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Diagnostic Correlation and Agreement Between the Reflux Symptom Score-12 and the Reflux Symptom Index in Vietnamese Outpatients with Suspected Laryngopharyngeal Reflux: A Preliminary Study

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ABSTRACT

Objective: Clinical diagnosis of laryngopharyngeal reflux (LPR) remains challenging due to nonspecific symptoms and limited access to objective testing. While the reflux symptom index (RSI) is widely used as a symptom-based screening instrument, the newly developed reflux symptom score-12 (RSS-12) incorporates symptom severity, frequency, and quality of life impact. This study aimed to evaluate the correlation and agreement between RSS-12 and RSI in Vietnamese patients with suspected LPR.

Methods: A cross-sectional study was conducted between January and October 2024. Adult outpatients with symptoms suggestive of LPR completed both the RSS-12 and the RSI questionnaires. Spearman's correlation coefficient and Cohen's kappa were used to assess the relationship and agreement between the 2 tools.

Results: Among 102 participants (70.6% female, mean age 48.7 ± 13.9 years), the mean RSI score was 11.3 ± 7.2, with 57 patients (55.9%) scoring > 13, suggesting suspected LPR. In comparison, the mean RSS-12 score was 36.5 ± 33.7, with 71 patients (69.6%) scoring > 11, identifying a higher proportion of potential LPR cases than RSI. A strong positive correlation was found between RSI and RSS-12 scores (Spearman's $r_s = 0.801$, $P < .001$), with substantial agreement (Cohen's $\kappa = 0.712$, $P < .001$).

Conclusion: Reflux symptom score-12 demonstrated strong correlation and substantial agreement with RSI in identifying suspected LPR. With its broader symptom assessment and quality of life focus, RSS-12 may serve as a reliable alternative or complementary tool to RSI in routine clinical practice. However, agreement between the 2 instruments does not establish diagnostic accuracy or clinical significance.

Keywords: Agreement, correlation, laryngopharyngeal reflux, RSI, RSS-12

Introduction

Laryngopharyngeal reflux (LPR) is a common inflammatory condition of the upper aerodigestive tract caused by gastric content reflux. It affects approximately 15% of ear, nose, and throat (ENT) outpatients and up to 50% of patients with laryngeal disorders.[1,2] Symptoms such as hoarseness, chronic cough, throat clearing, and globus sensation are nonspecific and often overlap with other ENT conditions, complicating diagnosis and monitoring.[3-5]

The reflux symptom index (RSI), introduced by Belafsky in 2002, has become one of the most widely used symptom-based screening instruments for identifying suspected LPR.[6,7] However, the RSI has several limitations, including its inability to capture symptom frequency and its exclusion of certain clinically relevant manifestations such as throat pain or halitosis.

To address these limitations, the reflux symptom score-12 (RSS-12) was developed as a more comprehensive,

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multidimensional instrument. Reflux symptom score-12 includes severity, frequency, and impact on daily life for each symptom, offering a broader assessment of the patient's symptom burden.[8]

Despite increasing interest in RSS-12, comparative data with RSI in specific populations remain limited. This study assesses the correlation between RSS-12 and RSI in Vietnamese patients and further evaluates RSS-12's clinical utility as a screening tool for LPR.

Methods

Design of Study and Participants

This descriptive cross-sectional study was conducted between January and October 2024. Patients presenting with symptoms suggestive of LPR at the outpatient clinic of the otorhinolaryngology department were recruited. Inclusion criteria included adults experiencing LPR symptoms such as throat clearing, hoarseness, cough, or globus sensation. Exclusion criteria were: smoking, alcohol use, pregnancy, recent upper respiratory tract infection (within the past month), use of anti-reflux medications, a history of neck trauma or surgery, prior endotracheal intubation, previous ENT radiotherapy, benign or malignant vocal cord lesions, allergic rhinitis, or chronic rhinosinusitis.

This study was approved by the Ethics Committee of the University of Pham Ngoc Thach (Approval No. 919/TDHYKPNT—HDDD, Date: November 14, 2023). All patients received written information about the study and were given the opportunity to decline participation; those who did not opt out were enrolled.

Assessment Tools

All enrolled patients completed 2 validated questionnaires: RSI and RSS-12.

- Reflux symptom index consists of 9 items assessing symptom severity, each scored from 0 (no problem) to 5 (severe problem), with a total score ranging from 0 to 45. An RSI score > 13 is indicative of suspected LPR.[6]
- Reflux symptom score-12 is a multidimensional tool comprising 12 LPR-related items. Each symptom is rated based on frequency (0 to 5) multiplied by severity (0 to 5), resulting in a symptom score range of 0-25 per item, and a total score range of 0-300. A score > 11 suggests possible LPR. The questionnaire also includes a separate quality of life (QoL) section, scored from 0 to 60.[8]

Statistical Analysis

Statistical analysis was conducted using the Statistical Package for the Social Sciences (SPSS) for Windows, version 22.0 (IBM, Armonk, NY). Descriptive statistics were used to summarize demographic and clinical data. Correlation and agreement between RSS-12 and RSI were assessed via Spearman's rank correlation and weighted Cohen's kappa. Because neither instrument was compared with an objective reference standard, these analyses were intended to evaluate association and agreement between symptom-based instruments rather than diagnostic accuracy. A *P*-value < .05 was considered statistically significant.

Main Points

- Reflux symptom score-12 (RSS-12) showed strong correlation and agreement with reflux symptom index in the assessment of suspected laryngopharyngeal reflux.
- Reflux symptom score-12 evaluates symptom severity, frequency, and quality of life impact and may serve as a practical symptom-based assessment tool in outpatient settings.

Results

A total of 102 patients were enrolled in the study, of whom 70.6% were female. The mean age was 48.7 ± 13.9 years, and the mean body mass index (BMI) was 22.9 ± 3.2.

Symptoms Distribution and Scores

The mean RSI score was 11.3 ± 7.2. Symptoms most frequently reported (≥ 50% prevalence) included throat clearing (55.9%), excess throat mucus or postnasal drip (59.8%), coughing after eating or when lying down (52.0%), troublesome/annoying cough (54.9%), globus sensation (65.7%), and heartburn, chest pain, indigestion, or stomach acid regurgitation (58.8%). Based on RSI scores, 55.9% of patients (n = 57) met the criteria for suspected LPR (RSI > 13) (Table 1).

Reflux symptom score-12 scores ranged from 2 to 154 with a mean total score of 36.5 ± 33.7. The mean RSS-12 QoL score was 6.7 ± 8.6. In addition to the common symptoms listed in the RSI, the RSS-12 also identified throat pain or pain during swallowing as a frequently reported symptom, with a high prevalence of 69.6%. Using the diagnostic threshold of RSS-12 > 11, LPR was suspected in 69.6% of patients (n = 71) with the mean RSS-12 and QoL scores of 48.9 ± 33.4 and 9.4 ± 9.1, respectively (Table 2). Notably, RSS-12 classified 14 additional patients as having suspected LPR, whereas RSI did not.

Correlation and Agreement Analysis

Reflux symptom score-12 demonstrated a strong correlation with RSI, with a Spearman correlation coefficient (r_s) = 0.801 (*P* < .01).

The agreement between RSI and RSS-12 was reflected by a kappa value of 0.712 (*P* < .01), with an overall consistency rate of 86.2% (88/102) (Table 3).

Discussion

Laryngopharyngeal reflux is highly prevalent in Asia, affecting approximately 25% of the population, but remains a diagnostic challenge due to its nonspecific symptoms and the limited availability of objective diagnostic tools, especially in resource-constrained settings such as Vietnam.[9-11] Twenty-four-hour hypopharyngeal–esophageal multichannel intraluminal impedance-pH monitoring (HEMII-pH) is considered the gold standard for comprehensive reflux assessment.[12] However, it is invasive, expensive, and not widely available.[10] Salivary pepsin testing offers a convenient, non-invasive alternative, yet its diagnostic accuracy remains debated due to various influencing factors such as sample timing and diet.[13] An empirical proton pump inhibitor trial is frequently employed but may be ineffective for non-acidic LPR and carries risks with prolonged use.[14]

Table 1. RSI in All Patients and in Patients with RSI > 13

Symptoms	All Patients (N = 102)	Patients with RSI > 13 (n = 57)
Hoarseness or a problem with your voice	1.2 ± 1.6	1.7 ± 1.8
Clearing your throat	1.2 ± 1.4	1.8 ± 1.5
Excess throat mucus or postnasal drip	1.5 ± 1.5	2.0 ± 1.5
Difficulty swallowing food, liquids, or pills	0.6 ± 1.1	0.9 ± 1.3
Coughing after you ate or after lying down	1.5 ± 1.7	2.3 ± 1.7
Breathing difficulties or choking episodes	0.8 ± 1.3	1.3 ± 1.5
Troublesome or annoying cough	1.7 ± 1.8	2.5 ± 1.8
Sensation of something sticking in your throat or a lump in your throat	1.5 ± 1.5	2.3 ± 1.5
Heartburn, chest pain, indigestion, or stomach acid coming up	1.4 ± 1.6	2.0 ± 1.7
RSI total	11.3 ± 7.2	16.7 ± 4.4

RSI, reflux symptom index.

In this study, the RSS-12 demonstrated strong correlation and agreement with the established RSI, supporting its potential utility as a symptom-based screening tool for LPR. However, agreement with RSI does not establish diagnostic accuracy or necessarily demonstrate clinical significance. Compared to the original RSS, RSS-12 enhances clinical efficiency without compromising diagnostic accuracy, offering quicker evaluation, improved patient compliance, and reduced response bias.[8]

This study demonstrated a strong correlation between RSS-12 and RSI and substantial agreement between the 2. These findings align with previous studies, including Lechien et al[8] and Guimarães et al, Yang et al, and Zheng et al.[15-17] The strong correlation and agreement reinforce RSS-12 as a concise, reliable, and clinically valuable tool for LPR diagnosis and monitoring.

Importantly, RSS-12 provides a multidimensional assessment of LPR symptoms, capturing both frequency and severity, along with the impact on QoL. This comprehensive approach may explain its higher detection rate of suspected LPR cases compared to RSI. In this cohort, RSS-12 identified 14 additional patients who were classified as suspected LPR by RSS-12 but not by RSI. However, these additional classifications cannot be interpreted as evidence of superior sensitivity or reduced underdiagnosis because no objective reference standard was used.

With quick completion time of approximately 5 minutes, RSS-12 is efficient, minimizing patient fatigue, while maintaining diagnostic reliability. Its structured format streamlines workflow, making it valuable in busy outpatient settings. Patients find it easy to complete, improving compliance compared to longer tools.

Table 2. RSS-12 in All Patients and in Patients with RSS-12 > 11

Symptoms	All Patients (N = 102)	Patients with RSS-12 > 11 (n = 71)
Hoarseness or a voice problem	3.0 ± 5.7	4.0 ± 6.6
Throat pain or pain during swallowing	3.4 ± 4.4	3.9 ± 5.0
Difficulty swallowing (pills, liquids, or solid foods)	1.4 ± 3.4	1.9 ± 3.9
Throat clearing (not cough)	3.2 ± 5.7	4.5 ± 6.4
Sensation of something being stuck in the throat	4.3 ± 6.3	5.8 ± 7.0
Excess mucus in the throat and/or postnasal drip sensation	4.4 ± 6.7	6.0 ± 7.4
Bad breath	1.7 ± 4.7	2.3 ± 5.5
Heartburn, stomach acid coming up, regurgitation, burping, or nausea	3.9 ± 5.5	5.1 ± 6.1
Abdominal pain or diarrhea	0.6 ± 2.0	0.9 ± 2.3
Indigestion, abdominal distension, and/or flatus	2.6 ± 5.4	3.6 ± 6.2
Coughing (not just throat clearing)	5.4 ± 7.2	7.4 ± 7.8
Breathing difficulties, breathlessness, or wheezing	2.5 ± 5.5	3.6 ± 6.4
RSS-12 total	36.5 ± 33.7	48.9 ± 33.4
RSS-12 QoL	6.7 ± 8.6	9.4 ± 9.1

RSS-12, reflux symptom scale-12; QoL, the impact of symptoms on quality of life.

Table 3. Consistency Analysis Between RSS-12 and RSI

Item	Category	RSS-12		Total (n)
		Positive (n)	Negative (n)	
RSI	Positive (n)	57	0	57
	Negative (n)	14	31	45
Total (n)		71	31	102
Kappa value	0.712			
P	< .01			

Despite its subjective nature, RSS-12 is a practical and accessible symptom-based assessment tool that may be useful for screening patients with suspected LPR, particularly in outpatient settings where objective reflux testing may not be readily available.

This study has some limitations. First, the diagnosis of LPR was based solely on symptom assessment tools (RSS-12 and RSI) without confirmation by an objective reference standard. In particular, HEMII-pH would provide an objective method for evaluating reflux events and would be valuable for future validation of RSS-12. Therefore, the observed agreement between RSS-12 and RSI should not be interpreted as evidence of diagnostic accuracy or necessarily as evidence of clinical significance. Second, the study population was relatively small and limited to a single center. Additionally, the study did not assess therapeutic response, thereby limiting conclusions about the utility of RSS-12 in monitoring treatment efficacy.

Conclusion

This study highlights the strong correlation and substantial agreement between RSS-12 and RSI in the evaluation of suspected laryngopharyngeal reflux among Vietnamese outpatients. With its broader symptom assessment and quality of life focus, RSS-12 may serve as a reliable alternative or complementary tool to RSI in routine clinical practice. However, agreement between the 2 symptom-based instruments does not establish diagnostic accuracy or necessarily translate into clinical significance. Further studies with larger cohorts and validation against an objective reference standard, such as HEMII-pH, are needed to determine the diagnostic performance and clinical utility of RSS-12.

Data Availability Statement: The data that support the findings of this study are available on request from the corresponding author.

Artificial Intelligence Usage Statement: This study used ChatGPT to improve language and clarity during the preparation of the manuscript. The authors take full responsibility for the scientific content of this manuscript.

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Informed Consent: Written informed consent was obtained from the patients who agreed to take part in the study.

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