Journal of Voice
Vol. 16, No. 2, pp. 274-277

Validity and Reliability of the Reflux Symptom Index (RSI)

Peter C. Belafsky, Gregory N. Postma, and James A. Koufman

Center for Voice Disorders of Wake Forest University, Winston–Salem, North Carolina

Summary: Laryngopharyngeal reflux (LPR) is present in up to 50% of patients with voice disorders. Currently, there is no validated instrument that documents symptom severity in LPR. We developed the reflux symptom index (RSI), a self-administered nine-item outcomes instrument for LPR. The purpose of this investigation was to evaluate the psychometric properties of the RSI. For validity assessment, 25 patients with LPR were evaluated prospectively before and six months after b.i.d. treatment with proton pump inhibitors (PPI). Each patient completed the RSI as well as the 30-item voice handicap index (VHI). For reliability assessment, the study patients were given the RSI on two separate occasions before the initiation of treatment. Normative RSI data were derived from 25 age-matched and gender-matched controls taken from an existing database of asymptomatic individuals without any evidence of LPR. The mean RSI (± standard deviation) of patients with LPR improved from 21.2 (± 10.7) to 12.8 (± 10.0), and the mean VHI improved from 52.2 (± 24.7) to 41.5 (± 25.0) after 6 months of therapy ($p = 0.001$ and 0.065, respectively). Of the three VHI subscales (emotional, physical, functional), only the functional subscale improved significantly ($p = 0.037$). Patients who experienced a five point or better improvement in RSI were 11 times more likely to experience a five-point improvement in VHI (95% confidence interval = 1.7, 76.8). For reliability assessment, the first and second pretreatment RSIs were 19.9 (±11.1) and 20.9 (± 9.6), respectively (correlation coefficient = 0.81, $p < 0.001$). The single-item correlation coefficients ranged from 0.41 to 0.91 ($p < 0.05$ for all items). The mean pretreatment RSI in patients with LPR was significantly higher than controls (21.2 versus 11.6; $p < 0.001$). The mean RSI of patients with LPR after 6 months of PPI therapy approached that of asymptomatic controls ($p > 0.05$). The RSI is easily administered, highly reproducible, and exhibits excellent construct and criterion-based validity. **Key Words:** Outcomes—Outcome measures—Reflux—Gastroesophageal reflux—Symptoms—Quality of life—Laryngopharyngeal reflux.

Accepted for publication November 12, 2001.

Address correspondence and reprint requests to James A. Koufman, MD, Center for Voice Disorders of Wake Forest University, Department of Otolaryngology, Wake Forest University School of Medicine, Medical Center Boulevard, Winston–Salem, North Carolina 27157-1034, USA.

e-mail: jkoufman@wfubmc.edu

INTRODUCTION

Laryngopharyngeal reflux (LPR) has been implicated in the etiology of many laryngeal disorders, including reflux laryngitis, subglottic stenosis, laryngeal carcinoma, contact ulcers and granulomas, vocal nodules, and arytenoid fixation.[1–5] LPR may be pres-

ent in up to 50% of patients with voice disorders.[6] Signs and symptoms of LPR include hoarseness, vocal fatigue, excessive throat clearing, globus pharyngeus, chronic cough, postnasal drip, and dysphagia.[5] Symptomatic improvement of LPR occurs after two months of proton pump inhibitor (PPI) therapy in a majority of patients, and this improvement precedes resolution of physical findings associated with LPR.[7]

LPR differs from classic gastroesophageal reflux disease (GERD) in many ways, including its presentation; while heartburn and regurgitation are common symptoms of GERD, such symptoms are not present in most LPR patients.[2,5,8] A GERD questionnaire was developed and validated by Locke et al[9] and by Colwell et al[10] in order to assess severity and response to treatment. However, these outcome instruments are lengthy and rely heavily on typical GERD symptoms. Shaw et al[11] recently presented a 12-item symptom questionnaire to assess GERD, but again it concentrates on symptoms such as acid taste, burning, and chest pain.[11] There is currently no validated instrument for use by the otolaryngologist to assess outcomes in LPR patients.

We have developed a self-administered nine-item reflux symptom index (RSI) for the assessment of symptoms in patients with LPR. The 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; see Table 1. The purpose of this investigation was to evaluate the reliability and validity of the RSI.

MATERIALS AND METHODS

Twenty-five patients with LPR were enrolled and followed prospectively. In all cases, the clinical diagnosis of LPR was confirmed by ambulatory, 24-hour, double-probe (simultaneous esophageal and pharyngeal) pH monitoring. The authors' technique of pH monitoring has been described elsewhere and will not be reiterated other than to stress that the proximal probe was placed 1 cm above the upper esophageal sphincter under manometric guidance.[2,12]

Study patients were given the RSI as well as the 30-item voice handicap index (VHI) at the initial visit, and they were brought back for a readministration before the initiation of treatment. Antireflux therapy consisted of behavioral modification and treatment with twice-daily PPIs.

After a treatment period of 6 months, the RSI and VHI were readministered. All data were coded and recorded into Statistical Program for Social Sciences (SPSS) 6.1.1 for the Macintosh computer (Chicago, Il). The paired-sample *t*-test and the chi-square test were utilized to evaluate statistical differences between continuous and categorical data, respectively. The Pearson product-moment correlation coefficient was used to evaluate the linear association between index measures.

All persons with LPR were assigned a gender-matched and age-matched control from a normative database of asymptomatic persons without any evidence of LPR.[13] The independent-samples *t*-test was

Table 1. *The Reflux Symptom Index (RSI)*

Within the last month, how did the following problems affect you? *Circle the appropriate response.*	0 = No Problem 5 = Severe Problem					
1. Hoarseness or a problem with your voice	0	1	2	3	4	5
2. Clearing your throat	0	1	2	3	4	5
3. Excess throat mucus or postnasal drip	0	1	2	3	4	5
4. Difficulty 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. Sensations of something sticking in your throat or a lump in your throat	0	1	2	3	4	5
9. Heartburn, chest pain, indigestion, or stomach acid coming up	0	1	2	3	4	5
	TOTAL					

utilized to compare the RSI values between the control group and subjects with LPR before and after 6 months of treatment with PPIs.

RESULTS

The mean age of the LPR cohort was 57 (± 17) years. Fifty-six percent (14/25) were male. The mean RSI of patients with LPR at the initial pretreatment visit was 19.9 (± 11.1), and the mean RSI at the second pretreatment visit was 20.9 (± 9.6) (Pearson correlation coefficient = 0.81, $p < 0.001$). The mean duration between the initial and second pretreatment visit was 8 (± 4) days. The mean RSI at the completion of the 6-month treatment period improved from 20.9 to 12.8 (± 10.0) ($p < 0.001$).

The VHI improved from a mean pretreatment value of 52.2 (± 24.7) to 41.5 (± 25.0) after 6 months of therapy ($p = 0.065$). Of the three VHI subscales (emotional, physical, functional), only the functional subscale improved significantly ($p = 0.037$). Patients who experienced a five point or better improvement in RSI were 11 times more likely to experience a five point improvement in VHI [95% confidence interval (CI) = 1.7, 76.8].

The mean RSI of asymptomatic individuals without any evidence of LPR was 11.6 (95% CI = 9.7, 13.6). This normative value was significantly less than that of untreated persons with LPR but statistically similar to that of persons with LPR after 6 months of therapy with twice-daily PPI.

DISCUSSION

The clinical dichotomy between LPR and classic GERD is based on differences in symptoms, manifestations, patterns, mechanisms, and responses to therapy.[1–3,7,8] Patients with LPR are usually upright (daytime) refluxers with excellent esophageal motor function, and they uncommonly have esophagitis or heartburn.[2] By comparison, GERD patients are supine (nocturnal) refluxers with heartburn, esophagitis, and esophageal dysmotility.[2,5]

Because of the clinical differences, the same outcome measures cannot be used for both LPR and GERD. 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. The association between RSI improvement and improvement in the VHI (RR = 11; 95% CI = 1.7, 76.8) indicates that the instrument also displays good construct validity.

The high correlation between the initial and second pretreatment survey demonstrates that the measure is highly reproducible. The 95% upper confidence limit for the RSI in controls was 13.6. Thus, we consider an RSI greater than 13 to be abnormal. The similarity between the RSI in asymptomatic individuals and in persons with LPR treated for 6 months with twice-daily PPIs suggests that maximum treatment efficacy is achieved by 6 months of medical therapy for LPR. Utilization by other investigators is encouraged to determine whether these results can be replicated by other clinicians at other centers.

CONCLUSIONS

The RSI is a nine-item outcome instrument for patients with LPR. It is easily administered, highly reproducible, and exhibits excellent construct-based and criterion-based validity. Some degree of reflux is present in normal individuals, and we consider an RSI of >13 to be abnormal.

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