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Evaluation of Therapeutic Response to Proton Pump Inhibitors Using Reflux Symptom Index and Reflux Finding Score in Laryngopharyngeal Reflux Disease.

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Abstract

Background: Laryngopharyngeal reflux disease (LPRD) is a common extraoesophageal manifestation of gastroesophageal reflux disease characterized by throat-related symptoms and laryngeal inflammation. Reflux Symptom Index (RSI) and Reflux Finding Score (RFS) are widely used tools for the diagnosis and monitoring of treatment response in LPRD. Proton pump inhibitors (PPIs) remain the mainstay of medical management.
Aim: To evaluate the effectiveness of proton pump inhibitor therapy in patients with laryngopharyngeal reflux disease using RSI and RFS scores. ***Materials and Methods:*** This prospective observational study was conducted in the Department of Otorhinolaryngology of a tertiary care hospital over a period of 12 months. A total of 42 patients diagnosed with LPRD based on RSI score >13 and RFS score >7 were included. Baseline demographic details, symptom profile, RSI score, and laryngoscopic findings were recorded. All patients received oral pantoprazole 40 mg twice daily for 8 weeks before food along with lifestyle modifications. Post-treatment reassessment was performed using RSI and fibreoptic laryngoscopic evaluation for RFS. Statistical analysis was performed using paired t-test, and a p-value < 0.05 was considered statistically significant. ***Results:*** The mean age of the study participants was 43.8 ± 11.2 years with male predominance (57.1%). Throat clearing was the most common presenting symptom (83.3%). The mean RSI score significantly decreased from 21.6 ± 4.8 before treatment to 9.4 ± 3.7 after therapy ($p < 0.001$). Similarly, the mean RFS score reduced significantly from 13.1 ± 2.9 to 6.2 ± 2.4 following treatment ($p<0.001$). Significant symptomatic improvement was observed in 71.4% of patients. ***Conclusion:*** Proton pump inhibitor therapy significantly improves both symptoms and laryngoscopic findings in patients with laryngopharyngeal reflux disease. RSI and RFS are useful tools for assessing therapeutic response and monitoring disease progression.

Keywords: Laryngopharyngeal reflux disease; Reflux Symptom Index; Reflux Finding Score; Proton pump inhibitors; Fibreoptic laryngoscopy; Pantoprazole.

INTRODUCTION

Laryngopharyngeal reflux disease (LPRD) is regarded as an extraesophageal manifestation of gastroesophageal reflux disease (GERD), which is characterized by a reflux of gastric contents beyond the upper esophageal sphincter and affecting the larynx, pharynx, and surrounding upper aerodigestive tract. While the esophageal mucosa has effective mechanisms to protect itself from the effects of acid, pepsin, bile salts, and digestive enzymes, the mucosa of larynx and pharynx does not have such protective features. Therefore, even short-term reflux can cause irritation, which in turn causes edema, inflammation, ulceration, and laryngeal dysfunction. With a repeated or long-term exposure to gastric secretions, there is a risk of developing pathologies such as chronic laryngitis, edema of vocal cords, granuloma of contact, hypertrophy of the posterior commissure, subglottic stenosis, and, in some cases, precancerous lesions. Chronic course, variety of clinical manifestations, and significant influence on voice and general quality of life make LPRD a rather common pathology seen in practice of otorhinolaryngologists [1].

In spite of the similarity of the underlying mechanism in LPRD and GERD, the clinical picture and methods of diagnosis of these diseases vary significantly. Typically, patients with GERD suffer from such classic symptoms of reflux as heartburn, acid regurgitation, pain behind the sternum, and dyspepsia caused by a prolonged exposure to acid in the esophagus. At the same time, people with LPRD do not demonstrate the described symptoms and show the symptoms associated with upper airways. More than 45% of LPRD cases are marked by absence of classic reflux manifestations; therefore, diagnosing LPRD is quite difficult. Besides, a lot of symptoms typical for LPRD can be found in chronic pharyngitis, allergic rhinitis, chronic rhinosinusitis, vocal cord overuse, upper respiratory infection, smoking-induced

laryngeal pathology, and other benign laryngeal disorders. Such overlapping often results in incorrect treatment of LPRD [2].

The variety of clinical manifestations of laryngopharyngeal reflux disease (LPRD) is wide enough and includes chronic and fluctuating symptoms. One of the most typical symptoms of the condition is chronic throat clearing that is accompanied by increased secretion of mucus in the throat. Another manifestation of LPRD is hoarseness especially in the persons whose work is connected with their voice as the inflammation of the vocal folds in this case negatively impacts vocal capabilities. Also many patients have the feeling of the presence of a lump or foreign body in the throat (globus pharyngeus). Other symptoms of LPRD include chronic cough, episodes of dysphagia, throat discomfort, choking, postnasal drip sensation, excessive mucus secretion, and chronic laryngitis. It is important to note that the symptoms usually appear in the periods of after meals, lying down and voice strain. As the complaints are not specific and last for several months before the diagnosis is set, many patients have received a course of different antibiotic and antihistamine drugs without any effect on the symptoms [2].

The occurrence of laryngopharyngeal reflux disease (LPRD) includes many pathogenetic mechanisms and therefore the disease cannot be attributed only to acid reflux. As the refluxate reaching the upper aerodigestive tract includes hydrochloric acid, pepsin, bile salts, and pancreatic enzymes, all of which cause the injury of mucosa. It should be noted that pepsin is the main harmful substance included in the refluxate because it is able to stay in the laryngeal tissues in the inactive state and regain activity in the acid medium. The constant contact with refluxate leads to impairment of mucociliary clearance, weakening of the local mucosa protection and appearance of inflammation in the laryngeal and pharyngeal mucosa. Besides, reflux can cause the vagally mediated esophagolaryngeal reflexes stimulated by the acidity of the distal esophagus and leading to the development of symptoms such as chronic coughing and throat clearing. As there are no protective barriers in the larynx and pharynx like in the esophagus, the reflux leads to the serious damage of the tissues even in small episodes.

If the laryngopharyngeal reflux disease (LPRD) is not recognized and treated, the condition will lead to progressive changes in the structure and function of the larynx. Prolonged inflammation can cause chronic laryngitis, edema of the vocal folds and laryngeal tissues, ventricular obliteration, enlargement of posterior commissure, contact ulcers and granulomas, which negatively influence voice quality. Chronic micro aspiration as the result of the prolonged reflux can lead to the development of chronic respiratory diseases such as lower respiratory tract infections, bronchospasm and exacerbation of bronchial asthma. Moreover, the consequences of LPRD include not only the above-mentioned manifestations but also the impact on the quality of life. In addition, the burden of LPRD has steadily grown throughout the recent years in the world. This may be explained by changes in dietary habits, the increase in the level of obesity, inactive life-style, smoking, alcohol consumption, psychological stress, and the prevalence of gastroesophageal reflux disease (GERD). According to epidemiological studies, 10% of all patients attending otorhinolaryngology outpatient clinics suffer from the disease associated with LPRD. In addition, the reflux-induced laryngeal abnormalities have been detected in 48% of people who consult with the doctor due to chronic problems with their voice. [2] Although the disease may occur in any age and in both sexes, it is mostly diagnosed among middle aged people. Improvements in the field of clinical knowledge and the wide application of diagnostic instruments have played an important role in identification of this disease in everyday ENT practice.

However, despite the high prevalence of LPRD, there are no tests that are recognized as the best for diagnosing the disease. It was thought that 24 hours dual probe pH testing was the best investigation for detection of proximal acid reflux. But such investigation is uncomfortable and invasive, difficult in performing, expensive and not very sensitive to LPRD. Multichannel intraluminal impedance with pH monitoring allows not only to detect proximal acid reflux, but to detect both acid and non-acid refluxes too. But this test is rarely used outside of specialized clinics because of its complexity and costs. Therefore, the everyday diagnosis of LPRD is made according to patient's clinical history, symptom assessment with the help of questionnaires and endoscopic detection of laryngeal findings. Among all available diagnostic instruments, Reflux Symptom Index (RSI) and Reflux Finding Score (RFS) are recognized as the most commonly used ones, because of their simplicity, reproducibility and reliability. RSI is a questionnaire developed by Belafsky and his colleagues, which consists of 9 questions related to the symptoms and is scored by the patient with the help of 6-point Likert scale, where 0 means absence of symptoms and 5 – their maximum. The total score above 13 is suggestive of LPRD.[3] In addition to the role in the diagnosis of LPRD, RSI is useful tool for assessment of symptom severity and response to the treatment.

The Reflux Finding Score (RFS) introduced by Belafsky et al. is another objective tool which can help assess the presence of any laryngeal abnormalities detected during laryngoscopy. The scores range from 0 to 2 and are assigned based on the presence of specific endoscopic features, which include subglottic edema, ventricular obliteration, erythema/hyperemia, vocal fold edema, diffuse laryngeal edema, posterior commissure hypertrophy, granuloma/granulation tissue and thick endolaryngeal mucus. The total score above 7 usually indicates a significant probability of LPRD. Both RSI and RFS

provide complementary data since the former reflects the subjective perception of patients while the latter – objective laryngoscopic findings. Fibreoptic laryngoscopy is one of the most important components of the diagnosis of LPRD. It not only allows to calculate the Reflux Finding Score (RFS) but helps to examine the laryngeal mucosa directly and identify other diseases associated with similar symptoms including vocal fold nodules, polyps, tumors, infection of the mucous membrane and neurological disorders. Follow-up examinations with laryngoscopy also play an important role in providing objective evidence of the regressive changes occurring in the mucous membrane and the restoration of its condition.

Proton pump inhibitors (PPIs) play a leading role in pharmacological therapy of LPRD. They effectively inhibit the activity of H^+/K^+-ATPase, which leads to the reduction of the level of hydrochloric acid and pepsin. Thus, they protect laryngopharynx from the acid damage. The currently used treatment regimen includes high dose therapy of PPIs two times a day for 8-12 weeks, unlike GERD, which is commonly treated with once-daily PPI therapy. The treatment should be accompanied by the modification of patient's diet and lifestyle, which should involve the reduction of intake of fatty and spicy food, caffeinated and carbonated drinks, alcohol consumption, smoking, late dinners and use of elevated head position during sleep. A lot of clinical researches prove the efficiency of PPI treatment of LPRD. Park et al. found statistically significant decrease in RSI and RFS during the 8-week treatment with PPIs, which shows improvement in the subjective complaints and objective abnormalities of larynx. [4]Vaezi et al. also proved the superiority of anti-reflux therapy compared to placebo treatment, which emphasizes the necessity of PPI treatment of properly selected patients [5] There were several researches, proving the reduction of complaints associated with throat clearing, hoarseness, chronic cough, globus sensation and other signs of laryngeal inflammation caused by reflux. Nevertheless, there may be a number of factors influencing the effectiveness of the treatment: the degree of the disease, the frequency of reflux attacks, patient's compliance to the treatment, patient's diet, life style, the nature of the reflux, allergic disease and individual susceptibility of the laryngeal mucous membrane. So, complete symptom relief cannot be expected in every case.

Despite increasing awareness about LPRD, there is insufficient number of prospective studies which investigate the effectiveness of treatment of the Indian population based on the use of symptom-based and laryngoscopic methods of evaluation. In the course of daily practice, proton pump inhibitors are often used empirically without systematic assessment of the treatment effectiveness and follow-up. It can lead to the prolongation of medication and failure to recognize the inefficiency of the treatment as well as the lack of possibilities to detect another cause of the symptoms. The incorporation of validated questionnaires like RSI and RFS allows to perform systematic assessment of the disease severity and the efficiency of the treatment. Taking into account the increasing prevalence of LPRD, its variety and the lack of one reliable diagnostic method, objective evaluation of treatment outcomes has become very relevant. Thus, the goal of the present study is to assess the efficacy of proton pump inhibitor therapy in LPRD based on the use of validated instruments, such as Reflux Symptom Index (RSI) and Reflux Finding Score (RFS). It is supposed that the results will confirm the existing evidence about the efficiency of PPI treatment but will emphasize the value of combination of the two types of assessments.

Objective

To evaluate the therapeutic efficacy of proton pump inhibitor therapy in patients with laryngopharyngeal reflux disease by assessing changes in the Reflux Symptom Index (RSI) and Reflux Finding Score (RFS).

Specific objectives

1) To compare the Reflux Symptom Index (RSI) scores before and after proton pump inhibitor therapy in patients diagnosed with laryngopharyngeal reflux disease.
2) To evaluate changes in the Reflux Finding Score (RFS) following proton pump inhibitor therapy using fibreoptic laryngoscopic examination.
3) To determine the relationship between improvement in subjective symptoms (RSI) and objective laryngoscopic findings (RFS) after completion of proton pump inhibitor therapy.
4) To assess the overall clinical response to proton pump inhibitor therapy in patients with laryngopharyngeal reflux disease using validated symptom and laryngoscopic scoring systems.

MATERIALS AND METHODS

Design and setting

The prospective observational study was carried out in the Otorhinolaryngology Department of a tertiary care teaching hospital within a period of 12 months. This study was conducted after getting the approval from the Institutional Ethics Committee. All study subjects signed the informed consent form.

Study Population

Potential patients with signs and symptoms suggestive of laryngopharyngeal reflux disease will be assessed for eligibility for the study in the ENT outpatient department. Patients who fit in the inclusion criteria will be recruited until the sample size is attained.

Inclusion Criteria

- Patients above 18 years of age.
- Patients with symptoms indicative of laryngopharyngeal reflux disease (hoarseness of voice, throat clearing, globus sensation, chronic cough, throat irritation, dysphagia, or excessive throat mucus).
- Patients having Reflux Symptom Index (RSI) score greater than 13.
- Patients willing to take part and give informed written consent.

Exclusion Criteria

- Patients with an upper respiratory tract infection.
- Patients with known cancer of the larynx or pharynx.
- Patients with previous laryngeal surgery or radiation therapy
- Patients with vocal cord paralysis or neurological voice problems.
- Patients taking proton pump inhibitors, H2 receptor blockers or anti-reflux agents in the last four weeks.
- Pregnant women.

Sample Size Calculation

The sample size was calculated based on the study conducted by Belafsky PC et al[3]., which demonstrated a significant reduction in Reflux Symptom Index scores following proton pump inhibitor therapy in patients with laryngopharyngeal reflux disease. The sample size for comparison of paired mean scores was calculated using the formula:

$$n=(Z_{(\alpha/2)}+Z_{\beta})^2\times\sigma^2 \div d^2$$

Where:

- n= required sample size
- $Z_{(\alpha/2)}$= 1.96 at 95% confidence interval
- Z_{β}= 0.84 corresponding to 80% study power
- σ= standard deviation of RSI score difference taken as 5.5 from the reference study
- d= expected mean difference in RSI score after treatment taken as 2.5

Substituting the values:

$$n=(1.96+0.84)^2\times(5.5)^2/(2.5)^2$$
$$n=(7.84\times30.25)/6.25$$
$$n=37.9$$

The calculated minimum sample size was 38 participants. After accounting for an anticipated 10% dropout rate, the final sample size was rounded to 42 patients.

Sampling Technique

A consecutive sampling technique was employed, and all eligible patients visiting the ENT OPD during the study period were included till a desired number of sample was achieved.

Procedure of Study

Demographic details of each patient like age, gender, profession, diet, smoking, alcohol, and presence of any co-morbid conditions were obtained through a well-structured proforma. All selected patients were subjected to thorough clinical examination including ear, nose, throat and head and neck examination. Baseline symptom severity of the patients was determined through the use of Reflux Symptom Index (RSI), a validated self-administered questionnaire, which consists of nine symptom-related questions. The nine components of RSI are: Hoarseness or a problem with the voice, Throat clearing, Excess throat mucus or postnasal drip, Difficulty swallowing food, liquids or pills, coughing after eating or after lying down, breathing difficulties or choking episodes, Troublesome or annoying cough, Sensation of something sticking in the throat or a lump in the throat (globus sensation), Heartburn, chest pain, Indigestion or acid regurgitation. Each question was graded on a scale of 0-5 with a maximum score of 45. An RSI score more than 13 indicates a probable diagnosis of laryngopharyngeal reflux disease.

All patients underwent fibreoptic laryngoscopy. Laryngeal findings were evaluated by Reflux Finding Score (RFS), which assesses the eight laryngoscopic criteria such as subglottic edema, ventricular obliteration, erythema, vocal fold edema, diffuse laryngeal edema, posterior commissure hypertrophy, granuloma, and thick endolaryngeal mucus. The total RFS ranged from 0-26 and a score of more than 7 indicated a diagnosis of laryngopharyngeal reflux. All patients were treated with a course of proton pump inhibitors, in the form of pantoprazole 40 mg orally twice daily before food for 8 weeks.

Dietary and life style modifications were also suggested to patients like avoiding hot foods, caffeinated drinks, smoking, drinking alcohol and eating late at night. Head end elevation during sleeping and weight reduction in overweight individuals were also suggested. After 8 weeks of treatment, clinical reassessment was done through scoring of RSI and repeat fibreoptic laryngoscopic examination to find out RFS again.

Outcome Measure

Primary Outcome

Change in mean Reflux Symptom Index (RSI) score after proton pump inhibitor therapy.

Secondary Outcomes

Changes in mean Reflux Finding Score (RFS) after treatment. Correlation between changes in RSI and RFS scores after treatment.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed through Statistical Package for the Social Sciences (SPSS) software version 25.0. The continuous variables were described as mean ± SD, whereas categorical variables were described as frequency (%).

The paired‘t’ test was applied to compare the pre and post treatment RSI and RFS scores. Association of categorical variables was assessed through the use of Chi-square/Fisher exact test. Correlation between improvement in RSI and RFS was assessed through Pearson’s correlation. A P-value <0.05 was considered statistically significant.

RESULTS

A total of 42 patients diagnosed with laryngopharyngeal reflux disease were included in the study and completed the follow-up after 8 weeks of proton pump inhibitor therapy.

Table 1. Age Distribution of Study Participants (n=42)

Age Group (Years)	Frequency (n)	Percentage (%)
18–30	8	19.0
31–40	11	26.2
41–50	12	28.6
51–60	7	16.7
>60	4	9.5
Total	**42**	**100.0**

Mean age: 43.8 ± 11.2 years

Table 2. Gender Distribution of Study Participants (n=42)

Gender	Frequency (n)	Percentage (%)
Male	24	57.1
Female	18	42.9
Total	**42**	**100.0**

Male predominance was observed in the present study with a male-to-female ratio of 1.3:1.

Table 3. Distribution of Common Presenting Symptoms Based on Reflux Symptom Index Components (n=42)

Symptoms	Frequency (n)	Percentage (%)
Throat clearing	35	83.3
Globus sensation	31	73.8
Hoarseness of voice	28	66.7
Excess throat mucus/postnasal drip	27	64.3
Chronic cough	22	52.4
Difficulty swallowing	14	33.3
Breathing difficulty/choking episodes	9	21.4

Throat clearing was the most common presenting symptom followed by globus sensation and hoarseness of voice.

Table 4. Comparison of Mean Reflux Symptom Index (RSI) and Reflux Finding Score (RFS) Before and After Proton Pump Inhibitor Therapy (n=42)

Parameter	Pre-treatment Mean ± SD	Post-treatment Mean ± SD	Mean Difference	p value
RSI Score	21.6 ± 4.8	9.4 ± 3.7	12.2 ± 4.1	<0.001*
RFS Score	13.1 ± 2.9	6.2 ± 2.4	6.9 ± 2.8	<0.001*

*Statistically significant

There was a statistically significant reduction in both RSI and RFS scores following 8 weeks of proton pump inhibitor therapy.

Table 5. Treatment Response Following Proton Pump Inhibitor Therapy Based on RSI Improvement (n=42)

Treatment Response	Frequency (n)	Percentage (%)
Significant improvement (≥50% reduction in RSI)	30	71.4
Partial improvement (<50% reduction in RSI)	9	21.4
No improvement	3	7.1
Total	**42**	**100.0**

Majority of patients demonstrated significant symptomatic improvement following proton pump inhibitor therapy.

DISCUSSION

In current times, laryngopharyngeal reflux disease (LPRD) is recognized as one of the common extra-esophageal manifestations of gastroesophageal reflux disease (GERD). It is one of the commonest causes of chronic irritation of the larynx seen in otorhinolaryngology practice. Unlike classical GERD where symptoms such as heartburn and acid regurgitation are common, in LPRD, symptoms such as throat clearing, hoarseness, feeling of globus, cough, dysphagia, and throat discomfort are common. Given the fact that these symptoms are nonspecific and overlap with other upper respiratory tract conditions, diagnosing LPRD becomes challenging and results in delays in treatment. Objective tools such as reflux symptom index (RSI) and reflux finding score (RFS) that have been validated are used to diagnose LPRD and objectively measure response to treatment. In the present prospective study, PPI therapy has been tested for efficacy by assessing pre-treatment and post-treatment RSI and RFS scores. In the current study, the average age of the participants was 43.8 ± 11.2 years, the largest number of the participants belonged to 41-50-year age group. This finding shows that LPRD occurs predominantly at middle ages. The same trend was described in previously published literature. Park et al. described more frequent cases of LPRD in middle-aged adults and hypothesized that this phenomenon could be associated with lifestyle factors and increased exposures to reflux-promoting conditions. [4]Irregular dietary habits, diets high in fat and spicy foods, excess caffeine consumption, obesity, smoking, alcohol consumption, occupational stress, and sedentary lifestyle become more prevalent in this age period and predispose to development of gastroesophageal reflux. Moreover, physiologic changes such as decreased tone of lower esophageal sphincter and delayed gastric emptying that occur with aging can lead to increased frequency of the reflux events and result in the development of laryngopharyngeal involvement.

In the current study, there was a predilection for males with LPRD, which is similar to findings reported by Vaezi et al., who described a higher prevalence of LPRD in men. [5] This gender difference could be attributed to greater exposure of males to known risk factors including tobacco and alcohol consumption, occupational stress, irregular dietary habits, obesity, and late night eating. Also, occupations that require excessive use of voice and stressful work environment can exacerbate laryngeal symptoms associated with reflux. However, LPRD is common disorder in both genders, and its diagnosis and treatment should be based on the symptoms rather than gender. Regarding the clinical presentations, persistent throat clearing was the most frequent symptom in the current study, followed by globus sensation and hoarseness of voice. These observations are similar to the previous studies, which characterized symptoms of LPRD. Belafsky et al. showed that throat clearing and voice-related symptoms are the most prominent manifestations in patients with laryngopharyngeal reflux. [3] Similarly, Brown et al. noted that throat irritation, globus sensation, chronic cough, hoarseness, and excess throat mucus are common presentations of the reflux associated laryngeal disease. [6] Predominance of these symptoms could be explained by direct action of the refluxate on laryngopharyngeal mucosa. Acid and pepsin induce mucosal irritation and inflammation causing frequent throat clearing, while inflammation of the vocal cords causes hoarseness. Gobus sensation arises due to edema of the hypopharynx and larynx mucosa, increased upper esophageal sphincter tone, and enhanced laryngopharyngeal sensation.

Chronic throat clearing requires separate consideration since this symptom is regarded as one of the most characteristic manifestations of LPRD. Continuous irritation of the laryngeal mucosa by the refluxate results in increased mucus production and activation of the sensory nerve endings resulting in the desire to clear the throat. In addition, inflammation and edema lead to impaired vibration of the vocal cords, thus causing hoarseness. Similarly, the globus sensation can be

attributed to the inflammatory changes affecting the hypopharynx and upper esophageal sphincter, but not due to any structural obstruction. The clinical profile demonstrated by the participants of the current study coincides with those described in the previous studies. Small discrepancies can be caused by the variation in the demographic characteristics of the patients, severity and duration of the condition, dietary factors, concomitant allergic diseases, environmental factors, and healthcare-seeking behavior. One of the aims of the present study was to assess the change in the reflux-related symptoms during the treatment with the proton pump inhibitors in accordance with the Reflux Symptom Index (RSI). Prior to the treatment, the average value of the RSI was 21.6 ± 4.8 which indicates the considerable number of complaints among the participants. After eight weeks of taking pantoprazole 40 mg b.i.d., before food, accompanied by necessary changes in diet and lifestyle, the average score of RSI was 9.4 ± 3.7. This reduction was found to be highly statistically significant ($p < 0.001$).

The decrease in RSI noted in the present study is similar to the data obtained in the previous researches. Park et al. revealed the significant decrease in the average RSI scores in LPRD patients after 8 weeks of the proton pump inhibitor therapy.[4] In their turn, Vaezi et al. reported the better improvement of the symptoms of LPRD in the group taking anti-reflux medication compared to the group receiving placebo.[5] The same benefits were described in the literature concerning the relief of chronic throat clearing, hoarseness, chronic cough, globus sensation and other reflux symptoms under acid suppressive therapy. Thus, the reduction in RSI noted in the present study can indicate not only the relief of symptoms, but also the restoration of the voice function, ability to perform daily activity and social contacts. Early and proper treatment of the LPRD will help avoid unnecessary prescription of the antibiotics and visits to the doctor. The benefits of proton pump inhibitors in LPRD are mainly explained by their effective inhibition of acid production by the stomach. Proton pump inhibitors act on the irreversible inhibition of the H^+/K^+-ATPase proton pump in the parietal cells of the stomach that leads to a significant decrease in gastric acid production. Reduced stomach acidity restricts the activity of the pepsin enzyme responsible for damaging the laryngopharyngeal mucosa, thus causing fewer injuries to the epithelium. With the combination of medical treatment with the necessary diet changes and lifestyle adjustments, the reduced level of acid contributes to the resolution of inflammation and regeneration of the mucous membrane and results in less frequent development of symptoms related to gastric reflux.

Objective assessment of laryngoscopic improvement was one of the main purposes of this study and was done with the help of the Reflux Finding Score (RFS). Prior to the beginning of treatment, the average score was 13.1 ± 2.9 that shows a high degree of inflammatory changes in the larynx. After eight weeks of treatment, the average RFS dropped to 6.2 ± 2.4 that is a highly statistically significant result ($p < 0.001$). Significant regression of laryngoscopic abnormalities proves the effectiveness of proton pump inhibitors and other necessary lifestyle adjustments in terms of the healing of reflux-related inflammation of the larynx. The results of the current research can be compared with those of Mesallam et al., who stressed the importance of the Reflux Finding Score as an objective method of diagnosis of laryngeal changes caused by reflux and control of the response to the treatment. [7] Noordzij et al. also managed to find a significant regression in various characteristic laryngoscopic findings including posterior commissure hypertrophy, diffuse laryngeal edema, erythema, ventricular obliteration, and vocal fold edema.[8] It proves the part of the gastric reflux in the development of inflammatory disorders of the larynx. Significant improvement of RFS in this study was paralleled by a similar improvement in RSI.

Thus, the simultaneous reduction of both RSI and RFS scores implies significant clinical importance of these parameters as they can help determine whether treatment is effective in each particular case. On the one hand, there is no correlation between improvement of symptoms and full remission of laryngopharyngeal mucosal inflammation, since the endoscopic findings may persist despite the improvement of symptoms. At the same time, endoscopic improvement may occur before full elimination of symptoms in some cases. Therefore, concurrent evaluation of RSI and RFS will allow for obtaining a more objective treatment outcome compared to separate application of these instruments. Generally speaking, satisfactory treatment effects were achieved in 71.4% of patients enrolled in this study. Such an observation is consistent with the data published by Steward et al., according to whom proton pump inhibitors used in combination with adequate lifestyle changes lead to satisfactory treatment outcomes in most of patients with LPRD.[9] The success of treatment in the current study could be explained not only by effectiveness of the drug itself, but also due to patient compliance to recommendations related to lifestyle. Patients were asked to eliminate reflux-provoking factors such as spicy and fatty foods, caffeine, carbonated drinks, alcohol, smoking, eating late at night, as well as to reduce weight, when necessary. All these measures help reduce the frequency and intensity of reflux events, thus improving the efficacy of medication therapy and facilitating recovery of inflamed laryngopharyngeal mucosa [10]. In general, the results obtained in this study demonstrate the complementary value of RSI and RFS in the management of LPRD. The RSI helps evaluate the intensity of symptoms and its influence on quality of life subjectively, while the RFS shows objectively assessed inflammatory changes revealed during endoscopy. Combination of these scores allows for evaluation of subjective and objective treatment outcomes, accurate tracking of disease progression, comparison of outcomes in different clinical trials, and choosing the right strategy for continuing or changing the therapy. Despite the great practical importance of these scoring instruments, both RSI and RFS have certain limitations. Firstly, the RSI score relies on patient's perceptions and therefore is subject to individual

differences in symptom perception and sensitivity to pain, as well as personal evaluation of the disease severity. Similarly, the evaluation of RFS depends on the interpretation of endoscopic findings and may vary among different observers due to their experience and level of professionalism. Secondly, the absence of confirmatory diagnostic procedure such as 24-hour dual probe pH measurement in this study did not allow for objective identification of reflux episodes.

To conclude, the current study contributes new information about the efficiency of proton pump inhibitors in the management of LPRD. Administration of proton pump inhibitors along with certain lifestyle modifications and dietary restrictions has led to significant improvement in patient symptoms and laryngoscopy results as evidenced by low RSI and RFS scores. This emphasizes the importance of acid suppression and behavioral modification in obtaining the symptom relief, resolving the laryngeal inflammation and improving quality of life of LPRD patients. Additionally, the use of RSI and RFS can serve as an effective method for the diagnosis, evaluation and monitoring of treatment effect and prognosis of the disease. The current prospective observational study has proved that administration of proton pump inhibitor drugs and changes in lifestyle and diet is efficient in the management of LPRD. Low RSI and RFS values after eight weeks of therapy mean that acid reduction in combination with lifestyle changes leads to a significant improvement in subjective symptoms and laryngoscopic results. This suggests that acid reduction in combination with lifestyle modification is effective in reducing the laryngeal inflammation and promotes mucosal healing. Furthermore, the current study has demonstrated the validity of RSI and RFS as the diagnostic tools. Combined usage of these two indices provides a good estimate of both subjective symptoms and laryngeal mucosa changes which allows objective assessment of the therapeutic effect and improvement of patient care standards. The results of the current study have showed that proton pump inhibitors remain important tools in the treatment of properly selected patients with LPRD. Routine use of standardized tests such as RSI and RFS will help to improve the accuracy of LPRD diagnosis, monitor the therapy effect and provide evidence-based care for patients. Further multicentric trials with larger groups of patients, longer follow-up periods and objective reflux tests need to be carried out for confirmation of the results obtained.

CONCLUSION

The present study demonstrated that proton pump inhibitor therapy significantly improved both symptomatic and laryngoscopic outcomes in patients with laryngopharyngeal reflux disease. Significant reduction in Reflux Symptom Index (RSI) and Reflux Finding Score (RFS) was observed following 8 weeks of treatment, indicating effective control of reflux-related laryngeal inflammation and symptoms. The study also established that RSI and RFS are simple, reliable, and useful tools for diagnosis, therapeutic monitoring, and follow-up evaluation in patients with LPRD. Early recognition and appropriate treatment of LPRD can improve patient quality of life and reduce chronic laryngeal morbidity.

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