

# Empirical Treatment With Anti-Reflux Medication In Patients With Suspected Laryngopharyngeal Reflux.

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## Abstract

**Objectives:** Anti-reflux medication is given empirically in cases of laryngopharyngeal reflux without monitoring the pH. We aimed to evaluate the effect of empiric anti-reflux treatment on laryngopharyngeal symptoms and signs in patients with gastro esophageal reflux (GER) and suspected laryngopharyngeal reflux (LPR). **Methods:** Gastroesophageal Reflux disease (GERD) was determined 115 Patients. Patients with pathology other than LPR which may be responsible from laryngopharyngeal symptoms and signs were excluded from the study. Forty patients diagnosed as cases of laryngopharyngeal reflux according to Reflux symptom index (RSI) and reflux finding score (RFS) comprised the study group. After eight weeks of anti-reflux treatment, RSI and RFS were calculated again. The statistical analyses were made according to the changes in the severity and frequency of each symptom and sign. **Results:** There was significant improvement in RSI and RFS after treatment when compared with initial scores, complete resolution of the disease was not observed generally. **Conclusion:** Anti-reflux treatment has a significant improving effect on laryngopharyngeal symptoms and signs. There may be needed longer times of treatment for complete resolution.

## INTRODUCTION

Laryngopharyngeal reflux refers to the retrograde flow of gastric contents into the laryngopharynx, whereby gastric material comes into contact with upper aero-digestive tract tissue and consequently damages it. Koufman was the first to recognize laryngopharyngeal reflux (LPR) as an entity distinct from classical gastro-esophageal reflux [1]. In clinical practice, empiric antireflux medication is preferred in patients with symptoms and signs which are suspected to be related to LPR [2].

Laryngopharyngeal reflux give rise to so many symptoms and signs confined to laryngopharynx. These symptoms include globus pharyngeus, hoarseness, post-nasal drip, dysphagia, chronic cough, dyspnea, laryngospasm and throat pain. The signs are laryngeal edema, hyperemia, posterior commissure hypertrophy, ventricular obliteration, granulation and thick endolaryngeal mucus [3,4,5]. However, these signs and symptoms are common in vocal abuse, trauma, smoking, alcoholism, asthma, allergy, infection or previous intubation. Also these sign and symptom may be seen without any cause in normal person. The definite role of laryngopharyngeal reflux on laryngopharyngeal pathology is not clearly defined; the therapeutic efficacy of antireflux medication on these signs

and symptoms remains controversial.

We aimed to evaluate the effect of antireflux treatment in selected patients without any possible insult other than LPR.

## MATERIAL AND METHODS

The study was carried out from April 2010 to January 2011. We enrolled 115 consecutive patients from our Otorhinolaryngology clinic at Gandaki Medical College Charak Hospital.

The patients with allergy, chronic upper respiratory tract infection, smoking and consuming excessive alcohol, taking NSAID, malignancy of hypo pharynx and esophagus, neurological cause of dysphonia and dysphagia, gastrointestinal surgery, history of throat trauma, prior intubation, concomitant proton pump inhibitor treatment or adverse reactions secondary to proton pump inhibitor treatment were excluded from the study.

The study proposal was reviewed and approved by Gandaki Medical College Charak Hospital Ethical committee. After getting approval from the ethical committee of our institution, the written informed consent was obtained from all patients. Gastroenterological evaluation was performed with flexible gastroduodenoscopy by the same

gastroenterologist. Endoscopic findings were evaluated with Los Angeles Classification.

Grade A: 1 or more mucosal breaks confined to folds, B5 mm,

Grade B: 1 or more mucosal breaks [5 mm] confined to folds but not continuous between tops of mucosal folds,

Grade C: mucosal breaks continuous between tops of two or more mucosal folds but not circumferential,

Grade D: circumferential mucosal break [6].

All patients were asked to complete the questionnaire proposed by Belafsky et al. [7]. It is 0–5 point scale to grade the symptoms. Reflux symptom index (RSI) was calculated for each patient. Based on this analysis, one can be 95% certain that a patient with a RSI greater than 13 presents LPR [7]. This questionnaire was performed to all patients by the same otolaryngologist. Another otolaryngologist who is blinded to the result of RSI performed fiberoptic nasopharyngolaryngoscopy examination to the patients. Reflux finding score (RFS) which was proposed by Belafsky et al. [8] was calculated for each patient. It is an eight-item clinical severity scale for judging laryngoscopic findings. Based on this analysis, one can be 95% certain that a patient with a RFS of 7 presents LPR [8]. The patients having an RSI greater than 13 and RFS greater than 7 were accepted to have LPR. The patients with a RSI score 13 or less, and a RFS score 7 or less were excluded from the study. As a result, remaining forty patients diagnosed as cases of laryngopharyngeal reflux according to RSI and RFS comprised the study group.

All patients were prescribed Esomprazole 40 mg (Esonorm 40mg, Deurali-Janta pharmaceutical private limited, Nepal) B.D. for 8 weeks. Dietary modification including avoidance from excess fat, chocolate, and coffee was advised. At least 3 hour interval between dinner and sleep, elevation of the head of the bed and avoidance from tight dressings were advised. RSI and RFS were calculated again after the treatment by the same researchers. The comparison of the pretreatment and post-treatment values of each symptom and sign were done in terms of severity and frequency.

Paired sample t-test, was used in a 95% confidence interval and accepted to be significant when  $p < 0.05$ .

## RESULTS

There were 15 male (37.5%) and 25 female (62.5%) patients

with a mean age of  $37.5 \pm 11.8$  years. Initial RSI of the patients were ranging between 15 and 32 with a mean of  $22.33 \pm 3.63$ . Post treatment RSI were ranging between 3 and 14 with a mean of  $7.2 \pm 2.1$ . The decrease in RSI was found to be highly statistically significant ( $p < 0.01$ ) (Table 1).

**Figure 1**

Table 1. Evaluation of the pretreatment and post-treatment values of Reflux symptom index

	Min-max	Mean	SD	Median	P value
Before Treatment	15-32	22.33	3.63	22	0.001
After treatment	3-14	7.00	2.22	6	

Initial RFS of the patients were ranging between 8 and 22 with a mean of  $12.6 \pm 3.26$ . Post treatment RFS were ranging between 2 and 7 with a mean of  $3.8 \pm 1.35$ . The decrease in RFS was found to be highly statistically significant ( $p < 0.01$ ) (Table 2).

**Figure 2**

Table.2 Evaluation of the pretreatment and post-treatment values of Reflux finding score

	Min-max	Mean	SD	Median	p value
Before Treatment	8-22	12.60	3.264	12	0.001
After treatment	2-7	3.85	1.350	4	

The initial and post treatment scores of each symptom were shown separately in Table 3. The change in the severity score of every symptom was found to be highly statistically significant ( $p < 0.01$ ) (Table 3).

**Figure 3**

Table 3. Evaluation of the severity of parameters of Reflux symptom index.

Symptom	Mean	S D	Median	p Value
<b>Hoarseness</b> before treatment after treatment	2.50 .43	1.502 .844	2 0	0.001
<b>Throat clearing</b> before treatment after treatment	4.03 1.05	.832 .932	2 1	0.001
<b>Post nasal discharge</b> before treatment after treatment	1.78 .88	1.050 .822	2 1	0.001
<b>Dysphagia</b> before treatment after treatment	1.88 .90	1.202 .778	2 1	0.001
<b>Cough after lying</b> before treatment after treatment	1.00 .43	1.013 .675	1 0	0.009
<b>Breathing difficulty</b> before treatment after treatment	1.08 .38	.797 .628	1 0	0.001
<b>Troublesome cough</b> before treatment after treatment	1.60 .40	1.057 .632	1.5 0	0.001
<b>Lump</b> before treatment after treatment	3.90 1.65	.810 1.167	4 2	0.001
<b>Heart burn</b> before treatment after treatment	2.95 .90	1.085 .744	3 1	0.001

The initial and post treatment scores of each finding were shown separately in Table 4. The change in the scores of severity of each finding was found to be statistically significant. ( $p < 0.05$ ) (Table 4).

**Figure 4**

Table 4. Evaluation of the severity of parameters of Reflux finding score

Sign	Mean	SD	Median	p value
<b>Pseudosulcus</b> before treatment after treatment	.65 .03	.949 .158	0 0	0.001
<b>Ventricular obliteration</b> before treatment after treatment	1.15 .30	.189 0.648	2 0	0.001
<b>Erythema -hyperemia</b> before treatment after treatment	2.70 .98	1.067 1.000	2 0.5	0.001
<b>Vocal Cord edema</b> before treatment after treatment	.98 .45	1.291 .552	0 0	0.022
<b>Diffuse laryngeal edema</b> before treatment after treatment	2.31 .77	1.127 .706	2 1	0.001
<b>Posterior commissure hypertrophy</b> before treatment after treatment	3.08 1.28	.797 .877	3 1	0.001
<b>Granuloma</b> before treatment after treatment	.30 .00	.723 .000	0 0	0.012
<b>Thick endo-laryngeal mucus</b> before treatment after treatment	1.50 .08	.877 .267	2 0	0.001

**DISCUSSION**

Laryngopharyngeal reflux is a relatively newly diagnosed condition in Nepal. In the western world, however, there is a high incidence of this disease approximately 10–30 per cent of patients visiting the otolaryngologist, and more than half of all patients with voice and laryngeal problems, have conditions related to laryngopharyngeal reflux [7,9]

Efficacy of antireflux medical treatment is highly variable in the literature. In prospective studies with placebo control, anti reflux medication showed marked improvement in reflux symptoms and signs [10 ]while it failed to demonstrate significantly greater improvement in other studies when compared to placebo [11,12]. However, in many studies without placebo control, anti reflux medication was found to be effective in resolution of laryngeal symptoms and signs. The efficacy was reported to be around 65% [13,14].

In this study, empiric antireflux treatment with duration of 8 weeks yielded statistically significantly improvement in RSI and RFS. This means that the treatment had decreased the severity of the symptoms significantly in all subtopics but could not eradicate the complaints totally in significant number of the patients

Mild to moderate Hoarseness resolved in 55% of patients. Severe hoarseness resolved in only 13 % of patient. Throat clearing and globus was present in all patients in our study. Resolution throat clearing seen in 14(35%) and globus in 9(23%) patient but severity of the complaint had decreased significantly at all patients.

Cough after lying and breathing difficulty was seen in 28% patients in our study. These symptoms decreased in severity but could not resolve completely. Pseudosulcus was seen in 32% of the cases. Complete resolution occurred in 5 patients.

Erythema, vocal cord edema, diffuse laryngeal edema and posterior commissure hypertrophy were the most commonly observed signs in this study. They all had statistically resolved in terms of both severity and frequency. Granuloma was seen in 6 patients in our study. After treatment no granuloma was found, but we add lifestyle modification and adjuvant speech therapy in those patient.

In general, symptom and signs were improved significantly from the treatment but did not disappear completely. The duration of treatment was not enough for complete cure of disease. So increase in the duration of treatment may cure the disease. Absence of control group is the limitation of this study. Putting control group in such study with placebo treatment may cause problem. Patient were selected according to Reflux symptom index and Reflux finding score, which is easier for otolaryngologists to start antireflux treatment in clinical practice.

## **CONCLUSION**

Empiric antireflux treatment provided significant improvement in Reflux symptom index (RSI) and Reflux finding score (RFS). Therefore antireflux treatment is an effective and reliable method for the treatment of patients having both gastro esophageal reflux disease (GERD) and Laryngopharyngeal reflux (LPR) related symptoms and signs. Symptoms and signs generally decrease but do not disappear. Eight weeks is not enough for complete resolution of the disease, so longer duration of treatment are needed.

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