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The Brief Esophageal Dysphagia Questionnaire shows better discriminative capacity for clinical and manometric findings than the Eckardt score: Results from a multicenter study

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Abstract

Introduction: Grading dysphagia is crucial for clinical management of patients. The Eckardt score (ES) is the most commonly used for this purpose. We aimed to compare the ES with the recently developed Brief Esophageal Dysphagia Questionnaire (BEDQ) in terms of their correlation and discriminative capacity for clinical and manometric findings and evaluate the effect of gastroesophageal reflux symptoms on both.

Methods: Symptomatic patients referred for high-resolution manometry (HRM) were prospectively recruited from seven centers in Spain and Latin America. Clinical data and several scores (ES, BEDQ, GERDQ) were collected and contrasted to HRM findings. Standard statistical analysis was performed.

Key Results: 426 patients were recruited, 31.2% and 41.5% being referred exclusively for dysphagia and GERD symptoms, respectively. Both BEDQ and ES were independently associated with achalasia. Only BEDQ was independently associated with being referred for dysphagia and with relevant HRM findings. ROC curve analysis for

Abbreviations: AC, Absent Contractility; ANOVA, Analysis of variance; AUC, Area under the curve; BEDQ, Brief Esophageal Dysphagia Questionnaire; CC, Chicago Classification; DES, Distal Esophageal Spasm; EGJOO, Esophagogastric Junction Outflow Obstruction; ES, Eckardt score; FP, Fragmented Peristalsis; GERD, Gastroesophageal Reflux Disease; GERDQ, Gastroesophageal Reflux Disease Questionnaire; HE, Hypertensive Esophagus; HRM, High-Resolution Manometry; IEM, Ineffective Esophageal Motility; PRO, patient reported outcome; ROC, Receiver operating characteristic.

achalasia diagnosis showed AUC of 0.809 for BEDQ and 0.765 for ES, with the main difference being higher BEDQ sensitivity (80.0% vs 70.8% for ES). GERDQ independently predicted ES but not BEDQ. In the absence of dysphagia (BEDQ = 0), GERD symptoms significantly determine ES.

Conclusions and Inferences: Our study suggests both the BEDQ and ES can complementarily describe symptomatic burden in achalasia. BEDQ has several advantages over the ES in the dysphagia evaluation, basically due to its higher sensitivity for manometric diagnosis and independence of GERD symptoms. ES should be used as an achalasia-specific metric, while BEDQ is a better symptom-generic evaluating tool.

KEYWORDS
achalasia, Brief Esophageal Dysphagia Questionnaire, dysphagia evaluation, Eckardt score

KEY POINTS

- The Eckardt score is the most commonly used metric to evaluate dysphagia, but has shown suboptimal psychometric properties, unlike BEDQ.
- Only BEDQ independently predicts clinical and manometric relevant categories/diagnosis. The Eckardt score is influenced by GERD symptoms, even in the absence of dysphagia.
- BEDQ should be the preferred tool to grade generic dysphagia.

1 | INTRODUCTION

Esophageal dysphagia is a symptom that affects 3–9% of the general population[1,2] and is associated with different diseases. Its standardization/grading is crucial as it guides treatment decisions, defines treatment success, and allows standardization of outcome comparisons between treatment options. Dysphagia may not be clearly correlated with an objective evaluation of esophageal function, making it more of a subjective sensation. In this context, esophageal dysphagia should be evaluated using a patient reported outcome (PRO) assessment tool.[3]

Several PROs evaluate dysphagia, either as a generic or disease-specific tool.[4] Among them, the Eckardt Score (ES) is by far the most used.[5] It was designed in 1992 as a standardized tool to evaluate dysphagia in a study determining response predictors to pneumatic dilation in achalasia.[6] The authors chose to evaluate the frequency or severity of four symptoms: dysphagia, regurgitation, chest pain, and weight loss. The ES has been extensively used to define response to different achalasia treatments[7-9] and, even though it was designed to be an achalasia-specific tool, it has been repeatedly used in nonachalasia conditions including Ineffective Esophageal Motility (IEM),[10] Esophagogastric Junction Outflow Obstruction (EGJOO)[11] and different spastic/hypercontractile disorders.[12,13] Despite the ES's wide use, its psychometric properties have only been evaluated by two recent studies, both showing fair reliability.[14,15] In their latest achalasia guidelines, both the American College of Gastroenterology and the American Society for Gastrointestinal Endoscopy have acknowledged limitations of the ES.[5,16,17] Recently, Taft et al. developed the Brief Esophageal Dysphagia Questionnaire (BEDQ) following FDA recommendations for construction and validation of PROs.[3,18] It is intended to specifically evaluate esophageal dysphagia. Both the original and a recent evaluation of the BEDQ in a large Hispano–American population have shown good validity and reliability, with Cronbach's alpha >0.9.[18,19] Thus, the aims of this study are as follows: (1) Directly compare the ES and BEDQ discriminative capacities for clinical and manometric findings; (2) Evaluate the relationships of the ES and BEDQ score with gastroesophageal reflux symptoms assessed with the GERDQ.

2 | MATERIAL AND METHODS

Seven centers from Spain, Mexico, and South-America participated: (1) Clinica Alemana de Santiago (Chile-CAS), (2) Hospital Clínico de la Pontificia Universidad Católica de Chile (Chile-UC), (3) Hospital San Ignacio-Pontificia Universidad Javeriana de Bogotá (Colombia), (4) Hospital Universitari Germans Trias i Pujol-Badalona (Spain-Badalona), (5) Hospital Universitario, Fundación Favaloro-Buenos Aires (Argentina), (6) Hospital Clínico San Carlos, Universidad Complutense-Madrid (Spain-Madrid), and (7) Universidad Veracruzana, Medical Biological Research Institute-Veracruz (Mexico). Individuals referred for a high-resolution esophageal manometry (HRM) to evaluate esophageal symptoms were recruited from December 2018 to July 2019.

Before performing the HRM, all patients filled forms for epidemiological data and responded to several symptomatic scores, including the ES, Gastroesophageal Reflux Questionnaire (GERDQ), and BEDQ. We used validated Spanish language versions for all the questionnaires.[15,19,20] Reason for referral was extracted from the referring physician's order. When the reason was not available, it was assigned by the local researcher after interviewing the patient before the HRM study.

2.1 | Study questionnaires

2.1.1 | Eckardt score (ES)

The ES is a self-report questionnaire consisting of 4 questions (ES weight loss, ES dysphagia, ES chest pain, and ES regurgitation), each scored on a 0–3 scale (lowest to highest).[6] Total score ranges from 0 to 12 and a value 3, or lower, is traditionally used to define successful treatment in achalasia.[5,6]

The Gastroesophageal Reflux Disease Questionnaire (GERDQ) The GERDQ is a disease-specific PRO consisting of 6 questions, each evaluated using a 4-point Likert scale.[21] It has been extensively validated[20,22,23] and is one of the most used PROs to evaluate GERD. The score is calculated by summing 4-graded Likert scale items of four positive predictors (scored 0–3) and two reverse Likert scale items of negative predictors (scored 3–0). A score >8 is considered positive for GERD diagnosis.

The Brief Esophageal Dysphagia Questionnaire (BEDQ): The BEDQ consists of 10 questions that specifically score dysphagia.[18] The first 8 items evaluate dysphagia frequency and severity related to different food consistencies, pain, and swallow-related cough. Each item is evaluated using a 6-point Likert scale (Low to High) that includes avoidance behaviors. The 8-point Likert-scaled items are summed to yield scores ranging from 0 (asymptomatic) to 40. The BEDQ also includes two extra items that evaluate the number of food impaction and related emergency room visits that are not included in the total score.

2.2 | Physiological assessment

HRM was performed using the standard CC v3.0 protocol. All participant centers use Medtronic system, and all studies were analyzed using Manoview ESO 3.0 analysis software (Medtronic, Duluth, GA). Clinical diagnosis was assigned according to CC v3.0 criteria.[24] We defined a relevant manometric category that includes Distal Esophageal Spasm (DES), Hypercontractile Esophagus (HE), and Absent Contractility (AC). Patients with an HRM classification of EGJOO and IEM were not included due to the clinical inconclusiveness associated with these HRM findings.[25]

All patients signed informed consent before participation. The study was approved by each center's Review Board.

2.3 | Statistical analysis

A priori sample size was calculated using G*Power 3.1.9.2 considering two-tailed analysis with a power $(1 - \beta) = 0.95$ and significance of $p(\alpha) = 0.05$. Medium effects size was assumed using Cohen's criteria.[26] Required sample size was 138, 343, 368, 153, and 409 for Pearson's correlation ($\rho = 0.3$), one-way ANOVA ($f = 0.25$), *t*-test ($d = 0.40$), linear regression ($f^2 = 0.15$) and logistic regression (OR = 1.5. $\beta = 0.10$), respectively. Thus, we aimed to recruit 410 patients.

Statistical analysis was performed using SPSS 15.0 (2006). In the initial evaluation for data distribution, P-P graphs and values of skewness and kurtosis (all values were in the +1 to −1 range) did not indicate the need for nonparametric tests for any of the continuous variables. Descriptive data are displayed using mean ± SD or frequency with percentage, as appropriate. For sensitivity analysis, we used previously suggested thresholds for ES ≥ 4[5,6] and BEDQ ≥ 10.[18] Between-group comparisons were made using *t*-test and one-way ANOVA (continuous) or Chi-square (categorical) analysis, as appropriate. Prediction of dependent variables was done using forced entry linear or logistic regression, as appropriate. Pearson's *r* comparison was done calculating the *t*-statistic for the difference according to Chen et al.,[27] considering a 2-tail test. In all analysis a $p < 0.05$ was required for statistical significance.

3 | RESULTS

3.1 | Study sample

A total of 426 symptomatic patients were recruited from the seven participant centers. Table 1 summarizes demographic and clinical data. The sample was middle aged (52.6 ± 15.2 years) with some female preponderance (253/426, 59.6%). Mean BMI was 26.56 ± 11.91 kg/m^2. The most common CC v3.0 diagnosis were Normal 235 (55.2%), Achalasia 72 (16.9%), and IEM 60 (14.1%).

One hundred and thirty-three patients were referred exclusively for dysphagia evaluation (Table 1). Among this subgroup, Achalasia (42.9%) and Normal (34.6%) were the most common manometric findings, with less than 10% meeting any other CC v3.0 category. These patients scored significantly higher for both scores than patients referred for other reasons (ES: 5.30 (2.90) vs 3.44 (2.49). $t = -6.81$. BEDQ: 17.74 (11.00) vs 7.17 (8.95). $t = -10.49$. $p < 0.0001$ for both). Among patients referred for dysphagia, a significantly higher proportion scored BEDQ ≥ 10 than ES ≥ 4 (97/133 (72.9%) vs 90/133 (67.7%), respectively. $\chi^2(1) = 26.59$. $p = 0.001$). A logistic regression analysis showed that only BEDQ and not ES can independently predict dysphagia as a referral reason (Table 2).

3.2 | BEDQ and ES

In the whole sample, mean (SD) values were 10.47 (10.80) for BEDQ and 4.02 (2.76) for ES. There was a significant, moderate correlation between the two scales ($r = 0.679$. $p < 0.001$). As expected, the only strong correlation between BEDQ and specific ES items was with the dysphagia question ($r = 0.71$. $p < 0.0001$), with all other r being below 0.5 (Supplementary material S1). Using recommended cutoffs (BEDQ ≥ 10 and ES ≥ 4), both scores were significantly associated ($\chi^2 = 112.9$ (1). $p < 0.001$). Nevertheless, there were many discordant results: 36/185 (19.46%) BEDQ ≥ 10 had ES < 4 and 69/241 (28.63%) BEDQ < 10 had ES ≥ 4. Among the 105 cases of discordant results, patients with BEDQ ≥ 10 and ES < 4 had

TABLE 1 Study sample clinical and demographic characteristics

	n (%)
Participant center	
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)
CC3.0 diagnosis	
Normal	235 (55.3)
Achalasia	72 (16.9)
EGJOO	21 (4.9)
IEM	60 (14.1)
DES	8 (1.9)
HE	6 (1.4)
AC	23 (5.4)
FP	1 (0.2)
Referral reason	
Dysphagia	133 (31.2)
GERD	177 (41.5)
GERD and dysphagia	42 (9.9)
Chest pain	16 (3.8)
Other	55 (12.9)

Notes: Clinical and manometric characteristic of the study simple.

Abbreviations: AC, Absent Contractility; DES, Distal Esophageal Spasm; EGJOO, Esophagogastric Junction Outflow Obstruction; FP, Fragmented Peristalsis; HE, Hypertensive Esophagus; IEM, Ineffective Esophageal Motility.

significantly higher proportions of being referred for dysphagia and achalasia/relevant HRM than those with BEDQ < 10 and ES ≥ 4 (Table 3). The latter group had significantly more frequency of GERD referral.

3.3 | Symptomatic scores and manometric findings

Table 1 depicts specific manometric diagnosis in our sample. One-way ANOVA showed that both BEDQ and ES have a different distribution across CC v3.0 diagnosis ($F(7) = 15.34$ and $F(7) = 11.10$, respectively; $p < 0.001$ for both) (Figure 1).

BEDQ showed significantly higher scores when comparing normal to relevant category (DES, HE, and AC) while ES did not (BEDQ: 8.07 (9.11) vs 12.35 (2.56); $p < 0.001$. ES: 3.6 (2.45) vs 3.84 (2.56). $p = 0.59$) (Figure 2). This was concordant with the fact that only BEDQ and not ES independently predicted the presence of a relevant diagnosis in logistic regression (Table 2).

Within the sample, 72 patients met manometric criteria for achalasia. These patients have significantly higher scores on both ES and BEDQ when compared to nonachalasia and to normal manometry (all $p < 0.001$). Both the ES and BEDQ are independently associated with achalasia in logistic regression (Table 2). ROC curve analysis showed AUC of 0.809 for BEDQ and 0.765 for ES (Figure 3). For recognizing achalasia, BEDQ ≥ 10 had a sensitivity of 80.0% and a specificity of 67.5%, while for ES ≥ 4 sensitivity was 70.8% and specificity 66.9%.

3.4 | Scores and GERD symptoms

Both the BEDQ and ES correlate moderately with GERDQ (ES: $r = 0.40$. BEDQ: $r = 0.30$; $p < 0.001$ for both), but this correlation was significantly higher for ES ($p < 0.01$). Among patients referred for GERD symptoms, significantly more patients had ES ≥ 4 than BEDQ ≥ 10 (72/177 (40.68%) vs 44/177 (24.86%), respectively. $\chi^2(1) = 32.5$, $p < 0.0001$). Patients with ES ≥ 4 showed significantly higher GERDQ than those with ES < 4 (8.55 (4.89) vs 4.91 (4.07), respectively. The values $t(424) = -8.73$; $p < 0.001$) and also have a significantly greater proportion of GERDQ > 8 (50.92% vs 17.78%, respectively. $\chi^2(1) = 51.53$, $p < 0.0001$). We also evaluated 108 patients who scored a 0 on the BEDQ to assess the effect of GERD symptoms on ES in the absence of dysphagia. Among these patients, those with ES ≥ 4 had significantly higher GERDQ than those with ES < 4 (8.59 (4.79) vs 4.43 (3.57). $t(106) = 4.53$, $p < 0.0001$) (Figure 4), suggesting that ES can be explained mostly by GERD-related symptoms in the absence of relevant dysphagia.

We also used partial correlation analysis to evaluate independent associations between the scores. When controlling (fixing) ES, BEDQ is no longer correlated with GERDQ ($r = 0.041$. $p = 0.396$), while when controlling (fixing) BEDQ, ES still correlates significantly with GERDQ ($r = 0.28$. $p < 0.001$). Multiple lineal regression confirmed these findings, as GERDQ is an independent predictor of ES and not of BEDQ (Table 4).

4 | DISCUSSION

We aimed to compare the performance of the BEDQ versus the ES in a large cohort of patients presenting for esophageal workup across 7 centers. Patients with achalasia scored significantly higher for both ES and BEDQ. But, more importantly, both the BEDQ and ES can independently predict the finding of achalasia in HRM, suggesting that they are complementary in describing the symptom burden in this disease.

Our study was conducted in different countries, including places where HRM is not widely available, and its costs usually constitute a relevant barrier for patients. Therefore, being referred for dysphagia constitutes a hypothetical good surrogate marker of a significant symptom burden. One main finding of our study is that more of these patients with a relevant dysphagia burden can be detected using BEDQ than ES and, more importantly, only BEDQ is independently associated with this referral reason. We also found that only BEDQ

TABLE 2 Multiple logistic regression analysis for clinical and manometric findings

		Beta	OR (95% CI)	*p* value
Achalasia ($R^2 = 0.17$)	BEDQ	0.72	1.07 (1.04–1.11)	<0.0001
	ES	0.189	1.21 (1.06–1.37)	0.004
Relevant HRM ($R^2 = 0.15$)	BEDQ	0.071	1.07 (1.04–1.09)	<0.0001
	ES	0.081	1.06 (0.95–1.18)	0.319
Dysphagia (referral) ($R^2 = 0.18$)	BEDQ	0.093	1.09 (1.07–1.13)	<0.0001
	ES	0.015	1.02 (0.91–1.13)	0.795

Notes: Relevant HRM includes DES, HE, and AC. For evaluation of each model, R^2 (Cox & Snell) is depicted in parenthesis.

TABLE 3 Clinical and manometric comparisons in patients with discordant ES and BEDQ results

		BEDQ < 10 + ES ≥ 4	BEDQ ≥ 10 + ES < 4	Statistic	*p* value
Referral reason	Dysphagia	17.39%	52.77%	$\chi^2(1) = 17.61$	<0.0001
	GERD	55.07%	27.77%	$\chi^2(1) = 93.57$	<0.0001
Manometric findings	Normal	63.76%	61.1%	$\chi^2(1) = 6.943$	0.008
	Achalasia	8.69%	19.44%	$\chi^2(1) = 59.43$	<0.0001
	Relevant HRM	7.24%	13.80%	$\chi^2(1) = 68.81$	<0.0001
GERDQ (mean (SD))		8.55 (4.35)	6.22 (5.04)	$t = -2.46$	0.083

Notes: Relevant HRM category includes DES, EH, and AC.

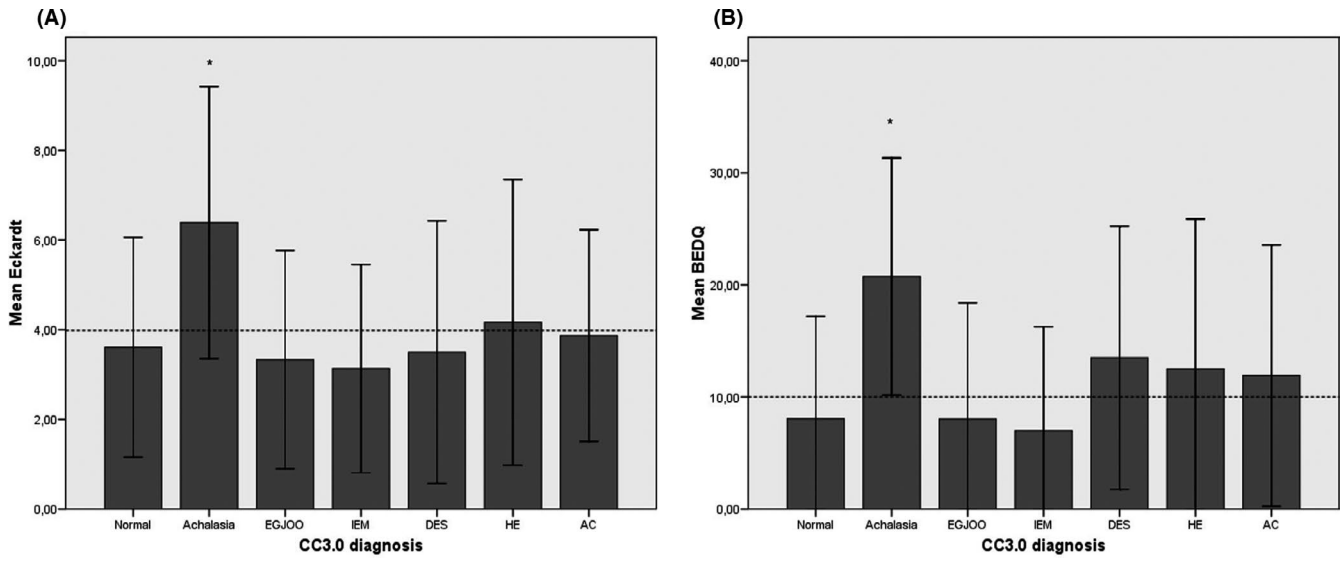

FIGURE 1 ES and BEDQ according to manometric diagnosis. Mean (±1 SD in bars) ES (A) and BEDQ (B) scores across different CC3.0 diagnosis. *$p < 0.001$ for comparison with normal. Dotted lines in the recommended cutoffs for each score

is an independent predictor of relevant HRM diagnosis. Thus, the simultaneous use of ES does not add predictive capacity to the use of BEDQ for these purposes.

We can hypothesize several reasons to explain this significantly better discriminative capacity of BEDQ over ES. First, there are important reliability differences, which refers to the consistency of the results from each score. The most common way to evaluate reliability is via Cronbach's alpha metric. The general consensus is that a PRO should have a Cronbach's alpha ≥0.7 to be used in clinical trials.[4,28] Our groups have recently published psychometric evaluations in large different populations, showing remarkable similar results, with Cronbach's alpha for ES between 0.57 and 0.67[14,15] and between 0.90 and 0.91 for BEDQ.[18,19]

The ES includes the evaluation of regurgitation and chest pain. These symptoms are frequent in achalasia,[29] but are also present in other conditions, like GERD. As the prevalence of GERD is several times higher than that of achalasia[30-32] and other esophageal diseases, the ES positive predictive value is significantly affected. Our study demonstrates that in the absence of relevant dysphagia (when BEDQ = 0), an ES ≥ 4 can be explained by GERD symptoms, and

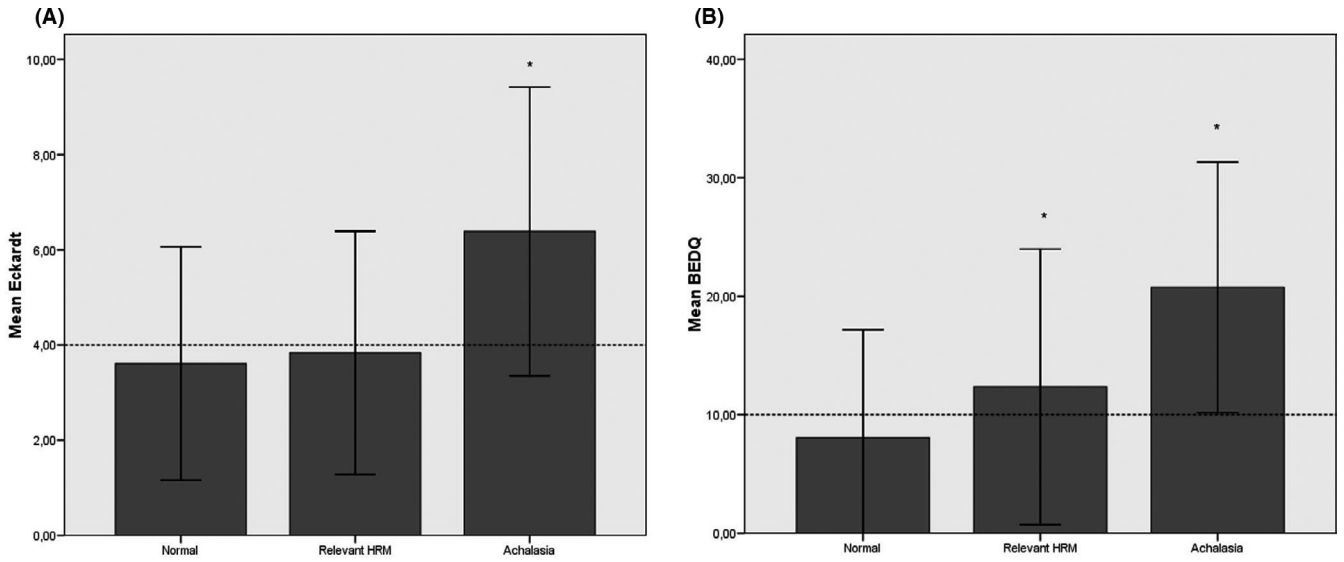

FIGURE 2 ES and BEDQ for achalasia and relevant diagnosis. Mean (±1 SD in bars) ES (A) and BEDQ (B) according to manometric CC3.0 diagnostic/categories. Relevant HRM includes DES; HE and AC. Dotted lines show suggested cutoffs. *$p < 0.05$ versus normal

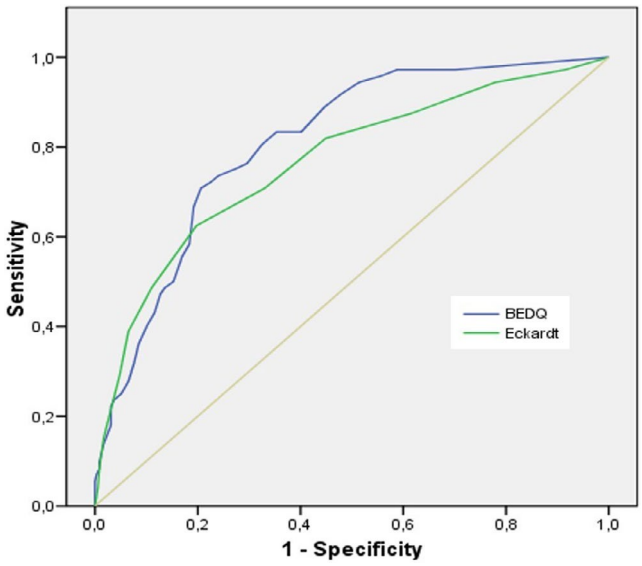

FIGURE 3 ROC curve for achalasia. ROC curve analysis for the discriminative capacity of BEDQ and ES for achalasia

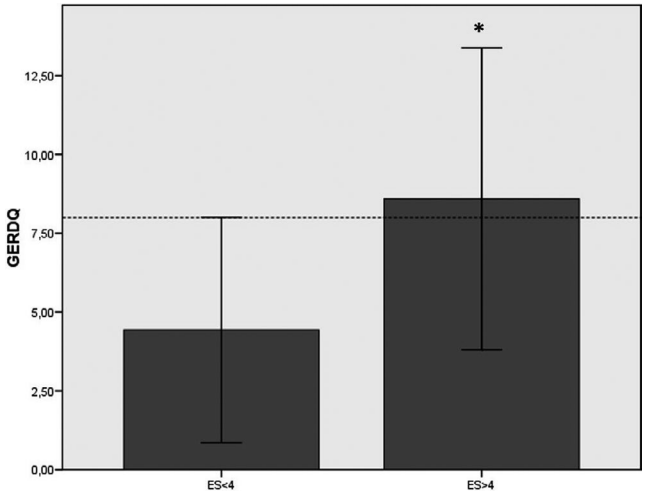

FIGURE 4 GERD according to ES status in patients with no dysphagia. Mean GERDQ (± 1 SD in bars) in patients with no dysphagia (BEDQ = 0), according to ES. *$p < 0.0001$. Dotted line is GERDQ 8, the suggested cut-off

that GERD symptoms are independently predictive of ES. On the other hand, BEDQ repeatedly demonstrated independence of GERD symptoms in our study. As such, a second reason to explain the better BEDQ performance is its higher specificity for dysphagia. From a psychometric point of view, this independence of GERD constitutes a relevant argument in favor of BEDQ discriminate validity.

To increase the sensitivity for dysphagia burden evaluation, the BEDQ was developed explicitly to contain factors not included in previous PROs, like simultaneous evaluation of severity and frequency of symptoms and the presence of avoidance behaviors. The latter has a significant impact in the patient's quality of life and can mask the occurrence of symptoms. Using previously suggested cutoffs, we found a significantly higher proportion of patients with abnormal HRM having high BEDQ than high ES. We also found that BEDQ has a higher sensitivity for achalasia (80% vs 70%). So, a third reason to explain the better performance of the BEDQ is its higher sensitivity.

It should be emphasized that our data should not be interpreted as a recommendation for the use of BEDQ to decide when to perform a manometric study. In fact, the predictive value of a model including only BEDQ is low, for either achalasia or relevant HRM diagnosis. The correct evaluation of the risk of having a relevant HRM diagnosis should also include other data, like some epidemiological and the presence of anxiety and hypervigilance to esophageal symptoms.[33,34] However, our data suggest is that for this multifactorial evaluation, dysphagia burden graduation should be measured using BEDQ.

TABLE 4 Multiple lineal regression for predicting ES and BEDQ

Score		Standardized beta	*T* score	*p* value
ES ($R^2 = 0.50$)	BEDQ	0.615	17.128	<0.0001
	GERDQ	0.216	6.005	<0.0001
BEDQ ($R^2 = 0.46$)	ES	0.666	17.130	<0.0001
	GERDQ	0.033	0.849	0.396

Notes: For evaluation of each model, R^2 (Cox & Snell) is depicted in parenthesis.

The recent CC v4.0 suggests that several manometric diagnosis require the presence of symptoms to be considered clinically relevant (actionable).[35] A final implication of our findings is that BEDQ is potentially a better tool to evaluate the presence of dysphagia than ES.

Our study has several limitations. We only had HRM as the objective evaluation of esophageal dysfunction. Nevertheless, esophageal manometry is traditionally considered a first approach in the evaluation of nonobstructive dysphagia and is more available. We did not have control over the referral of the patients, suggesting some bias risk but probably similar to the risk experienced during routine care in our laboratory. Also, we were underpowered to evaluate the scores in the context of infrequent findings, like DES. Other studies aimed to evaluate specifically these subgroups will be needed in the future. Finally, we used CC v3.0 to classify our patients, as it was the current recommendation at the time of recruitment. The recently published iteration (CC v4.0) has suggested changes in both protocol and criteria. Nevertheless, there were no changes in manometric criteria for achalasia, DES, AC, and HE, which were the diagnosis used in this study.

In summary, we have shown that in the context of achalasia, ES and BEDQ can complementarily describe symptomatic burden. BEDQ has several advantages over the ES in its use as a generic dysphagia evaluation, basically due to its higher sensitivity for manometric diagnosis and independence of GERD symptoms. ES should be used as an achalasia-specific metric, while BEDQ is a better symptom-generic evaluating tool.

DISCLOSURE

José Maria Remes-Troche has served as a member of the advisory board for Commonwealth, Allergan and Carnot; has received grant support for research from Sanfer and Asofarma; and also has served as speaker for Takeda, Allergan, Carnot, and Sanfer. Carlson: Medtronic (speaking; consulting).

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; DAC 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, JPS, 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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