

Usefulness of The Reflux Symptom Index in the Management of Laryngopharyngeal Reflux

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ABSTRACT

Introduction

Laryngopharyngeal Reflux (LPR) is highly prevalent in the general population and its impact on health systems is growing dramatically by the day. The contents of the stomach flowing back into the oesophagus, pharynx and larynx because of a transient relaxation of the lower oesophageal sphincter leads to a spectrum of symptoms diagnosed as LPR and Gastroesophageal Reflux Disease (GERD). The aim was to study in detail the symptoms of LPR and to ascertain if and how they hamper the routine of an individual by using the Reflux Symptom Index (RSI).

Materials and Methods

The Reflux Symptom Index (RSI) is a self-administered nine-item outcomes instrument for LPR. Ninety-one patients with clinically diagnosed LPR were taken up for this study and were issued the RSI (translated into the local language for better results) before and after treatment. Data was assessed at the end of 3 months and 6 months.

Results

The tabulated data showed significant improvement in the symptomatic index after treatment.

Conclusion

It can thus be concluded that RSI is still highly valid in the follow-up for patients with LPR because it can be easily administered and gives accurate results with excellent validation.

Keywords

Laryngopharyngeal Reflux

Reflux of gastroduodenal contents into the larynx because of transient relaxation of the upper and lower oesophageal sphincter may cause inflammation and symptoms resulting in chronic laryngeal signs often referred to as Laryngopharyngeal Reflux (LPR).¹ It is often associated with chronic cough, hoarseness, dysphonia, recurrent throat clearing and

globus pharyngeus (sensation of a lump in the throat).

Due to nonspecific symptoms, laryngoscopy is often performed to rule out malignancy and the diagnosis of LPR is considered in the presence of any signs of laryngeal inflammation.² 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 exposure of laryngopharyngeal mucosa to acid, pepsin and bile acid. The indirect mechanism is thought to be a result of refluxate interactions with structures distal to the larynx, evoking a vagus nerve mediated bronchoconstriction.³ LPR is estimated to account for 10% of all ear, nose and throat clinic patients and 50% of all patients with voice complaints.⁴ However, due to the lack of a gold-standard in testing, the prevalence of LPR can be overstated, with

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one meta-analysis that reviewed data from pH probe readings reporting that 10% to 60% of normal subjects demonstrated reflux.⁵

LPR differs from classic Gastroesophageal Reflux Disease (GERD) in many ways. While heartburn and regurgitation are common symptoms of GERD, such symptoms are not present in most LPR patients.⁴ LPR, on the other hand presents with laryngeal inflammation and reflux in upright position. LPR is the preferred term for use in Otorhinolaryngology. It is also ubiquitous and pernicious in paediatric patients. The diagnosis may be particularly difficult to make because infants and children almost never complain of heartburn or other symptoms related to reflux. Physiologic barriers against the development of reflux include the lower oesophageal sphincter, oesophageal peristalsis, saliva that buffers the refluxed contents and mucus covering of the stomach-oesophagus-larynx-pharynx along with the upper oesophageal sphincter.

Shaw et al presented a 12-item symptom questionnaire to assess GERD, but again it concentrates on symptoms such as acid taste, burning and chest pain.⁶ The questionnaire from a GERD perspective and from a LPR perspective has to be different since the symptoms vary ever so slightly. The LPR questionnaire must focus more on the symptoms relating to throat and voice as compared to the GERD questionnaire which needs to assess the condition of the oesophagus with relation to the damage done by the anti-peristaltic movement.

Till 2002, there was no validated and approved questionnaire for the diagnosis and follow-up of patients with LPR. The Reflux Symptom Index (RSI) is a self-administered nine-item score sheet for the symptomatic assessment of patients with Laryngopharyngeal Reflux. It was developed by Belafsky et al and it has been in use ever since.⁷ The RSI has its advantages in the fact that it is easy to use, inexpensive and is easily available in print. A copy can be simply administered to the patient. Thus, this criterion-based score has become an important tool in diagnosis.

This study deals with the relevance of the RSI in local population whilst treating properly diagnosed patients with LPR. Diagnosis was made on the basis of RSI and Laryngeal Endoscopy findings. Data was accumulated

and analysed at the start of treatment and 3 & 6 months thereafter.

Materials and Methods

This prospective study was conducted between January 2018 and December 2019 over a period of 24 months.

The patients included in the study were diagnosed with Laryngopharyngeal Reflux, had RSI greater than or equal to 13, showed laryngeal endoscopy findings secondary to reflux, were 18 years and above, gave consent to treatment and procedure and agreed to be part of the study.

Patients with co-morbidities, Gastroesophageal Reflux Disease, extremes of age, severe disease requiring surgical intervention and those found unfit to take treatment for a 6-month period, were excluded from the study.

All statistical analyses were performed using SPSS Statistics 19 for Windows (IBM Corp., Armonk, NY, USA). Samples were compared and evaluated by means of a paired t-test. A p-value of <0.05 was considered statistically significant. The confidence interval was set at 95%.

All the 91 patients presented to the Out Patient Department of Otorhinolaryngology with complaints related to difficulty in swallowing, difficulty in speech, sensation of foreign body in the throat, voice changes and a feeling of acid in the mouth. Such patients were assessed with a Laryngoscopy and the Reflux Symptom Index instrument. RSI ≥ 13 was taken as significant.⁷

According to the Reflux Finding Score (RFS), the various laryngeal changes which can be seen in these patients on a laryngeal endoscopy include Oedema (Vocal cords/Subglottis), Ventricular obliteration, Erythema/hyperaemia, Mucus, Granuloma/granulation.⁸

After thorough counselling and acquiring proper consent, each patient was given the RSI instrument before the beginning of the treatment. If the patient was unable to understand English, the same was explained in the local language (Tamil) and a translated version of the same was given (Tables I and II). The risks of treatment and the necessity to continue for a particular amount of time were mentioned.

Table I: Reflux Symptom Index in English.⁷

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
2. Clearing your throat	0	1	2	3	4	5
3. Excess throat mucus or post nasal drip	0	1	2	3	4	5
4. Difficulty in 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. Sensation of something sticking in your throat or a lump in your throat	0	1	2	3	4	5
9. Heart burn, chest pain, indigestion or stomach acid coming up	0	1	2	3	4	5

கடந்த ஒரு மாதத்தில், கீழ்க்கண்ட கஷ்டங்கள் உங்களை எப்படி பாதித்தது?	0 = எந்த பிரச்சினையும் இல்லை 5 = கடுமையான சிக்கல்					
	1. கூச்சல் அல்லது உங்கள் குரலில் சிக்கல்	0	1	2	3	4
2. உங்கள் தொண்டையை சரி செய்து கொள்வது	0	1	2	3	4	5
3. அதிகப்படியான தொண்டை சளி அல்லது பிந்தைய நாச சொட்டு	0	1	2	3	4	5
4. உணவுகள், திரவங்கள் அல்லது மாத்திரைகளை விழுங்குவதில் சிரமம்	0	1	2	3	4	5
5. நீங்கள் சாப்பிட்ட பிறகு அல்லது படுத்த பிறகு இருமல்	0	1	2	3	4	5
6. சுவாசிப்பதில் சிரமங்கள் அல்லது மூச்சுத் திணறல்கள்	0	1	2	3	4	5
7. தொந்தரவான அல்லது எரிச்சலூட்டும் இருமல்	0	1	2	3	4	5
8. உங்கள் தொண்டையில் ஏதோ ஒட்டிக்கொண்டிருக்கும் உணர்வு அல்லது உங்கள் தொண்டையில் ஒரு கட்டி	0	1	2	3	4	5
9. நெஞ்செரிச்சல், மார்பு வலி, அஜீரணம் அல்லது வயிற்று அமிலம் வரும் உணர்வு	0	1	2	3	4	5

Table II: Reflux Symptom Index in Tamil

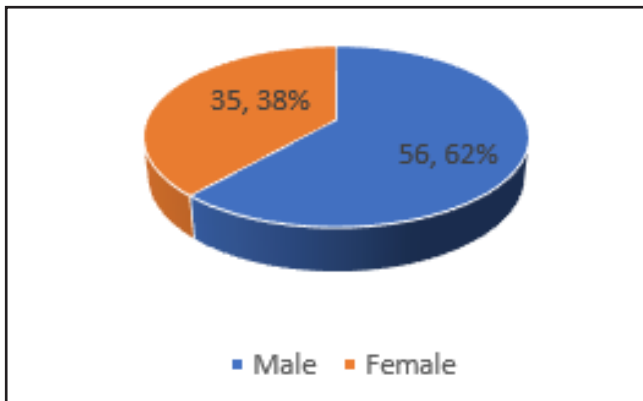


Fig. 1. Gender Distribution

The RSI instrument contains 9 questions. Each question carries 5 points on a 0-5 severity scale wherein 0 indicates no problem and 5 indicates severe problem. Each patient was asked to fill this up without any prompting. Thus, the maximum score a patient could get was 45. Any value of ≥ 13 was considered significant and part of study.⁷

The treatment modality was multi-fold and each patient was asked to follow the same pattern.

The dietary modifications included no eating or drinking within 3 hours of bedtime, avoiding over eating or reclining right after meals, fried food, coffee, tea, chocolate, mints, soda, alcohol, sticking to low fat diet and a particular increase in the intake of water.

The lifestyle modifications included elevation of the head end of the bed, avoiding wearing tight fitting clothes or belts and quitting tobacco.

The Medical management included Liquid Antacid – Magnesium Hydroxide and Aluminium Hydroxide (1 tablespoon after each meal and at bedtime) and Proton Pump Inhibitor (PPI) – Pantoprazole, 20 mg half an hour before the first and last meals of the day.

After the aforementioned therapy, patients were asked to follow-up once a month for the next 6 months. The RSI instrument was again given to the patient at the end of 3 months and 6 months. The results were tabulated. After the end of the 6-month period, patients were asked to slowly wean off the medications and strictly follow the lifestyle changes to keep the symptoms under control.

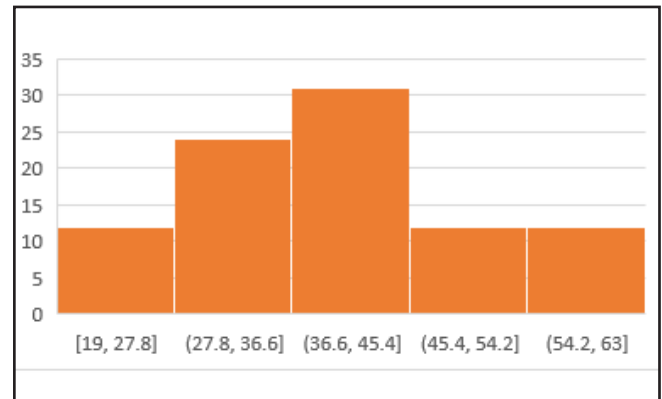


Fig.2. Age Distribution

Results

Among the 91 people included in the study, 56 were male and 35 were female. (Fig. 1)

The average age of the study group was found to be 39.62 years. The maximum number of patients were found to be in the age bracket of 36-45 years. The youngest case reported in our study was 19 years with the oldest being 62 years. (Figure 2)

The average RSI score before treatment was 23.78. Before treatment, the symptom causing the most trouble was “Heart burn, chest pain, indigestion or stomach acid coming up” which docked at 4.109/5 and the symptom causing the least trouble was “Breathing difficulties or choking episodes” which docked at 1.637/5.

At the end of 3 months, the sensation of heart burn/acid in throat improved by about 56% and by the end of 6 months it reached to about 65%. During the treatment i.e. at the 3-month and 6-month intervals, the relative improvement was found to be the most in “Difficulty in swallowing food, liquids or pills” at a significant 11%.

The total score improved by about 49% after 3 months and 58% after 6 months (Table III) and the p-value was found to be significant (Tables IV & V).

Discussion

There is a difference in the symptomatology of GERD and LPR. The patterns, mechanisms, manifestations and treatment of LPR and GERD differ and the

Table III: Average RSI Score at 0, 3 and 6 month timeline

WITHIN THE LAST MONTH, HOW DID THE FOLLOWING PROBLEMS AFFECT YOU?	BEFORE	AFTER 3 MONTHS	AFTER 6 MONTHS
Hoarseness or a problem with your voice	2.538	1.318	1.055
Clearing your throat	2.142	1.142	0.912
Excess throat mucus or post nasal drip	2.406	1.241	1.165
Difficulty in swallowing food, liquids or pills	3.032	1.571	1.253
Coughing after you ate or after lying down	1.912	1.021	0.868
Breathing difficulties or choking episodes	1.637	0.978	0.868
Troublesome or annoying cough	2.56	1.274	1.066
Sensation of something sticking in your throat or a lump in your throat	3.439	1.67	1.429
Heart burn, chest pain, indigestion or stomach acid coming up	4.109	1.824	1.418
TOTAL	23.775	12.044	10.034

gastroenterology model of reflux disease does not apply to LPR. LPR patients have head and neck symptoms, but heartburn is uncommon. Consequently, LPR is often called silent reflux. LPR patients have predominantly upright (day-time) reflux and normal oesophageal motility; most do not have oesophagitis, which is the diagnostic entity of GERD. Laryngopharyngeal epithelium is far more susceptible to reflux-related tissue injury than is the oesophageal epithelium. Because of these differences, treatment algorithms for LPR and GERD vary.⁹

The RSI is a nine-item self-administered outcome instrument that accurately documents symptom improvement of patients with LPR, thus displaying excellent criterion-based validity.⁷

The questionnaire from a GERD perspective and from an LPR perspective has to be different since the symptomatology vary ever so slightly. The LPR questionnaire must focus more on the symptoms in the throat and voice as compared to the GERD questionnaire which needs to assess the condition of the oesophagus with relation to the damage done by the anti-peristaltic

Table IV: Paired Sample Correlations after 3 months.

	PAIRED DIFFERENCES					T	SIG.	CORRELATION
	MEAN	STANDARD DEVIATION	STANDARD ERROR MEAN	95% CONFIDENCE INTERVAL OF THE DIFFERENCE				
				LOWER	UPPER			
RSI before to RSI after 3 months	11.74	3.32	0.35	11.05	12.42	33.9	0.001	0.69

SD: Standard deviation, CI: Confidence interval, SE: Standard error

Table V: Paired Sample Correlations after 6 months.

	PAIRED DIFFERENCES					T	SIG.	CORRELATION
	MEAN	STANDARD DEVIATION	STANDARD ERROR MEAN	95% CONFIDENCE INTERVAL OF THE DIFFERENCE				
				LOWER	UPPER			
RSI before to RSI after 6 months	13.75	3.4	0.35	13.04	14.45		0.001	0.66

SD: Standard deviation, CI: Confidence interval, SE: Standard error

movement.

Symptoms of LPR improve over 2 months of therapy. The physical findings of LPR resolve more slowly than the symptoms and this continues throughout at least 6 months of treatment. The physical findings of LPR are not always associated with patient symptoms and treatment should continue for a minimum of 6 months or until complete resolution of the physical findings.¹⁰

The diagnosis of LPR is usually made on the basis of presenting symptoms and associated laryngeal signs. Current recommendation for management of this group of patients is empiric therapy with twice daily proton-pump inhibitors for 2–4 months.¹¹ In majority of those who are unresponsive to such therapy, other causes of laryngeal irritation is considered.

Although acid can be controlled by proton pump inhibitor (PPI) therapy, all of the other damaging factors (i.e. pepsin, bile salts, bacteria and pancreatic proteolytic enzymes) remain unchanged on PPI therapy and may have their damaging ability enhanced.¹²

Changing food, lifestyle and habits will go a long way in reducing the drug intake and maintaining long term cure. Laryngopharyngeal reflux still has many aspects in its etio-pathogenesis as well as treatment which need to be understood before we can achieve complete cure rates.¹³ Awareness regarding LPR in general population will also help reduce the severity with which the patients present to the primary care physician.

PPIs remain the cornerstone of treatment of LPR. The current management recommendation for this group of patients is empiric therapy with twice-daily PPIs for 1

to 2 months.¹⁴

Various studies have found that the RFS as a clinical tool for diagnosis of LPR should be viewed with limited utility as it exhibits low inter-rater reliability.¹⁵ Thus, it becomes all the more necessary that the RSI be assessed extensively for symptomatic betterment of the patient.

Every fifth patient who reports to their family medicine physician shows symptoms of LPR. At primary health care levels, it is possible to establish some form of prevention, diagnostics and therapy for LPR in accordance with suggested algorithms. Only a small number of patients require surgical procedures and do not show improvement with medical management.¹⁶

Research has proved that the RSI is a quality tool in the assessment of LPR. It can be used in regular ENT practice to analyse the improvement in patients after the commencement of therapy.^{17,18}

Conclusion

The diagnosis and management of Laryngopharyngeal Reflux is tough in clinical practice since the symptoms are loosely related to Gastroesophageal Reflux Disease. Specific tools are thus needed which can aid in the assessment of improvement or deterioration of the patient after the treatment modality is administered. One of those tools include the Reflux Symptom Index which is by far the easiest to use because of its non-invasive and time-saving nature and cost effectiveness. In our study, we found that the RSI improved by about 49% after 3 months and 58% after 6 months. It can thus

be concluded that the RSI is a relevant tool to assess patients with LPR in our population.

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