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Validation and psychometric evaluation of the Spanish version of Brief Esophageal Dysphagia Questionnaire (BEDQ): Results of a multicentric study

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Abstract

Background: The recently developed Brief Esophageal Dysphagia Questionnaire (BEDQ) evaluates esophageal obstructive symptoms. Its initial evaluation showed strong psychometric properties. The aims of this study were to (a) translate and validate an international Spanish version of BEDQ and (b) evaluate its psychometric properties in a large Hispano-American sample of symptomatic individuals.

Methods: A Spanish BEDQ version was performed by Hispano-American experts using a Delphi process and reverse translation. Patients were prospectively recruited from seven centers in Spain and Latin America among individuals referred for high-resolution manometry (HRM). Patients completed several scores: Hospital Anxiety & Depression Scale (HADS), Eckardt score (ES), Gastroesophageal Reflux Questionnaire (GERDQ), and the BEDQ. Standardized psychometric analyses were performed.

Key Results: A total of 426 patients were recruited. Spanish BEDQ showed excellent reliability (Cronbach's alpha = 0.91). Factor analysis confirmed its unidimensional character. Moderate significant correlations between BEDQ and other symptomatic scores were found, suggesting sufficient convergent validity. Patients with abnormal or obstructive HRM findings scored significantly higher when compared to normal or non-obstructive findings, respectively. Using a cutoff of 10, BEDQ showed a sensitivity of 65.38% and a specificity of 66.21% and an area under the curve of 0.71 for obstructive or major manometric diagnosis.

Conclusions and Inferences: A widely usable Spanish BEDQ version has been validated. We confirm its excellent psychometric properties in our patients, confirming the appropriateness of its use in different populations.

KEYWORDS
Brief Esophageal Dysphagia Questionnaire (BEDQ), dysphagia evaluation, high-resolution manometry, psychometric evaluation, reliability, validity

1 | INTRODUCTION

Dysphagia is a frequent symptom, affecting 3% to 9% of the general population[1,2] and up to 20% in individuals older than 50 years.[3] It is determined by a complex interaction between anatomical, functional/motor, and sensation mechanisms. Given that, there is no objective measure that can fully describe its occurrence, and its grading depends basically on the patient's description.

Patient-reported outcome (PRO) measures are defined as 'any report of the status of a patient's health condition that comes directly from the patient without interpretation of the patient's response by a clinician or anyone else'.[4] As for a laboratory test, the correct use of a PRO requires the previous determination of its reliability (the extent to which it provides stable and consistent results) and validity (the extent to which it measures what it purports to measure).[5] The US Food & Drug Administration (FDA) strongly recommends only the use of PROs that have demonstrated these characteristics in specific populations using psychometric analysis.[6]

The Eckardt score (ES) is the most commonly used PRO to evaluate obstructive esophageal symptoms including dysphagia. It has been extensively used in achalasia[7,8] and other esophageal diseases[9,10] to score symptomatic burden and treatment response. Despite its extensive use, it was not until 2018 that the first psychometric evaluation of ES was published.[11] In that study, Taft showed only fair reliability (with Cronbach's α and Guttmann statistic below 0.7) and validity of ES in achalasia patients. Cisternas et al recently reported that ES showed Cronbach's α of 0.57 and 0.65 in non-achalasia and achalasia, respectively.[12] These studies question the appropriateness of ES use, as it has been suggested that a Cronbach's $\alpha > 0.7$ is appropriate for clinical use.[13]

For that reason, it is relevant to perform a psychometric evaluation of other esophageal symptoms PROs. Recently, Taft et al developed and validated the Brief Esophageal Dysphagia Questionnaire (BEDQ) following FDA recommendations.[14] In its original description in American population, BEDQ showed a very good reliability with Cronbach's $\alpha > 0.7$ and validity, with moderate significant correlations with scores evaluating esophageal symptoms and anxiety. BEDQ scored significantly higher in patients with major manometric findings and obstructive etiologies. The FDA recommendations also suggest that the attributes of a certain PRO (like its reliability and validity) cannot be assumed to be relevant in all the populations in which the instrument is used. In the case of populations from other regions of the world, it recommends the translation and cultural adaptations of the instruments.[6]

The aims of this study are to (a) translate and validate an international Spanish version of BEDQ and (b) evaluate its psychometric properties in a large Hispano-American sample of symptomatic individuals.

Key message

- A Spanish BEDQ translation was developed and validated.
- Principal component factor analysis confirms the unidimensional structure of the original version.
- Spanish BEDQ shows excellent reliability and validity.

2 | MATERIALS AND METHODS

2.1 | BEDQ Spanish version development

One of the researchers (DC) performed an initial BEDQ translation to Spanish. We recruited six experts in esophageal diseases from Latin America and Spain. They participated in a Delphi process, evaluating every phrase of the translation in terms of (a) its congruency with the original English BEDQ version and (b) its comprehensibility in wide populations in their own country. We used a 5-point Likert scale to evaluate agreement with the translation (0 = complete disagreement, 1 = disagreement, 2 = neither agree nor disagree, 3 = agreement, and 4 = complete agreement). We considered a phrase approved if 80% of responses had a score ≥3. Researchers proposed changes for every item they scored 2 or less. Using these comments, a revision of the translation was done and Delphi process was repeated until all items received a score ≥3. This translated version development and validation process have been successfully used in the past, including for Spanish esophageal dysphagia scores.[15] The final Spanish BEDQ version was used to develop a reverse translation (Spanish into English) by an independent professional translator (PC). Finally, both English versions (original and reverse translation) were compared to check that the meaning of every phrase was maintained (DAC and TT).

2.2 | BEDQ psychometric evaluation. Patient selection and gathered information

Participants were prospectively recruited among adult patients referred for a high-resolution esophageal manometry (HRM) due to esophageal symptoms from December 2018 to July 2019. Participant centers were as follows: Clinica Alemana de Santiago (Chile-CAS), Hospital Clínico de la Pontificia Universidad Católica de Chile (Chile—UC), Hospital San Ignacio-Pontificia Universidad Javeriana de Bogotá (Colombia), Hospital Universitari Germans Trias i Pujol-Badalona (Spain—Badalona), Hospital Universitario, Fundación Favaloro-Buenos Aires (Argentina), Hospital Clínico

San Carlos, Universidad Complutense-Madrid (Spain—Madrid) and Universidad Veracruzana, Medical Biological Research Institute-Veracruz (Mexico).

Prior to the HRM study, patients reported epidemiological data (age, gender, the reason for referral, previous foregut surgery) and completed several self-report symptomatic scores (Hospital Anxiety & Depression Scale (HADS), Eckardt score (ES), Gastroesophageal Reflux Questionnaire (GERDQ), and the Brief Esophageal Dysphagia Questionnaire (BEDQ).

The HADS is a 14-item questionnaire aimed to quantify psychological distress, used as a screening tool for anxiety and depression, each corresponding to a specific factor.[16] Each item is rated on a 3-point Likert scale. Points are summed for the whole score and separately for each factor (anxiety and depression). HADS is widely used in different clinical ambulatory situations, including esophageal conditions.[17–19]

The ES is a 4-question measure that evaluates symptom burden in achalasia patients.[20] Each item is scored on a 0-3 scale and total score based on the sum of the four items. Traditionally, a score <3 is considered indicative of successful treatment in achalasia.

The GERDQ is a 6-item score that evaluates GERD symptoms.[21] It evaluates symptoms during the previous 7 days. Each item is rated on a 4-point Likert scale. The score is generated by summing four graded Likert scale items of four positive predictors (scored 0-3) and two reverse Likert scale items of negative predictors (scored 3-0). GERDQ scores >8 are considered positive for a GERD diagnosis.

The BEDQ is a 10-item measure that scores esophageal dysphagia.[14] It includes 8 items that evaluate dysphagia related to different food consistencies, pain, and swallow-related cough over the previous 14 days. Each item is evaluated using a 6-point Likert scale that includes avoidance behaviors. The 8 Likert-scaled items are summed to yield scores ranging from 0 (asymptomatic) to 40, with greater scores indicating greater esophageal dysphagia severity. The BEDQ also includes two extra items that evaluate the number of food impaction and related emergency room visits.

HRM was performed per standard protocol. All studies were analyzed using Manoview ESO 3.0 analysis software (Medtronic). Specific HRM diagnosis and categorization (obstructive, major, minor, and normal) were assigned according to Chicago 3.0 classification (CC 3.0).[22]

The study was approved by each Review Board´s participant center and all participants gave informed consent.

2.3 | Statistical analyses

A priori power analyses (G*Power 3.1) indicated a minimum sample size of 80 was required for the principal components analyses of the BEDQ (10 items per question; 10 × 8) based on standard acceptable samples for principal component factor analysis (PCFA). Additional power analyses indicated a minimum sample of 140 for one-way ANOVA and 352 for two-tailed independent samples *t* test with a medium effect size (d = 0.5), power of $\beta = 0.80$, and statistical significance of $p < 0.05$. For sensitivity/specificity analysis, we calculated a minimum sample size of 250 patients ($\alpha = 0.05$. confidence interval = 0.05 sensitivity and specificity = 0.95). Based on these findings, we aimed to recruit a minimum of 360 participants to the study.

Data from the study were imported from Microsoft Excel to SPSS v26 for Macintosh operating systems (Chicago, IL). Total scores for the BEDQ, GERDQ, HADS Depression, and HADS Anxiety using published guidelines for each scale were calculated. Initial assessment of data normality using standard cutoffs for skewness and kurtosis (±2.0) did not indicate the need for non-parametric tests. Descriptive statistics including mean (SD) for continuous variables and frequency (%) for categorical variables were calculated. Cronbach's alpha measured internal consistency and the Guttman statistic determined split-half reliability of the total BEDQ score. PCFA with Varimax rotation evaluated the subscale structure of the BEDQ for comparison to the original validation study. An eigenvalue >1 determined factor loading. Pearson's correlations determined convergent validity of the BEDQ via relationships with the GERDQ, ES, and HADS. Differences in BEDQ between categories based on CC 3.0 diagnosis (Major, Minor, Normal, or Obstructive) and study center were measured using univariate analysis of variance (ANOVA) with Tukey post hoc test. Differences in BEDQ between CC 3.0 diagnostic category dichotomized as “Normal” or “Abnormal,” genders, and surgical history were measured using independent samples *t*-tests. A receiver operator characteristic analysis was performed to analyze BEDQ performance to predict relevant HRM diagnosis and determine optimal cutoff. Statistical significance was set to $p < 0.05$ for all analyses.

3 | RESULTS

3.1 | BEDQ Spanish translation

The whole translation process occurred between July and August 2018. The original translation document consisted of 28 phrases. In the first round of the Delphi process, 23/28 phrases achieved the defined significant agreement. In the second round, 5/5 phrases achieved agreement. Using all the agreed phrases, a reverse translation was performed. It was unanimously considered to maintain original meaning by the translation team. Appendix S1 shows both final Spanish and original English BEDQ versions. After being used in more than 400 participant patients, there were no blank items. No patient reported any difficulty answering the score.

3.2 | Patients recruited

A total of 426 participants were recruited from the seven participant centers (Chile—CAS: 104 (24.4%), Chile—UC: 58 (13.6%), Colombia: 31 (7.3%), Spain—Badalona: 41 (9.6%), Argentina: 48 (11.3%), Spain—Madrid: 14 (3.3%), Mexico: 102 (23.9%)). Mean age was 52.6 ± 15.2 years and 253/426 (59.6%) were female. All participants

TABLE 1 Pearson's correlations between BEDQ, Eckardt Score, GERDQ, and Psychological Function

	BEDQ	Eckardt score	GERDQ	HADS anxiety	HADS depression
BEDQ	-				
Eckardt score	0.69**	-			
GERDQ	0.30**	0.40**	-		
HADS anxiety	0.28**	0.28**	0.30**	-	
HADS depression	0.35**	0.27**	0.22**	0.69**	-

**$p < 0.001$.

were symptomatic and reasons for referral were as follows: dysphagia 133 (31.2%), GERD 177 (41.5%), GERD and dysphagia 42 (9.9%), chest pain 16 (3.8%), and other 55 (12.9%). 49/426 (11.5%) had any previous foregut surgery.

According to CC3.0, most frequent diagnosis was as follows: normal 235 (55.2%), achalasia 72 (16.9%), ineffective esophageal motility (IEM) 60 (14.1%), absent contractility (AC) 23 (5.4%), and esophagogastric junction outflow obstruction (EGJOO) 21 (4.9%). CC3.0 categories were as follows: normal 235 (55.2%), obstructive 93 (21.8%), major 37 (8.7%), and minor 61 (14.3%).

3.3 | Reliability and factor structure of the Spanish BEDQ

The internal consistency of the Spanish BEDQ was excellent (Cronbach's alpha = 0.91) as was the split-half reliability (Guttman statistic = 0.89). The PCFA yielded one total scale for the eight-item BEDQ, which aligned with the original validation study. Items 9 and 10 were not included in the total score, but retained as modifiers per the original BEDQ scoring guidelines.

3.4 | Validity of the Spanish BEDQ

Relationships between the BEDQ and measures of esophageal dysphagia and GERD symptom severity, anxiety, and depression are presented in Table 1. Small to moderate significant relationships existed between the BEDQ and all measures, indicating sufficient convergent validity of the translated scale. As expected, the highest correlation was with ES.

3.5 | Performance of BEDQ across clinical groups

The BEDQ did not differ by age, but women scored significantly higher than men (Fem: 11.82 vs. male: 8.61, $p = 0.003$). Patients seen in Chile-UC scored significantly higher on the BEDQ than those seen in Argentina, Chile—CAS, and Mexico. As expected, patients diagnosed with obstructive HRM classifications scored the highest on the BEDQ compared with the other CC 3.0 categories (Table 2). Smaller differences existed between major and minor motility disorders, while no differences existed between minor motility disorders and normal manometry patients. When dichotomized as "abnormal" vs. "normal" CC 3.0 diagnosis type, patients in the abnormal category scored significantly higher on the BEDQ (abnormal: 13.50 vs. normal: 8.10, $p < 0.001$). Patients with a history of prior esophagogastric surgery did not differ from those who had not had surgery ($p = 0.19$).

Receiver operator characteristic analysis showed an area under the curve of 0.71 and suggested and optimal BEDQ cutoff value of 10 for obstructive or major manometric diagnosis (Figure 1; Table 3). Using this cutoff, BEDQ showed a sensitivity of 65.38% and a specificity of 66.21% (positive likelihood ratio = 1.94 and negative likelihood ratio = 0.52).

4 | DISCUSSION

Esophageal conditions vary per race. For example, eosinophilic esophagitis shows prevalence and clinical presentation race-related differences.[23,24] This implies PROs are expected to have different behavior in different populations. In this line, the FDA suggests that translation and cultural adaptations of the instruments should be performed.[6] To date, BEDQ has only been evaluated in an American, primarily white population.[14] We present here a validated language and culturally translated version of BEDQ. Spanish is spoken in widely different areas around the globe, with known grammatical and phonetic differences.[25] The translation process described in this study was performed by experts in esophageal diseases from wide different areas of Spain and Latin America. The final version got unanimous acceptance. Even though we did not perform formal cognitive interviews, its use in a large sample from many different regions with no difficulties in understanding and filling the forms suggests that it can be widely used. Neither linguistic nor cultural differences would affect the wide use of this Spanish BEDQ version.

BEDQ was described in 2016 and validated in a large sample of patients, involving several years of recruitment.[14] It was designed with items no included in previous scores (such as ES), like the distinction between different food consistencies and the evaluation of avoidance behaviors. It also includes two items evaluating food impaction. This broader design resulted in good construct validity, including discrimination capacity for major motor esophageal

TABLE 2 BEDQ according to CC 3.0 categories

CC 3.0 Type	BEDQ Mean	SD	Difference	*p*
Obstructive	17.88	11.8	>Major	0.043
			>Minor	<0.001
			>Normal	<0.001
Major	12.69	11.6	>Minor	0.05
			>Normal	0.05
Minor	7.28	9.5	=Normal	0.94
Normal	7.10	9.12	<Obstructive	<0.001
			<Major	0.05
			=Minor	0.94

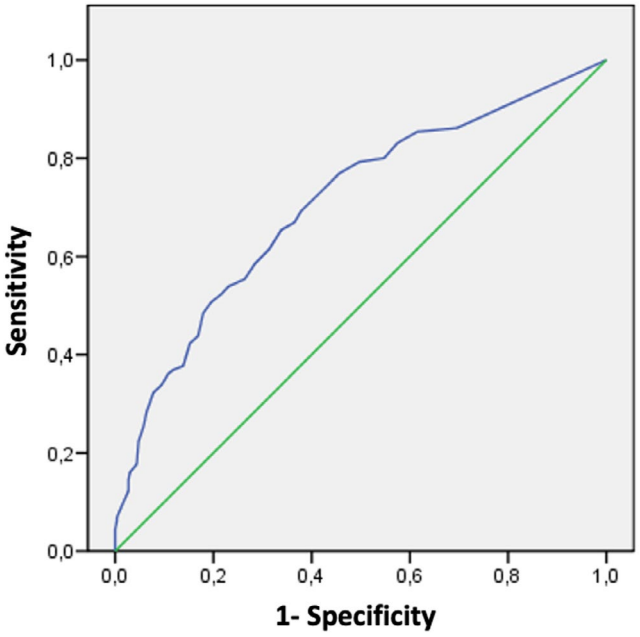

FIGURE 1 ROC curve for BEDQ to predict HRM relevant diagnosis. Receiver operating characteristic (ROC) curve for BEDQ to predict HRM relevant diagnosis. Relevant diagnosis refers to obstructive or major categories. The area under the curve was 0.71

disorders and mechanical obstruction. These qualities have not been described for other scores evaluating esophageal dysphagia. The results of our study are similar to original Taft´s study, including excellent reliability (Cronbach's alpha = 0.91 and split-half Guttman statistic = 0.89) and construct validity. We also confirmed its one-dimensional character. These findings suggest that these good psychometric properties are characteristics of the score per se and can be extrapolated to other populations. We found that in Spain and Latin America, it can be used with confidence as it is a reliable and valid tool.

We found significant correlations with other scores usually used in the evaluation of patients with esophageal symptoms. Not surprisingly, the best correlation was with ES and then GERDQ scores, both evaluating esophageal symptoms. Correlation with GERDQ was greater for ES that BEDQ. This reflects the fact that BEDQ is designed to specifically evaluate esophageal dysphagia and ES includes items evaluating chest pain and weight loss, which are frequent in the context of GERD.[20]

We found that BEDQ scores differently across the HRM spectrum. Patients with obstructive findings had significantly higher BEDQ than all other HRM categories. In the case of the comparison with major motility disorders, this could be due to the fact that hypertensive esophagus and distal esophageal spasm may present with heterogeneous symptoms, including chest pain and GERD symptoms and not only dysphagia.[26,27] In fact, in our series, 15/37 patients with major HRM findings had suspected GERD as the reason for referral. Patients with minor motility disorders had similar BEDQ than patients with normal HRM. This is in line with previous evidence that questions the clinical relevance of minor motility disorders.[28–30] Our group showed in a large sample that minor motility disorders were present in a significant proportion of healthy asymptomatic individuals.[31]

In our series, BEDQ showed a sensitivity and specificity around 66% for predicting a relevant manometric diagnosis. This is nearly identical to the performance characteristics in the initial BEDQ validation study in the American cohort.[14] This situation is similar to EAT-10, that has shown strong psychometric properties[32] but suboptimal sensitivity/specificity when compared to fluoroscopic evaluation of aspiration/penetration.[33] Another example is the repeatedly used GERDQ, which has shown sensitivity/specificity of 66%/64% for an objective GERD diagnosis,[34] but more important, it should be emphasized that the gold standard used is a manometric one and HRM suffers from known limitations when evaluating esophageal dysphagia. In fact, we found that only 30.5% of our symptomatic patients had any relevant HRM finding, but it is in this low yield context that BEDQ can be most useful, as it has a LR (+) of

TABLE 3 BEDQ performance as relevant HRM diagnosis predictor across different cutoffs

Cutoff	Sensitivity (%)	Specificity (%)
4.5	79.23	50.34
5.5	76.92	54.39
6.5	73.85	57.43
7.5	69.23	62.16
8.5	66.92	63.51
9.5	65.38	66.22
10.5	61.54	68.58
11.5	58.46	71.62
12.5	55.38	73.65
13.5	53.85	77.03
14.5	52.31	78.38
15.5	50.77	80.41

Note: Only cutoffs with both specificity and sensibility >50% are shown. Relevant HRM diagnosis includes obstructive and major categories.

1.94 and a LR (–) of 0.52, significantly modifying pretest probability of relevant manometric findings. These values will change with future CC iterations. Nevertheless, it should be emphasized that BEDQ is primarily intended to be used as an esophageal dysphagia grading tool rather than a method to decide when to perform a HRM.

We expect that BEDQ will be helpful in the evaluation of EGJOO. It has been described in normal healthy individuals[31] and has been related to a very good long-term prognosis in patients, even in the absence of any treatment.[35] For that reason, several efforts have been done to determine predictors of "relevant" EGJOO. It has been shown that the lack of dysphagia at presentation is associated with a very low probability of "relevant" EGJOO.[36] It can be speculated that grading esophageal dysphagia using BEDQ could be helpful to better predict it. Studies aimed to specifically evaluate this issue are needed.

Our study has some limitations. We did not perform cognitive interviews to certify that the Spanish BEDQ version is easily understood. On the other hand, we did not have access to more objective data evaluating the esophageal function, like endoscopy and barium studies. Nevertheless, all the data that we found shows very good psychometric properties, remarkably similar to the original BEDQ evaluation in a non-Hispanic population. We had large sample of patients, beyond what was calculated for statistical significance.

In summary, we translated and validated a Spanish BEDQ version, suitable to be used all over Spain and Latin America. We demonstrated robust psychometric properties of this score, reinforcing its characteristics of a reliable and useful tool to quantify esophageal dysphagia.

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CONFLICT OF INTEREST

No competing interests declared.

AUTHOR CONTRIBUTIONS

DC contributed to conception and study design, recruitment, data acquisition, analysis and interpretation, manuscript drafting, editing, critical revision, and final approval; TT contributed to data analysis and interpretation, manuscript editing, critical revision, and final approval; DCA contributed to study conception, data interpretation and manuscript editing, critical revision, and final approval; HM contributed to study design, recruitment, data acquisition, analysis and interpretation, manuscript drafting, editing, critical revision, and final approval; EG, PR, AH, AAF, AL, CB, AD, AV, JA, JRT, ARL, JPD, IM, and JS contributed to patient recruitment, manuscript critical revision, and final approval; all authors approved the final manuscript version.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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