



Laryngopharyngeal Reflux in Dysphonics—Understanding the Significance and the Efficacy of Clinical Diagnosis: A Case-based Study

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ABSTRACT

Objective: To determine the prevalence of laryngopharyngeal reflux (LPR) in patients with voice disorders and to find out the efficacy of reflux symptom index (RSI) and reflux finding score (RFS) in the diagnosis.

Methods: This prospective analytical study was conducted on 554 patients who presented with dysphonia and symptoms suspicious of LPR. They were then subjected to clinical work up based on symptomatic history based RSI and video stroboscopic RFS scoring criteria. The results were analyzed statistically. The differences between RSI and RFS were calculated by Fisher's two sided test and the comparison between the two is calculated using kappa statistics to check the strength of agreement.

Results: Among 554 patients, 457 (82.4%) patients were diagnosed to have LPR based on RSI score of more than 13. Among 448 (80.8%) patients RFS score was positive. Vocal nodule (23.64%), laryngitis (22.38%) and the vocal polyp (20.03%) constitute the majority, with a female preponderance in vocal nodule. Both RSI and RFS were poor or almost absent in conditions such as spasmodic dysphonia, tremors, vocal cord palsy, hemorrhage, functional aphonia and traumatic conditions. The Pearson correlation coefficient showed a good correlation and agreement between RSI and RFS was statistically significant.

Conclusion: The association of LPR in patients with voice disorders is significantly high. The RSI and RFS based clinical diagnosis is reliable and valid in the diagnosis of LPR as revealed in our study.

Keywords: Dysphonia, Laryngopharyngeal reflux, RSI, RFS, Agreement.

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INTRODUCTION

Chronic exposure of laryngeal airway to acid reflux can manifest as extra esophageal disorders ranging from simple laryngitis to life-threatening laryngeal malignancies and is designated as laryngopharyngeal reflux (LPR).¹⁻³ Presumed to be an important etiological factor in patients with voice disorder, the detection of LPR has become an important step in the management of voice disorders^{4,5} and has been reported to occur in 55 to 79% of patients with intractable hoarseness.^{6,7} The current literature clearly defines LPR as more or less separate clinical entity having a different mechanism from the well described gastroesophageal reflux (GERD) and has gained much attention recently.⁸

Even though a wide variety of laryngeal symptoms have been found to be caused by LPR, the diagnosis of LPR and its causal relationship is still difficult. Double probe 24 hours pH monitoring has been accepted as the gold standard, however the invasive nature, time consumption, high cost and limited availability with expertise prevents it from being used widely in daily clinical practice.⁹ The introduction of a validated 9-item self-administered questionnaire—the reflux symptom index (RSI)—is reported to be a valid and reliable tool in the clinical diagnosis of LPR. With the advent of videostroboscopy laryngologist have now acquired a more understanding of the pathological effects of larynx. Reflux finding score (RFS) which is an 8 item clinical severity rating scale is also another marker of LPR which has been designed to characterize the morphological lesions presumably associated with LPR. Both RSI and RFS have high comparability with the gold standard double probe 24 hours pH monitoring.^{8,10,11} With this scenario, we conducted a prospective study on a large group of patients with dysphonia to analyze the etiological significance of LPR who were diagnosed primarily based on RSI and then compared with RFS. The efficacy of RSI and RFS also has been studied statistically to assess the relative value of each in the routine work-up of dysphonic

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patients with LPR. To the best of our knowledge such a comparative study is the first in the English literature on a large cohort.

METHODS

This study was part of the original work conducted by the primary author over a period of 3 years in a teaching institution in India. A total of 554 patients with symptoms suggestive of LPR by a comprehensive clinical history and examination were enrolled for the study. The subjects then underwent examination based on RSI and RFS scoring system (Tables 1 and 2). Patients whose videostroboscopic assessment could not be done either due to excessive gagging reflex or due to noncooperation were excluded from the study.

Reflux symptom score scale for each individual item (hoarseness of voice, clearing of throat, excess throat mucus, difficulty in swallowing, coughing after lying down or meals, breathing difficulty, troublesome cough, sticky sensation of throat, and heartburn with or without chest pain or indigestion) ranges from 0 (no problem) to 5 (severe problem) with a maximum of score 45 (see Table 1). RFS was based on video stroboscopic findings (Strotz 8706 CJ, 90°, Camera Atmos K2 with VHS recorder Panasonic AG-7350, monitor Sony CVM-1810E) and were categorized as 0, 1 and 2 for different pathologies as enumerated in Table 2. An RSI score of more than 13 was considered positive (RSI+) and score below 13 was denoted as negative (RSI-). RFS was considered negative for scores below 7 (RFS-) and positive for those above 7 (RFS+). It has been described both RSI score of more than 13 and RFS of greater than 7 are suggestive of positive dual probe Ph study.^{8,9}

The data was tabulated and analyzed using the software program Statistical Product and Service Solutions (SPSS) version 12. The differences between RSI and RFS were

calculated by Fisher's two sided test and the agreement between RFS and RSI was measured using the kappa coefficient. Landis and Koch (1977) guideline¹² was used to interpret the kappa coefficient. The results were analyzed and a review of literature is also highlighted.

RESULTS

Among 554 patients, 317 (57.2%) were males and 237 (42.7%) were females. The age of the patients ranged between 7 and 68 years and the duration of hoarseness ranged from 3 months to 4 years. Vocal nodule (23.64%), laryngitis (22.38%) and the vocal polyp (20.03%) constituted the majority, with a female preponderance in vocal nodule. An individual distribution of laryngeal abnormalities with respective mean RSI and RFS is displayed in Table 3. The mean RSI and RFS score generally showed higher values in patients with vocal polyp, granuloma, leukoplakia, laryngeal carcinoma, vocal nodule, laryngitis, muscle tension dysphonia and Reinke's edema (see Table 3). Mean RSI score was highest for vocal polyps (26) where as RFS score was high in conditions like laryngitis¹⁷ and vocal nodule¹⁶ in comparison. Both RSI and RFS were poor or almost absent in conditions such as spasmodic dysphonia, tremors, vocal cord palsy, hemorrhage, functional aphonia and traumatic conditions.

Overall 457 (82.4%) patients were diagnosed to have LPR based on RSI score of more than 13. Among 448 (80.8%) patients RFS score was positive. The Pearson correlation coefficient showed a good correlation and agreement between RSI and RFS (Table 4) and p-value was statistically significant. The nonrandom agreement between two scores was assessed using the kappa coefficient. According to the criteria of Landis and Koch (1977)¹², a kappa coefficient of 0.85 (95% CI 0.79-0.91) indicates an almost perfect agreement between the RFS and RSI.

Table 1: The reflux symptom index⁸

Within the last month, how did the following problems affect you?		0 = No problem 5 = Severe problem					
		0	1	2	3	4	5
1	Hoarseness or a problem with your voice	0	1	2	3	4	5
2	Clearing your throat	0	1	2	3	4	5
3	Excess throat mucous or postnasal drip	0	1	2	3	4	5
4	Difficulty swallowing food, liquids or pills	0	1	2	3	4	5
5	Coughing after you ate or after lying down	0	1	2	3	4	5
6	Breathing difficulties or choking episodes	0	1	2	3	4	5
7	Troublesome or annoying cough	0	1	2	3	4	5
8	Sensations of something sticking in your throat or a lump in your throat	0	1	2	3	4	5
9	Heartburn, chest pain, indigestion or stomach acid coming up	0	1	2	3	4	5
Total							

Table 2: The reflux finding score¹⁰

Finding	Score
Subglottic edema	2 = Present 0 = Absent
Ventricular obliteration	2 = Partial 4 = Complete
Erythema/hyperemia	2 = Arytenoids only 4 = Diffuse
Vocal cord 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	2 = Present 0 = Absent
Thick endolaryngeal mucus/other	2 = Present 0 = Absent
Total	

DISCUSSION

In the literature, the prevalence of LPR in voice disorders is quite high.^{6,7,13} Recent studies show that LPR is having a different clinical picture unlike GERD such as the prevalence of the diurnal reflux, absence of heart burn and the predominance of upright refluxes.^{8,14} The negative impact of LPR on lives has been studied recently as it has implicated in the development of devastating laryngeal conditions such as granuloma, leukoplakia, subglottic stenosis and squamous cell carcinoma if left untreated.¹⁵⁻¹⁸

In our study of 554 patients with the voice disorders, LPR has been associated in the majority of patients. Koufman et al and McNally et al have estimated that up to half of the patients with laryngeal voice disorders had reflux.^{6,7} However, the range varies from 16.5%¹³ to 80%¹⁹ in the literature. In our study, we found LPR in 82.4% of patients. Most of the previous studies reported that the most common manifestation of LPR was reflux laryngitis with or without granulation or granuloma formation.²⁰⁻²³ In contrast, in our study, vocal nodule was the major pathology followed by laryngitis and vocal polyp

Table 3: Distribution of voice disorders, mean reflux symptom index and reflux finding scores of patients with different vocal pathologies

Voice disorder	Distribution	Male	Female	RSI		RFS	
				Mean	SD	Mean	SD
Muscle tension dysphonia	6.49% 36/554	16	20	21	2.1	12	2.8
Reinke's edema	1.08% 6/554	5	1	17	1.2	13	2.4
Vocal polyp	20.03% 111/554	60	51	26	3.2	15	4.1
Vocal nodule	23.64% 131/554	56	75	22	2.8	16	3.2
Laryngitis	22.38% 124/554	67	57	22	1.4	17	4.8
Laryngeal carcinoma	3.97% 22/554	22	—	23	2.6	17	3.9
Spasmodic dysphonia	2.16% 12/554	2	10	3	0.9	0	0
Tremors associated with Parkinsonism	0.72% 4/554	4	—	6	1.1	0	0
Vocal cord palsy	8.30% 46/554	30	16	8	1.6	3	0.4
Puberphonia	2.16% 12/554	12	—	4	1.3	1	0.3
Leukoplakia	4.69% 26/554	26	—	24	3.4	14	4.2
Granuloma	2.16% 12/554	10	2	25	2.5	15	4.7
Vocal cord hemorrhage (phonotrauma)	0.90% 5/554	4	1	6	1.4	3	1.1
Functional aphonia	0.72% 4/554	—	4	4	0.86	0	0
Traumatic injury to larynx	0.54% 3/554	3	—	6	0.13	3	0.2
Total		317	237				

RFS: Reflux finding score; RSI: Reflux symptom index; SD: Standard deviation

Table 4: Agreement between reflux symptom index and reflux finding score in study population (n = 554)

	RFS+	RFS-	
RSI+	440	17	457
RSI-	8	89	97
	448	106	554

RSI+: Reflux symptom index more than 13; RSI-: Less than 13; RFS+: Reflux finding score more than 7; RFS-: Less than 7; Chance corrected agreement = $\kappa = 0.85$ with a 95% confidence interval of 0.79-0.91

(see Table 3). Laryngitis and vocal polyp were more common in males whereas vocal nodule was commonly encountered in female patients probably consequent on to high pitched voice and voice abuse. Granuloma as such was least commonly encountered (2.16%).

The current gold standard in the diagnosis of LPR is multichannel intraluminal impedance double probe 24 hours pH testing but not popular as a routine diagnostic test.²⁴⁻²⁶ Belafsky et al⁸, in 2002, developed a 9-item symptom-based questionnaire RSI scoring to assess the symptoms in their 25 study patients with LPR and found it to be an excellent construct and criterion based valid diagnostic tool in the routine work-up of LPR. In addition, laryngeal RFS has developed to characterize the morphological lesions of larynx associated with LPR.¹¹ Haberman et al¹⁰ concluded that both RSI and RFS are easily administered tool in the routine care to measure the effect of treatment on LPR in dysphonic patients and is cost effective. However a few previous studies have found RSI and RFS to have limited value and were less valid when used in isolation.^{27,28} These authors pointed out the necessity of future work on a large cohort of participants which would have a greater chance of establishing the significant relationship between the scores. On the other hand, certain studies have reported both scoring systems were valid and found to have 95% statistical possibility of a positive dual probe pH study, the current gold standard.^{8,10,11}

In our study, out of 475 patients who had positive RSI, 440 (96.2%) had positive endoscopic findings (RFS+), whereas in ninety seven patients who had negative RSI, 87 patients turned out to be negative on RFS. The corrected kappa is 0.85 with 95% confidence interval of 0.79-0.91 with a perfect agreement between RSI and RFS. Our study thus demonstrates that in clinical situations, both RSI and RFS are really useful in identifying those patients who have high likelihood of having LPR and hence raises the concern of whether it is justifiable to use expensive double pH monitoring as a routine diagnostic tool for LPR when the RSI and RFS in combination is equally comparable. The current study did not compare the results of clinical diagnosis with the current gold standard because of unavail-

ability which was a limiting factor in our study. Further comparative study with gold standard and also the effect of treatment on LPR based on a case control study are really warranted to reconfirm the results of our study in the future.

CONCLUSION

The LPR is a significant co-morbidity associated with a large majority of dysphonic patients as revealed in our study; vocal nodule being the most common abnormality. The neurological conditions seem to be a separate clinical entity not having a direct relation with LPR. The clinical evaluation of LPR with a combination of RSI and RFS is highly reliable and valid as diagnostic tool with high agreement and are complementary to each other; however, whether it can be an alternative to double probe 24 hours pH monitoring is not yet clear. Further studies are needed to establish the sensitivity and specificity of such a diagnostic test with respect to the current gold standard.

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