



Original Research Article

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A STUDY ON CLINICAL VALIDITY AND RELIABILITY OF THE BENGALI LANGUAGE TRANSLATED GASTROESOPHAGEAL REFLUX DISEASE QUESTIONNAIRE IN GASTROESOPHAGEAL REFLUX DISEASE PATIENTS

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Abstract

Background: Gastroesophageal reflux disease (GERD) is a common upper gastrointestinal disorder with significant global and national prevalence. In India, GERD affects a substantial proportion of the population, including Bengali-speaking individuals. However, the lack of a

validated Bengali version of the Gastroesophageal Reflux Disease Questionnaire (GERDQ) limits accurate clinical assessment and research in this linguistic group.

Objective: To translate, culturally adapt, and validate the Gastroesophageal Reflux Disease Questionnaire (GERDQ) into Bengali for use in clinical and research settings.

Methods: A cross-sectional validation study was conducted at The Calcutta Homoeopathic Medical College & Hospital, Kolkata. The English version of the GERDQ was translated into Bengali following the standardized WHO and Sousa et al. translation guidelines, including forward-backward translation, e

xpert committee review, and pilot testing to ensure semantic, conceptual, and cultural equivalence. A total of 80 clinically diagnosed GERD patients (aged 18–65 years) completed the Bengali GERDQ. Reliability was assessed using Cronbach's alpha coefficient, and item responses were analyzed for internal consistency and comprehensibility.

Results: The Bengali GERDQ was well comprehended by participants and demonstrated strong internal consistency. The Cronbach's α value was 0.836, confirming excellent reliability. The translated version showed good face and content validity, and items were culturally appropriate with no ambiguous or misinterpreted terms reported during pretesting.

Conclusion: The Bengali-translated GERDQ is a valid, reliable, and culturally adapted instrument for assessing GERD symptoms in Bengali-speaking patients. Its implementation will enhance the accuracy of diagnosis, enable consistent symptom monitoring, and facilitate clinical and epidemiological research within this linguistic population.

Keywords

Gastroesophageal Reflux Disease, GERDQ, Translation, Validation, Bengali Adaptation, Reliability

Acknowledgement

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Ethics Statement

The study was conducted after obtaining clearance from the Institutional Ethics Committee of The Calcutta Homoeopathic Medical College & Hospital (Approval No. CHMCH/IEC/13/2023). Written informed consent was obtained from all participants before

enrolment. Confidentiality and anonymity of participant data were strictly maintained throughout the study.

Disclosure Statement

The authors declare no conflict of interest related to this study. No funding was received from any commercial or financial agency.

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Introduction

Gastroesophageal reflux disease (GERD) is one of the most prevalent upper gastrointestinal disorders worldwide, characterized by the reflux of gastric contents into the oesophagus, resulting in typical symptoms such as heartburn and regurgitation. The global prevalence of GERD has shown a steady increase over the last few decades, with estimates ranging between 10% and 30% across various populations, reflecting a growing public health concern. ^[1] A comprehensive review by El-Serag and colleagues (2014–2020) reported prevalence rates reaching up to 33% in certain Asian populations, attributing this rise to rapid urbanization,

dietary westernization, obesity, and lifestyle changes. [2] In India, GERD prevalence demonstrates significant regional variation. Population-based surveys have documented rates of 8.2% in southern India [3], while a recent meta-analysis estimated an overall pooled prevalence of approximately 15.6% nationwide. [4] Further regional studies have indicated prevalence as high as 31.3% in West Bengal [1] and ranging from 8% to 20% in rural Bihar. [5] Despite this, true prevalence in Bengali-speaking populations may still be underestimated due to a lack of validated and culturally adapted symptom-assessment tools in the Bengali language. Bengali, the native language of more than 242 million individuals and spoken as a second language by an additional 43 million, is the sixth most spoken native language and seventh most spoken language globally. [6] However, in clinical gastroenterology research, very few standardized instruments have been linguistically validated for Bengali speakers. This gap hinders both clinical diagnosis and quality-of-life assessment in patients presenting with reflux-related symptoms. Therefore, the translation, cultural adaptation, and validation of GERD-specific tools such as the Gastroesophageal Reflux Disease Questionnaire (GERDQ) scale in Bengali is essential. This instrument enable accurate evaluation of symptom severity, disease impact, and treatment outcomes, improving both patient care and research reliability within the Bengali-speaking population.

Gap in the Literature: Absence of Bengali Versions

Although the GERDQ questionnaires have been widely validated and utilized in multiple countries, no validated Bengali translations currently exist. This absence poses a significant gap in accurately assessing GERD symptoms and related quality-of-life outcomes among Bengali-speaking patients. The issue is particularly critical in resource-limited and rural healthcare settings, where language barriers often impede reliable symptom evaluation and clinical follow-up.

In contrast, several other linguistic and cultural adaptations of this instrument have already been developed and validated:

Arabic GERDQ: culturally adapted and psychometrically validated for Middle Eastern populations, demonstrating high internal consistency and construct validity. [7]

Malay and Korean GERDQ: both versions exhibited strong internal consistency and excellent test-retest reliability, confirming their robustness in Asian populations. [8]

Philippine regional languages: validated in Tagalog, Ilocano, Cebuano, Bisaya, and Hiligaynon, following rigorous translation protocols involving forward and backward translation, expert committee review, and cognitive debriefing. ^[9,10]

These studies adhered to internationally accepted cross-cultural adaptation methodologies, including forward-backward translation, expert panel evaluation, pretesting, and psychometric validation. Their success underscores the pressing need to undertake similar linguistic validation in Bengali, one of the world's most widely spoken languages, to ensure accurate clinical diagnosis, effective treatment evaluation, and standardized research comparability for GERD in Bengali-speaking populations.

MATERIALS AND METHOD

Study design, participants, and setting

A cross-sectional validation study was conducted at The Calcutta Homoeopathic Medical College & Hospital, Kolkata, between March 2023 and May 2024. The study aimed to validate the Bengali version of the Gastroesophageal Reflux Disease Questionnaire (GERDQ) among Bengali-speaking patients diagnosed clinically with GERD.

Participants aged 18–65 years, of either sex, who were clinically diagnosed with non-erosive gastroesophageal reflux disease (GERD) according to the American College of Gastroenterology (ACG) criteria, were eligible for inclusion. The diagnosis was based solely on clinical symptoms such as heartburn and regurgitation, consistent with the Montreal definition of GERD, without upper gastrointestinal endoscopy. Patients already on regular proton pump inhibitor (PPI) therapy and those scoring positive on the GERD Impact Scale were also included. Individuals on stable doses of essential medications for controlled comorbidities (e.g., antidiabetic, antihypertensive, or thyroid drugs) were allowed to continue their regimen throughout the study period.

Exclusion criteria included:

- Patients with erosive GERD, history of haematemesis or melena, dysphagia, or odynophagia.
- Individuals diagnosed with esophageal stricture, Barrett's esophagus, or esophageal adenocarcinoma.
- Patients with uncontrolled or complicated comorbidities (e.g., diabetes mellitus, hypertension, cardiovascular, renal, gastrointestinal, endocrine, gynecological, or systemic infections) that could affect quality of life.
- Those with psychiatric disorders, vital organ failure, or having received homeopathic treatment for chronic disease within the last six months.

- Individuals with immune-compromised states, alcohol or drug dependence, inability to adhere to the study protocol, and pregnant or lactating women were also excluded.

Study Objective

To translate, culturally adapt, and validate the GERDQ into Bengali, addressing the absence of a linguistically validated tool for Bengali-speaking populations. This adaptation was intended to minimize linguistic bias and improve the reliability of GERD symptom assessment in clinical and research settings.

Study population

All eligible GERD patients attending the Outpatient Department (OPD) of The Calcutta Homoeopathic Medical College & Hospital, Kolkata, during the defined 12-month data collection period, were approached for inclusion.

Sample Size

As no prior translation and validation of the GERDQ was available, we intended to carry out the translation with the complete enumeration format and in the respective time period of the study and a total 80 patients were included to complete the translation and validation.

Sampling Technique

A non-probability convenience sampling method was employed to recruit participants consecutively during the specified data collection period. This approach allowed inclusion of all eligible patients meeting the inclusion criteria within the study timeframe.

Study Tools

The primary assessment instrument used in this study was the Gastroesophageal Reflux Disease Questionnaire (GERDQ). The GERDQ is a standardized, self-administered questionnaire designed to diagnose and evaluate GERD symptoms in clinical and research settings. It consists of six items, including four positive predictors—heartburn, regurgitation, sleep disturbance due to reflux, and use of over-the-counter medications—and two negative predictors—epigastric pain and nausea.

Each item is rated on a four-point Likert scale (0–3), based on symptom frequency over the preceding week, giving a total score range of 0–18. A score of ≥ 8 has been established as a diagnostic threshold for identifying GERD with good sensitivity and specificity. The GERDQ has been extensively validated and widely applied for evaluating symptom burden,

monitoring treatment response, and quantifying disease impact in both clinical trials and real-world practice.

Instrument translation, procedure, and data collection

The translation and validation process of the GERDQ followed internationally accepted cross-cultural adaptation methods and the framework outlined by Sousa et al. and the World Health Organization (WHO). The procedure comprised two stages:

Translation and Cultural Adaptation:

The original English GERDQ was forward-translated independently into Bengali by two qualified bilingual translators with expertise in medical terminology and cultural nuances. The forward translations were reviewed by an independent expert panel and compared with the source version to ensure conceptual and semantic equivalence. A reconciled preliminary Bengali version was back-translated into English by two new translators who were blinded to the original questionnaire. The back-translated version was compared with the original English GERDQ by the research team. No major discrepancies were found, confirming semantic and conceptual accuracy. After expert consensus, the pre-final Bengali version of the GERDQ (Bn-GERDQ) was prepared.

Pilot Testing and Validation:

The pre-final Bengali GERDQ was pilot-tested on 80 Bengali-speaking GERD patients attending the outpatient department. Participants were asked to complete the questionnaire and comment on clarity, comprehension, and cultural appropriateness. Minor linguistic refinements were made based on feedback. The final version was reviewed by professional Bengali linguists for grammatical accuracy and cultural suitability, resulting in the final validated Bn-GERDQ tool.

Statistical Analysis

All quantitative and qualitative variables were entered into Microsoft Excel (version 7.0) and analyzed using IBM SPSS Statistics (version 16.0). Qualitative variables were summarized as frequencies and percentages, whereas quantitative variables were expressed as mean $\pm$ standard deviation (SD). The internal consistency and reliability of the Bengali GERDQ were evaluated using Cronbach's alpha coefficient (α), with values ≥ 0.70 considered acceptable for good reliability.

Statistical Analysis

The dataset included both quantitative and qualitative variables. Data management was initially carried out using Microsoft Excel (version 7.0), and subsequently, the dataset was imported into IBM SPSS Statistics (version 16.0) for statistical analysis. Qualitative variables

Variables	No. (%)	were
Gender		
Male	60 (75.0)	
Female	20 (25.0)	
Marital Status		
Unmarried	12 (15.0)	
Married	63 (78.8)	
Divorced/Separated/Widow	5(6.2)	
Educational Qualification		
Less than Class Xth	25 (31.2)	
Class Xth- Class XII th	22 (27.5)	
Graduate & above	33 (41.2)	

summarized using frequencies with their relative percentages. Quantitative variables were presented using descriptive statistics: the mean and standard deviation (SD) were reported for normally distributed data. The reliability of the GERD-Q questionnaire in Bengali version was measured by computing Cronbach's alpha.

Ethical Consideration

The study was conducted after obtaining clearance from the Institutional Ethics Committee (CHMCH/IEC/13/2023).The confidentiality of data was maintained.

RESULT AND OBSERVATION

Table1.0 Baseline Demographic presentation of the study participants for GERDQ Questionnaire (n= 80)

The above **table (1.0)** shows the Baseline Demographic presentation of the study participants. Out of total 80 GERD patients most of them were female 60 (75.0%). Majority of the study participants were married 63 (78.8%) followed by unmarried 12 (15.0%). Majority of the participants were graduate or above.

Table 2.0 0 Frequency distribution of GERDQ related response of the study participants

Response related to question on GERDQ	No. (%)
Burning feeling behind the breastbone heartburn	
0 Days	28(35.0)
1 Days	17(21.2)
2-3 Days	16(20.0)
4-7 Days	19(23.8)
Total	80(100.0)
Stomach contents moving up to the throat or mouth regurgitation	
0 Days	18(22.5)
1 Days	22(27.5)
2-3 Days	22(27.5)
4-7 Days	18(22.5)
Total	80(100.0)
Pain in the middle of the upper stomach area	
0 Days	29(36.2)
1 Days	14(17.5)
2-3 Days	20(25.0)
4-7 Days	17(21.2)
Total	80(100.0)
Nausea	
0 Days	26(32.5)
1 Days	21(26.2)
2-3 Days	25(31.2)

4-7 Days	8(10.0)
Total	80(100.0)
Trouble getting a good nights sleep because of heartburn or regurgitation	
0 Days	26(32.5)
1 Days	19(23.8)
2-3 Days	22(27.5)
4-7 Days	13(16.2)
Total	80(100.0)
Need for over-the-counter medicine for heartburn or regurgitation such as antacids in addition to the medicine your doctor prescribed PPIs	
0 Days	25(31.2)
1 Days	24(30.0)
2-3 Days	18(22.5)
4-7 Days	13(16.2)
Total	80(100.0)

Table2.0 Frequency distribution of GERDQ related response of the study participants

In response to the GERDQ questionnaire among 80 participants, 28 (35.0%) reported no burning feeling behind the breastbone (heartburn), while 17 (21.2%) reported mild symptoms, 16 (20.0%) moderate, and 19 (23.8%) severe. Regarding regurgitation, 18 (22.5%) reported no symptoms, 22 (27.5%) mild, 22 (27.5%) moderate, and 18 (22.5%) severe. For pain in the middle of the upper stomach, 29 (36.2%) had no symptoms, 14 (17.5%) had mild pain, 20 (25.0%) moderate, and 17 (21.2%) severe. Nausea was absent in 26 (32.5%) participants, while 21 (26.2%) experienced it mildly, 25 (31.2%) moderately, and 8 (10.0%) severely. Trouble in getting a good night's sleep because of heartburn or regurgitation was not reported by 26 (32.5%), mild in 19 (23.8%), moderate in 22 (27.5%), and severe in 13 (16.2%). Finally, the need for over-the-counter medicine such as antacids in addition to prescribed PPIs was absent in 25 (31.2%), mild in 24 (30.0%), moderate in 18 (22.5%), and severe in 13 (16.2%).

	N	Mean	Median	Std. Deviation	Minimum	Maximum	Percentiles
Age	80	43.18	40.00	15.73	16	82	25 (31.0); 50(40.0); 75(55.0)
Sum	80	7.84	6.50	4.90	1	17	25 (3.0); 50(6.50); 75(12.75)

Table 3.0 Mean and Standard deviation of the total GERDQ Score for the study participants.

The content validity of GERDQ was checked through the experts of the concerned subject. The measure of reliability for GERDQ was found to be 0.836 (perfectly reliable)

Discussion

The present study represents the first effort to translate, culturally adapt, and validate the Gastroesophageal Reflux Disease Questionnaire (GERDQ) into Bengali. The translated version (Bn-GERDQ) successfully retained semantic, conceptual, and cultural equivalence with the original English version. The high Cronbach's alpha value of 0.836 indicates excellent internal consistency, demonstrating that the Bengali version is both reliable and comprehensible for Bengali-speaking patients. The psychometric reliability found in this study is comparable to previous validation studies conducted in other linguistic and cultural contexts. The Arabic version of the GERDQ reported a Cronbach's alpha of 0.86 [7], while the Malay and Korean versions demonstrated alpha values of 0.82 and 0.83, respectively [8]. These findings affirm that the Bengali GERDQ performs consistently across diverse populations, underscoring the robustness of the translation methodology adopted. The distribution of symptom frequencies observed in our study—particularly heartburn, regurgitation, and sleep disturbance—reflects the substantial burden of GERD among Bengali-speaking patients. This aligns with epidemiological reports suggesting a rising prevalence of GERD in India, especially in urban and semi-urban areas where dietary habits, obesity, and stress levels are contributing factors. The availability of a validated Bengali GERDQ addresses a significant gap in clinical gastroenterology and research in India. It provides healthcare professionals, including homeopathic practitioners, with a

standardized and culturally appropriate diagnostic and monitoring tool. The Bn-GERDQ can be employed in routine outpatient evaluations, patient follow-ups, and in assessing treatment outcomes, thereby promoting more objective and quantifiable symptom monitoring. Furthermore, the instrument's validation strengthens the foundation for future clinical research in gastroenterology and homeopathy, especially for studying GERD symptom patterns, treatment response, and patient-reported outcomes in Bengali-speaking populations. The tool may also be used in public health surveys and epidemiological studies to estimate GERD prevalence and related risk factors across different socio-demographic strata.

Study Strengths and Limitations

The major strength of this study lies in its methodological rigor, including adherence to WHO and Sousa et al. guidelines for translation and cross-cultural adaptation, and its focus on a linguistically homogenous population. The use of Cronbach's alpha for internal consistency provides robust psychometric validation.

However, certain limitations must be acknowledged. The study did not employ upper gastrointestinal endoscopy, relying instead on clinical diagnosis based on ACG criteria, which may have led to the inclusion of patients with functional dyspepsia or overlapping conditions. Additionally, the study was conducted at a single tertiary care homeopathic hospital with a moderate sample size ($n = 80$), which may limit generalizability to broader populations. Future studies incorporating larger, multi-center samples and test-retest reliability assessments would further strengthen external validity.

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Declaration of interest

None

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