Linguistic Adaptation, Reliability, Validation, and Responsivity of the Chinese Version of Reflux Symptom Index

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Summary: Objectives. Currently, there is no cost-effective tool available to diagnose laryngopharyngeal reflux (LPR) in the developing country of China. The aim of this study was to achieve a linguistic adaptation of the Chinese version of the Reflux Symptom Index (RSI-CH).

Study Design. A nonrandomized, controlled, prospective trial.

Methods. A total of 107 patients at the outpatient clinic of Peking University People's Hospital were enrolled. They were asked to fill out the RSI-CH and underwent fiber-optic laryngoscopy to complete the Reflux Finding Score (RFS). Patients underwent pH monitoring if the RSI-CH was greater than 13 or if the RFS was not less than 7. Patients were treated with Omeprazole 20 mg twice a day for 3 months if the pH monitoring was positive. The reliability (Cronbach alpha coefficient and Spearman correlation analysis), validity (sensitivity, specificity, and positive and negative predictive values), and responsivity of RSI-CH were determined.

Results. RSI-CH had a good reliability (Cronbach alpha coefficient was greater than .7, whereas the test-retest validity for the total score and for each item were 0.750–0.971. The scale had a good criterion validity. The consistency (66.7%), sensitivity (61.76%), and specificity (75%), and the positive and negative predictive values (80.8% and 53.6%) were considered good. The RSI-CH scores changed from 15 to 7 after treatment, and the average score of the controlled group was 6.5.

Conclusions. The RSI-CH developed and validated by this study can be used as an effective diagnostic tool in identifying differentiating LPR diseases in patients whose native language is Chinese.

Key Words: Laryngopharyngeal reflux–Laryngopharyngeal Reflux Symptom Index–Reliability–Validity–Scale.

INTRODUCTION

The reflux of gastric content creates severe damage to the upper esophageal sphincter, the signs and symptoms of which have been termed laryngopharyngeal reflux (LPR) since 1995.[1] Koufman[2] found that LPR patients account for approximately 10% of patients in otolaryngology outpatient services in America. Powell and Cocks[3] found that at least one laryngopharyngeal mucosal sign associated with LPR was identified in 64–93% of healthy volunteers and in 17–85% of gastroesophageal reflux disease sufferers in UK. The prevalence of LPR in a representative sample of the Greek population is 8.5%.[4] Lam et al[5] observed a lower prevalence of pH-documented LPR in native patients of Hong Kong, China with clinically suspected reflux laryngitis, compared with white patients. However, there are no conclusive data regarding the prevalence of LPR in China, as Chinese doctors are only beginning to understand LPR; further pursuing that this topic might be the goal of our next study. The tools that have been used to diagnose LPR in Western countries for years vary, including 24-hour double-pH monitoring (the gold standard), the Reflux Symptom Index (RSI), Reflux Finding Score (RFS), multichannel intraluminal impedance, and the level of pepsin in the sputum. Most of these tools, with the exception of RSI, are invasive or expensive. As citizens of a developing country, Chinese doctors encounter some difficulty in persuading patients to undergo expensive and invasive examination. Instead, we hope to develop a more cost-effective method to eliminate this need (Table 1).

RSI is an efficient diagnostic tool for LPR, as shown in Table 2. It is easy to use, even for those who know little about LPR. It does not require special equipment or examinations and is inexpensive. Thus, it can be considered highly efficient and cost-effective.[6] These features will be the key to future epidemiologic studies on the prevalence of LPR in the Chinese population. Unfortunately, as of today, no Chinese validated scale is yet available for clinical use and consideration in the diagnosis of LPR. Therefore, we translated, formulated, and validated a Chinese version of the RSI (RSI-CH) to allow for its application in the Chinese Mandarin language for use in China and in other countries with Mandarin speakers.

METHODS

The study protocol was approved by the Institutional Review Board of the Peking University People's Hospital. Each patient provided informed consent before any study procedure was initiated.

Development of the RSI-CH

An integrative translation method was developed based on the method of translation and back-translation after permission

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TABLE 1.
Glossary

Abbreviation	Full Name
RSI-CH	Chinese version of Reflux Symptom Index
LPR	Laryngopharyngeal reflux
RFS	Reflux Finding Score
pH	Potential of hydrogen

and authorization were received from the original author, Belafsky. Two translators, one senior otolaryngology professor and one bilingual expert, both of whom are native Chinese speakers fluent in English, translated the RSI into Chinese. Two other translators, one senior otolaryngology professor and one bilingual expert, performed a reverse translation, followed by a comparison of the original version with the translated English version. Each discrepancy was carefully analyzed, and the Chinese version was modified and improved. This improved RSI-CH was used in this pilot study to assess reliability, validity, and responsivity.

Filling out the RSI-CH

A sample size of at least 25 (preferably 50) was required if the purpose of the pilot study was to examine whether the measurements are reliable and valid.[7] From January 2011 through May 2012, a total of 107 patients at the outpatient clinic at Peking University People's Hospital were enrolled into the validation study. All the patients' education levels indicated that they at least understood Chinese. Thus, they were able to independently complete the RSI-CH. Patients with an RSI-CH >13 were deemed RSI-CH–positive, and pH monitoring was suggested.[6] All the patients were asked to repeat the scale a week later. During this week, they did not receive any treatment (such as proton-pump inhibitors, H-2-receptor blockers, and stomach power drugs).

Filling out RFS

All the patients underwent fiber-optic laryngoscopy protocol to examine for signs of LPR and fill out the RFS. The RFS is an eight-item clinical severity scale based on findings during fiber-optic laryngoscopy. Both fiber-optic laryngoscopy and RFS were performed by two trained senior otolaryngology professors. Patients with an RFS $\geq$7 were deemed RFS-positive, and the investigators suggested that they undergo pH monitoring.[8]

TABLE 2.
Reflux Symptom Index

Item	Description
1	Hoarseness or a problem with your voice
2	Clearing your throat
3	Excess throat mucus or postnasal drip
4	Difficulty swallowing food, liquids, or pills
5	Coughing after eating or after lying down
6	Breathing difficulties or choking episodes
7	Troublesome or annoying cough
8	Sensations of something sticking in your throat or a lump in your throat
9	Heartburn, chest pain, indigestion, or stomach acid coming up

pH monitoring protocol

Patients with an RSI >13 or RFS $\geq$7 were recommended to undergo ambulatory, 24-hour double-probe (simultaneous esophageal and pharyngeal) pH monitoring. The pH sensors were placed 5 cm above the lower esophageal sphincter and slightly above the upper esophageal sphincter, just behind the laryngeal inlet, under the guidance of the manometric sphincter location.[9] The criteria for a LPR episode included the following: the pH of the throat was less than 4.0[10]; the decrease of the pH of the throat did not occur earlier than that at the far electrode; the lowest value of the pH of the throat was no less than that at the far end; a rapid decline of the pH value was noted at the proximal receptor; and eating or swallowing did not contribute to the decrease in the pH. Patients with LPR >3 during the 24 hours were deemed pH monitoring–positive and were recommended to seek medical treatment.[11]

Treatment protocol

Patients were prescribed Omeprazole 20 mg twice a day, 30 min before each meal.[12] They were also asked to complete the RSI-CH again after 3 months after the persistent treatment.

Criteria for inclusion and exclusion for LPR

Seventy-two subjects with symptoms of LPR, which were persistent and/or recurrent for 3 or more months, were included in the suspicious LPR group.[2]

Thirty-five persons without a history of proton-pump inhibitors, H-2-receptor blockers, or stomach power drugs were included to establish a gender-matched and age-matched control groups.[13] These included volunteer students and workers in the hospital, as well as volunteer patients with troubles of deafness or tumors of the parotid, thyroid, or submandibular glands at the outpatient clinic.

Patients were not diagnosed with LPR unless the pH monitoring was positive. Thirty-four patients had diagnosed LPR after the pH monitoring.

Those without disposing capacities to read Chinese were excluded from the study. Pregnant women and children were also excluded.

Statistical methods

SPSS for windows 17.0 (SPSS, Inc., Chicago, IL) was used. The measurement data were normality tested by Kolmogorov-Smirnov test. Data with normal or near normal distribution were described as $\overline{x} \pm$ SD. Data with skewed distributions were described as medians (min–max). A P value <0.05 indicated statistical significance.

Internal consistency was measured by Cronbach alpha coefficient, and reliability, by test-retest correlations. The sensitivity, specificity, and positive and negative predictive values were calculated to evaluate the consistency between the RSI-CH and pH monitoring. The Wilcoxon rank sum test was used to compare the differences in RSI-CH scores between the