showing better improvement in the posttreatment RSI values (Table 5).

The mean RFS was 6.73 in group A and 6.77 in group B before starting treatment. The mean posttreatment RFS was 4.09 in group A and 4.55 in group B. The mean difference in RFS was found to be 2.64 in group A and 2.23 in group B. Independent sample *t*-test was applied for the mean difference in RFS and the *p*-value was found to be 0.372. Even though the improvement in RFS was better in group A than group B following treatment, there is no statistically significant difference in the improvement of RFS between group A and group B (Table 6).

These results indicate that patients who underwent counseling for lifestyle modifications and followed the advice showed better

**Table 3:** Showing age-wise distribution in both the groups

	3 3		•
S. No	Age (in years)	Number	In %
1	10-20	0	0
2	21–30	8	18.18
3	31–40	17	38.63
4	41–50	10	22.73
5	51-60	5	11.36
6	61–70	4	9.09

Table 4: Showing lifestyle habits in both the groups

6.11	1.6 . 1 1 1.5	Group A $(n = 22)$	Group $B$ ( $n = 22$ )	Average
S. No	Lifestyle habits	(%)	(%)	(%)
1	Smoking	27.27	31.81	29.54
2	Alcohol intake	27.27	36.36	31.81
3	Caffeine intake	13.63	9.09	11.36
4	Antacid use	31.81	31.81	31.81
5	Histamine 2 blocker use	9.09	9.09	9.09

improvement in their respective symptoms at the end of 6 weeks and that there was no significant improvement in the signs of the disease.

## Discussion

Laryngopharyngeal reflux is defined as the reflux of contents of the stomach into the laryngopharynx causing tissue damage in the upper airway due to the acidity of gastric secretions. The main risk factors of LPR include the consumption of alcohol, coffee, junk food, smoking, and psychological reasons. In LPR, esophageal acid clearance is usually normal, with brief 'flashes' of reflux reaching to the upper esophageal sphincter and beyond, into the laryngopharynx. The refluxate is said to damage the upper airway than the esophagus itself when it occurs.

Though LPR is a commonly diagnosed disease in the OPD, its treatment guidelines are controversial.<sup>9</sup>

There is a paucity of literature regarding the role of dietary modification in the treatment of LPR. Koufman<sup>10</sup> reported a significant improvement in RSI with the use of a low-acid diet. Another study reported the use of alkaline water in the treatment of LPR.<sup>11</sup>

Zalvan CH et al.<sup>12</sup> in their study, compared the treatment of patients with LPR with PPI therapy and standard reflux precautions for 6 weeks and a 90% plant-based Mediterranean-style diet with standard reflux precautions for 6 weeks. The results suggest that PPI therapy alone did not have a significant advantage over a dietary approach and that the addition of a dietary approach led to a greater reduction in RSI.

Based on our results, we note that the RSI is a more sensitive index in monitoring the prognosis of LPR and that it can be incorporated into our daily practice easily.

Based on the previous studies, importance was given only to treating patients with medications and dietary advice, and less importance was given to LSM. So we decided to start patients on PPI's for a period of 6 weeks and also effectively counsel them about LSM and its importance in LPR. <sup>12</sup>

Results in our study showed that patients between 31 and 50 years are affected more. Smoking in males and over-the-counter use of antacids are the common lifestyle habits in all of our patients. Results showed a significant improvement in RSI in group A than in group B, similar results were found in a study conducted by Mattoo O et al. Which showed that the symptoms improved much earlier than the laryngeal signs. The relative change in RFS over any given period of time was significantly higher than the relative change in RFS.

In our study, the RSI showed a significant improvement within 6 weeks. A study conducted by Tsunoda K et al.<sup>14</sup> showed results

Table 5: Showing the mean difference between the pre- and posttreatment RSI

		Pretreatment RSI		Pretreatment RSI Posttreatment RSI		ment RSI	Mean difference RSI		
Group	Ν	Mean	SD	Mean	SD	Mean	SD	p-value	
A	22	12.23	0.92	6.27	1.12	5.95	1.62	0.003	
В	22	12.41	1.18	8.36	2.06	4.05	2.15	0.002	

Table 6: Showing the mean difference between the pre- and posttreatment RFS

		Pretreatment RFS		Posttreatment RFS		Mean difference RFS		
Group	N	Mean	SD	Mean	SD	Mean	SD	p-value
Α	22	6.73	1.70	4.09	0.87	2.64	1.65	0.372
В	22	6.77	1.93	4.55	1.26	2.23	1.34	0.372

requiring long-term medical therapy for control thus resulting in an increased financial burden. Another study conducted by Bhargava A et al.<sup>15</sup> showed results requiring 12 weeks of treatment with PPIs. So we conclude the treatment with PPIs and effective counseling for LSM will show earlier relief in symptoms of LPR. This can be cost-effective for patients. The shorter duration of therapy with PPIs and LSM also decreases the chance of side effects arising from long-term use of PPIs.

On the other hand, there was an improvement in RFS in both the groups, but the results were found to be insignificant. This shows that even after following treatment for 6 weeks, the laryngeal signs continue to persist. So the chances of recurrence could be more. Patients need to continue these lifestyle changes for a long time in order to prevent a recurrence. Our patients were advised to follow the LSM measures lifelong even if they don't have any symptoms.

## Conclusion

Laryngopharyngeal reflux is a common disease now. The change in our personal and food habits made this condition a common occurrence in all age-groups of people. Long-term medical therapy, compliance in follow-up, and irregular practice of lifestyle modifications are some of the challenges faced in the treatment of LPR.

Lifestyle modification alone does not suffice in the treatment of LPR. A combination of both, with effective counseling is needed for the successful treatment of LPR. From our study, we conclude that patients who are effectively counseled for LSM had faster resolution of symptoms than patients who did not follow LSM.

## ETHICAL APPROVAL

Institutional Ethics Committee approval was obtained for this study.

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