Validity and Reliability of the Filipino Reflux Symptom Index

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Summary: Objectives. This study aimed to establish validity and reliability of the Filipino Reflux Symptom Index (FRSI) and to test it among patients with laryngopharyngeal reflux (LPR) before and after 6 months' trial of rabeprazole.
Study Design. A case-control study was carried out.
Methods. There were 35 LPR patients and 30 controls who were twice-administered the FRSI and Filipino Voice Handicap Index (FVHI) for test-retest reliability, and videostroboscopy was performed to obtain baseline reflux finding scores (RFSs). Patients took rabeprazole 20 mg twice daily for 6 months. The FRSI and FVHI were readministered a third time, repeat videostroboscopy was performed, and repeat RFS was obtained. Reliability, validity, and internal consistency were computed.
Results. A total of 58 participants, 29 patients and controls each, aged 22–65 years completed the study. FVHI 2:1 and FRSI 2:1 significantly correlated with no significant differences between FRSI 2:1. FRSI had good item-total correlations indicating psychometrically sound items. There were significant differences between patients and controls for FRSI scores and mean scores. FRSI 3 scores were significantly lower than FRSI 1 scores, suggesting symptoms improved after treatment. There were no significant differences between RFS 2 and 1. Significant differences between FRSI 3 and 1, but not between FVHI 3 and 1, suggest the FRSI was more sensitive to changes in reflux after 6 months' intervention than the FVHI.
Conclusions. The FRSI is a valid and reliable tool for assessing LPR symptoms and may be used for primary care screening among Filipinos. Initial response to a 2-week empirical proton pump inhibitor trial may support an impression of LPR; non-response warrants specialist referral for further investigation.
Key Words: Laryngopharyngeal reflux–Reflux symptom index–Outcome measures–Rabeprazole–Filipino.

INTRODUCTION

Laryngopharyngeal reflux (LPR) has a growing prevalence in up to 60% of gastroesophageal reflux disease (GERD) patients,[1] which is more common in Asians than previously thought.[2] Increasingly recognized by generalists, pulmonologists, and otolaryngologists,[1,3] LPR affects 10% of patients consulting the latter.[4,5] Together with diet and lifestyle modification, LPR is treated by proton pump inhibitors (PPIs) such as rabeprazole.[6,7] However, clinical assessment of LPR may be difficult because laryngeal findings cannot always be reliably determined from clinician to clinician, and such variability may make precise laryngoscopic diagnosis highly subjective.[1,8,9]

LPR has been diagnosed by the Reflux Symptom Index (RSI)[10,11] and reflux finding score (RFS).[12] Because it is found in more than 50% of patients with hoarseness,[4,13] it might also be diagnosed (albeit indirectly) by the Voice Handicap Index (VHI).[14,15] The RSI is a self-administered nine-item instrument to detect and document LPR.[10] Valid and highly reproducible,[10] it has served as a standard for other studies.[16] Resonating the need for culture-specific versions of such measures,[17] it has been translated and validated in Hebrew,[18] Italian,[19] and Greek.[20] Both the RSI and VHI have been translated into the Filipino RSI (FRSI)[21] and Filipino VHI (FVHI),[22] but the former has not been validated. Establishing FRSI validity and reliability may provide a simple screening tool for LPR diagnosis and clinical assessment of therapy that can be used among 100 million Filipinos worldwide, particularly in primary healthcare settings.

This study aims to establish the validity and reliability of the FRSI among a sample of LPR patients and controls, and to test the validated FRSI before and after 6 months' trial of rabeprazole.

METHODS

With Institutional Review Board approval and informed consent, 35 adult LPR patients and 30 age- and gender-matched controls were prospectively recruited from outpatients at the Philippine General Hospital, Manila, Philippines. Inclusion criteria of patients were as follows: aged 18–70 with LPR diagnosis by current or previous English RSI >13 or documented RFS >7 and ability to accomplish the FRSI unassisted. Patients of the principal investigator, those on PPI therapy within 6 months, or with comorbidities unrelated to LPR that could potentially compromise well-being by study participation were excluded. Antacids, H2 blockers, or prokinetics were ceased 2 weeks before videostroboscopy. Age- and gender-matched controls had no history or diagnosis of LPR or GERD. The study was registered on the Philippine Health Research Registry.

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Instruksyon: Sa loob ng nakaraang buwan, paano ka naapektuhan ng mga sumusunod na problema? Bilugan lamang ang iyong mga sagot batay sa sumusunod na iskala: 0 = Walang problema. 5 = Matinding problema.						
Pamamalat/pamamaos o problema sa iyong boses.	0	1	2	3	4	5
Pag-alis ng bara sa lalamunan (hal. pag-ehem).	0	1	2	3	4	5
Labis na plema sa lalamunan.	0	1	2	3	4	5
Hirap sa paglunok/paglulon ng pagkain, inumin, tableta o kapsula.	0	1	2	3	4	5
Pag-ubo matapos kumain o matapos humiga.	0	1	2	3	4	5
Hirap sa paghinga o madalas na nasasamid/nabibilaukan	0	1	2	3	4	5
Pag-ubong nakaaabala o nakapeperwisyo.	0	1	2	3	4	5
Pakiramdam na parang may nakadikit o nakabara sa lalamunan.	0	1	2	3	4	5
Pangangasim/paghapdi ng sikmura, pananakit ng dibdib, hindi natunawan, o pagsikad ng asido mula sa tiyan.	0	1	2	3	4	5

FIGURE 1. Filipino Reflux Symptom Index.

The nine-item FRSI was independently thrice translated, and each translation was thrice back-translated by three otolaryngolgists, three non-otolaryngologist physicians, and three lay persons, with the final version approved by the National Commission on Filipino Language[21] (Figure 1). The FRSI was pretested for internal consistency (FRSI 1), and FVHI was administered for comparison (FVHI 1). The FRSI and FVHI were repeated after 1–2 weeks for inter-rater test-retest reliability (FRSI 2, FVHI 2), and videostroboscopy was performed by a blinded examiner who obtained baseline reflux finding scores (RFS 1) using a Digital Videostroboscopy System 9295E and Light Source 9100B with 5.8-mm 70° rigid Laryngoscope 9106 (Kay Elemetrics, NJ, USA). Topical Lidocaine 10 mg/dose (10%) spray × 3 (AstraZeneca AB, Sweden) was administered as needed. Videostroboscopic images were captured using integrated system software, and the findings were scored by the same examiner and tabulated by an encoder.

The 35 patients took rabeprazole 20 mg twice daily for 6 months, with standard behavior modification instructions**.** After 6 months, FRSI and FVHI were administered a third time (FRSI 3, FVHI 3), repeat videostroboscopy was performed, and repeat RFS was obtained (RFS 2).

Data were encoded using Microsoft Excel 2010 Version 14 (Microsoft, Redmond, Washington). Only participants with complete data were included in the final sample for statistical analysis. Test-retest reliability and validity indices (Pearson *r*; Student *t* test) and internal consistency (Cronbach alpha [α]) were computed using STATISTICA 12, 64-bit version (Dell StatSoft, Inc., Tulsa, OK).

RESULTS

Although 35 patients and 30 controls serially met inclusion criteria and consented to participate, 5 patients did not complete the study, and no controls were matched for them, whereas data for 1 patient were incomplete. Eliminating the matched control for this patient yielded 58 participants (29 patients and 29 controls; 7 males and 22 females each), aged 22–65 years old (mean 41.7, SD = 12.1).

Nine misclassified patients (low FRSI 1 scores) and 1 misclassified control (high FRSI 1 score) were excluded *post hoc* from LPR vs control analysis but included in FRSI analysis before treatment. After matching remaining patients and controls, there were 20 matched pairs for each comparison of FRSI and FVHI scores. No adverse events or drug reactions were encountered during the study period.

Reliability assessment

Test-retest reliability (Pearson *r*) showed FRSI 2 scores significantly correlated with FRSI 1 scores; $r(48) = .92$, $P < 0.001$, demonstrating FRSI is a reliable test. The FVHI 2 moderately correlated with FVHI 1; $r(48) = .66$, $P < 0.001$, demonstrating the FVHI may also be reliable. There were no significant