Reflux Symptom Index and Reflux Finding Score in Diagnosis of Laryngopharyngeal Reflux

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ABSTRACT

Background

Although laryngopharyngeal reflux is a common condition encountered in otolaryngological practice, its diagnosis is not very easy because of its indistinct symptoms

Objective

To assess the efficacy of proton pump inhibitors versus proton pump inhibitors with lifestyle modification in patients with laryngopharyngeal reflux.

Method

Prospective, analytical study conducted in Department of Otorhinolaryngology and Head and Neck Surgery at Dhulikhel Hospital, Kathmandu University Hospital between January 2015 to January 2016. Eighty two patients with laryngopharyngeal reflux having Reflux symptom index > 13 and Reflux finding score > 7 were included. Patients were divided into 2 groups. Group A comprised of patients treated with proton pump inhibitors alone and Group B with Proton pump inhibitors with lifestyle modification. Pre and post therapeutic reflux finding score and reflux symptom index were compared.

Result

The mean reflux symptom index score difference before and after treatment in group A was 16.70 and group B was 14.58. Similarly, mean reflux finding score difference before and after treatment in group A was 8.68 and group B was 9.92. Comparison of reflux finding score and reflux symptom index scores before and after treatment revealed improvement in both groups and the difference was statistically significant ($p<0.001$). However, comparison of pre and post therapeutic and scores between group A and B, showed no statistical significance.

Conclusion

The extent of symptomatic improvement correlated positively with both proton pump inhibitor therapy alone as well as with proton pump inhibitor therapy along with lifestyle modification. Although addition of lifestyle modification offered incremental benefit for treating laryngopharyngeal reflux, it was not found to be statistically significant.

KEY WORDS

Laryngopharyngeal reflux, reflux finding score, reflux symptom index

INTRODUCTION

Reflux of gastroduodenal contents into the larynx may cause inflammation and symptoms resulting in chronic laryngeal symptoms and signs often referred to as laryngopharyngeal reflux (LPR).[1] The economic impact of LPR and extraesophageal reflux is estimated to be more than $50 billion dollars, which is 3 to 4 times that of typical gastroesophageal reflux disease. Thus, LPR is a significant clinical issue with much needed attention.[2]

The most common clinical manifestations of LPR include hoarseness, chronic cough, throat clearing and sore throat, globus sensation, and vocal cord granulomas. Other less common manifestations include buccal burning, halitosis, otalgia, stridor, and loss of taste.[3-7] The two predominant pathophysiological mechanisms for LPR are direct and indirect exposure of the larynx to injurious gastric contents. The direct exposure is due to acid, pepsin, and bile acid exposure to laryngopharyngeal mucosa. The indirect mechanism is thought to be a result of refluxate interactions with structures distal to the larynx, evoking a vagus nerve mediated response to bronchoconstriction.[8]

Definitive diagnosis of LPR is difficult to determine. Although, ambulatory 24 hour double-probe pH monitoring is considered as gold standard, it is expensive, invasive and lacks sensitivity. This has led many otolaryngologists to base initial diagnosis on physical findings during endoscopic examination using reflux symptom index (RSI) and reflux finding score (RFS).[9,10]

Our aim is to assess the efficacy of Proton pump inhibitors versus Proton pump inhibitors with lifestyle modification in management of patients with LPR using RSI and RFS.

METHODS

This was a prospective, analytical study conducted in the Department of Otorhinolaryngology and Head and Neck Surgery at Dhulikhel Hospital, Kathmandu University Hospital between January 2015 to January 2016. A total of 82 patients with LPR were recruited for this study. The instruments used for the study were RSI and RFS. RSI (Table 1) is a chart with nine questions which aims to determine the severity of the symptoms related to LPR. Since some degree of reflux is found in normal patients, a RSI greater than 13 is considered to be abnormal.[11] The RFS is an 8 item clinical severity scale based on findings during fiberoptic laryngoscopy (Table 2). The scale ranges from 0 (no abnormal findings) to a maximum of 26 (worst score possible). The RFS was developed to standardize the laryngeal findings of LPR so that clinicians may better diagnose, evaluate clinical improvement, and assess therapeutic efficacy of patients with LPR.[12] In our study, the different symptoms of patients were evaluated with the help of a structured questionnaire of RSI in a Nepalese translation and a RSI score was derived. RSI pre and post therapy was also derived. Patients who had a total RSI score of more than 13 and a RFS score of more than seven, which is suggestive value for LPR were included in study.[13] Each of the nine RSI questions were rated on the scale of 0(no problem) to 5(severe problem) by all the participants. The otorhinolaryngologists performed a transnasal fiberoptic laryngoscopy and determination of RFS at each visit. The total RFS score was calculated with a range of 0(no abnormal physical findings) to 26(every physical finding present to the most severe degree). Patients who were non-compliant, those with RSI score less than 9, patients with malignant diseases, intolerance to proton pump inhibitors (PPI), current medication with PPI, history of rhinosinusitis, otological/sinonasal pathology which can mimic the symptoms of LPR, previous surgery of upper digestive tract, pregnancy, breastfeeding, underlying psychiatric illness, use of non-steroidal anti-inflammatory drugs were excluded from our study. Written informed consent was taken. Approval for this study was

Table 1. Questionnaire used for the study- The Reflux Symptom Index[11]

Symptoms	
Hoarseness or other voice problems	Within the past month, how did the following problems affect? Ordinal scale:0-5(0=No problem,5=Severe problem)
Clearing throat	
Excess throat mucus or postnasal drip	
Difficulty swallowing food ,liquid or pills	
Coughing after eating or after lying down	
Breathing difficulties or choking episodes	
Troublesome or annoying cough	
Sensations of something sticking in throat or lump in throat	
Heartburn,chest pain, indigestion, or stomach acid coming up	

Table 2. Instrument used to derive a score on the basis of findings on fiberoptic laryngoscopy using Reflux finding score[12]

Reflux Finding Score	
Subglottic edema	0=absent
	2=present
Ventricular obliteration	2=partial
	4=complete
Erythema/hyperemia	2=arytenoids only
	4=diffuse
Vocal fold 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 tissue	0=absent
	2=present
Thick endolaryngeal mucus	0=absent
	2=present

obtained from Kathmandu University School of Medical Sciences Institutional Review Committee. A detail history and clinical examination was performed which included examination of the nose and paranasal sinuses, oral cavity and oropharynx, ears, and endolarynx. A clinical proforma was filled up. The possible risk factors were also evaluated. Upper gastrointestinal endoscopy was done in patients not responding to treatment (response score <2, less than 75% improvement).

Patients were divided into 2 groups. Group A comprised of patients who were treated with Proton Pump inhibitors alone (Esomeprazole 40 mg twice daily). Group B constituted patients treated with PPI (Esomeprazole 40 mg twice daily) with lifestyle modification. The lifestyle modifications recommended included the following: avoidance of eating or drinking three hours before lying down; avoidance of tight-fitting clothing, avoidance of tobacco products, alcohol, fried foods, fatty foods, chocolate, citrus juices, fizzy drinks, caffeine, spicy foods and head end elevation. Patients were randomly allocated into 2 groups based on computer generated randomization table. Allocation concealment was not done. All these patients received treatment for a total of three months. The clinical response was noted after completion of treatment according to the scale response suggested by a study conducted at Ohio, United States of America.[14]

Collected data were entered and analyzed using IBM SPSS statistical software 21.0. RFS score and RSI score before and after treatment were compared by using Wilcoxon signed rank test. Independent sample t test was used to compare the pre and post therapeutic RFS and RSI scores in between group A and B. Both descriptive and inferential statistics were measured; p-value<0.001 was considered a measure of statistical significance.

RESULTS

Out of 82 patients recruited for the study, 28(34.14%) were male and 54(65.85%) were female. The age of patients ranged from 16 to 63 years (mean age 35.02 years). The socio-demographic data are shown in table 3. The risk factors for LPR in these patients were fatty food (68.29%), tea and coffee (60.97%), voice abuse (50.00%), type A personality (35.36%), smoking (24.39%) and alcohol (22%). A total of 28(34.14%) patients underwent upper gastrointestinal endoscopy. The findings in upper gastrointestinal endoscopy were mild antral gastritis in 12(14.63%), hiatus hernia in 1(1.21%), grade I oesophagitis with antral gastritis in 6(7.31%) and normal findings in 9(10.97%) patients. Forty seven (57.31%) patients had >75% or disappearance of symptoms, 19(23.17%) had up to 50% or mild response, 12(14.63%) had 50-74% or clear response and 9(10.97%) complained of no response to treatment.

Table 3. Sociodemographic variables

Variable	Frequency	Percentage
Sex		
Male	28	34.14
Female	54	65.85
Age		
15-25	19	23.17
26-35	24	29.26
36-45	22	26.82
46-55	9	10.97
56-65	8	9.75

Table 4. Comparision between Pre and post-therapeutic RSI and RFS

Group	Pretherapeutic RSI Vs Posttherapeutic RSI Median(Interquartile range)		P value(Wilcoxon signed rank test)
A	20(10)	4(6)	<0.001**
B	24(7)	6(16)	<0.001**
Group	**Pretherapeutic RFS Vs Posttherapeutic RFS Median(Interquartile range)**		**P value(Wilcoxon signed rank test)**
A	12(5)	4(2)	<0.001**
B	16(5)	5(7)	<0.001**

**highly significant

The mean of RSI score difference before and after treatment in group A was 16.70 and group B was 14.58. Similarly, the mean of RFS score difference before and after treatment in group A was 8.68 and group B was 9.92. When the RFS score and RSI score before and after treatment were compared by using Wilcoxon signed rank test, it showed improvement in both the groups of patients and the difference was found to be statistically significant (Table 4). However, when Independent sample t test was used to compare the pre and post therapeutic RFS and RSI scores in between group A and B, no statistical significance was observed.

DISCUSSION

In our study, most of the patients were females. Our findings are similar to one of the previous study and in contrast to another one, where nearly equal predilection of LPR was reported among men and women.[9,11] It is unclear whether this finding represents gender specific reactions of laryngopharyngeal mucosa to reflux.

Our findings imply that fatty food, tea and coffee, voice abuse, Type A personality, smoking and alcohol are factors of importance. Similar results were reported in a recent study from India.[10]

The therapeutic approaches against LPR include life style modifications, acid suppressive therapy and surgical therapy.[8,15,16] In a study done in Texas, United States of America,[17] the authors found that mean score on the Laryngopharyngeal Reflux Disease Index for experimental patients after six weeks of PPI therapy was significantly

higher than that for control patients (9.50 versus 2.92, p< 0.001), and post treatment scores were significantly lower than pretreatment scores (7.35 versus 9.50, p< 0.001).

In another prospective analysis carried out at New York, United States of America,[18] LPR was treated by using a standardized behavior modification form in combination with medical management and found that the extent of symptomatic improvement correlated positively with both medical therapy and behavior modification. Conversely, in one multi center study conducted in 145 patients with LPR,[19] the authors did not report any benefit in patients treated with esomeprazole 40 mg bid for 4 months versus placebo.

In the present study, the treatment options used for patients in Group A was proton pump inhibitors alone and group B was Proton pump inhibitors with lifestyle modification. Comparison of pre and post treatment RFS and RSI revealed significant improvement in both the groups of patients. Our findings suggest that, both the forms of treatment are quite effective for treating the symptoms of LPR. However, when the pre and post therapeutic RFS and RSI scores were compared in between group A and B, no statistical significance was observed. This observation shows that even though lifestyle modification is found to be beneficial for treating LPR, it is not of statistical significance. This could probably be because of the small sample size in our study. While many studies exist which have compared placebo with PPI, to the best of our knowledge, there has been no research till date comparing PPI alone with PPI in combination with lifestyle modification like ours to compare our findings. Clearly, more well designed large scale studies focusing on this area are warranted in the future.

Although life style modifications have not been evaluated in controlled studies,[20] several studies reported a decrease in distal esophageal acid exposure with the elevation of head end of the bed, decreased fat intake, decrease in smoking, and avoiding recumbency for three hours postprandially.[21] This is in contrast to our findings that addition of lifestyle modification along with PPI therapy in treatment of LPR was not found to offer any additional benefit. The duration of treatment with PPI in LPR is a matter of debate. The use of twice daily dosing of PPI therapy in the current study is supported by many of the previously performed studies and is the one that is recommended by both gastrointestinal and ENT experts and guidelines.[14,22,23]

Our study also has some limitations. The sample size in this study is small. Another limitation of our study is the randomly allocation of patients into two groups based on computer generated randomization table. Allocation concealment was not done. Further research involving larger sample size and considering these limitations is warranted.

CONCLUSION

Reflux symptom index and reflux finding score are very useful tools for assessment and documentation of efficacy of treatment in patients with LPR. The extent of symptomatic improvement correlated positively with both proton pump inhibitor therapy alone as well as with proton pump inhibitor therapy along with lifestyle modification. Addition of lifestyle modification offered incremental benefit for treating LPR although statistical significance was not reached. Further study is required in this aspect.

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