

EFFECT OF PANTOPRAZOLE ON ACID LARYNGITIS: A CLINICAL STUDY

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ABSTRACT: OBJECTIVES: We evaluated the results of cases of acid laryngitis with empirical trial of Pantoprazole as a diagnostic tool after clinical assessment by RSI and RFS is one such cheaper, simple and readily available option, which needs to be explored. **METHODS:** 100 patients were selected by non-probability convenience method of sampling, which were divided into experimental group ($RSI \geq 13$ and $RFS \leq 7$) and control group ($RSI < 13$ and $RFS < 7$) with sample size of 50 in each group. Pantoprazole trial was given to experimental group and all the patients assessed for RSI and RFS within the group and between the groups. **RESULTS:** The response rate to Pantoprazole at 04 and 08 weeks interval ($RSI < 13$ and/or $RFS < 7$) was 60% and 76% respectively. The response to Pantoprazole given to the experimental group with $RSI \geq 13$ and $RFS \geq 7$ was significant at 04 weeks and 08 weeks duration ($p < 0.0001$). The response however increased with increasing duration of treatment. The change in RSI and RFS in the control group at 04 and 08 weeks was significant ($p < 0.0001$). The change in RSI and RFS in the experimental group getting Pantoprazole was significantly more than the control group ($p < 0.0001$). **CONCLUSIONS:** Reflux symptom index (RSI) and Reflux finding score (RFS) are good clinical tools to assess and diagnose patients with acid laryngitis, based on the clinical diagnosis an empirical trial of proton pump inhibitor (PPI) can be given to patients for duration of 02 months or more resulting in a good response and thus confirming the diagnosis.

KEYWORDS: Acid laryngitis, reflux symptom index, Reflux finding score, Proton pump inhibitor, Pantoprazole.

INTRODUCTION: Of all of the causes of laryngeal inflammation, gastroesophageal reflux disease (GERD) is the most common cause and as many as 10 to 50% of patients with laryngeal complaints have a GER-related underlying cause when refluxed material escapes the esophagus and enters the laryngopharynx above, the event is termed laryngopharyngeal reflux (LPR). Although the terms gastroesophageal reflux and laryngopharyngeal reflux are often used interchangeably, the latter is more specific. Laryngopharyngeal reflux is the preferred term for use in otolaryngology because the patterns, mechanisms, and manifestations of LPR differ from classic GERD.¹

Laryngopharyngeal reflux affects both children and adults and may be associated with an acute, chronic, or intermittent pattern of laryngitis, with or without granuloma formation, indeed, LPR has also been implicated in the development of laryngeal carcinoma and stenosis, recurrent laryngospasm and cricoarytenoid joint fixation, as well as with many other otolaryngology-related conditions, including globus pharyngeus, cervical dysphagia and subglottic stenosis^{2, 3, 4}.

ORIGINAL ARTICLE

The symptoms of LPR are quite different from those of classic GERD as seen in the gastroenterology patients, who characteristically have heartburn, regurgitation and esophagitis. Patients with "reflux laryngitis" (LPR) present with hoarseness, but almost two-thirds deny ever having heartburn. Other throat symptoms such as globus pharyngeus (a sensation of a lump in the throat), dysphagia, chronic throat clearing and cough are often associated with LPR. A nine-item reflux symptom index (RSI) has been developed and validated to quantify patients' symptoms of LPR and evaluate treatment efficacy. This outcome instrument has displayed excellent reproducibility and criterion-based validity.⁵

Physical findings of LPR can range from mild, isolated edema and /or erythema of the area of the arytenoids cartilages to diffuse laryngeal edema and hyperemia with granuloma formation and airway obstruction. An eight-item reflux finding score (RFS) has been validated to document the severity of the clinical findings of LPR. Use of the RFS not only helps physicians identify subtle findings of reflux, it also assists in evaluating the severity of laryngeal tissue injury, as well as documenting treatment efficacy.⁶

Ambulatory 24-hours double-probe (simultaneous esophageal and pharyngeal) pH monitoring (pH-metry) is the current gold standard for the diagnosis of LPR. The distal probe is placed 5cm above the lower esophageal sphincter (LES) and the proximal probe is placed in the hypopharynx 1cm above the upper esophageal sphincter (UES), just behind the laryngeal inlet. The traditional technique of probe placement is to place both the proximal and distal pH probes under monometric guidance.

A monometer is inserted through the nasal cavity and advanced through the esophagus into the stomach. It is then slowly withdrawn, and the locations of the LES and UES are determined. The correct pH catheter is then chosen based on these measurements. An alternative technique involves placing the proximal probe just above the UES under direct fiberoptic visualization. The distance between the proximal and distal pH probes is fixed at 15cm. This technique is easier, less time consuming, and less costly than using monometric guidance.

Placement of the proximal probe above the UES can be performed accurately using this method. This technique, however is unable to estimate precisely inter-probe distances. Thus, the exact location of the distal probe is uncertain and the esophageal data are often grossly inaccurate using this technique. pH-metry has been available for many years, and standards (normal values) have been established in many laboratories. In general, the most important parameter used to evaluate the presence of GERD at the distal probe is the percentage of time that the pH is less than 4. This measurement is usually recorded for time in the upright position, time in the supine position, and the total time of the study. For the upright period, the upper limit of normal is approximately 8.0% and for the supine period, approximately 2.5%.⁷

The proximal pharyngeal probe is invaluable in patients with LPR because it is placed behind the larynx just above the cricopharyngeus; thus, reflux recorded by it is diagnostic of LPR. In addition, it has been found that without the proximal (pharyngeal) probe, the diagnosis of LPR will be missed in approximately 30 to 50% of patients. It is also advisable to evaluate the esophagus of patients with LPR. This may be accomplished by performing a barium esophagogram or, more recently, transnasal esophagoscopy. Although the prevalence of

ORIGINAL ARTICLE

esophagitis in patients with LPR is only 20%, the percentage of other esophageal abnormalities such as barrett's metaplasia may be high.⁷

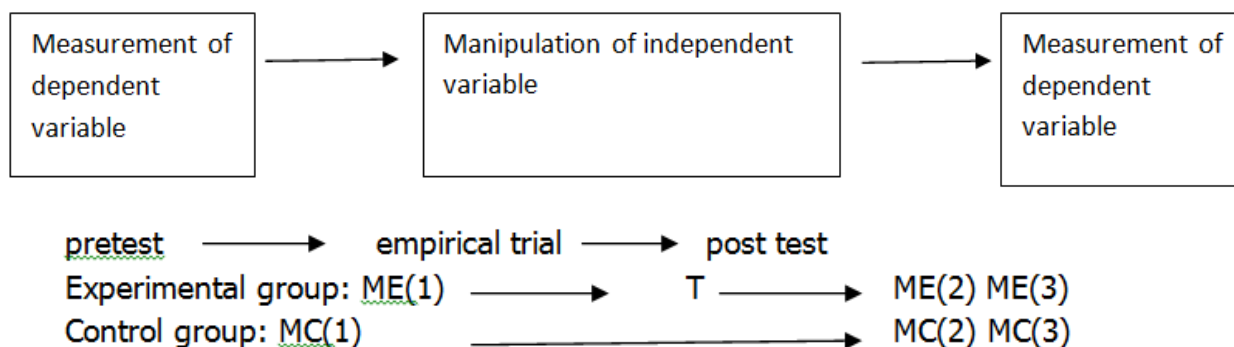
Laryngopharyngeal reflux (LPR) is the retrograde movement of gastric contents (acid and enzymes such as pepsin) in Laryngopharynx leading to symptoms. Possible mechanisms for LPR are micro aspiration of gastric contents or vagally mediated mechanism. Acidification of distal esophagus can stimulate acid sensitive receptors resulting in cough, broncho-constriction and asthma. Anti reflux mechanism consists of lower esophageal sphincter (LES), crural diaphragm, and anatomical location of gastroesophageal junction. Apart from incompetent barrier, reflux occurs when (a) gastric volume is increased (postprandial, pyloric stenosis etc) (b) when gastric contents are near gastro-esophageal junction (Recumbency, bending etc) (c) when gastric pressure is increased (pregnancy, obesity, tight clothing).^{8,9, 10}

MATERIALS AND METHODS:

It includes:

1. Research design
2. Setting of the study
3. Variables
4. Population
5. Sample size
6. Sample technique
7. Criteria for selection of sample
8. Technique and tools
9. Plan for data analysis

RESEARCH DESIGN



Where: -

ME(1): Reflux symptom index and reflux finding score in patients presenting to ENT out – patient department of J.S.S Hospital.

T; Empirical trial with proton pump inhibitor (pantoprazole).

ORIGINAL ARTICLE

ME(2): Reflux Symptom Index and Reflux Finding Score at 04 weeks post treatment with Pantoprazole.

ME(3): Reflux symptom index and reflux finding score at 08 weeks post treatment with Pantoprazole.

MC(1): Reflux symptom index and reflux finding score in control group at the time of presentation to ENT out –patient department of J.S.S Hospital.

MC(2): Reflux symptom index and reflux finding score in control group at 04 weeks.

MC(3): Reflux symptom index and reflux finding score in control group at 08 weeks

SETTING OF THE STUDY: The study was conducted in ENT department of J.S.S hospital Mysore. This institution is a multispecialty hospital. The study was conducted during the period Sep 2010 to June 2012.

VARIABLES

Dependent: Reflux symptom index and reflux finding score in patients presenting in ENT outpatient department of J.S.S hospital.

Independent: proton pump inhibitor (pantoprazole)

POPULATION: The population comprised of all the patients visiting the outpatient department of otorhinolaryngology in J.S.S hospital, Mysore.

SAMPLE SIZE: The sample size consisted of 100 patients who visited the ENT outpatient department of J.S.S hospital and fulfilled the criteria. The 100 samples were divided into 02 equal groups of 50 each based on RSI and RFS for the purpose of control.

SAMPLING TECHNIQUE: The technique used was non-probability convenience method of sampling (random sampling)

CRITERIA FOR SELECTION OF SAMPLE

INCLUSION CRITERIA

1. Patients who presents to ENT outpatient department of J.S.S hospital with clinical features of laryngopharyngeal reflux and having a reflux symptom index of ≥ 13 and Reflux Finding score ≥ 7 were included in the experimental group.
2. Patients having a reflux symptom index < 13 and reflux finding score < 7 were included in the control group
3. Patient in the age group 18 -60 years.

ORIGINAL ARTICLE

EXCLUSION CRITERIA:

1. Patient with any other systemic complaints presenting to the ENT outpatient department of J.S.S hospital.
2. Patients <18 years and >60 years.

TECHNIQUE AND TOOL: Patients who satisfied the criteria of selection were taken as subjects of the study.

The data of the patient was collected in a case proforma, all the patients were subjected to: -

- (A) **History:** A brief history of past one month related to the symptoms of laryngopharyngeal reflux was taken and each symptom was scored on the self assessment scale of 0 to 5. The symptoms and the scoring were based on reflux symptom index (RSI).

Finding							
Within the last month, how did the following problems affect you?	0=no problem 5=severe problem						
	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 mucus or postnasal drip	0	1	2	3	4	5	
4. Difficulty swallowing food, food, liquids, or pills	0	1	2	3	4	5	
5. Coughing after you ate or 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. Sensation 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						

Reflux symptom index

- B) **Clinical examination**
- (i) Otological examination
 - (ii) Anterior and posterior rhinoscop
 - (iii) Throat examination
 - (iv) Indirect laryngoscopy
 - (v) Neck examination
 - (vi) Fibreoptic laryngoscopy

Patients who had any obvious organic cause for the various clinical presentations were treated accordingly and excluded from the study. Patients with Indirect laryngoscopy findings and the findings confirmed with fiberoptic laryngoscopy were given the reflux finding score (RFS).

ORIGINAL ARTICLE

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= sever 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	
Reflux finding score	

The reflux symptom Index and reflux finding score were then taken into consideration together with other otorhinolaryngological examination and a clinical diagnosis of laryngopharyngeal reflux was made in patients with RSI ≥ 13 and RFS ≥ 7 .

(c) Empirical trial with proton pump inhibitor was given to the experimental group for a period of 04 weeks and then the RSI and RFS was recorded again at the end of 08 weeks.

(d) The RSI and RFS of the control group were recorded at the time of entry into the study and thereafter at 04 weeks and 08 weeks of the study.

(e) The data collected was subjected to appropriate statistical and analysis.

PLAN FOR DATA ANALYSIS:

Data analysis was done on the basis of objectives of the study:

- (a) RSI score will analyzed within the experimental and control group at 0, 4 and 8 weeks using paired t-test
- (b) RFS score will be analyzed within the experimental and control group at 0, 4 and 8 weeks using paired t-test
- (c) RSI score will be analyzed between the experimental and control group at 0, 4 and 8 weeks using t-test
- (d) RFS score will be analysed between the experimental and control group at 0, 4 and 8 weeks using t-test.

ORIGINAL ARTICLE

RESULTS:

METHODS OF STATISTICAL ANALYSIS

Statistical analysis was done by using the following methods: -

- Paired t-test for comparison of Reflux symptom index within the experimental group
- Paired t-test for comparison of reflux finding score within the experimental group
- Paired t-test for comparison of reflux symptom index within the control group
- Paired t-test for comparison of reflux finding score within the control group.
- T-test between the experimental and control group for reflux symptom index
- T-test between the experimental and control group for reflux finding score

Sps10.0 was used to perform the statistical tests.

Gender	(f)	%	(f)	%
Females	28	56	34	68
Males	22	44	16	32

TABLE 1A: Frequency and percentage distribution of sample

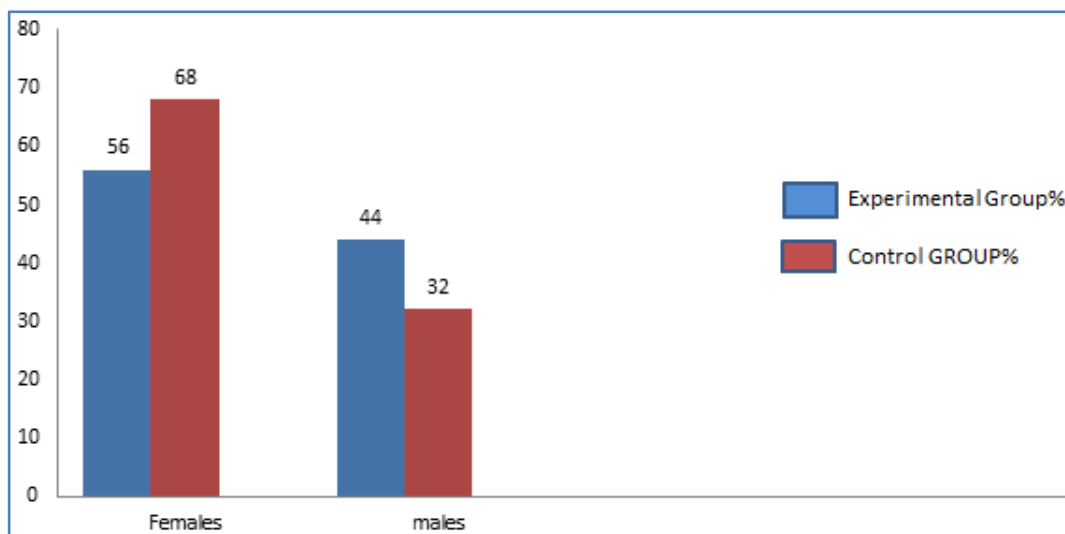


Fig. 1: Graph showing percentage distribution of sample according to gender

Experimental Group (n=50)

Control group (n=50)

	ME1	ME2	ME3
Average	16.44	11.7	9.94
SD	1.70	2.08	2.53

Table 1B: Average Reflux Symptom index in Experimental group

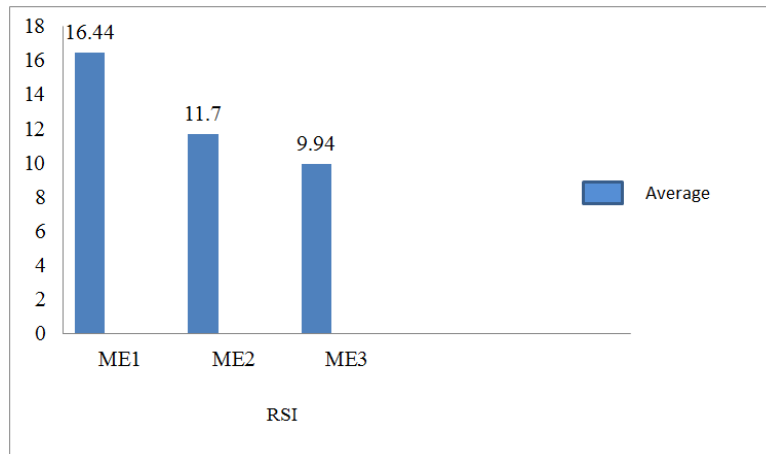


Fig. 2: Graph showing average Reflux symptom index score at 0, 4, 8 weeks in experimental group

ME(1): Reflux Symptoms Index in Patients Presenting to ENT out-patient department of J.S.S Hospital.

ME(2): Reflux Symptoms Index in experimental group at 04 weeks Post treatment with pantoprazole.

ME(3): Reflux Symptom Index in experimental group at 08 weeks Post treatment with pantoprazole.

	ME1	ME2	ME3
Average	7.26	5.88	4.62
SD	1.61	1.45	1.40

Table 1c: Average Reflux Finding Score in Experimental group

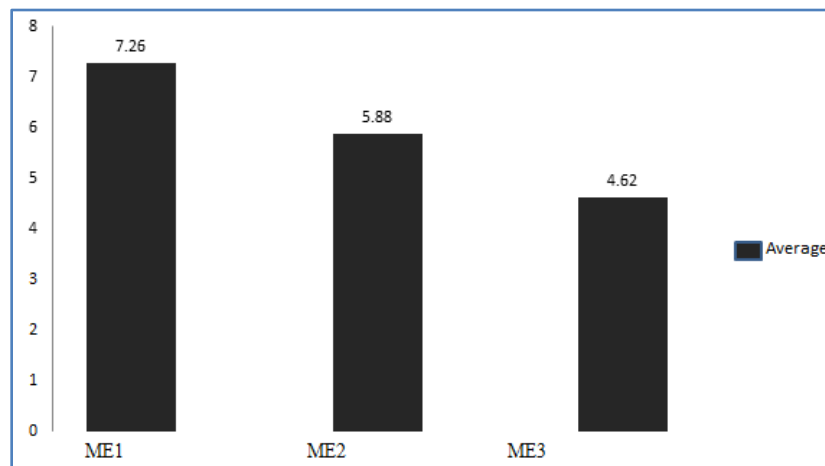


Fig. 3: Graph showing average Reflux finding Score at 0, 4, 8 weeks in experimental group

ORIGINAL ARTICLE

ME(1): Reflux finding score in patients presenting to ENT out-patient department of J.S.S. Hospital

ME(2): Reflux Finding score in experimental group at 04 weeks post treatment with pantoprazole.

ME(3): Reflux Finding score in experimental group at 08 weeks post treatment with pantoprazole.

	MC1	MC2	MC3
Average	10.6	9.06	7.78
SD	1.07	1.49	1.45

Table 1D: Average Reflux Symptom index in control group

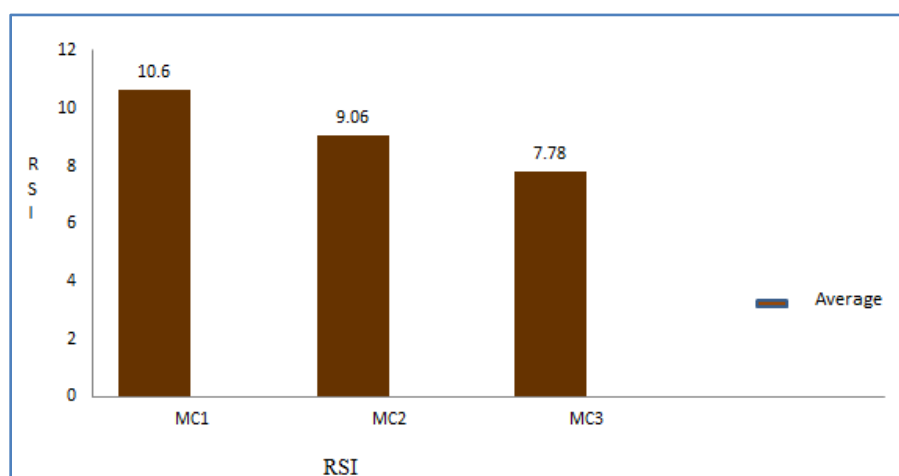


Fig. 4: Graph showing average Reflux Symptom index at 0, 4, 8 weeks in control group

MC(1): Reflux symptom index in control group at the time of presentation to ENT out patient department of J.S.S hospital

MC(2) Reflux symptom index in control group at 04 weeks

MC(3) Reflux symptom index in control group at 08 weeks

	MC1	MC2	MC3
Average	3.94	3.68	2.64
SD	1.19	1.28	1.01

Table 1E: Average Reflux finding score in control group

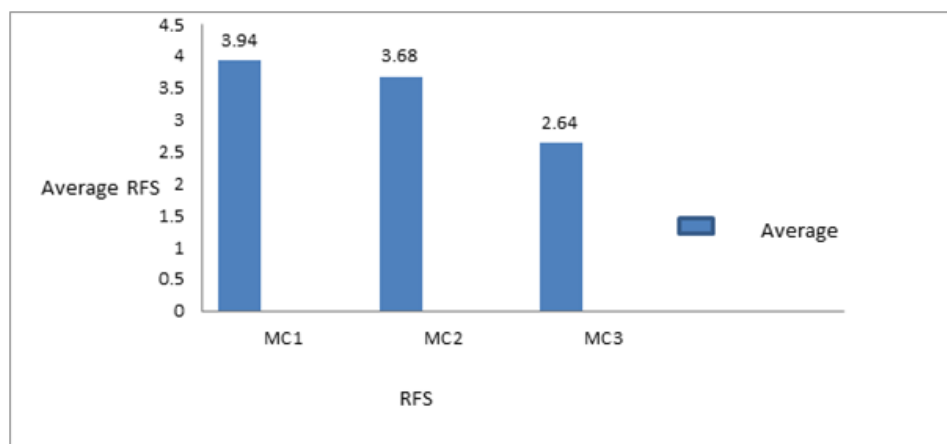


Fig. 5: Graph showing average Reflux finding score at 0, 4, 8 weeks in control group

MC(1): Reflux Finding score in control group at the time of presentation to ENT out patient department of J.S.S hospital.

MC(2): Reflux Finding Score in Control Group At 04 weeks

Mc(3): Reflux Finding Score in Control Group at 08 weeks

Symptom	Average score
1. Hoarseness or a voice problem	0.76
2. Throat clearing	3.14
3. Excess throat mucus or postnasal drip	1.76
4. Difficulty swallowing foods, liquids, or pills	0.82
5. Cough after eating or after lying down	0.52
6. Breathing difficulties or choking episodes	0.48
7. Troublesome or annoying cough	3.36
8. Sensations of something sticking in the throat or a lump in the throat	3.24
9. Heartburn, chest pain, indigestion, or stomach acid coming up	2.34

DISCUSSION: In our study with 50 patients with laryngopharyngeal reflux, the sex distribution was females 56% (n=28) and males 44% (n=22). The common presentations of patients with laryngopharyngeal reflux seen in this study were annoying cough (100%), something sticking in the throat (100%), frequent throat clearing (100%), heartburn/chest pain/indigestion (96%) and excess throat mucus or post nasal drip (84%). Other less common symptoms were hoarseness of voice (50%), dysphagia (68%), cough after eating or lying (42%) and breathlessness or choking episodes (36%).

In our study the common findings seen on laryngoscopy were erythema/hyperemia of the arytenoids (96%), diffuse laryngeal edema (94%), other less commonly seen are subglottic

ORIGINAL ARTICLE

edema (20%), ventricular obliteration (16%), granuloma/granulation (10%) and thick endolaryngeal mucus (32%).

In our study it was observed that on treatment with twice daily Pantoprazole for 04 weeks, the response rate was 60%, which on further evaluation after treatment for 08 weeks was 76%. In the control group there was a significant reduction in RSI and RFS after lifestyle modifications, however, on comparison with experimental group getting Pantoprazole, the experimental group showed a significant improvement in RSI and RFS ($P < 0.0001$)

In the study by Vaezi MF, only about 50% of patients with laryngoscopic signs potentially related to GERD had abnormal acid exposure when tested irrespective of the location of the pH probe (distal esophagus or hypopharyngeal). Distal and proximal esophageal pH probes are at best 75% and 50% sensitive respectively, in detecting acid reflux in a group of patients with signs and symptoms of classic acid reflux disease, including heartburn, acid regurgitation, and esophagitis.

Furthermore, studies using distal, proximal, or hypopharyngeal probes in patients with laryngeal pathology yielded conflicting data about the ability to predict clinical improvement based on abnormal findings each of the pH probes. The use of hypopharyngeal acid exposure as a possible predictor of response in patients suspected of having GER-related laryngitis is confounded by recent findings that those with abnormal hypopharyngeal acid reflux are no more likely to respond to acid-suppressive therapy than are those in whom no pharyngeal acid is detected by pH monitoring.

However, the role of hypopharyngeal reflux in this group of patients should be further investigated in centers that have access to and substantial experience with, pharyngeal pH monitoring techniques. The confusion in using pH monitoring in this group of patients has led some physicians to suggest empiric therapy for suspected cases of GER-related laryngeal abnormalities, whereas others still believe that pH monitoring should be done easily in the diagnosis of this group of disorders.

Therefore, the role of pH monitoring – and its location – prior to treating patients with acid-related laryngeal complaints remains controversial. At this time it is not recommended to use pretherapy pH monitoring. However, it can be used after therapy to evaluate the effectiveness of medical therapy in normalizing esophageal acid exposure.¹¹

The diagnostic test of choice for LPR is twenty-four-hour double-probe pH monitoring, but it has many disadvantages. Thus, an empiric trial of anti-reflux therapy has been suggested as an alternative method for diagnosis. The purpose of the study conducted by Bilgen C and colleagues was to evaluate the validity of this alternative method in the management of LPR. The results of the 24-hour double-probe pH monitoring showed no significant difference between the study and the control groups ($p > 0.05$).

The significant improvement in the MRSI and the RFS during the course of proton pump inhibitor therapy relates the patients' symptoms and physical findings to LPR. This implies the validity of the method, not only in the treatment of LPR, but in the diagnosis of this disorder, as well. Unfortunately, 24-hour double-probe pH monitoring has failed to differentiate LPR patients from healthy individuals.¹²

ORIGINAL ARTICLE

Laryngeal signs are not pathognomonic for laryngopharyngeal reflux because many of these signs can be found in healthy volunteers. A combination of signs and symptoms should be sought before suspecting this diagnosis. Most investigators consider pH monitoring the best currently available instrument to diagnose gastroesophageal reflux, even though it is not considered to be 100% sensitive and specific. The correlation between laryngeal signs and symptoms and pH-documented reflux is less than perfect, whereas the combination of pH testing and signs and symptoms is better in detecting patients with a favorable response to acid-suppressing therapy. Multidisciplinary trials are needed to establish the optimal combination of sign and symptom scores, reflux monitoring results, and empiric treatment trials for the most accurate diagnosis of laryngopharyngeal reflux.¹³

There is no pathognomonic symptom or finding, but characteristic symptoms and laryngoscopic findings provide the basis for validated assessment instruments (the Reflux Symptom Index and Reflux Finding Score) useful in initial diagnosis. There are 3 approaches to confirming the diagnosis of LPR: (1) response of symptoms to behavioral and empirical medical treatment, (2) endoscopic observation of mucosal injury, and (3) demonstration of reflux events by impedance and pH-monitoring studies and barium swallow esophagogram.

Additional studies, including radiography, esophageal manometry, spectrophotometric measurement of bile reflux, and mucosal biopsy, can provide information useful in targeting therapy. Laryngopharyngeal reflux should be suspected when the history and laryngoscopy findings are suggestive of the diagnosis. Failure to respond to a 3-month trial of behavioral change and gastric acid suppression by adequate doses of proton pump inhibitor medication dictates need for confirmatory studies. Multichannel intraluminal impedance and pH-monitoring studies are most useful in confirming LPR and assessing the magnitude of the problem. Because many patients respond well to behavioral modification and initial medical management, an acid suppression trial is a frequently used approach to initial diagnosis.¹⁴

In another study by book DT and colleagues, symptoms most related to reflux were throat clearing (98.3%), persistent cough (96.6%), heartburn (95.7%), globus (94.9%), voice change (94.9%), physical findings related to reflux were arytenoids edema (97.5%), vocal chord edema (95.7%), vocal chord erythema(95.75), posterior commissure hypertrophy(94.9%), arytenoids edema (94%). Fiberoptic laryngoscopy was the most commonly performed diagnostic visualization procedure (75.7%).¹⁵

In a study by Jonaitis and colleagues it was seen that important significant changes in patients with LPR were mucosal lesions of IAN, vocal cords and edema of vocal cords. These 3 signs together distinguished patients from controls in 95.9% cases.¹⁶

Issing WJ and colleagues in their study reported an improvement in 68% patients at 04 weeks and 95% at 08 weeks on treatment with PPIs.¹⁷ In another study by siupsinskeine N and colleagues the response rate at 01 month was 56% and at 03 months it was 92%.¹⁸

35% of patients remained non-responders after 04 months of PPIs (proton pump inhibitors) in a study conducted by Quadeer MA and colleagues.¹⁹

In a study done by DelGaudio JM and colleagues after 04 weeks of treatment with once daily PPI, only 8 of 30 patients had significant improvement and at 08 weeks of treatment, 19 of

ORIGINAL ARTICLE

30 patients had significant improvement. 40% of non-responders improved further after increasing their dosage to twice a day.²⁰

Bove MJ and colleagues in their study concluded that laryngopharyngeal reflux is suspected when the history and laryngoscopic findings are suggestive of the diagnosis. Failure to respond to an empiric treatment suggests the need for confirmatory studies and consideration of alternative diagnosis. pH monitoring and multichannel impedance studies are the most useful modalities for directing further investigations or therapy.²¹

Carrau and colleagues in their study showed that patients with laryngopharyngeal reflux often reported multiple symptoms, most frequently, chronic throat clearing (85.5%), globus (82.1%), and hoarseness (80.3%).²²

Three approaches to confirm the diagnosis of LPR are a) Response of symptoms to empirical treatment with PPIs b) Endoscopic observation of mucosal injury and c) Demonstration of reflux events by impedance and pH monitoring studies and Barium swallow esophagogram. Multi-channel intraluminal impedance and 24 hr pH monitoring considered to be gold standard for diagnosis of LPR are expensive, cumbersome and not readily available in all centers. In clinical practice a reliable tool for diagnosis of LPR is a RSI and RFS and an empirical trial with PPIs for more than 08 weeks. An improvement in the symptoms and findings on laryngoscopy confirm the diagnosis of LPR.

CONCLUSIONS: Reflux symptom index (RSI) and Reflux finding score (RFS) are good clinical tools to assess and diagnose patients with acid laryngitis. Based on the clinical diagnosis an empirical trial of proton pump inhibitor (PPI) can be given to patients for duration of 02 months.

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