



Cross-Cultural Adaptation, Validation, and Arabic Translation of the Eustachian Tube Dysfunction Questionnaire (ETDQ-7)

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Abstract

Introduction The Eustachian Tube Dysfunction Patient Questionnaire (ETDQ-7) scale is used to assess the effectiveness of the treatment and to determine the severity of the eustachian tube dysfunction (ETD). There is currently no validated Arabic version of the ETDQ-7.

Objectives The aim of the present study is to test the validity and the reliability of a translated Arabic version of the ETDQ-7.

Methods A multicenter prospective validation study was conducted in Riyadh, Saudi Arabia. The ETDQ-7 was adapted and translated into Arabic using a standard validation methodology. Fifty-one patients diagnosed with Eustachian tube dysfunction and 45 healthy individuals were enrolled in the study. The known-groups method was used in the validity analysis. The test-retest method, item-total score correlation, and internal consistency analysis were used for the reliability analyses.

Result The overall internal consistency of the Arabic ETDQ items was measured using Cronbach α (Cronbach $\alpha = 0.803$). The average and total ETDQ scores were significantly higher in the ETD group (17.6) than in the control group (9.87) ($p < 0.001$). The results indicate a good to excellent correlation (> 0.7). The area under the curve for the total ETDQ score was 88.6% (95% confidence interval [CI]: 80.3–96.8%)

Conclusion The Arabic version of the ETDQ-7 scale is a valid instrument for evaluating ETD. It can also be used as an important tool for diagnosis, patient follow-up, and treatment management.

Keywords

- ▶ eustachian tube
- ▶ validation study
- ▶ translation

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Introduction

The Eustachian tube (ET), or pharyngotympanic tube, is an important canal located in the middle ear, linking it with the nasopharynx.¹ Normally, the ET remains passively closed with periodical openings.² The main three functions of the Eustachian tube are to equalize the middle ear pressure with that of the external environment and to provide ventilation and protection.³ Any disruption in these functions can result in Eustachian tube dysfunction (ETD). This condition is quite common, affecting up to 5% of the adults seen in otorhinolaryngology practice, and can have a significant impact on the quality of life of the patient if it becomes chronic.⁴

The main symptom of ETD is a feeling of pressure in the ears or the inability to rapidly equilibrate middle ear pressure. Other symptoms can include muffled hearing, tinnitus or a popping sound in the ear, and a sensation of the ears being clogged or being underwater. The clinical evaluation of these symptoms is subjective; diagnosis of this condition usually emerges as a combination of symptoms and clinical evaluation conducted to estimate the severity of the condition and treatment outcomes.⁵ However, application of ET function tests, such as sonotubometry,^{6,7} forced response test,^{8,9} tubomanometry,^{10,11} videoendoscopy,^{9,12} pressure chamber test,¹³ and inflation-deflation test,⁷ is limited by the need for high-cost equipment and trained staff, which are primarily available in specialized centers.

For this reason, a simple tool, such as a questionnaire, can help the physician to reach a diagnosis of ETD.

McCoul et al.¹⁴ developed the Eustachian Tube Dysfunction Questionnaire-7 (ETDQ-7), a reliable and valid method for clinical applications, as a way to assess ETD severity and treatment outcomes. The ETDQ-7 has been translated into German,¹⁵ Dutch,¹⁶ Turkish,¹⁷ European and Brazilian Portuguese,^{3,18} and traditional Chinese.¹⁹ It has been used for the clinical evaluation of ETD,²⁰ and as an objective measure

of surgical procedure outcomes, such as balloon dilation of the ET.²¹

The aim of the present study was to develop an Arabic version of the ETDQ-7 scale and to examine its validity and reliability.

Methods

Study Design

A multicenter prospective cross-sectional study was conducted in Riyadh between August 2019 and October 2020 to develop an Arabic version of the ETDQ-7 and assess its validity and reliability. The ETDQ-7 includes seven items, responses to which are ranked on a 7-point Likert scale, ranging from 1 (no problem) to 7 (severe problem). The total and average scores are then calculated for each respondent. All the participants filled out the questionnaires twice: first at the time of diagnosis and then 6 weeks later for test-retest reliability.

Questionnaire Translation and Adaptation

The English version of the ETDQ-7 (► Fig. 1) was translated into Arabic by two independent certified translators. These Arabic versions (► Fig. 2) were then checked by two otolaryngologists and compared with the original English version. The two Arabic versions were merged into one version, which was then back translated into English by another independent translator who was not aware of the original English version of the ETDQ-7. There were no significant differences between the back translated version and the original English version.

Subjects

All patients included in the present study were at least 18 years old and native Arabic speakers. The subjects were divided into two groups: an ETD group and a control group.

The Seven-Item Eustachian Tube Dysfunction Questionnaire.

Over the past 1 month, how much has each of the following been a problem for you?							
	No Problem		Moderate Problem			Severe Problem	
1. Pressure in the ears?	1	2	3	4	5	6	7
2. Pain in the ears?	1	2	3	4	5	6	7
3. A feeling that your ears are clogged or "under water"?	1	2	3	4	5	6	7
4. Ear symptoms when you have a cold or sinusitis?	1	2	3	4	5	6	7
5. Crackling or popping sounds in the ears?	1	2	3	4	5	6	7
6. Ringing in the ears?	1	2	3	4	5	6	7
7. A feeling that your hearing is muffled?	1	2	3	4	5	6	7

Fig. 1 Original ETDQ-7 questionnaire, by McCoul et al.

من فضلك أكمل الاستبيان التالي، عن طريق اختيار الرقم الأنسب والذي يعكس مدى تأثرك بالأعراض التالية على مدار الشهر الماضي:

مشكلة سببها جدا			مشكلة متوسطة			لا توجد مشكلة على الإطلاق	
7	6	5	4	3	2	1	ضغط في الأذن
7	6	5	4	3	2	1	ألم في الأذن
7	6	5	4	3	2	1	شعورك بانسداد في أذنيك أو "الشعور وكأنك تحت الماء"
7	6	5	4	3	2	1	أعراض في الأذن عند الإصابة بنزلة برد أو التهاب الجيوب الأنفية
7	6	5	4	3	2	1	الشعور بصوت طقطقة أو فرقعة بالأذن
7	6	5	4	3	2	1	طنين أو رنين في الأذن
7	6	5	4	3	2	1	شعورك بتخفيفات السمع

Fig. 2 Validated Arabic version of the ETDQ-7.

Patients in the former group had been diagnosed with ETD due to their history of at least two of the following symptoms in one or both ears over the preceding month: a sensation of clogged or muffled hearing, aural fullness or pressure, and inability to rapidly equilibrate middle ear pressure. Patients also exhibited abnormal tympanic membrane examination on otoscopy. A pure tone audiogram was performed for all patients at the time of diagnosis

The exclusion criteria included any evidence of recent acute upper respiratory infection, history of ear diseases (such as chronic suppurative otitis media; cholesteatoma; or ear, nose, throat, head, or neck surgery within the previous 3 months), evidence of adenoid hypertrophy, nasal polyposis, or cleft palate.

For the control group, patients who did not meet the ETD group inclusion criteria and who had presented with medical complaints unrelated to ETD were included. All of these patients had a normal tympanic membrane, middle ear, nasal cavity, and nasopharynx on examination. Written informed consent was obtained from each subject, and institutional review board approval was obtained in advance from the Medical Research Center, College of Medicine, Imam Mohammad Ibn Saud Islamic University, Riyadh, Saudi Arabia (Project Number: 38-2019).

Questionnaire Validation and Statistical Analysis

For the reliability of the questionnaire items, Cronbach α was used. A minimum value of 0.7 was considered a measure of good internal consistency. The Pearson correlation was used to assess the test-retest reliability of the items. A receiver operating curve (ROC) was used to assess the predictive power of the total score in predicting the disease condition. The area under the curve (AUC) and the corresponding 95% confidence interval (CI) were calculated. A minimal threshold of 0.7 was deemed acceptable. The Youden index was used to estimate the optimal cutoff point for the total score. Bootstrapping (using 100 bootstrapped samples) was used to validate the cutoff point and performance metrics. The test-retest reliability of the ETDQ items and total score were

assessed using the intraclass correlation coefficient (ICC) for the seven individual items and the total ETDQ score.

Statistical analysis was performed using R v 3.6.3. (RStudio, Inc.: Boston, MA, USA). Counts and percentages were used to summarize the distribution of categorical variables, while the mean \pm standard deviation (SD) were used to summarize the distribution of the questionnaire items. An unpaired *t*-test was used to compare the distribution of questionnaire items between the ETD and control groups. The Epi and cutpoint packages were used for ROC analysis. Hypothesis testing was performed at a 5% level of significance.

Results

A total of 51 patients with ETD and 45 controls completed the questionnaire (**Table 1**). Cases and groups were balanced regarding age ($p=0.314$) and gender ($p=1$). There was a statistically significant difference in the severity of symptoms between both groups ($p<0.001$).

The results showed that the average scores for all ETDQ-7 items (except item 7) were significantly higher in the ETD group compared with controls ($p<0.001$). Similarly, the average and total ETDQ scores were significantly higher in the ETD group than in the control group ($p<0.001$, **Table 2**). All Arabic ETDQ items were significantly correlated with the total ETDQ score ($p<0.001$, **Table 3**). The overall internal consistency of the Arabic ETDQ items, as measured by Cronbach α , was satisfactory (Cronbach $\alpha=0.803$).

The results showed that the self-reported severity of symptoms was higher in cases than in controls (**Fig. 3**). The prevalence of symptoms grades 5, 6, 7 (higher severity) in cases was 12, 22, and 22% for items 1, 3, and 4, respectively. In the controls the percentages were 0, 2, and 0%, respectively. The proportion of respondents who reported moderate symptoms was also higher in cases than in controls, specifically for item 1 (22 versus 4%, respectively). Almost all respondents in the control group responded with 1, 2, and 3.

Table 1 Descriptive statistics for the study sample

	All <i>n</i> = 96	Case <i>n</i> = 51	Control <i>n</i> = 45	Overall <i>p</i> -value
Gender				
Female	41 (42.7%)	22 (43.1%)	19 (42.2%)	1.000
Male	55 (57.3%)	29 (56.9%)	26 (57.8%)	
Age (years old)	31.1 (9.30)	32.0 (9.26)	30.1 (9.33)	0.314
Location of the symptoms				
Both ears	46 (47.9%)	33 (64.7%)	13 (28.9%)	< 0.001
Right ear	15 (15.6%)	7 (13.7%)	8 (17.8%)	
Left ear	14 (14.6%)	11 (21.6%)	3 (6.67%)	
No symptoms	21 (21.9%)	0 (0.00%)	21 (46.7%)	

Table 2 Comparison of Arabic ETDQ scores between cases and controls

	[ALL] <i>n</i> = 96	Case <i>n</i> = 51	Control <i>n</i> = 45	<i>p</i> -value
Ear pressure	2.11 (1.29)	2.84	1.29	< 0.001
Ear pain	1.73 (1.14)	2.25	1.13	< 0.001
Ear clogged	2.41 (1.68)	3.10	1.62	< 0.001
Ear symptoms after cold or sinusitis	2.38 (1.62)	2.90	1.78	< 0.001
Crackling sound in ear	1.78 (1.23)	2.27	1.22	<0.001
Ringing ears	1.96 (1.26)	2.51	1.33	<0.001
Muffled hearing	1.60 (1.16)	1.71	1.49	0.356
Total score	14.0 (6.41)	17.6	9.87	<0.001
Mean score	2.00 (0.92)	2.51	1.41	<0.001

Table 3 Correlation between the ETDQ total score and scores for individual items

	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7
Ear pressure							
Ear pain	0.474***						
Ear clogged	0.576***	0.386***					
Ear symptoms after cold or sinusitis	0.478***	0.408***	0.470***				
Crackling sound in ear	0.503***	0.453***	0.367***	0.230*			
Ringing ears	0.505***	0.438***	0.395***	0.362***	0.510***		
Muffled hearing	0.275**	0.162	0.331***	0.227*	0.158	0.228*	
Mean score	0.791***	0.630***	0.777***	0.709***	0.602***	0.665***	0.444***

Computed correlation used spearman-method with listwise-deletion.

* $p < 0.05$.

*** $p < 0.001$.

The retest questionnaire was completed by 48 of the 51 ETD patients ~ 6 weeks after the first questionnaire. The results indicate a good to excellent correlation (> 0.7), which indicates good test-retest reliability. All ICCs were statisti-

cally significant ($p \leq 0.05$), which indicates that the pretest scores are significantly associated with the post-test scores (► **Table 4**). The results showed an excellent predictive power for the ETDQ total score, with an AUC ~ 0.9 (► **Fig. 4**), which

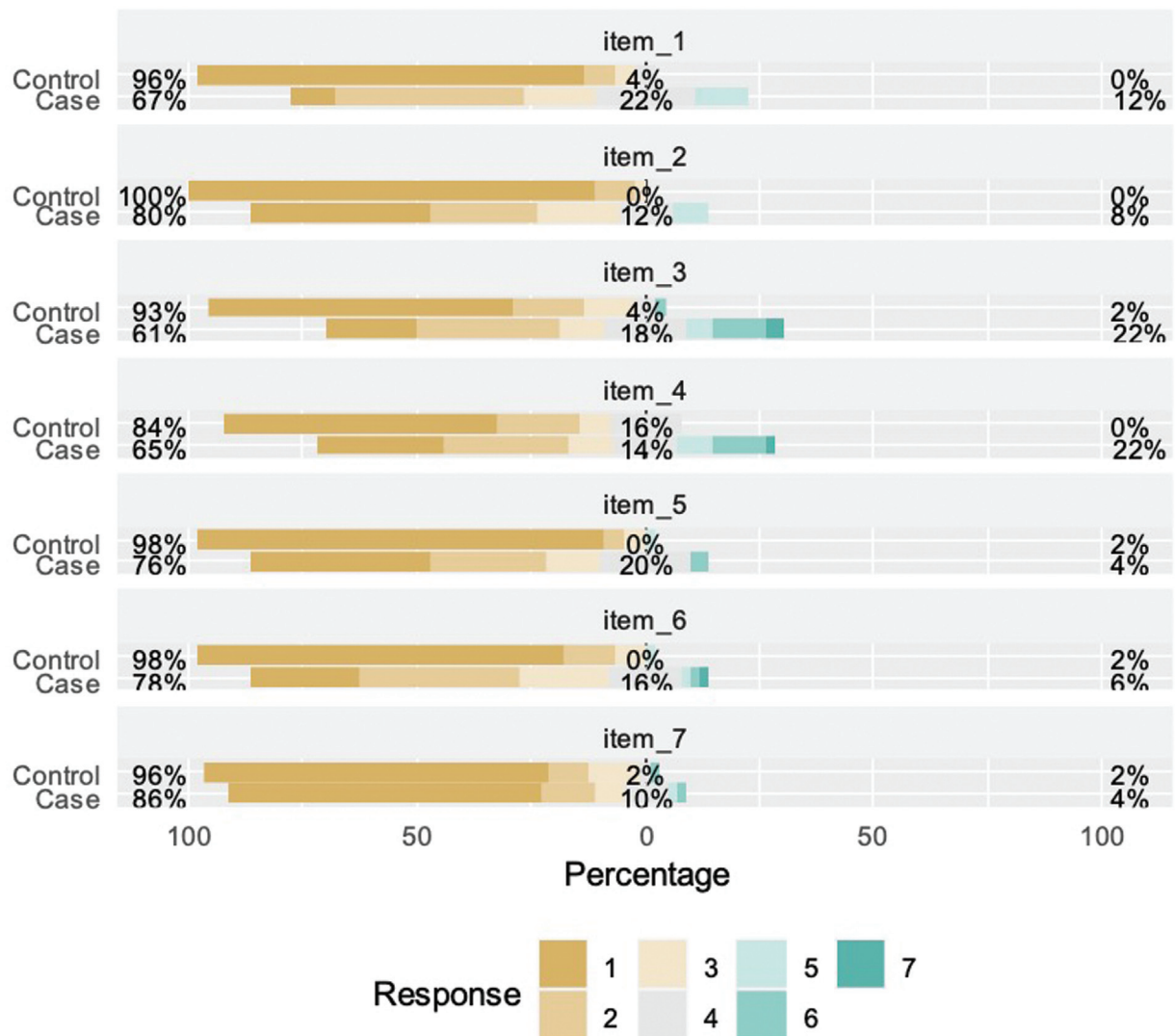


Fig. 3 Likert scale plot for the ETDQ items.

Table 4 Test re-test reliability of the ETDQ items

Item	ICC	95% CI	P
Ear pressure	0.93	0.87–0.96	< 0.001
Ear pain	0.87	0.78 - 0.92	< 0.001
Ear clogged	0.91	0.84 - 0.95	< 0.001
Ear symptoms after cold or sinusitis	0.91	0.85–0.95	< 0.001
Crackling sound in ear	0.90	0.83–0.94	< 0.001
Ringing ears	0.94	0.89 - 0.96	< 0.001
Muffled hearing	0.92	0.86–0.95	< 0.001
total	0.95	0.92 - 0.97	< 0.001

suggests that the Arabic ETDQ-7 can be used to differentiate between patients with and without ETD.

The cutoff value and performance of the ETDQ total score were validated using 100 bootstrapped samples (► Fig. 5).

Model performance was assessed using sensitivity, specificity, positive and negative predictive values (PPV and NPV), accuracy, and AUC (► Table 5). The results showed that a cutoff value of 13 resulted in the best model performance. The AUC for the total ETDQ score was 88.6% (95%CI: 80.3–96.8%).

Discussion

The diagnosis and treatment of ET diseases have been gaining considerable interest worldwide. Various diagnostic tools have been suggested in an attempt to test ET function.¹⁶ Several studies have focused on translating and testing the validity and reliability of the ETDQ-7 in regions like Europe, where various languages are spoken, including German,¹⁵ Dutch,¹⁶ Turkish,¹⁷ and European Portuguese.¹⁸ The EDTQ-7 has also been translated into Brazilian Portuguese³ and traditional Chinese.¹⁹ Since no validated and reliable Arabic version has yet been published in the literature, the present study aimed to develop an Arabic version of the ETDQ-7 scale

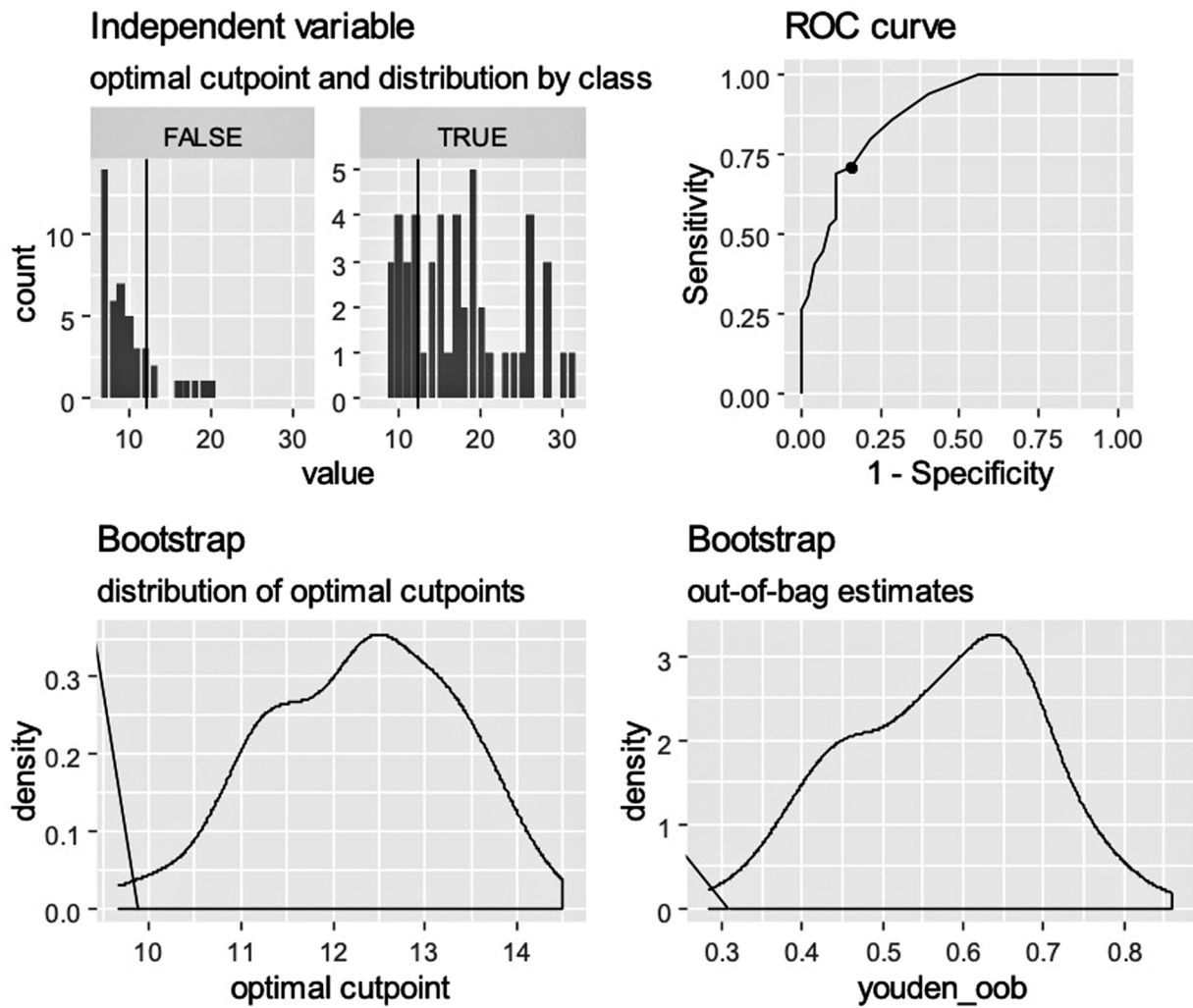


Fig. 4 ROC curve for the ETDQ total score.

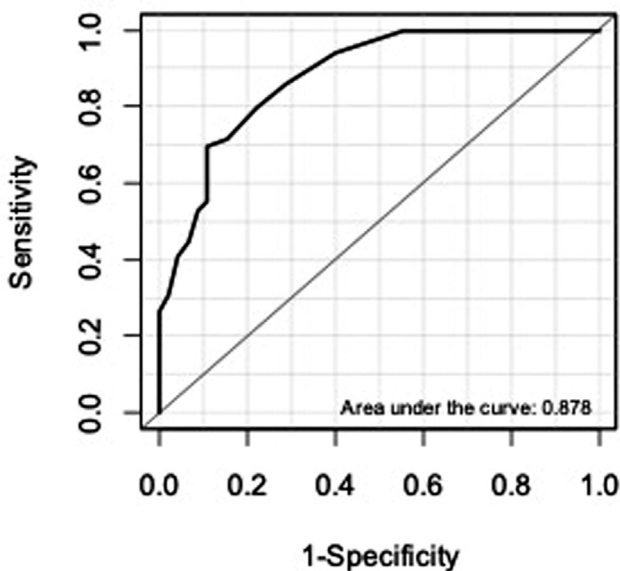


Fig. 5 Validation of the model using bootstrapping (B = 100).

and to examine the validity and reliability of the Arabic version among Arabic speakers living in Saudi Arabia.

The sample was divided into an EDT group (those who met the inclusion criteria) and a control group. Three patients in the EDT group failed to attend their follow-up appointments and, therefore, did not complete the test-retest questionnaire. The results indicate a good to excellent correlation (> 0.7) between measurements taken at the time of the first and second questionnaires, which indicates good test-retest reliability. This is in line with the findings of the study originally conducted to develop the ETDQ-7 (Spearman rank correlation coefficient = 0.78).¹⁴

All ETDQ items (except item 7) were found to be significantly higher in the EDT group compared with the control group ($p < 0.001$), which is similar to the original study.¹⁴ Furthermore, a study conducted in 2015 found that the mean ETDQ-7 total score was 9.91 in a control group and 25.77 in patients with obstructive ET dysfunction, in comparison with our results, which were 17.6 and 9.87, respectively.¹⁶ Item 3 (feeling clogged or “underwater”) had the highest mean score (3.06 ± 1.78), which is consistent with another

Table 5 Validated cut-off value for the total ETDQ score

Cut-off value	Sensitivity	Specificity	PPV	NPV	Accuracy	AUC
≥ 13	71.4%	84.4%	83.3%	73.1%	77.9%	88.6% [80.3% - 96.8%]

study.¹⁷ Item 7 (feeling muffled) had the lowest mean score (1.71 ± 1.27). We believe that the average age in the ETD group (32 ± 9.39 years old) possibly affected the results of all items, especially item 7.

The overall internal consistency in the original study was $\alpha = 0.711$ (95%CI: 0.570–0.818). All items were close to measuring the same underlying construct, and no additional items were deleted from the instrument.¹⁴ In the present study, the internal consistency was sufficiently good (Cronbach $\alpha = 0.803$). In addition, all Arabic questions were significantly correlated with the total score ($p < 0.001$).

Previous studies have reported the AUC to be between 0.95 and 1.0.^{14,15} The results of our study were similar and showed an excellent predictive power for the total score (AUC ~ 0.9), which suggests that the Arabic version of ETDQ-7 can be used to differentiate between patients with and without ETD.

Our current findings suggest that the Arabic version of the ETDQ-7 is a reliable instrument with reproducibility and validity that can be used to assess any native Arabic speaker despite their nation since we used standard Arabic to translate the questionnaire. The limitations of our study include its small population size. In addition, our study did not test pediatric age groups. Therefore, we recommend that future studies include patients in the pediatric age group because of the high incidence of ETD in children.

Conclusion

In conclusion, the Arabic version of the ETDQ-7 is a reliable and valid scale that can be used as an adjunct to the patient history-taking process as a method to evaluate and diagnose ETD. It can also be used as an important tool for patient follow-up.

Conflict of Interests

The authors have no conflict of interests to declare.

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