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Assessment and Diagnostic Accuracy Evaluation of the Reflux Symptom Index (RSI) Scale: Psychometric Properties using Optimal Scaling Techniques

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Abstract

Objectives: To investigate the psychometric properties of the reflux symptom index (RSI) as short screening approach for the diagnostic of laryngopharyngeal reflux (LPR) in patients with confirmed diagnosed regarding the 24-hour multichannel intraluminal impedance-pH monitoring (MII-pH).

Methods: From January 2017 to December 2018, 56 patients with LPR symptoms and 71 healthy individuals (control group) were prospectively enrolled. The LPR diagnosis was confirmed through MII-pH results. All subjects ($n = 127$) fulfilled RSI and the Reflux Finding Score (RFS) was performed through flexible fiberoptic endoscopy. The sensitivity and the specificity of RSI was assessed by ROC (Receiver Operating Characteristic) analysis.

Results: A total of 15 LPR patients (26.8%) of the clinical group met MII-pH diagnostic criteria. Among subjects classified as positive for MII- pH diagnoses, RSI and RFS mean scores were respectively 20 (SD $\pm$ 10.5) and 7.1 (SD $\pm$ 2.5), values not significantly different compared to the negative MII-pH group. The metric analysis of the items led to the realization of a binary recoding of the score. Both versions had similar psychometric properties, α was 0.840 for RSI original version and 0.836 for RSI binary version. High and comparable area under curve (AUC) values indicate a good ability of both scales to discriminate between individuals with and without LPR pathology diagnosis. Based on balanced sensitivity and specificity, the optimal cut-off scores for LPR pathology were ≥ 5 for RSI binary version and ≥ 15 for RSI original version. Both version overestimated LPR prevalence. The original version had more sensitivity and the RSI Binary version had more specificity.

Conclusions: It would be necessary to think about modifying the original RSI in order to improve its sensitivity and specificity (RSI binary version, adding or changing some items), or to introduce new scores in order to better frame the probably affected of LPR patient.

Keywords

Reflux Symptom Index, laryngopharyngeal reflux, psychometric properties, optimal scaling techniques

Introduction

Laryngopharyngeal reflux (LPR) is an inflammatory disease characterized by the back flow of gastric and/or duodenal content into the laryngopharynx where it comes in contact with mucosa of the upper aerodigestive tract.[1]

LPR symptomatology mainly consists of hoarseness, throat clearing, cough, dysphagia, globus sensation, or postnasal drip.[2] LPR may be involved in many ear, nose, throat, and lung diseases including otitis media,[3] asthma[4,5] chronic rhinosinusitis,[6] obstructive apnea syndrome (OAS)[7,8] and tooth erosion.[9,10] Laryngeal inflammation is often attributed to gastric acid and non-acid reflux episodes that occur through the relaxation of upper esophageal sphincter.[11-14]

The diagnostic approach of LPR is still controversial but many physicians agree with the consideration of multichannel intraluminal impedance-pH monitoring (MII-pH) as the best diagnostic tool.[15-18] However, MII-pH is not available

in many centers and less used among the otolaryngologists.[19] The majority of physicians used clinical tools such as reflux symptom index (RSI) or reflux finding score (RFS)[20,21] which are still criticized regarding the lack of reliability and the lack of consideration of many LPR-related symptoms and findings.[14,22-24]

Treatment options include lifestyle modifications and the use of proton pump inhibitors, alginate or other anti-reflux medications.[1,14,25-30] Regarding the non-specificity of symptoms and findings associated with LPR, the use of clinical tools is recommended for precisely assessing the treatment efficacy. Another challenge is the lack of specificity of LPR symptoms, which yields the diagnosis difficult. Several studies have shown a poor correlation between LPR symptoms, laryngeal signs and MII-pH findings.[31,32] In a previous study, we found that only 41.6% of suspected LPR patients had pathological non-erosive reflux disease (NERD) or hypersensitive. Besides, the differences observed among different patients (ERD/NERD, HE, GERD; no gastroesophageal reflux disease), assessed with esophageal pathophysiological analysis (MII-pH), were not demonstrated with the symptom questionnaire (RSI) or with the laryngoscopic findings (RFS). In this study, we performed a categorical correlation (pathological vs non pathological) considering endoscopic and esophageal pathophysiological examinations (results of endoscopy, MII-pH, Acid Exposure Time Value, total number of reflux events, number of proximal refluxes, gas refluxes, Symptom reflux probability); no match results were statistically significant. Only the number of gaseous reflux episodes was associated with the RFS findings. Therefore, based on our findings, laryngopharyngeal symptoms seem to be not always due to GERD and LPR. Although RFS and RSI are useful scores for otolaryngologists and phoniatrics, they are not able to accurately identify patients with LPR.[24]

This study aims to investigate the psychometric properties of RSI as short screening test for LPR pathology and to compare RSI results with 24-hour MII-pH used as "gold standard"

Material and Methods

Study Subjects

This study was carried out in the unit of ear, nose, and throat (ENT), audiology and phoniatrics of Pisa University with the collaboration of the department of gastroenterology. From January 2017 to December 2018, 56 patients with LPR-associated symptoms were included (clinical group). We also enrolled 71 healthy individuals as control group. They had no LPR or GERD symptoms, and no history of voice disorder.

Individuals signed a written informed consent form before participating in the study. Patients less than 18 years of age, pregnant patients, patients affected by eating disorders with vomiting, psychiatric illness, peptic ulcer or using non-steroidal anti-inflammatory drugs and aspirin, were excluded from the study. The patients, who were treated by PPIs or alginate therapy in the previous 3 months and those who underwent upper gastrointestinal (GI) or neck surgeries, were excluded.

Subjects were assessed by a trained laryngologist through an accurate anamnesis, a general ENT examination and benefited from a videolaryngostroboscopy. RFS was completed by the otolaryngologist (RFS $>$ 7, suggestive value for LPR). Individuals were asked to complete RSI (RSI $>$ 13, suggestive value for LPR).[20,21] Manometry and MII-pH were performed after an overnight fast as described below.

Outcome Measurements

RSI and RFS

Symptoms were assessed through the Italian version of RSI.[33] RFS was assessed through a flexible fiberoptic endoscopy.

RSI is a self-administered nine-item index for the assessment of symptoms in patients with LPR. RSI can be completed in less than one minute. The scale for each individual item ranges from 0 (no problem) to 5 (severe problem), with a maximum total score of 45[21](Table 1).

RFS is an 8-item clinical severity scale based on findings during fiberoptic laryngoscopy (Table 2). The scale ranges

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Table 1. The Reflux Symptom Index (RSI): Original* Version [21] and the Italian** Adaptation Version.[33]

		0 = No problem					5 = Severe problem
Within the last month, how did the following problems affect you?*							
Circle the appropriate response*							
Nel corso dell'ultimo mese in che modo e`stato colpito dai seguenti sintomi?**							
Segnare la risposta corretta**							
1	*Hoarseness or a problem with your voice**	*0*	*1*	*2*	***3***	*4*	*5*
	*Raucedine o un problema vocale***						
2	*Clearing your throat**	*0*	*1*	*2*	***3***	*4*	*5*
	*Schiarirsi la gola***						
3	*Excess throat mucous or postnasal drip**	*0*	*1*	*2*	*3*	*4*	*5*
	*Eccesso di muco in gola o caduta retronasale di secrezioni **						
4	*Difficulty swallowing food, liquids or pills**	*0*	*1*	*2*	*3*	*4*	*5*
	*Difficoltà ad inghiottire cibo, liquidi, o pillole***						
5	*Coughing after you ate or after lying down**	*0*	*1*	*2*	*3*	*4*	*5*
	*Tosse dopo aver mangiato o essersi sdraiato***						
6	*Breathing difficulties or choking episodes**	*0*	*1*	*2*	*3*	*4*	*5*
	*Difficoltà a respirare o episodi di soffocamento***						
7	*Troublesome or annoying cough**	*0*	*1*	*2*	*3*	*4*	*5*
	*Tosse problematica o fastidiosa***						
8	*Sensations or something sticking in your throat**	*0*	*1*	*2*	*3*	*4*	*5*
	*Sensazione di qualcosa di bloccato o di massa in gola***						
9	*Heart burn, chest pain, indigestion, or stomach acid coming up**	*0*	*1*	*2*	*3*	*4*	*5*
	*Bruciore di stomaco, dolore toracico, cattiva digestione o acido gastrico che risale***						

Table 2. The Reflux Finding Score (RFS).[20]

Subglottic edema	*0 = absent*
	2 = present
Ventricular	*2 = partial*
	4 = complete
Erythema/hyperemia	*2 = arytenoids only*
	4 = diffuse
Vocal fold edema	*1 = mild*
	2 = moderate
	3 = severe
	4 = polypoid
Diffuse laryngeal edema	*1 = mild*
	2 = moderate
	3 = severe
	4 = obstructing
Posterior commissure hypertrophy	*1 = mild*
	2 = moderate
	3 = severe
	4 = obstructing
Granuloma/ granulation tissue	*0 = absent*
	2 = present
Thick endolaryngeal mucus	*0 = absent*
	2 = present

from 0 to a maximum of 26. The final items included in the scale include subglottic edema, ventricular obliteration, erythema/hyperemia, vocal fold edema, diffuse laryngeal edema, posterior commissure hypertrophy, granuloma/ granulation tissue, and excessive endolaryngeal mucus.[20]

Esophageal Manometry

Subjects underwent esophageal manometry to determine the length of esophagus and the position of the lower esophageal sphincter (LES). This study was performed by means of an eight-channel water-perfused manometric catheter with an external diameter of 4.5 mm (Dyno 2000® Menfis, BioMedica, Bologna Italy), equipped with computer-based data recording and storage. Esophageal body motility and LES relaxation were tested by at least 10 wet swallows of 5 mL of water. Wave amplitude and duration were measured by means of four openings located at 5, 10, 15, and 20 cm above the LES. A stationary pull-through technique was then used to accurately locate the position of the LES.

Esophageal MII-pH

MII-pH was performed using a polyvinyl catheter (diameter: 2.3 mm), equipped with an antimony pH electrode and several cylindrical electrodes, with a length of 4 mm, placed at intervals of approximately 2 cm.[34] Each pair of adjacent electrodes represented an impedance-measuring segment corresponding to one recording channel. The single-use MII-pH catheter was positioned with the pH electrode 5 cm

above the LES and the six impedance recording channels positioned at 3, 5, 7, 9, 15, and 17 cm above the LES.

The methodology of probe calibration, catheter placement, patient instruction and performance has been previously described.[35]

Statistical Analyses

Statistical analysis was performed by using software (SPSS version 23.0). Categorical variables are expressed as percentages, while all continuous variables are expressed as mean ± standard Deviation.

Internal Validity

The Principal Component Analysis (PCA) was performed to examine the assumed construct validity and uni-dimensionality of RSI. The number of dimensions and the item loading structure of the PCA with orthogonal rotation (varimax method) was conducted on the correlation matrix of the RSI items.

Three classical criteria from PCA were used:

a) eigenvalue rule (number of factor with eigenvalue of >1);
b) Scree plot (number of factor before the break in the Scree plot);
c) factor loading rule (item–factor correlations of >0.32, suggested for behavioural phenotypes interpretation).

When the scale uni-dimensionality was supported, we recoded the Likert points of the items of the RSI by an "optimal scaling" method via the Multiple Correspondence Analysis.[36,37]

Additionally, Cronbach Index (α), which is a scale reliability coefficient based on the internal consistency, were also computed.

The MCA method uses the Likert points as nominal categories responses, and enables optimal grading for each category response of the Likert questions (called "optimal weights"); consequently, an "optimal score" for each subject may be obtained. The optimal score of a subject is the sum of the optimal weights of the item options chosen. Thus, the Reflux Symptom Index (RSI) optimal scales were performed. These new versions of the scale were called RSI-Binary version. The test-retest reliability of the Italian version of RSI has been well documented by the Italian study.[33]

External Validity

The analysis of independent sample t tests was used to assess differences in RSI mean scores by MII-pH. The pairwise correlation between the scales (RSI original version, RSI-binary version and RFS) was tested with the Spearman rank correlation. In order to determine optimal thresholds for all the RSI versions (original and RSI-binary version) when compared to MII-pH diagnose, Receiver Operator Characteristic (ROC) curve analysis was performed. To determine the best balance between sensitivity and specificity, for the cut-off values selection the Youden Index (Y = sensitivity + specificity − 1) was chosen as criterion. Statistical significance was set at $P < .05$ (two-sided).

Results

Description of the Sample

The analyzed sample consists of 127 individuals, with a mean age of 50.1 ± 12.7 years (42.9% males;). No significant difference of age and gender were observed between control and clinical group.

A total of 26.8% of the clinical group (15/56) met MII-pH diagnoses criteria (33.3% males; 21.9% females). Among the control group, RSI mean scores was 5.4 ± 4.03. The RSI and RFS mean scores of subjects classified as positive LPR regarding MII-pH versus negative MII-pH were 20.0 ± 10.5 and 7.1 ±2.5, respectively. These values were not significantly different compared with the negative pH group.

The BMI was not significantly different between the two groups (BMI: clinical group 22.1 ±2.9; control group 21.6 ± 2.7.

Dimensionality Analysis and Optimal Scaling

The PCA identified one Principal Component (PC) for RSI items with eigenvalue of >1 (4.140), that explained for 46.99% of the observed total variance. The uni-dimensionality of the RSI was also supported.

Given the successful uni-dimensionality testing of RSI scale, the optimal scaling via MCA was performed. The descriptive indices calculated are showed in Table 3. The first part of the table represented the "factor loadings" (the square root of the discrimination coefficients), for example the correlation of the optimal recoded RSI item 1. "Hoarseness or a problem with your voice" and the first-dimension is 0.633, and explains the (0.633)^2 = 40.1% of the score variability, while for the recoded RSI item 5 "Coughing after you ate or after lying down" the correlation is 0.774, and explains the (0.774)^2 = 59.9% of the score variability. For the RSI the Cronbach Index is 0.84 (95% CI: 0.806-0.885) but the Cronbach's alpha increases if items 1, 3 or 9 are deleted, the same items with the lowest loadings.

Table 3. MCA Results (Loadings, Reliability) for RSI Orignal.

		RSI Orignal-version	
		Loadings	Cronbach's Alpha When Item Deleted
1	*Hoarseness or a problem with your voice*	*0.633*	*0.842*
2	*Clearing your throat*	*0.709*	*0.822*
3	*Excess throat mucus or postnasal drip*	*0.525*	*0,844*
4	*Difficulty swallowing food, liquids, or pills*	*0.682*	*0.833*
5	*Coughing after you ate or after lying down*	*0.774*	*0.818*
6	*Breathing difficulties or choking episodes*	*0.669*	*0.839*
7	*Troublesome or annoying cough*	*0.692*	*0.827*
8	*Sensation of something sticking in your throat or a lump in your throat*	*0.663*	*0.831*
9	*Heartburn, chest pain, indigestion, or stomach acid coming up*	*0.566*	*0.839*
	Cronbach's alpha	α **0.840**	*95% CI: 0.806 − 0.885*

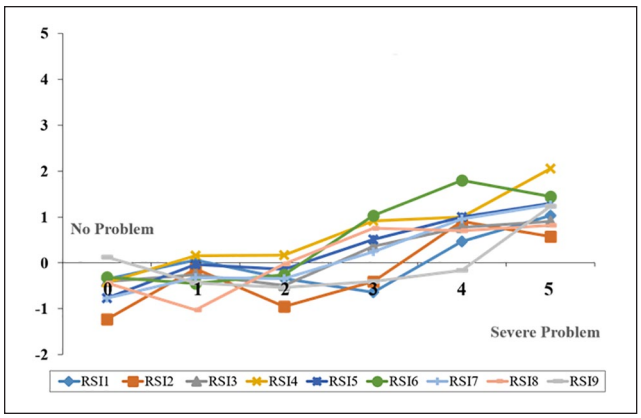

Figure 1. The transformation plot of Multiple Correspondence Analysis optimal weights for the Likert RSI scale. Response options RSI item six: 0 = No proplem to 5 = Severe problem.

Summary Measures

The transformation plots of the optimal weights for each Likert scale (RSI) are displayed in Figure 1. The RSI items not seem to describe a Likert form, so the relationship between the scoring systems could be not considered as a linear transformation from continuous to ordinal scale, but rather it would seem binary answers.

This aspect highlight in Table 4 summarizes the MCA optimal weights of the RSI questionnaire. Columns show the several Likert options, while rows show the different item number for the scale. The equidistance assumption of RSI items was not respected; some response options in many items had the same weights. In fact, the RSI optimal values of the fifth and the sixth answers of items 2, 3, 5, 6, and 8 had a similar weight, while for the items 1, 7, and 9, the first three option had the same weights. So, subjects had the same score to the response options with the same weights.

The optimal weight values were recoded and transformed in binary answers (0 = No; 1 = Yes) respect to original Likert format (0: No problem; 5: Severe problem). For example, if subject response pattern is: 3, 3, 3, 1, 2, 2, 2, 2, 6, the recoded response pattern will be: 0, 0, 1, 1, 0, 0, 0, 0, and 1, and subject score will be: 0 + 0 + 1 + 1 + 0 + 0 + 0 + 0 + 1 = 3 (Table 3). Computing a score using the recoded format the total score item responses of RSI-Binary version ranging from 0 to 9.

For the RSI-binary version the Cronbach Index is 83.6 (95% CI: 76.4-86.0), so the items recoded by MCA are quite homogeneous. As for the original, the version the items with the lowest loading are 1, 3, and 9.

Moreover, it is possible to show the graphical representation of the optimal scores and the modalities of the answer of the RSI items through the Multiple Correspondence Analysis in order to evaluate the appropriate order of the presentation of the items. This method allows sort in ascending order the questions according to their clinical severity, from least severe to the severest. The option item map results (Figure 2) showed that the order of items was not maintained.

The RSI-1 question was the second in the previous order and last (Items 4) was the fourth in the previous order. Thus, the prevalence of symptoms in the cases group corresponds to the order proposed by the MCA analysis. The most common symptom in the case group were related to the second question (RSI-2) "Clearing your throat," with a prevalence of 94.6%. Then the second (RSI-9) most common symptom is related to heartburn "Heart burn, chest pain, indigestion, or stomach acid coming up" (case group, 83.9%). The third (RSI-1) related to "Hoarseness or a problem with your voice" (76.8%). The least frequent symptoms were RSI-6 (44.6%) and RSI-4 (37.5%), which correspond to the most severe symptoms for the diagnosis of LPR. Symptom prevalence table shown in supplementary materials.

Table.4. Multiple Correspondence Analysis Optimal Weights Recording of the RSI Likert Format Items and Summary measures (Loadings, Reliability) for RSI-Binary version.

			No Problem					Severe Problem		Cronbach's alpha When Item Deleted
			0	1	2	3	4	5	Loadings	
1	Hoarseness or a problem with your voice	a	–0.41	–0.11	–0.14	–0.08	0.88	1.89	0.601	0.833
		b	0	0	0	0	1	1		
2	Clearing your throat	a	–0.67	–0.51	–0.41	0.29	1.17	1.47	0.654	0.785
		b	0	0	0	1	1	1		
3	Excess throat mucus or postnasal drip	a	–0.42	–0.06	–0.05	0.51	1.13	1.79	0.509	0.812
		b	0	0	0	1	1	1		
4	Difficulty swallowing food, liquids, or pills	a	–0.33	0.29	0.69	2.00	0.94	3.34	0.552	0.815
		b	0	1	1	1	1	1		
5	Coughing after you ate or after lying down	a	–0.48	0.08	0.45	1.56	1.76	2.00	0.715	0.784
		b	0	1	1	1	1	1		
6	Breathing difficulties or choking episodes	a	–0.26	–0.27	0.18	1.09	2.88	1.96	0.686	0.802
		b	0	0	1	1	1	1		
7	Troublesome or annoying cough	a	–0.55	–0.30	0.13	0.92	1.27	1.67	0.632	0.804
		b	0	0	1	1	1	1		
8	Sensation of something sticking in your throat or a lump in your throat	a	–0.43	–0.38	0.33	0.61	1.54	1.70	0.606	0.806
		b	0	0	1	1	1	1		
9	Heartburn, chest pain, indigestion, or stomach acid coming up	a	–0.40	–0.44	–0.18	0.16	0.59	2.20	0.550	0.805
		b	0	0	0	1	1	1		
	Cronbach's alpha								α **0.836**	95% ICI: 0.764 – 0.860

a) Optimal weight values. b) Optimal weight values trasformed in binary answers.

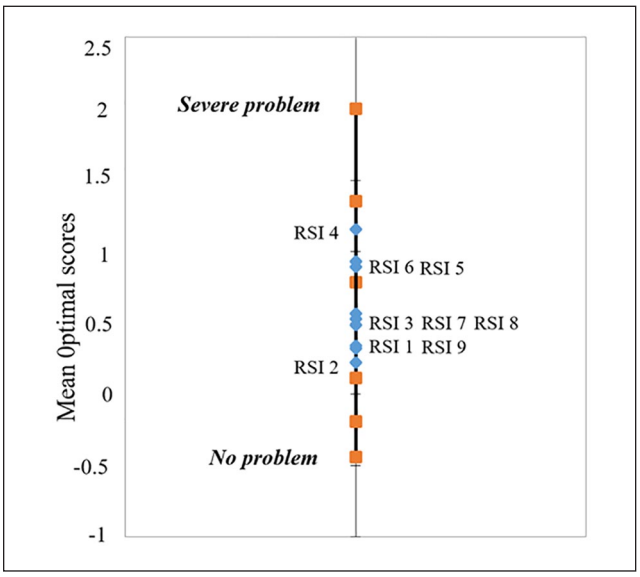

Figure. 2. Option item map.

Correlation Analysis and Receiver Operator Characteristic Curve Analysis

Spearman rank correlation showed a significant positive correlation between original and recoded RSI versions (r = 0.91; P = .01), but no significant correlation were observed between the two versions of RSI and the RFS.

When compared to pH monitoring diagnoses, the screening properties of the two versions of RSI are shows in Table 5. The observed Youden Index for the RSI original version (Y = 39.9) and for the RSI Binary version (Y = 44.8) was similar. A good trade-off between sensitivity and specificity was observed for the examined scale: for the RSI original version the Area Under ROC curve was 65.4 (95% CI: 46.3-74.6) and for the RSI Binary version was 69.5 (95% CI: 57.2-82.8). Although the AUC was equivalent in the two version, the RSI Original version was more sensitivity and the RSI Binary version was more specificity. The cut-off score obtained the LPR prevalence

Table 5. Screening Properties of the Version of RSI Original Version and Binary Version Considering the pH Monitoring Diagnoses Criteria as "Gold Standard."

	Se	Sp	AUC	95% CI AUC	Y	Cut-off	Pv %
RSI Original version	0.789	0.611	0.654	0.463-0.746	39.9	15	58.9
RSI Binary version	0.647	0.802	0.695	0.572-0.828	44.8	5	37.5

of 58.9% for the Original version and 37.5% for Binary version.

Discussion

Laryngopharyngeal Reflux has been involved in the etiology of many dysfunctional and organic pharyngolaryngeal diseases.[14,38] The best tool for diagnosing LPR is still MII-pH, whereas the most used clinical tools for the assessment of symptoms and signs are currently RSI and RFS.[20,21] In the last few years, several authors have stressed that the use of these scales is not always sufficient for the LPR diagnosis, besides the fact that values of RSI and/or RFS, suggestive for LPR, in reality they do not always correlate with the results of 24-hour double-probe pH monitoring.[13,23,31,32] Recently some authors have shown that RFS was not correlate with RSI.[39-42] These authors emphasize that the validity of RFS has to be investigated in large multicenter studies, while great care should be taken in the diagnosing LPR using only a clinical diagnosis based on symptoms or using RSI and RFS separately.[39-42] In the same vein, other authors proposed to insert new items in these scores or do not agree with the current cut-off values.[40,43,44]

In our previous study, the differences observed among ERD/NERD, HE, no GERD patients with esophageal pathophysiological analysis (MII-pH), were not demonstrated with RSI or RFS. Therefore, based on our findings, it would be possible that laryngopharyngeal symptoms may be not systematically due to LPR. Although RFS and RSI are useful scores for laryngologists, they are not able to accurately identify patients with LPR due to GERD, which often coexists with acid LPR.[13,14]

The aim of this study was to determine the psychometric properties of the Reflux Symptom Index (RSI). Our study, however, suggested a new alternative scoring methodology for RSI questionnaire; the metric analysis of the items led to the realization of a binary recoding of the score. The score was obtained as the sum of items recoded through the multiple correspondence analysis (MCA) results, and permitted maximizing item homogeneity from the scale. Finally, the binary score computed for the RSI was compared with the RSI original versions to determine optimal thresholds according to a pH monitoring diagnosis but also suggesting changes in the order of the questions.

Both binary and original scoring versions had similar psychometric properties. The psychometric properties in our study were comparable to those found by other validation study.[37,45-49] Li et al reported a Cronbach's alpha of 0.715 in the development of the Chinese version of the RSI, Schindler et al reported a higher reliability for the Italian RSI with a Cronbach's alpha of 0.99 and Lechien et al reported a Cronbach's alpha of 0.84.

The various response items of the nine questions of RSI contributed, with different weight, to the total score. The Cronbach's alpha seems to increase if items 3 or 9 are deleted (items with the lowest loadings). The item 3 could be difficult to understand by the respondent, while the item 9 "Heartburn, chest pain, indigestion, or stomach acid coming up," contains many different complaints. Therefore, in the first case, a simpler translation could be made for the reader, while item 3 could be divided into 3 specific questions in a future version of the RSI.[40,43,44] Psychometrics analysis of items performed through the Multiple Correspondence confirms the evidence emerged in the recent study by Lechien et al, highlighting also in our case that the most frequent symptoms are in patients with LPR that in in the controls are the 2, 9, 1, and 3 items. Symptoms that result ordered by clinical severity, from the least severe to the most severe, item 2 "Clearing your throat" (76.4%), Item 9, "Heartburn, chest pain, indigestion, or stomach acid coming up" (63.0%), item 1, "Hoarseness or a problem with your voice" (57.5%), item 3 "Excess throat mucous or postnasal drip" (55.9%).

In our population study, when analyzing cut-off scores AUC obtained were the same between binary and original version, but while the first one was more sensitivity the RSI-binary version was more specificity.

Cut-off scores in relation to pH monitoring diagnoses considered were 5 for the RSI-binary version and 15 for the RSI original version. Both versions overestimated LPR pathology prevalence; RSI original version detects a prevalence of 58.9%, while the RSI Binary version a prevalence of 37.5%. Figure 3 shows where the three scales agree and disagree. 12.5% of the subjects were screened as pathological by all the scales, but RSI Binary version and RSI original version overestimated respect to pH monitoring diagnoses criteria. Despite the proportion of overestimated users was not the same in the two scales (21.4% for RSI Binary version and 46.4% for RSI original version) they

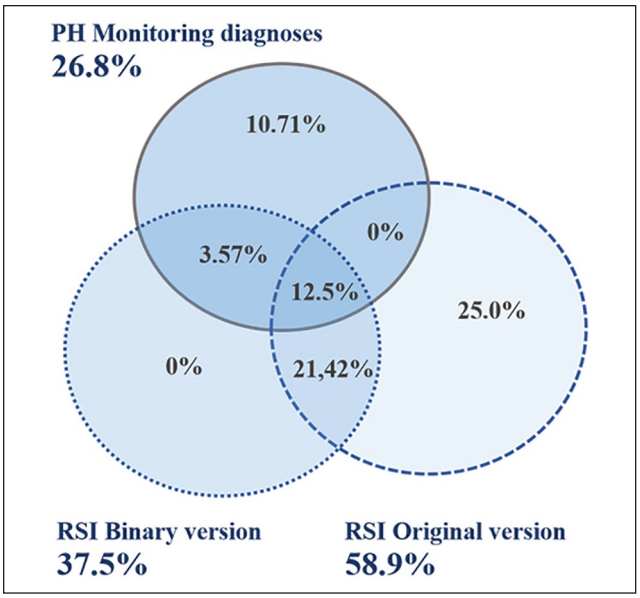

Figure 3. Union/Intersection chart for LPR pathology.

clearly capture different subjects. 10.71% of MII-pH diagnoses criteria screened subject were not found from the two RSI versions. Other studies in literature showed that traditional diagnostic test results for GERD, by pH monitoring or salivary pepsin diagnose,[50] may be often falsely negative in individuals with LPR.[51-53]

Other research showed that there was a high number of presumed false positive results, with a high number of with a high RSI having no objective evidence of reflux by either RFS or salivary pepsin. Using only RSI or RFS values for the diagnosis of LPR might lead us to false-positive diagnoses.[49,52,54-56]

In the our sample 26.8% of the clinical group met pH monitoring diagnoses criteria and similar prevalence, detected with the same gold standard, was reported in recent contemporary scientific research from the Asian,[57,58] Europe[59] and Italy.[60-62]

Although the threshold found with the original version is similar to the first validation work (Belafsky: 2002) the scores from RSI Binary version had better known-groups criterion validity, with prevalence values approaching the gold standard (26.8%), we would recommend this approach in future applications.

Our study has some limitations, the sample size in this research is not very large and the results refer to subjects enrolled in a single center. A multicenter research would improve future studies by providing larger samples with more generalizable finding.

Conclusion

The results of this study support the need for modifying the original RSI for improving both sensitivity and specificity or the use of a more complete patient-reported outcome questionnaire for both the diagnosis and the follow-up of LPR patients. RSI binary version is a self-administered nine-item tool used for the assessment of the initial symptoms and the efficacy of treatment of LPR patients. Our study reported that the RSI binary version had better known-groups criterion validity. RSI binary version with thresholds ≥ 5 were higher specificity and decreased sensitivity might be more appropriate if we prefer to not select people who do not need of intervention in order to minimize costs. With the aim of reducing false negatives, could be used the new scoring proposed in this study (RSI binary version), both for new studies and for prevalence-recalculation in previous research (APPENDIX_RSI_BINARY_SCORING).

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Supplemental Material

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