



Comparison of Diagnostic Methods in Laryngopharyngeal Reflux: A Prospective Study

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Abstract

Introduction: Laryngopharyngeal Reflux (LPR) is a condition characterized by the retrograde flow of gastroduodenal contents into the upper aerodigestive tract, potentially leading to mucosal inflammation. Its diagnosis is often challenging due to the nonspecific nature of symptoms and findings. Clinical tools such as the Reflux Symptom Index (RSI) and Reflux Finding Score (RFS) can aid in diagnosis, but objective confirmation remains limited. pH-impedance monitoring has emerged as a complementary method, allowing detection of proximal reflux episodes regardless of acidity.

Objectives: To evaluate and compare various diagnostic methods for LPR, namely through symptoms (RSI), Laryngoscopy Findings (RFS), and pH-Impedance monitoring (PHI).

Materials and Methods: A prospective study which included patients with symptoms of Gastroesophageal Reflux (GER) who underwent pH-impedance monitoring in the last 6 months of 2023 was conducted. Patients completed the RSI and were evaluated for laryngoscopy findings using the RFS. Scores from RSI, RFS, and PHI parameters, such as number of reflux episodes (acidic and non-acidic), percentage of proximal reflux, and reflux index (RI), were compared.

Results: Fifty-two patients, with a mean age of 64 years, were included. There were no statistically significant associations between RSI and RFS. Among patients with proximal reflux, the RSI-PHI analysis identified throat clearing as the most prominent symptom. There was a strong positive correlation between RFS and the number of acid reflux episodes ($r=-0.754$; $p=0.003$). Additionally, the absence of pathological GER did not exclude the presence of LPR, as 22/30 patients, despite normal RI and DeMeester score, showed the presence of altered proximal reflux.

Conclusion: Because RSI and RFS are inherently subjective, incorporating pH-impedance parameters may enhance diagnostic accuracy for LPR, particularly in patients with uncertain clinical findings.

Keywords: Proximal Reflux; Ph Impedance; Gastroesophageal Reflux Disease (Gerd); Ph Meter; Laryngopharyngeal Reflux Disease

Introduction

Laryngopharyngeal Reflux (LPR) and Gastroesophageal Reflux (GER) share similar pathophysiological mechanisms, involving the retrograde movement of gastric or duodenal contents into the upper aerodigestive tract. [1] However, they differ in their clinical manifestations and target tissues. GER primarily affects the esophagus, with typical symptoms such as heartburn and regurgitation, whereas LPR more often involves the pharynx and larynx, producing symptoms such as throat clearing, chronic cough, hoarseness, and globus sensation. These differences are partly explained by the greater sensitivity of the laryngeal mucosa to acidic and enzymatic injury [2].

LPR is a condition resulting from the direct and/or indirect effects of gastro-duodenal content reflux, leading to inflammation in the upper aerodigestive tract [1]. Its diagnosis is primarily clinical, based on the patient's symptoms and laryngoscopic findings, and is therefore inherently subjective. Scales such as the Reflux Symptom Index (RSI) for symptom assessment and the Reflux Finding Score (RFS) for laryngoscopic evaluation aim to standardize this process, but variability in interpretation remains [1-3] These scoring systems are indicative of LPR when the RSI score is ≥ 13 or the RFS score is ≥ 13 [2,3].

Although there is no universally accepted gold-standard test for LPR, pH-metry with impedance (PHI) has emerged as a complementary tool that may improve diagnostic objectivity. This technique

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enables continuous monitoring of Gastroesophageal Reflux (GER) by detecting the movement of liquids, solids, and air independent of the refluxate’s pH—whether acidic, weakly acidic, or weakly alkaline [4]. By identifying proximal reflux episodes that might be missed by conventional pH-metry, PHI can provide a more comprehensive and objective evaluation, potentially bridging the gap between subjective clinical assessment and measurable physiological evidence.

Proximal reflux is defined as a drop in impedance that reaches 1 or 2 of the most proximal impedance probe sensors, categorized as acidic, slightly acidic, or slightly alkaline according to the distal pH sensor’s recording [4]. According to the literature, which suggests that three episodes of proximal reflux with pH < 4 per week are sufficient to cause damage to the laryngeal epithelium, altered proximal reflux was defined as the presence of three or more episodes of acidic reflux at the proximal level by PHI [1].

Material and Methods

Study Design

Prospective observational study over a 6-month period (July to December 2023).

Inclusion and Exclusion Criteria

Patients referred for 24-hour pH-impedance monitoring due to symptoms suggestive of Gastroesophageal Reflux (GER) were included. All participants were aged 18 years or older.

Exclusion criteria included: prior laryngeal or upper gastrointestinal surgery, active use of anti-reflux medication (proton pump inhibitors or prokinetics) within the 3 weeks preceding the exam, history of head and neck malignancy, and incomplete or technically inadequate pH-impedance recordings.

Data Collection

Participants underwent 24-hour pH-impedance monitoring. The pH-impedance catheter was positioned according to standard protocol, with the distal pH sensor located 5 cm above the upper border of the lower esophageal sphincter.

Proximal reflux was defined as a drop in impedance reaching one or both of the two most proximal sensors of the catheter. Reflux episodes were classified based on pH as acidic (pH<4), weakly acidic (pH 4-7), or weakly alkaline (pH>7), according to the distal pH sensor.

Altered proximal reflux was defined as the presence of three or more proximal episodes of reflux during the 24-hour recording.

Additional data collected after the PHI, within a maximum of four months, included demographic characteristics, presenting symptoms, and RSI and RFS scores.

Statistical Analysis

Data were analyzed using IBM SPSS version 31.0. Descriptive statistics were used to summarize patient characteristics. Continuous variables were expressed as means and standard deviations or medians and interquartile ranges, depending on data distribution. Categorical variables were presented as frequencies and percentages. Comparisons between groups were made using chi-square or Fisher’s exact tests for categorical variables, and t-tests or Mann-Whitney U tests for continuous variables. Statistical significance was set at p<0.05.

Ethical Considerations

Formal ethical approval was waived as the study involved only prospective collection of clinical data during standard care procedures. No identifiable patient information was used.

Results

A total of 52 patients were included in the study, with a mean age of 64 ± 13,4 years (Table 1). The majority were female (61.5%), and most (84.6%) were on Proton Pump Inhibitor (PPI) therapy before PHI.

Regarding the RSI, the most prevalent symptoms were the sensation of a lump in the throat, excess throat mucus, and throat clearing. The mean total RSI score was 16.09 ± 4.22 (Table 2).

Based on laryngoscopic examination and the RFS, the most prominent signs were posterior commissure hypertrophy, erythema, and vocal fold edema. The mean score for posterior commissure hypertrophy was 3.00, and for erythema/hyperemia 3.27. The mean total RFS score was 11.09 ± 1.07 (Table 3).

Proximal reflux was detected in 65% of patients. Among those, 45.2% had non-acidic reflux. Of the 30 patients with a normal DeMeester score (i.e., without pathological gastroesophageal reflux), 22 (73.3%) still exhibited proximal reflux episodes. The average number of total reflux episodes was 45, with an average of 27.5 acidic, 17.9 non-acidic, and 35.5 proximal episodes (Table 4).

The RSI was suggestive of LPR in 56.5% of patients, while the RFS was suggestive in 93.5%. No statistically significant correlation was observed between the scores of the two scales (Table 5).

In patients with proximal reflux detected on PHI, throat clearing was the most frequently reported symptom. Moreover, a moderate and statistically significant positive correlation was found between

Table 1: Demographic and Clinical Characteristics of the Study Population (n = 52).

Variable	Value
Mean age (years)	64 ± 13,4
Sex, n (%)	
• Female	32 (61.5%)
• Male	20 (38.5%)
Use of proton pump inhibitors (PPIs)	42 (80.8%) using 10 (19.2%) not using

Table 2: RSI Symptom Scores (Mean ± SD, Scale 0-5).

RSI Item	Mean ± SD
Hoarseness	1.75 ± 0.64
Throat clearing	2.45 ± 0.57
Excess mucus	2.84 ± 0.73
Swallowing difficulty	0.64 ± 0.59
Cough after eating	0.79 ± 0.56
Breathing difficulty	1.21 ± 0.62
Annoying cough	0.79 ± 0.59
Sensation of lump in throat	3.3 ± 0.69
Heartburn, chest pain, indigestion	2.32 ± 0.54
Total RSI score	16.09 ± 4.22

Table 3: Mean Scores of Laryngoscopic Findings Based on the RFS (n = 52).

RFS Parameter	Mean ± SD
Subglottic edema	1.3 ± 0.7
Ventricular obliteration	2.0 ± 0.0
Erythema/hyperemia	3.27 ± 0.65
Vocal fold edema	2.15 ± 0.45
Diffuse laryngeal edema	2.06 ± 0.54
Posterior commissure hypertrophy	3.0 ± 0.0
Granuloma	0.0 ± 0.0
Thick endolaryngeal mucus	0.12 ± 0.43

Each parameter scored from 0 to 4

Table 4: Results of PH-Impedance Monitoring.

Parameter	Value
Patients with proximal reflux	34/52 (65.4%)
Among those with proximal reflux: non-acidic reflux	15/34 (45.2%)
Patients with normal DeMeester score (no pathological GER)	30/52 (57.7%)
Among patients with normal DeMeester: Proximal reflux present	22/30 (73.3%)
Mean number of reflux episodes (total)	45
• Acidic reflux episodes (mean)	27.5
• Non-acidic reflux episodes (mean)	17.9
• Proximal reflux episodes (mean)	35.5

Table 5: Correlation Between RSI, RFS, and PH-Impedance Parameters.

Variables Compared	Correlation Coefficient (r)	p-value
RSI × Proximal reflux (presence)	0.523	< 0.001
RFS × Number of acid reflux episodes	0.754	0.003
RSI × RFS	0.211	0.12

the RSI score and the presence of altered proximal reflux (r = 0.523; p < 0.001).

A statistically significant positive correlation was observed between RFS and the number of acid reflux episodes detected on PHI (r = 0.754; p = 0.003).

Discussion

Our findings highlight that the absence of a pathological GER, indicated by normal DeMeester Index and Reflux Index (RI), does not exclude the presence of Laryngopharyngeal Reflux (LPR). In fact, 73.3% (22/30) of patients with normal esophageal pH metrics still exhibited proximal reflux. This aligns with evidence showing that LPR frequently involves episodes of weakly acidic or non-acidic proximal reflux, which conventional pH thresholds may not capture [5].

A critical pathogenic factor in LPR is pepsin, which remains stable at pH levels up to approximately 6.8 and may be reactivated in future acid exposure events [6,7]. Recent experimental studies in animal models have confirmed that acid, weak acid, and pepsin exposure lead to direct laryngopharyngeal mucosal injury, including disruption of intercellular integrity [8].

Therefore, standard pH metry cut-offs (pH < 4) are insufficient indicators of potential mucosal damage, especially in the larynx where epithelial tolerance to acidic injury is markedly lower than in the esophagus [9]. This underscores the need for revised diagnostic

criteria for LPR that account for the larynx’s vulnerability and the pathogenic role of weakly acidic or non-acidic reflux.

The observed correlation between RFS and the number of proximal reflux episodes may reflect the inefficient clearance of refluxate from the pharyngo-laryngeal region-unlike the esophagus, this area lacks peristaltic mechanisms, leaving acid and pepsin in contact with the mucosa for prolonged periods, increasing the risk of damage [9].

Proximal reflux is associated with increased RSI scores, and it is important to consider that even if proximal reflux does not directly affect the pharyngo-larynx, it is known that irritation of the upper esophagus can evoke laryngeal reflexes mediated by the vagus nerve, which can cause changes [4].

No statistically significant associations were found between RSI and RFS. Among asymptomatic patients (RSI<7), 37% showed findings suggestive of LPR on laryngoscopy. According to Silva et al., most laryngoscopic signs associated with LPR have low specificity, as they can be found in up to 70% of asymptomatic patients [5]. Vázquez de la Iglesia et al. highlighted that the correlation between symptoms and signs in LPR is weak and that neither clinical questionnaires nor laryngoscopy alone are sufficient for definitive diagnosis [10].

In summary, these nuances support a conceptual shift in LPR diagnosis and management-highlighting that typical GER metrics may overlook LPR, that weak or non-acid reflux and pepsin play critical roles in mucosal injury, and that both symptom scales and laryngoscopic findings have limitations in terms of specificity. As highlighted by Karkos and Wilson, LPR represents a distinct clinical entity within the spectrum of aerodigestive dysfunction, often presenting without classical GER symptoms such as heartburn, and therefore requiring separate diagnostic consideration [11].

Our study has several limitations. First, the sample comprised patients already suspected of GER, and there was no healthy control group, which limits comparative analyses. Second, the subjectivity inherent to RSI and RFS may introduce observer or recall bias. Third, the sample size is modest, reducing statistical power and potentially underestimating some associations. Finally, the lack of biomarker analyses-such as pepsin assays or mucosal impedance-limits deeper insight into the mechanisms of injury.

Conclusion

The absence of pathological GER on pH-metry does not exclude the presence of LPR. Since RSI and RFS are subjective assessment scales, certain data provided by PHI, such as proximal reflux, may be important tools in diagnosing LPR.

In the future, using pH-metry with impedance and sensors in the hypopharynx may provide more specific results for LPR, as well as using pH values adapted for LPR in pH-metry, given the known difference in acid tolerance between the laryngeal and esophageal mucosa.

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