第五屆台灣胃腸神經與蠕動學會年會

The 5th Annual Meeting of Taiwan Neurogastroenterology and Motility Society

ASSESSING CONTENT VALIDITY OF THE CHINESE VERSION REFLUX SYMPTOM INDEX IN LARYNGOPHARYNGEAL REFLUX BASED ON THE US FDA GUIDANCE

Jung-Chi Hwang[1], Han-Chung Lien[1,2,3], Ja-Chih Fu[4], Chen-Chi Wang[2,5,6], Wen-Miin Liang[7], Hong-Zen Yeh[1,2], Sheng-Shun Yang[1,8,9], Chi-Sen Chang[1,8] 1. Division of Gastroenterology, Taichung Veterans General Hospital, Taichung, Taiwan; 2. School of Medicine, National Yang Ming Chiao Tung University, Taipei, Taiwan; 3. College of Medicine, National Chung Hsing University, Taichung, Taiwan; 4. Computer Aided Measurement and Diagnostic Systems Laboratory, Department of Industrial Engineering and Management, National Yunlin University of Science and Technology, Taiwan; 5. Department of Otolaryngology, Taichung Veterans General Hospital, Taichung, Taiwan; 6. School of Speech-Language Pathology & Audiology, Chung Shan Medical University, Taichung, Taiwan; 7. Department of Health Services Administration, China Medical University, Taichung, Taiwan.8. School of Medicine, Chung Shan Medical University, Taichung, Taiwan; 9. Institute of Biomedical Sciences, National Chung Hsing University, Taichung, Taiwan.

PURPOSE / OBJECTIVES

- The Reflux Symptom Index (RSI) is a validated patient-reported outcome (PRO) instrument widely used in patients with laryngopharyngeal reflux (LPR) to measure symptom severity, yet its content validity has not been evaluated.
- We aimed to assess the content validity of the RSI for use in pH-test-proven LPR patients undergoing proton-pump inhibitors (PPIs) treatment.

MATERIAL & METHODS

Main RSI measure evaluation study

- Conducted a longitudinal observational study in a tertiary medical center in Taiwan.
- Number of participants at baseline: 109 pH-test-proven LPR patients. (Fig. 1)
- Administration of the RSI instrument at run-in, baseline, 4w, 8w, and 12 w after proton-pump inhibitors therapy.

Participants completing and responsive to the treatment were invited to join the focus group discussions or cognitive interviews.

Focus groups & Cognitive interview

Evaluation of content validity: Substudy sample

- Number of participants: Focus groups: 9 (1st), 5 (2nd), 5 (3rd), 7 (4th).
- Number of participants to one-to-one cognitive interview: 9.
- Participants with various ages, genders, symptom severity, and education levels.

Content validation: Focus group discussion & cognitive interview

- **Focus groups**: conducted by 3 experienced facilitators (a gastroenterologist, an otolaryngologist, a group dynamic expert)
  - ◆Followed a semi-structured guide in an open-ended question manner
  - ◆Participants reflected on: LPR symptoms, coping strategies, and impacts on their daily life.
- **Cognitive interview**: semi-structured interview guide conducted by an experienced clinician, who had received mock interview training.
- Aforementioned interviews audio-recorded and transcribed verbatim.

Content validation: Analysis

- Transparent and vigorous iterative thematic analysis of transcribed data applied. Themes inducted from emerging issues relevant to LPR concepts; deducted from research aim and interview guide.
- Team-based approach using a modified Delphi process to reach consensus for each LPR relevant symptom code based on troublesomeness and responsiveness to treatment. (Fig. 2)
- Codebook developed after the first focus group discussion and modified subsequently to reflect new themes and to ensure in-depth symptom analysis
- A cognitive summary report for each RSI item to document participant understanding obtained from cognitive interviews.

Content validation: Data saturation monitoring & Conceptual matching

- Data saturation table developed to assess breath of content and new emerging issues.
- Team-based approach to assess and to document saturation.
- Team-based approach to assess the conceptual match by mapping the codes elicited from focus groups to the RSI-derived codes.

RESULTS

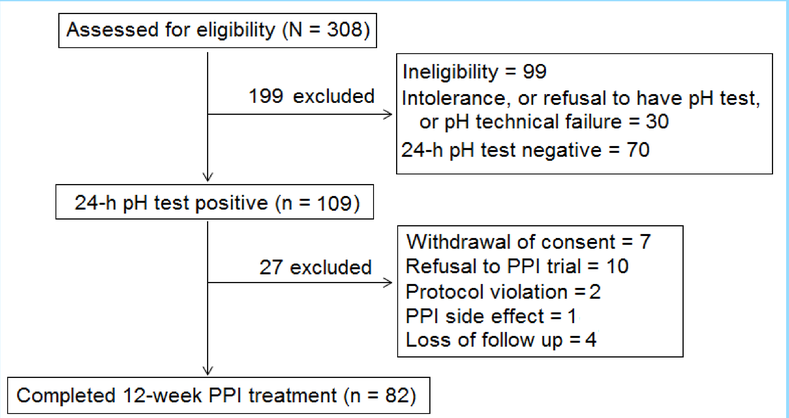
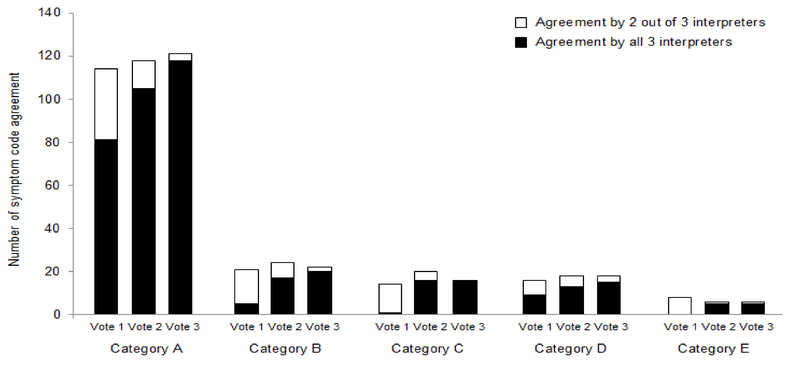


Figure 1. Flow-chart of main RSI measure evaluation study population enrollment.



Category A-Definite: troublesome and responsive to treatment
Category B-Probable: untroublesome (or uncertain) but responsive to treatment
Category C-Probable: troublesome but nonresponsive (or uncertain) to treatment
Category D-Possible: untroublesome and nonresponsive (or uncertain) to treatment
Category E-Irrelevance or indirect relevance: not anatomic or physiological related to LPR such as diarrhea, or symptoms secondary to LPR such as insomnia

Figure 2. Number of symptom code agreement with a modified Delphi process at each vote.

RESULTS

Table 1. Conceptual match between the codes elicited from focus groups and the RSI items using a combination of a saturation table and a structured codebook

RSI items	Codes (N = 26) elicited from focus groups	Saturation analysis by patient counts in successive focus groups: 1st (n_1 = 9)	2nd (n_2 = 5)	3rd (n_3 = 5)	4th (n_4 = 7)	Sum $\sum_{i=1}^{4} n_i$=26	Patient count endorsements based on the RSI items (%)
	RSI-derived codes (n = 18)						
(1) Hoarseness or a problem with your voice	(1) Hoarseness/Dysphonia	7	2	4	6	19	19(73%)
(2) Clearing your throat	(2) Throat clearing	7	3	3	5	18	18(69%)
(3) Excess throat mucus or postnasal drip	(3) Excess throat mucus	1	1	2	0	4	6(23%)
	(4) Postnasal drip	2	0	1	1	4	
(4) Difficulty swallowing food, liquids, or pills	(5) Dysphagia	1	0	0	1	2	2(8%)
(5) Coughing after you ate or after lying down	(6) Coughing after lying down	1	0	0	2	3	4(15%)
	(7) Coughing after eating	1	0	0	1	2	
(6) Breathing difficulties or choking episodes	(8) Breathing difficulties	0	1	1	0	2	4(15%)
	(9) Choking episodes	0	1	0	1	2	
(7) Troublesome or annoying cough	(10) Troublesome cough	6	1	1	0	8	8(31%)
(8) Sensations of something sticking in your throat or a lump in your throat	(11) Globus pharyngis	5	4	4	4	17	17(65%)
(9) Heartburn, chest pain, indigestion, or stomach acid coming up	(12) Heartburn	3	2	1	2	8	23(88%)
	(13) Regurgitation /Rumination	9	4	3	5	21	
	(14) Chest tightness	1	1	2	2	6	
	(15) Chest discomfort/pain	1	0	2	1	4	
	(16) Dyspepsia	2	2	0	1	5	
	(17) Belching	1	2	0	0	3	
	(18) Nausea	1	0	1	0	2	
Subtotal						130	
	Non-RSI-derived codes (n = 8)						
	(19) Throat discomfort/pain	2	4	2	3	11	
	(20) Throat burning	2	2	0	2	6	
	(21) Acid in throat	2	0	0	0	2	
	(22) Hypersalivation	0	0	1	0	1	
	(23) Sour taste in mouth	0	1	1	0	2	
	(24) Dry mouth	1	0	0	0	1	
	(25) Bad breath	1	0	0	2	3	
	(26) Earache	0	1	0	0	1	
Subtotal						27	
% of patient counts for the RSI derived codes among those elicited from focus groups		130/(130+27) = 82.8%					

RSI, Reflux Symptom Index.

SUMMARY / CONCLUSION

The study used a novel method to demonstrate how content validity of the Chinese version RSI was assessed which adapts the US Food Drug Administration guidance for patient-reported outcome measures.