Correlation Between Reflux Symptoms Score -12 and Reflux Finding Score in Patients with Laryngopharyngeal Reflux Symptoms

Original Article

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ABSTRACT

Background and Aim: The reflux symptoms score -12 (RSS-12) is a validated questionnaire with good sensitivity and specificity for diagnosis of laryngopharyngeal reflux disease (LPRD). However, the correlation between RSS-12 and reflux finding score (RFS) in patients with clinical symptoms suggesting LPR has not been investigated. In this study, we examined such correlation.

Patients and Methods: We conducted cohort cross sectional study over 6 months duration on 105 patients with typical gastroesophageal reflux disease (GERD) symptoms and clinical diagnosis of LPR based on RSS-12 >11. We excluded participants with medical conditions or lifestyle habits that could induce similar symptoms.

Results: The prevalence of LPRD (RFS > 7) in patients with a clinical diagnosis of LPR (RSS > 11) was 14.2% (15 patients). Laryngeal findings unrelated to LPRD were present in 16 patients (15.2%). RSS-12 and duration of symptoms are strongly correlated with the existence of abnormal laryngeal findings but not with RFS.

Conclusion: In patients with clinical symptoms suggesting LPR, RSS-12 can predict the existence of abnormal laryngeal findings but not the diagnosis of LPRD.

Key Words: Laryngopharyngeal reflux, reflux finding score, reflux symptom score-12.

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INTRODUCTION

Laryngopharyngeal reflux disease (LPRD) is an inflammatory condition related to reflux of gastroduodenal contents[1]. Approximately 10% to 30% of outpatients visiting otolaryngology clinics have LPR-related symptoms[2-4]. Diagnosis of LPR is still challenging and mainly based on suggestive symptoms and laryngeal signs of inflammation. Confirmation by impedance-pH testing is not commonly used because of its high cost and low sensitivity[5].

To aid in the clinical diagnosis of LPR, various questionnaires were created and validated based on their link with hypopharyngeal-esophageal pH monitoring and laryngoscopic findings. Belafsky *et al*. established the reflux symptoms index, the first symptoms questionnaire, in 2002[6]. RSI has some drawbacks as it has been developed with pH-only data and lacks consideration of some prevalent symptoms, such as throat pain, odynophagia, halitosis and also lacks consideration of the symptoms frequency[1].

For these reasons, the reflux symptom score-22, which is a French self-administered 22-items questionnaire, was created and validated to diagnose and monitor LPR. The RSS-22 is based on hypopharyngeal-esophageal multichannel intraluminal impedance pH testing (HEMII-pH) and avoids other disadvantages of RSI as it considers the most prevalent otolaryngological, digestive, and respiratory symptoms and evaluates symptom frequency, severity, and the potential impact on quality of life[7]. However, RSS-22 is time-consuming for the patient and the physician and for that reason, RSS-12 which is short version composed of 12 items was offered in English language by Jerome R *et al* in 2020. RSS-12 exhibits high sensitivity, specificity and external validity based on correlation with HEMII-pH[8].

As for symptoms, LPR has different findings by laryngoscopy. In 2001, Belafsky *et al*. created the reflux finding score (RFS), which consists of eight laryngoscopic findings: subglottic edema, ventricular obliteration, erythema/hyperemia, vocal fold edema, diffuse laryngeal

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edema, posterior commissure hypertrophy, granuloma/granulation tissue, and thick endolaryngeal mucus. The score ranges from 0 (normal) to 26 (worst possibility), and a score greater than 7 indicates LPRD[9].

Several studies confirmed a strong positive correlation between RFS and RSI[10-12]. However, no reports are available about the correlation between RFS and RSS-12. In this study, we examined the correlation between RSS-12 and RFS to determine the predictability of RSS-12 for diagnosing LPRD in patients with clinical symptoms suggesting LPR.

PATIENTS AND METHODS

Study design and ethics

This is a single-center cohort cross-sectional study conducted at tertiary Hospital over a period of six months. The study included patients who presented to the gastroenterology or otolaryngology clinic with symptoms of LPR. The study protocol for patients has been approved by the Ethics Committee of the Faculty of Medicine of Beni-Suef University in accordance with the Declaration of Helsinki (approval No. FMBSUREC/04012023). The participants have been informed about the study and its aim, and written consent was obtained from all patients.

Initial clinical evaluation

All cases were initially evaluated by history taking, including age, sex, duration of symptoms, smoking status, alcohol intake, comorbidities, drug intake, symptoms of GERD (heartburn, regurgitation, or both), and symptoms of LPR. We applied the RSS-12 (Appendix 1) for clinical diagnosis of the LPR. The RSS-12 consists of 12 symptoms, and for each symptom, there is a frequency and severity score that ranges from 0 to 5. The frequency and severity scores are multiplied, yielding the symptom score (0-25).The sum of the symptom scores of the 12 items corresponds to the final score (0–300), and RSS-12 > 11 is used as a diagnostic criterion for LPR[8]. Cases were also subjected to full clinical examination.

Inclusion criteria

1. Patient aged more than 18 years with GERD symptoms (heart burn, regurgitation, or both) and a clinical diagnosis of LPR based on RSS-12>11.
2. The duration of symptoms is more than one month, with symptoms occurring at least once per week.

Exclusion criteria

1. Smokers, alcoholics, asthmatic patients, or chronic obstructive pulmonary disease.
2. Treatment with proton pump inhibitors, antacids, or H2 inhibitors in the previous month.
3. Organic laryngeal disorders, previous head and neck surgeries, or radiotherapy.
4. Neuropsychiatric patients (stroke, bulbar palsy, cranial nerve palsy, etc.).
5. Patients with symptoms of LPR without GERD symptoms.
6. Chest pain other than heartburn.
7. Professional voice users (e.g., singers, teachers).
8. Exposure to occupational pollutants; history of allergic rhinitis; pharyngolaryngeal infection in the previous 3 months; tracheal intubation in the previous 12 months; and use of inhaled corticosteroids.

Evaluation by telescopic laryngeal examination

After initial clinical evaluation, the included patients were subjected to a telescopic laryngeal examination with a rigid 70-degree Karl Storz brand scope (Germany). The laryngeal examination was done blinded to the clinical data of the patients. After laryngoscopy, abnormal laryngeal findings were documented to define the factors predicting these abnormal laryngeal findings. Then we studied patients with and without LPRD based on RFS >7 or <7, respectively, to determine factors predicting the diagnosis of LPRD.

Statistical analysis

Statistical analysis was performed using the statistical package for social sciences (SPSS) computer software (version 22), IBM Software, USA. All data were expressed as means ± standard deviations for quantitative parameters and counts (percentages) for qualitative parameters. Univariate binary logistic regression was used to predict the effect of different risk factors on the end outcome: abnormal laryngoscopy and positive RFS. An adjusted odds ratio (OR) at 95% CI was obtained from univariate logistic regression to explain the magnitude of the effect of these risk factors. Multivariate binary logistic regression was used to predict the effect of significant risk factors (from univariate logistic regression), and adjusted OR was obtained at a 95% CI. OR is considered significant when 1 does not fall between the lower and upper CI. When zeros cause problems with the computation of the (OR) or its standard error, the OR was calculated using MedCalc's web tool. *P-values* of less than 0.05 were used to denote statistical significance.

RESULTS

Descriptive statistics

Descriptive statistics for the included cohort with symptoms of GERD and LPR

The study included 105 patients with symptoms of

GERD and LPR (59 females and 46 males) with a mean age of 36.18±11.51 years. The most frequent symptom was throat mucus or post-nasal drip (74.3%), followed by breathing difficulties (35.2%) and hoarseness or a voice problem (33.2%). The average RSS-12 was 31.65±4.75. The descriptive statistics of the included cohort are illustrated in (Table 1).

Table 1: Descriptive statistics for the included cohort with symptoms of GERD and LPR before laryngeal examination

Parameter	(n=105)
Age	36.18±11.51
Duration of symptoms by years	1.9 ±1.6
Reflux symptoms score -12	31.65±4.75
Male gender	46 (43.8%)
DM and or HTN	9 (8.6%)
Overweight or obese	79 (75.2%)
Symptoms of LPR:	
Throat clearing	26 (24.8%)
Throat mucus or post nasal drip	78 (74.3%)
Swallowing difficulty	15 (14.3%)
Something stiking or lump sensation	23 (21.9%)
Hoarseness (Dysphonia)or a voice problem	35 (33.3%)
Throat pain or pain during swallowing time	19 (18.1%)
Coughing (not just throat clearing)	11 (10.5%)
Breathing difficulties , breathlessness or wheezing	37 (35.2%)

DM, Diabetes mellitus; HTN, Hypertension; LPR, Laryngopharyngeal reflux

Mean± SD is used for description of the quantitative variables (Age, duration of symptoms and RSS). Count and percentage (%) is used for description of the qualitative variable (all other variables).

Descriptive statistics for laryngeal findings

Larynx was normal in 31 (29.5%) and abnormal in 74 (70.5%) of the total 105 included patients. According to RFS, 58 patients had only LPRD-related signs, 9 patients had only LPRD-non-related signs, and 7 patients had combination of LPRD related and non-related signs. The mean RFS was 3.7+ 2.8, and the prevalence of LPRD based on RFS > 7 was 14.2% (15 patients), while the prevalence of findings not related to LPRD was 15.2% (16 patients). The most frequent signs related to LPRD were diffuse congestion or edema (55.4%), followed by laryngeal granuloma or granulation tissue (51.3%) and vocal fold thickening (41.8%). The findings not related to LPRD were vocal fold nodules, polyps, and cysts. The descriptive results of laryngeal findings are illustrated in (Table 2).

Table 2: Prevalence and characteristics of the laryngeal findings

Laryngeal findings	Total n=105
Normal larynx	31 (29.5%)
Abnormal laryngeal findings:	74 (70.55)
Signs related to LPRD:	
Diffuse Congestion or edema:	41 (39%)
Mild	2 (1.9%)
Moderate	21 (20%)
Sever	18 (17.1%)
Granuloma or granulation tissue	38(36.1%)
Vocal fold thickening	31(29.5%)
Ventricular obliteration:	25(23.8%)
Partial	7(6.6%)
Complete	18(17.1%)
Vocal fold edema	5(4.7%)
Erythema or hyperemia:	2 (1.9%)
Arytenoid only	1(0.95%)
Diffuse	1(0.95%)
Posterior commissure hypertrophy	1(0.95%)
Inflammatory mucus membrane	1(0.95%)
Signs not related to LPRD:	
Nodules	7 (6.6%)
Polyps	5(4.7%)
Cysts	4(3.8%)

LPRD, Laryngopharyngeal reflux disease

Correlation statistics

Factors predicting aberrant laryngoscopy

In the univariate analysis, duration of symptoms and RSS-12 correlate positively with the abnormal laryngeal findings. In multivariate analysis, RSS-12 was the only risk factor for abnormal laryngeal findings, with an OR of 2.01 (95% CI 1.511–2.683) (Table 3).

Factors predicting diagnosis of LPRD (RFS>7)

After univariate and multivariate regression analysis, none of the studied clinical variables correlate with the diagnosis of LPRD (Table 4).

Table 3: Univariate and multivariate logistic regression analysis of the factors predicting abnormal laryngeal findings.

Risk factors	Univariate			Multivariate		
	OR	95% CI	*P.value*	OR	95% CI	*P.value*
Age	1.00	0.962-1.035	0.905			
Duration of symptoms	1.63	1.138-2.331	0.008*	1.19	0.746-1.898	0.465
Reflux symptoms score-12	2.05	1.546-2.729	<0.001*	2.01	1.511-2.683	<0.001*
Gender	0.93	0.398-2.151	0.925			
Comorbidities	1.52	0.297-0.738	0.618			
Overweight or obese	1.54	0.552-4.315	0.408			
Throat clearing	2.86	0.893-9.131	0.077			
Throat mucus or post nasal drip	1.99	0.764-5.006	0.142			
Swallowing difficulty	1.18	0.344-4.032	0.793			
Something stiking or lump sensation	0.73	0.273-1.955	0.532			
Hoarseness or a voice problem	2.69	0.982-7.342	0.054			
Throat pain or pain during swallow	0.66	0.234-1.89	0.442			
Coughing (not throat clearing)	4.69	0.574-38.312	0.150			
Breathing difficulties ,breathlessness or wheezes	1.51	0.634-3.568	0.354			

*: Significant at $P<0.05$.

Table 4: Univariete and multivariate logistic regression analysis of the factors predicting LPRD.

Risk factors	Univariate			Multivariate		
	OR	95% CI	*P.value*	OR	95% CI	*P.value*
Age	0.97	0.916-1.021	0.224			
Duration of symptoms	0.95 0.667-1.351	0.774				
Reflux symptoms score-12	1.01	0.881-1.167	0.848			
Gender	0.40	0.115-1.410	0.155			
Comorbidities	0.63	0.070-5.680	0.681			
Overweight or obese	0.62	0.155-2.467	0.495			
Throat clearing	0.83	0.232-2.954	0.772			
Throat mucus or post nasal drip	1.13	0.277-4.616	0.864			
Swallowing difficulty	1.59	0.367-6.920	0.534			
Something stiking or lump sensation	0.98	0.238-4.031	0.977			
Hoarseness or a voice problem	0.73	0.221-2.403	0.604			
Throat pain or pain during swallow	2.32	0.592-9.084	0.228			
Coughing (not throat clearing)	0.15#	0.008-2.747	0.086			
Breathing difficulties ,breathlessness or wheeze	1.41	0.398-4.997	0.594			

#: When zeros cause problems with computation of the OR or its standard error, OR was calculated using MedCalc's web tool.

DISCUSSION

In clinical practice, the diagnosis of LPR depends mainly on the correlation between clinical symptoms and laryngeal findings. Several questionnaires have been validated and correlated with RFS. The RS-12 is a simple questionnaire with good sensitivity and specificity for diagnosing LPR, but its correlation with RFS in patients with clinical symptoms of LPR has not yet been studied. In this research, we included 105 patients with typical GERD symptoms associated with symptoms of LPR based on the RSS-12 questionnaire to study such a correlation.

According to this study, the most common symptoms of LPR were throat mucus or post-nasal drip (74.3%), followed by breathing difficulties (35.2%), and hoarseness or a voice problem (33.2%). The prevalence of LPR symptoms has been extensively examined in several large cohort studies, but it varies between research due to differences in inclusion and exclusion criteria, diagnostic techniques, and clinical symptom identification and description. In a large cohort research by Habermann *et al*., the most common symptoms in 1044 patients with suspected LPR were globus feeling, throat clearing, and excessive throat mucus[13]. In another large cohort study, Lee *et al*. found that the most prevalent symptoms in 455 patients with suspected LPR were globus feeling, throat clearing, and hoarseness of voice[14].

In a comprehensive review of LPR, the most prevalent LPR symptoms in most published cohort studies are globus sensation, throat clearing, hoarseness, excess throat mucus, and postnasal drip[4].

The diagnosis of LPRD by laryngoscopy in this study was based on RFS. RFS is the first score developed by Belafsky *et al*. In 2001 that rates the laryngeal findings associated with LPR[9]. In recent Brazilian research, Eckley CA *et al*. confirmed the validation of RFS for the diagnosis of LPR after correlating RFS with confirmed LPR by positive reflux testing and found a sensitivity of 82.08%, a specificity of 93.94%, a positive predictive value of 95.60%, and a negative predictive value of 76.54%[15]. In another Polish study, Włodarczyk *et al*. assessed 100 patients with proven LPR by PH tests and another 55 healthy control persons and verified the reliability and specificity of RFS for the diagnosis of LPR[16].

However, a recent study by Dylan Vance *et al*. found no correlation between the RFS and 24-hour pH impedance testing and suggests that concerns about the validity and reliability of the RFS may be warranted[17]. Eckley CA *et al*. criticized RFS for diagnosing LPR, evaluating its sensitivity and specificity in three groups of patients with chronic laryngitis: group A (allergic rhinitis), group B (obstructive sleep apnea), and group C (LPR detected by impedance PH testing). The study indicated that RFS is not specific to reflux laryngitis and is more likely to result in false diagnosis if not used with diligence[5].

According to RFS, the signs related to LPR in this study were prevalent in 65 patients (61.9%), and the prevalence of LPRD based on RFS > 7 was 14.2%. Similarly Vardar *et al*. evaluated a total 684 patients with typical GERD symptoms, and the prevalence of LPRD was 70%, which is higher than ours due to the large sample size and variations in inclusion and exclusion criteria[18]. In a study by Lai Y-C *et al*., the prevalence of LPRD in 167 patients with an endoscopic diagnosis of reflux esophagitis was 23.9%, which is higher than ours because the patients were selected based on endoscopic evidence of reflux esophagitis rather than clinical symptoms[19]. In a more specific study done by Yun Wu *et al*., the prevalence of LPRD in GERD patients based on PH monitoring was 46.3% higher than ours[20].

In this research, the most frequent findings related to LPRD were diffuse congestion or edema, followed by granulation tissue and vocal fold thickening. The frequency of laryngoscopic findings related to LPRD varied among the previously published cohort studies, depending on many factors like inclusion criteria and tools used for the selection of the patients (clinical, endoscopic, endoscopic or PH tests). Habermann *et al*. examined 1044 patients with clinical symptoms of LPR using laryngoscopy, and the most common signs were posterior commissure hypertrophy, laryngeal congestion, and thick endolaryngeal mucus[13]. In another study, Chapity *et al*. found that the most common findings in 234 patients with clinical symptoms of LPR were dull tympanic membrane, arytenoid inflammation, and posterior pharyngeal wall inflammation[21]. Youssef TF conducted a more specific study based on clinical symptoms and PH monitoring and found that arytenoid erythema, endolaryngeal mucus, and laryngeal ulcers were the most common findings[22].

Sixteen (15.2%) of the studied patients had signs not related to LPRD in the form of benign VC lesions, most commonly nodules, followed by polyps and cysts. Seven of the patients with benign VC lesions had other signs related to LPRD, which support the association between LPR and the development of VC lesions. Although benign VC lesions were not described as diagnostic findings for LPRD, many research studies have confirmed the link between LPR and the development of benign VC lesions. Dai *et al*. recently analyzed 30 patients with VC polyps and discovered that patients with high pepsin in saliva (reflux) had greater pepsin concentrations and oxidative DNA damage in polyp tissue[23]. In another study, Beltsis A investigated the prevalence of pathological LPR in patients with resected benign true vocal fold lesions (TVFLs) compared to a typical GERD patient with normal laryngoscopy and concluded that pathological LPR is more prevalent in patients with TVFLs[24]. In a recent systemic review, the association between LPR and the development of nodules and polyps was investigated and verified in seven clinical studies that utilized objective LPR diagnoses by pH monitoring[25].

Previous reports about the correlation between symptoms and signs of LPR were based on correlating RSI and RFS, and majority of these studies confirmed a strong positive correlation between the two scores[10,26-28], however no reports available about correlation between RSS-12 and RFS. According to our study, RSS-12 and duration of symptoms correlated positively with the existence of abnormal findings by laryngoscopy, but no correlation was found with the diagnosis of LPRD (RFS > 7). The lack of a positive correlation between RSS-12 and RFS may be attributed to the weak validity of RFS in the diagnosis of LPRD if used alone. The other demographic and clinical factors had no correlation with existence of abnormal findings by laryngoscopy or the diagnosis of LPRD. Matching our results in a Greek study, the diagnosis of LPR was not related to any epidemiological factors or concomitant diseases apart from smoking and alcohol consumption[29]. Saruç *et al*., on the other hand, investigated the risk variables for LPR in GERD patients and discovered that, unlike us, male gender, longer duration of symptoms, and a high BMI were all risk factors for LPR incidence[30].

Finally, reflux that reaches the larynx is likely to cause damage to it. The patient's medical history must be carefully considered because symptoms that may be connected to LPR can be linked to other reasons. Mandatory laryngoscopy should come next. Voice problems frequently have multiple components contributing to their multifactorial nature, including several laryngeal and vocal risk factors. This degree of intricacy accounts for the scant scientific evidence and the reason why the involvement of GER is still largely unproven despite actual clinical observations.

We believe the study has some limitations. The sample size was small, and the diagnosis of LPRD was not based on PH or PH-impedance monitoring. Despite these limitations, our study had several strengths. It is the first study correlating RSS-12 with RFS. Patients with a clinical diagnosis of LPR were carefully selected by including only patients with typical GERD symptoms associated with RSS-12>11. We excluded smokers and alcoholics. All participants were subjected to an extensive medical evaluation to exclude other medical problems or lifestyle habits that could cause similar symptoms. Finally, we investigated the role of RSS-12 in predicting the existence of abnormal findings by direct laryngoscopy.

CONCLUSION

The long duration of symptoms and high RSS-12 in patients with clinical symptoms suggestive of LPR necessitate examination by direct laryngoscopy. RSS-12 cannot predict whether the symptoms are related to LPRD or other laryngeal diseases.

ABBREVIATIONS

DM: diabetes mellitus; **HTN:** hypertension; **GERD:** gastroesophageal reflux disease; **HEMII-pH:** hypopharyngeal-esophageal multichannel intraluminal impedance pH; **LPR:** laryngopharyngeal reflux; **LPRD:** Laryngopharyngeal reflux disease; **RSS:** Reflux symptoms score; **RSI:** Reflux symptoms index; **RFS:** Reflux finding score; **TVFLs:** true vocal fold lesions.

CONFLICT OF INTERESTS

There are no conflicts of interest.

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Appendix 1 .Reflux symptoms score-12

During the last month, how did the following problems affect you?	Disorder frequency : 0 = I do not have this complaint over the past month, 1;2;3;4 = I had this complaint 1-2;2-3;3-4;4-5 times weekly over the past month; 5 = complaint occurs daily	Disorder severity : 0 = problem is not severe, 5 = problem very troublesome when it occurs
Hoarseness or a problem with your voice	0-1-2-3-4-5	0-1-2-3-4-5
Throat pain or pain during swallowing time	0-1-2-3-4-5	0-1-2-3-4-5
Difficulty in swallowing (pills, liquids or solid foods)	0-1-2-3-4-5	0-1-2-3-4-5
Throat clearing (not cough)	0-1-2-3-4-5	0-1-2-3-4-5
Sensations of something sticking in your throat or a lump in your throat	0-1-2-3-4-5	0-1-2-3-4-5
Excess mucous in the throat and/or postnasal drip sensation	0-1-2-3-4-5	0-1-2-3-4-5
Bad breath	0-1-2-3-4-5	0-1-2-3-4-5
Heartburn, stomach acid coming up, regurgitations, burping or nausea	0-1-2-3-4-5	0-1-2-3-4-5
Abdominal pain or diarrhea	0-1-2-3-4-5	0-1-2-3-4-5
Indigestion, abdominal distension and/or flatus	0-1-2-3-4-5	
Coughing (not just throat clearing)	0-1-2-3-4-5	
Breathing difficulties, breathlessness or wheezing	0-1-2-3-4-5	

8. Lechien JR, Bobin F, Rodriguez A, Dequanter D, Muls V, Huet K, et al. Development and Validation of the Short Version of the Reflux Symptom Score: Reflux Symptom Score–12. Otolaryngology–Head and Neck Surgery. 2020;164(1):166-74.