



A PROSPECTIVE OBSERVATIONAL ANALYSIS ON CHANGES IN REFLUX SYMPTOM INDEX AND REFLUX FINDING SCORE IN LARYNGOPHARYNGEAL REFLUX PATIENTS AT A TERTIARY CARE FACILITY, AJMER

Otorhinolaryngology

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ABSTRACT

Background: Laryngopharyngeal reflux (LPR), also referred to as supra-esophageal reflux, refers to a condition in which gastroduodenal content rises up the esophagus and affects the throat, specifically the laryngopharynx. The most common symptoms of LPR include throat clearing, persistent cough, globus pharyngeus, hoarseness and contact ulcers.

Objective: The aim of the study was to assess the changes in reflux symptom index and reflux finding score in patients with laryngopharyngeal reflux pretreatment and following one month of empirical treatment and to find out correlation between the RFS and RSI.

Methodology: This hospital based, observational, prospective study was conducted at tertiary care facility Ajmer, Rajasthan from June 2019 to May 2020. All selected 80 patients were evaluated for reflux symptoms index (based on history and symptoms) >13 and reflux finding score (using 70 degree rigid laryngoscope) >7 using validated questionnaire following which empirical treatment with proton pump inhibitors was started for one month. Follow up for change in RSI and RFS was done after one month. Data was analysed using Microsoft Excel 2019.

Results: We observed that significant improvement was noted in RSI and RFS following 1 month treatment with PPIs and also that there was no statistically significant correlation between the baseline RSI and RFS ($r=0.013$, p value = 0.887) as well as the post-treatment follow up RSI and RFS values ($r=0.033$, p value = 0.709).

Conclusion: Our observations suggest that RSI and RFS scoring tool is a fast and convenient scale to plan the treatment of patients with LPR.

KEYWORDS

Gastroesophageal reflux disease, Laryngopharyngeal reflux, Reflux Finding Score, Reflux Symptom Index.

INTRODUCTION:

Laryngopharyngeal reflux (LPR) also known as extraesophageal reflux disease refers to retrograde flow of gastric contents to the upper aerodigestive tract [1]. Connor et al. reported that symptoms of LPR were also seen in 49% of the normal community [2]. The larynx and pharynx are devoid of the normal acid clearance found in the esophagus. For the esophagus, even up to 50 episodes of reflux per day is considered normal, whereas for the larynx even 3 episodes per week is seen to be associated with a significant disease [3].

In 1996, Koufman proposed the term laryngopharyngeal reflux for the symptoms, signs, or tissue damage resulting from aggression of the gastrointestinal contents into the upper aerodigestive tract [4]. Laryngeal symptoms of reflux are due to two or more possible mechanisms that may act simultaneously: local chemical irritation on the pharyngeal mucosa and stimulation of vagal reflex from esophageal irritation. Pepsin along with acid was found to be the most injurious agent and has a strong association with laryngeal lesions [5]. The delicate ciliated respiratory epithelium of the posterior larynx that normally functions to clear mucus from the tracheobronchial tree is altered due to repeated exposure, and the resultant ciliary dysfunction causes mucus stasis. The subsequent accumulation of mucus produces postnasal drip sensation and provokes persistent throat clearing. Direct reflux irritation can cause coughing and choking (laryngospasm) because sensitivity of laryngeal sensory endings is up-regulated by local inflammation. This combination of factors can lead to vocal fold edema, contact ulcers and granulomas that cause other LPR associated symptoms: hoarseness, globus pharyngeus, and sore throat. It is also implicated for premalignant lesions and squamous cell carcinoma of the larynx. [6-8]

The most common complaints in patients of LPR are cervical dysphagia (33%) followed by globus pharyngeus (19%), sore throat (17%) and chronic throat clearing (14%). The 24 hr pH monitoring is the gold standard for diagnosis of LPR but is a time-consuming, relatively invasive, and expensive technique. Due to lack of accurate diagnosis, most of these patients receive repeated courses of

antibiotics or are treated for asthma, sinusitis or chronic tonsillitis. Therefore, along with a detailed history, a visual examination of the larynx and pharynx is crucial to the initial diagnosis and subsequent planning of the treatment of patients with dysphonia and other complaints consistent with LPRD. Belafsky et al.[9,10] developed the reflux symptom index (RSI) and the reflux finding score (RFS) for the assessment of the patients with LPR. An RSI of greater than 13 is considered to indicate LPR. An RFS greater than 7 indicates that the patient has LPR with 95% certainty.

Aim of the study was to correlate RSI and RFS in patients with laryngopharyngeal reflux and to assess the change in scores of RSI and RFS following 1 month of treatment with proton pump inhibitor.

MATERIAL AND METHODS

This hospital based, observational, prospective study was conducted in Department of ENT and Head Neck Surgery of J.L.N. Medical college, Ajmer, Rajasthan from June 2019 to May 2020 after approval from ethical committee. Total 80 patients were enrolled in our study.

Present study included all the patients above 18 years of age who presented with symptoms of laryngopharyngeal reflux. Patients having chronic rhino sinusitis, chronic voice misuse, chronic chest infections, malignancy, chronic smokers and alcoholics were excluded from the study. A written and fully explained consent stating the voluntary participation of subjects in the study was taken before the enrolment of the subjects. All selected cases were evaluated using preformed proforma. A detailed history was taken as age, sex, socioeconomic status, occupation, nature and duration of symptoms etc. All selected patients were evaluated for reflux symptoms index (based on history and symptoms) >13 and reflux finding score (using 70 degree rigid laryngoscope) >7 following which empirical treatment with proton pump inhibitors was started for one month. Reflux symptom index (RSI) is a validated self-administered questionnaire with 9 questions that are answered by patients on a 5 point scale. The reflux finding score (RFS) is an 8-item clinical severity scale based on findings during fiberoptic laryngoscopy, this scale ranges from 0 (no

abnormal findings) to a maximum of 26 (worst score possible). Follow up for change in RSI and RFS was done. Collected data was entered in Microsoft excel 2019 spread sheets. Qualitative data was expressed as rate and proportion while quantitative data was expressed as mean and standard deviation. Appropriate statistical test was applied to analysis and to draw inference. P value <0.05 was considered as significant.

OBSERVATION AND RESULTS:

In present study, more than half 57.5% (46/80) of patients were female and rest 42.5% (34/80) were male. Mean age of patients was 41.8±11.4 years. More than half of patients 58.7% (47/80) were from urban area and rest 33(41.3%) were from rural area. Around two third 63.7% (51/80) patients were literate. Around half 48.7% (39/80) of patients belonged to upper middle socio-economic class as per modified BG Prasad scale.

Table 1- RSI score at baseline and after treatment with PPI

Variable		Baseline n(%)	Follow-up n(%)
Hoarseness	0	54(67.5)	65(81.3)
	1	2(2.5)	
	2	10(12.5)	9(11.3)
	3	14(17.5)	6(7.5)
Clearing your throat	0	19(23.8)	38(47.5)
	1	1(1.3)	1(1.3)
	2	16(20)	23(28.8)
	3	27(33.8)	14(17.5)
PND/Throat mucus	0	26(32.5)	41(51.3)
	1	1(1.3)	
	2	12(15)	17(21.3)
	3	25(31.3)	12(15)
Swallowing difficulties	0	47(58.8)	56(70)
	2	12(15)	15(18.8)
	3	16(20)	8(10)
	4	5(6.3)	2(2.5)
Coughing after eating/Lying down	0	49(61.3)	55(68.8)
	1	1(1.3)	
	2	10(12.5)	13(16.3)
	3	17(21.3)	10(12.5)
Breathing difficulty/ Choking episode	0	51(63.8)	60(75)
	2	9(11.3)	9(11.3)
	3	17(21.3)	10(12.5)
	4	3(3.8)	1(1.3)
Annoying cough	0	42(52.5)	47(58.8)
	2	8(10)	16(20)
	3	21(26.3)	12(15)
	4	9(11.3)	5(6.3)
Lump in throat	0	22(27.5)	31(38.8)
	2	8(10)	22(27.5)
	3	24(30)	15(18.8)
	4	26(32.5)	12(15)
Heart burn/chest pain	0	13(16.3)	35(43.8)
	1	0(0)	1(1.3)
	2	12(15)	26(32.5)
	3	36(45)	18(22.5)
	4	19(23.8)	

(Table-1) Heart burn/chest pain is the most common symptom among the study population (84%), followed by difficulty in clearing throat (76.8%). Other symptoms were lump in throat (76%) and Hoarseness was found to be the least common (32%) finding. Improvement was noted after giving a course of PPI (omeprazole 20 mg BD) for 1 month. All symptoms improved significantly during follow up (p value<0.05)

Table 2- RFS score at Baseline and after treatment with PPI

Variable		Baseline n(%)	Follow-up n(%)
Subglottic edema (0/2)	0	63(78.8)	65(81.3)
	2	17(21.3)	15(18.8)
Ventricular obliteration (2/4)	0	30(37.5)	29(36.3)
	2	44(55)	46(57.5)
	4	6(7.5)	5(6.3)

Erythema (2/4)	0	9(11.3)	15(18.8)
	2	45(56.3)	48(60)
	4	26(32.5)	17(21.3)
VF Edema (1-4)	0	16(20)	19(23.8)
	2	27(33.8)	31(38.8)
	3	37(46.3)	30(37.5)
Diffuse laryngeal edema (1-4)	0	28(35)	29(36.3)
	2	33(41.3)	34(42.5)
	3	19(23.8)	17(21.3)
PC Hypertrophy (1-4)	0	61(76.3)	62(77.5)
	1	1(1.3)	(0)
	2	16(20)	17(21.3)
Granuloma (0/2)	3	2(2.5)	1(1.3)
	0	77(96.3)	77(96.3)
Endolaryngeal mucus (0/2)	2	3(3.8)	3(3.8)
	0	72(90)	75(93.8)
	2	8(10)	5(6.3)

(Table -2) The most common symptom was erythema/hyperaemia (88.7%), followed by vocal fold edema (80%) and least common finding was Granuloma in 3.7% cases. All symptoms were improved after the treatment with PPI except ventricular obliteration which in fact worsened after treatment. Mean RSI and RFS score decreased significantly after treatment with PPI from the baseline (p Value<0.001). In present study, no statistically significant correlation between baseline RSI and RFS (r=0.013, p value = 0.887) and between those obtained on follow-up after the treatment (r = 0.033, p value = 0.709) was present.

DISCUSSION:

Laryngeal symptoms of reflux are due to two or more possible mechanisms that may act simultaneously: local chemical irritation on the pharyngeal mucosa and stimulation of vagal reflex from esophageal irritation and due to pepsin. The patients present with wide array of clinical presentation which may mimic the clinical profile of acute pharyngitis, acute tonsillitis, acute rhinosinusitis or asthma. Due to inaccurate diagnosis many of the times patients undergo repeated course of antibiotic. Hence, the present study was conducted to assess the changes in RSI and RFS score after one month of empirical treatment from baseline in patients of LPR and to find out correlation between the two.

The mean of all the 9 individual components of RSI showed statistically significant decrease after therapy. Present study results were comparable with study results of Satish et al. (2016) [1] Jasperson and Weber [11], Fathima et al (2019) [12], Alam et al.(2012)[13] demonstrated significant resolution of LPR symptoms after a 4 weeks treatment with PPI.

Only three findings i.e. erythema/hyperemia, vocal fold edema and endolaryngeal mucus were improved statistically significantly from baseline RFS values (p value <0.05). Improvements in other individual signs were also noted.

Out of 80 cases, 32 % cases of study populations showed significant improvement in RFS score after administration of PPI for 1 month. Our study results were comparable to those of Satish et al. (2016)[1] . Hill et al. demonstrated no changes in posterior commissure hypertrophy in patients with LPR on long term PPI therapy owing to the irreversible histological transformation in form of keratinisation and epithelial hyperplasia due to constant exposure to gastric secretions. [14,15]

In present study Mean RSI and RFS score decreased significantly after treatment with PPI from the baseline (p Value<0.001). Our results are comparable to those of Satish et al.[1] who found that the mean RSI at baseline was 12.56±3 and follow-up RSI was 7.90±3.65 with p value of the improvement being <0.001. However, changes in mean RFS were in contrast with those of our study with p value 0.241 which is not statistically significant. This might be due to small sample size of study population in their study.

We found that correlation between both baseline as well as 1 month follow up values of RSI and RFS was not statistically significant. Mesallam and Stemple (2007)[16] in their study demonstrated a highly significant correlation between the RFS and RSI. In another study by Vázquez de la Iglesia et al.[17], a statistically significant correlation

was found between the RSI and RFS and they also observed that the correlation is greater when the RFS score is more than 7 ($r = 0.3$, $P = 0.007$).

In our study, each symptom in the RSI score showed a statistically significant improvement on follow-up after treatment. RFS did not show any significant difference in findings on follow-up except for erythema and vocal fold edema which showed significant changes (while changes in endolaryngeal mucus showed just a borderline significance ($P = 0.045$)). Results of present study are similar to those of Satish et al. (2016)[1] Similar results were found in study done by Khurshid H. Alam (2012)[13]-

CONCLUSION:

The RFS alone cannot be used for diagnosis and treatment outcome because improvement in RFS is not consistent with improvement in LPR symptoms. So, it should be used in conjunction with RSI. Even though there is no correlation between the baseline RSI and RFS values, still these scales enable otolaryngologists to develop a common language for diagnosis of LPR. Significant improvement was noted in RSI and RFS following 1 month treatment with PPIs. Hence, our observations suggest that RSI and RFS scoring tool is a fast and convenient scale to plan the treatment of patients with LPR.

Limitations : We have followed up the patients for 1 month only, due to time constraints and the sample size for the study was limited. We advise a longer period of follow-up to note the improvements in the signs on a larger sample size.

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