Validity and Reliability of a French Version of Reflux Symptom Index

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Summary: Objective. To develop a French version of the Reflux Symptom Index (Fr-RSI) and to assess its internal consistency, reliability, and clinical validity.

Study Design. Controlled, prospective trial.

Materials and Methods. Forty-four patients with a reflux finding score > 7 and an Fr-RSI > 13 were enrolled and treated with 20 mg of pantoprazole twice daily and diet changes for 3 months. Ninety asymptomatic subjects were also included in the study. To assess reliability, Fr-RSI was completed twice within a 7-day period. Validity was assessed by comparing Fr-RSI scores with scores from the Voice Handicap Index (VHI) in 24 of 44 patients, at baseline and at 3 months posttherapy.

Results. The mean values of Fr-RSI at baseline and after 7 days were 20.17 ± 5.76 and 19.75 ± 7.08, respectively, for patients with laryngopharyngeal reflux (LPR) and 4.02 ± 3.49 and 3.71 ± 3.82, respectively, for controls. The test-retest reliability was high in patients with LPR ($r_{BP} = 0.78$) and in healthy subjects ($r_{BP} = 0.80$). Cronbach's alpha was 0.85, indicating high internal consistency. The mean Fr-RSI score significantly improved from a baseline of 20.17 ± 5.76 to 5.58 ± 3.65 after 3 months of treatment ($P = 0.001$), and the initial mean VHI total score significantly improved from 20.29 ± 19.62 to 12.87 ± 12.04 after treatment ($P = 0.029$), indicating validity of the results. However, of the subcategories of the VHI, only the mean physical score improved from a baseline of 11.19 ± 9.22 to 7.35 ± 5.96 after treatment ($P = 0.016$).

Conclusion. The Fr-RSI developed in this study demonstrated both reliability and validity. It can be easily administered to assist in diagnosing and monitoring of LPR in French-speaking patients.

Key Words: Laryngopharyngeal–Reflux–RSI–Voice–Validation.

INTRODUCTION

According to the 2002 position statement of the American Academy of Otolaryngology—Head and Neck Surgery, laryngopharyngeal reflux (LPR), also called "silent reflux" or "reflux laryngitis," is described as the backflow of gastric contents into the laryngopharynx where it comes in contact with tissues of the upper aerodigestive tract.[1] It could affect up to 10% of patients who seek an Ear, Nose, and Throat consultation[2] and 50% to 78% of the population with voice complaints in America.[3] Currently, the prevalence of LPR in French-speaking countries is unknown as there are no data available.

The presence of gastric contents in the larynx causes morphological and functional changes, leading to a myriad of symptoms. In a case series of 455 Korean patients who were evaluated using the Reflux Symptom Index (RSI) and the Reflux Finding Score (RFS), the most common symptoms associated with LPR were globus sensation (88.7%), throat clearing (82.7%), and voice disorders (79.0%).[4] The authors also reported that the most common signs observed in laryngostroboscopy (RFS) were posterior commissure hypertrophy (89.1%), vocal fold edema (79.7%), hyperemia (79%), and diffuse laryngeal edema (76.8%).[4]

In making a diagnosis, LPR is often missed because symptoms classically associated with gastroesophageal reflux disease (GERD) are frequently absent.[2,5,6] Ambulatory 24-hour double-probe pH monitoring is considered the gold standard[7]; however, this technique can lead to false-negative or false-positive diagnoses due to variations in probe placement or movement of the probe during monitoring. False-positive rates range from 7% to 17%,[8,9] and evidence suggests that intermittent reflux may not occur during the test period, which also leads to errors in diagnosis.[7] One study reported that healthy subjects have an average of 1.8 episodes of reflux per 24 hours,[10] whereas another study found that 52% of subjects had at least two episodes of LPR per day.[11] Ambulatory pH monitoring is expensive, and many patients do not tolerate the test. Due to the difficulty of testing a large number of healthy subjects, normal values for the test have not been established.[10,11] Because of the limitations of pH monitoring and because of its limited availability in some medical centers, other clinical tools have been developed to aid in the diagnosis of LPR.[12] In 2002, Belafsky et al developed the RSI and the RFS, two efficient, inexpensive, and cost-effective diagnostic tools that are now used worldwide in diagnosing LPR.[13–17] Belafsky et al have demonstrated that the combination of an RSI score > 13 and an RFS score > 7 is correlated with a pH < 4 using pH monitoring, which is indicative of pathology.[14]

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The RSI has also been translated into and validated in other languages including Italian,[15] Chinese,[16] and Arabic.[17] To date, there is no validated French version of the RSI scale available for use in French-speaking countries, which include more than 400 million inhabitants. In this paper, we present a version of the RSI adapted for French speakers (Fr-RSI), and we assess its test-retest reliability, internal consistency, and clinical validity with the aim of providing the French-speaking community with an efficient tool for the diagnosis and monitoring of LPR disease.

MATERIALS AND METHODS

The study protocol was approved by the local ethics committee of the EpiCURA hospital network, Baudour, Belgium (n°A2014/001). All patients were invited to participate, and informed consent was obtained from those who enrolled in the study. Permission to develop and publish Fr-RSI was received from Peter C. Belafsky (The University of California, Davis, CA, USA), the creator of the original RSI.

Translation and development of the Fr-RSI

A multidisciplinary team composed of two otolaryngologists, two psychologists, one statistician, two speech therapists, one linguist, and one physicist, all native French speakers, worked on the French adaptation of the American version of the RSI.[14] The Fr-RSI pilot version was administered to nonmedical personnel to verify comprehensibility and unambiguity of the translated questionnaire. Each misunderstanding was carefully analyzed, and the Fr-RSI was improved accordingly, leading to the final version used in this study (Figure 1).

Participants

Forty-four subjects with suspected LPR were enrolled from January 2015 to April 2016 through the Department of Otolaryngology at one of the three hospitals in the EpiCURA hospital network in Belgium. Subjects ranged from 23 to 84 years old. Diagnosis of LPR was made using the original thresholds used by Belafsky, RSI > 13 and RFS > 7.[13,14] Patients with an RSI ≤ 13 and/or RFS ≤ 7 were excluded. Patients were also excluded if they presented with one of the following conditions: smoking or alcohol addiction, pregnancy, neurological disease, psychiatric illness, upper respiratory tract infection within the last month, current use of antacid treatment, previous history of neck surgery, history of neck trauma, benign vocal fold lesions, malignancy, history of ear, nose, and throat radiotherapy, seasonal allergies, asthma, hypersensitivity to proton pump inhibitors, untreated thyroid disease, prior antireflux surgery, or chemical exposure causing laryngitis. Following diagnosis, patients with LPR were treated with diet and behavioral modifications combined with twice-daily pantoprazole (20 mg, administered 30 to 60 minutes before meals). Patients received a chart in French with recommended diet and behavior changes that were customized based on their eating habits. Prescribed diet recommendations were based on Koufman's advice.[18] The average body mass index of the patients with LPR was 25.24 kg/m^2. A follow-up visit to the hospital was arranged for each patient with LPR after 3 months of therapy. Twenty-four patients with LPR completed the whole study.

The control group was comprised of 90 subjects, ages 19 to 60 years old, selected from 130 asymptomatic subjects recruited at the University of Mons in Belgium. Each subject completed a questionnaire to determine the presence or absence of the exclusion conditions described. If the presence of one or more exclusion conditions was suspected, the subject was excluded from the control group.

Measures

At baseline, all participants (90 controls and 44 patients with LPR) were asked to complete the Fr-RSI twice over a 7-day period (Fr-RSI d0, which corresponds to the time of the diagnosis for patients with LPR, and Fr-RSI d7, which corresponds to 1 week after diagnosis). Twenty-four LPR subjects also completed the Fr-RSI after 12 weeks of treatment (Fr-RSI w12). In addition, at baseline and after 12 weeks of treatment, the LPR subjects completed the French version of the Voice Handicap Index (VHI; Woisard et al[19]) and underwent video laryngostroboscopy (StrobeLED—CLL-S1, Olympus Corporation, Hamburg, Germany) to measure the RFS (VHI d0, VHI w12, RFS d0, and RFS w12, respectively).

Reflux Symptom Index (RSI)	
Au cours du dernier mois, comment ces différents symptômes vous ont ils affectés ?	0 = aucun problème ; 5 = problème important
Voix enrouée et/ou problème de voix	0 1 2 3 4 5
Raclage de gorge	0 1 2 3 4 5
Excès de sécrétions dans la gorge ou sensation d'écoulements à l'arrière du nez	0 1 2 3 4 5
Difficulté d'avaler des aliments solides, liquides, ou des gélules	0 1 2 3 4 5
Toux après avoir mangé ou après être resté(e) couché(e)	0 1 2 3 4 5
Difficultés respiratoires ou épisodes d'étouffement	0 1 2 3 4 5
Toux gênante ou ennuyeuse	0 1 2 3 4 5
Sensation d'avoir une grosseur ou quelque chose de coincé dans la gorge	0 1 2 3 4 5
Brûlures d'estomac, douleurs dans la poitrine, mauvaise digestion, ou remontées acides	0 1 2 3 4 5
Total *(à compléter par le médecin)*	

FIGURE 1. The French version of RSI. A multidisciplinary team mainly composed of French native speakers translated the American version of RSI.