Malay Language Translation and Validation of the Seven-item Eustachian Tube Dysfunction Questionnaire [ETDQ-7(M)]

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ABSTRACT

INTRODUCTION: Eustachian tube dysfunction (ETD) is commonly left unidentified, and clinicians often had to deal with its consequences. Hence, ETD symptoms should be routinely explored to unmask the diagnosis. The seven-item Eustachian Tube Dysfunction Questionnaire (ETDQ-7) is a user-friendly and disease-specific instrument introduced by McCoul et al. to assess the severity of ETD symptoms and treatment effectiveness. However, there is no Malay version of ETDQ-7 [ETDQ-7(M)] available for local population. This study aims to translate and validate the ETDQ-7 in Malay language. **MATERIALS AND METHODS**: The ETDQ-7 was translated and culturally adapted into Malay language. 68 adult patients with ETD and 68 healthy patients who served as control completed ETDQ-7(M). It was repeated on patients with ETD after two weeks. Statistical analysis was performed to determine the psychometric properties of ETDQ-7(M). **RESULTS**: ETDQ-7(M) displayed excellent internal consistency (Cronbach's α=0.93) which is comparable to the original questionnaire. There was excellent test-retest reliability (r=0.86 – 0.99). No significant difference in total scores was observed between the first and second evaluations. The mean total score for patients with ETD and control group was 25.8 and 8.4 respectively. Discrimination between ETD and control group using a cut-off point of 13.5, yielded sensitivity and specificity of 100% respectively (area under curve=100%). **CONCLUSION**: ETDQ-7(M) is a validated questionnaire recommended for use in the management of ETD as a diagnostic tool and in treatment monitoring with excellent reliability and validity.

INTRODUCTION

The eustachian tube is a dynamic tube extending from the lateral wall of the nasopharynx to the anterior wall of the middle ear cavity. It intermittently opens to ventilate and equalize middle ear pressure, and actively clears middle ear secretions. It is often passively closed to protect the middle ear from loud sounds, pathogens, and secretions from the respiratory tract.[1, 2]

Impairment of any of the functions of the eustachian tube leads to eustachian tube dysfunction (ETD).[2] A series of recent studies reported the prevalence of ETD among the population in United States ranging from 3.25% to 8.25%.[3-5]

Various objective tests of eustachian tube function have been established, including tympanometry, sonotubometry, tubomanometry, tubo-tympano-aerodynamic-graphy, nine-step inflation-deflation test, pressure chamber tesrt and seven-item Eustachian Tube score.[6,7] However, there is no globally accepted gold standard objective test due to their low sensitivity and specificity.[2,6] In addition, these tests require specialized equipment which is not widely available. Hence, Schilder et al. agreed that the diagnosis relies on clinical history and examination.[2]

A disease-specific patient-reported instrument that measures symptoms or quality-of-life is valuable in the absence of a gold standard objective test as it permits repeatable and quantitative assessment of subjective domains.[8, 9] McCoul et al. developed the Seven-item Eustachian Tube Dysfunction Questionnaire (ETDQ-7) in 2012 as a quantitative measurement of ETD symptoms and treatment outcomes.[9] It consists of seven questions which are pressure sensation, otalgia, aural fullness, otological symptoms during upper respiratory tract infection, popping or crackling sound, tinnitus and muffled hearing. These are graded using a seven-item Likert scale with higher score indicating greater severity. The score can be reported as a total, ranging from 7 to 49, or as a mean, ranging from 1.0 to 7.0. Tympanometry was used as the objective measurement in the original study as well as ours in accordance with the consensus statement on diagnosis of ETD by Schilder et al.[2] A cutoff point of ≥ 14.5 (mean ≥ 2.1) indicated the presence of ETD with both sensitivity and specificity of 100%.[9] It has been validated and translated to multiple languages including German, Dutch, Turkish, Hebrew, Portuguese, Traditional Chinese and Danish. Studies with similar study group reported sensitivity of 87 – 100% and specificity of 67 – 100%.[10-18] Malaysia is a multicultural and multiracial country with Malay language as the common language among the population. As ETDQ-7 was originally written in English, cultural adaptation and translation of the questionnaire are required for it to be applied to our local population.[19] ETDQ-7 has not yet been developed in Malay. Hence, we aim to perform a translation, cultural adaptation, and validation of Malay version of ETDQ-7 [ETDQ-7(M)].

METHODS

This is a prospective instrument development study to translate, culturally adapt, and validate ETDQ-7 questionnaire into Malay language. Ethics approval was obtained from Medical Research and Ethics Committee, Ministry of Health Malaysia (NMRR-20-2971-57636) and National University of Malaysia (FF-2021-059).

Translation and Cultural Adaptation Phase

Permission was obtained from the original author for ETDQ-7. ETDQ-7 to be translated to Malay language.[19, 20] Forward translation was done by two bilingual translators, whose mother tongue is Malay language. One translator was aware of the concepts examined while the other was a naïve translator who is neither aware nor informed of the concepts examined and with no medical or clinical background. A common translation was synthesised from both forward translations. Backward translation into English was done by two independent naïve translators. A pre-final translation was synthesised via consensus by the authors and all translators. A preliminary test was conducted utilising the pre-final version of ETDQ-7(M) using 10 patients with ETD to ascertain face validity. The 10 respondents were interviewed on their thoughts on each item and their response to fine-tune the wordings. The final version of ETDQ-7(M) was synthesised based on the feedback. (Table I).

Validation Phase

Patients who attended outpatient clinic of tertiary referral centres of the authors' hospital between January 2021 to June 2022 were enrolled. All patients were above 18 years old. Patients in the ETD group were diagnosed as the consensus statement by Schilder et al. 2015 where patients had two or more of the following symptoms in either one or both ears in the past one month: aural fullness or pressure, sensation of clogged or muffled hearing, inability to rapidly self-equilibrate middle ear pressure after changes in ambient atmospheric pressure was noted, or recurrent or persistent middle ear effusion (defined as an effusion present on examination at least one month apart). Patients also had retracted or dull tympanic membrane on otoscopic examination and a tympanogram of Type B or C.[2]

Patients who presented with symptoms unrelated to ETD and did not fulfil inclusion criteria were enrolled into control group. They also had normal tympanic membrane

on otoscopic examination and tympanogram of Type A.

Exclusion criteria includes history of head or neck surgery in the past 3 months, history of radiation therapy to head and neck region, sinonasal malignancy, recent or ongoing upper respiratory tract infection, adenoid hypertrophy, nasal polyposis, cleft palate or history of cleft palate repair, craniofacial syndromes, cystic fibrosis, ciliary dysmotility syndrome or other systemic immunodeficiencies.

Written informed consent was obtained from all patients. Both groups completed the self-administered ETDQ-7(M) and the ETD group repeated the questionnaire after 2 weeks without any treatment in the interval.

Sample size (n) was calculated from nomograms for sensitivity and specificity by Carley et al.[21] By taking the confidence interval of 0.05, prevalence of disease in test population of 0.5, n for sensitivity of 95% was 136 while n for specificity of 95% was 130. Therefore, a sample size of a larger number, n=136 was taken with 68 patients with ETD and 68 patients as control group. The sample size calculated is adequate for t-test statistics.

STATISTICAL ANALYSIS

All statistical analysis was performed using Statistical Package for Social Sciences (SPSS) Version 26.0. All p value < 0.05 is considered as statistically significant.

Descriptive statistics was calculated for all data, where frequency and percentage calculated for categorical data, and mean, median, standard deviation and ranges for continuous data. Comorbidities and nasoendoscopic examination findings were compared between the groups using either Pearson Chi-square or Fisher's exact test.

Internal consistency reliability of the translated questionnaire was assessed using Cronbach's alpha. A minimum value of 0.7 was considered as good internal consistency. Test-retest reliability was assessed using intraclass correlation based on two-way mixed-effect, absolute agreement, single-rating for each individual question and average-rating for the sum of the scores. Intraclass correlation of less than 0.5 indicates poor

reliability, 0.5 to 0.75 indicates moderate reliability, 0.75 to 0.9 indicates good reliability and more than 0.9 indicates excellent reliability. Both evaluations were further assessed using paired sample t test. Criterion validity between both groups was assessed using independent sample t test and receiver operating curve (ROC). The area under the curve (AUC) was calculated. A 0.7 minimum threshold was regarded as acceptable.

RESULTS

The mean (±SD) age of ETD and control groups were 50.3 (±16.5) years and 35.8 (±9.2) years respectively. Both groups comprised of 27 (39.7%) males and 41 (60.2%) females respectively.

Aural fullness or pressure was the commonest symptoms reported by 54 (79.4%) of patients in the ETD group. Other symptoms reported by the rETD group in descending frequency were tinnitus, 46 (67.6%); muffled hearing, 42 (61.8%); feeling of clogged ears or "underwater", 32 (47.1%); crackling or popping sounds in the ears, 21 (30.1%); inability to rapidly self-equilibrate middle ear pressure following changes in ambient atmospheric pressure, 19 (27.9%); ear symptoms when having a cold or sinusitis, 14 (20.6%); and earache, 9 (13.2%).

Of the 136 ears examined in the ETD group, 35 (25.7%) ears had normal tympanic membrane appearance, 64 (47.1%) ears had retracted tympanic membrane, and 37 (27.2%) ears had dull tympanic membrane. As for tympanometry assessment, 36 (26.5%) ears had Type A, 87 (64.0%) ears had Type B, and 13 (9.6%) ears had Type C. All ears in control group had normal tympanic membrane appearance and type A tympanogram.

The overall internal consistency reliability analysis for the entire ETDQ-7(M) questionnaire yields a Cronbach's alpha of 0.93 which was excellent. All 68 patients in the ETD group completed both evaluations after two weeks interval without treatment in between. The test-retest reliability of ETDQ-7(M) revealed strong correlation between the scores of both evaluations answered by the same patient over time (r=0.86–0.99, p<0.01).

Table I The Malay language Seven-Item Eustachian Tube Dysfunction Questionnaire [ETDQ-7(M)] with the original English version.

Berapa terukkah simptom di bawah telah menjadi masalah kepada anda dalam sebulan lepas?	Tiada Masalah		Masalah Sederhana			Masalah Teruk	
Over the past 1 month, how much has each of the following been a problem for you?	No Problem		Moderate Problem			Severe Problem	
1. Rasa seperti ada tekanan dalam telinga? Pressure in the ears?	1	2	3	4	5	6	7
2. Sakit dalam telinga? Pain in the ears?	1	2	3	4	5	6	7
3. Perasaan telinga tersumbat atau "seperti dalam air"? A feeling that your ears are clogged or "under water"?	1	2	3	4	5	6	7
4. Simptom telinga semasa selsema atau resdung? Ear symptoms when you have a cold or sinusitis?	1	2	3	4	5	6	7
5. Bunyi keresek atau "pop" dalam telinga? Crackling or popping sounds in the ears?	1	2	3	4	5	6	7
6. Bunyi berdesing dalam telinga? Ringing in the ears?	1	2	3	4	5	6	7
7. Perasaan bahawa pendengaran terjejas? A feeling that your hearing is muffled?	1	2	3	4	5	6	7

Furthermore, there were no significant differences between the scores of both evaluations ($p > 0.05$). (Table II)

Table II Comparison between test and retest evaluations with test-retest reliability for ETDQ-7(M). ETD, eustachian tube dysfunction; CI, confidence interval.

Items	Test evaluation Mean ± SD	Retest evaluation Mean ± SD	Paired t-test		Intraclass correlation	
			t	P	r (95% CI)	p
Question 1	4.2 ± 1.4	4.2 ± 1.3	-0.34	0.73	0.86 (0.79 – 0.91)	<0.001
Question 2	2.4 ± 1.5	2.3 ± 1.6	0.85	0.40	0.93 (0.89 – 0.96)	<0.001
Question 3	3.8 ± 1.7	3.9 ± 1.7	-1.22	0.23	0.92 (0.87 – 0.95)	<0.001
Question 4	3.2 ± 1.7	3.1 ± 1.7	0.94	0.35	0.95 (0.93 – 0.97)	<0.001
Question 5	3.8 ± 1.6	3.8 ± 1.6	-0.45	0.66	0.94 (0.90 – 0.96)	<0.001
Question 6	4.0 ± 1.6	4.1 ± 1.6	-1.00	0.32	0.96 (0.93 – 0.97)	<0.001
Question 7	4.5 ± 1.8	4.5 ± 1.7	-0.19	0.85	0.93 (0.89 – 0.96)	<0.001
Total score	25.8 ± 7.3	25.9 ± 7.1	-0.56	0.58	0.99 (0.98 – 0.99)	<0.001

The mean total score of ETDQ-7(M) was 25.8 (±7.3) for the ETD group and 8.4 (±1.7) for the control group. The total and individual scores of the ETD group were significantly greater than those of the control group (p<0.001). (Table III) ROC analysis demonstrated excellent discriminative ability of ETDQ-7(M) with the optimal cut-off of 13.5 (mean 1.9), yielded both sensitivity

Table III TDQ-7(M) scores by item. ETD, eustachian tube dysfunction.

Items	ETD group Mean ± SD	Control group Mean ± SD	Independent t-test	
			t	p
Question 1	4.2 ± 1.4	1.2 ± 0.4	16.86	<0.001
Question 2	2.4 ± 1.5	1.1 ± 0.3	7.05	<0.001
Question 3	3.8 ± 1.7	1.1 ± 0.4	12.92	<0.001
Question 4	3.2 ± 1.7	1.4 ± 0.8	7.71	<0.001
Question 5	3.8 ± 1.6	1.2 ± 0.4	13.43	<0.001
Question 6	4.0 ± 1.6	1.3 ± 0.5	13.16	<0.001
Question 7	4.5 ± 1.8	1.2 ± 0.5	14.79	<0.001
Sum	25.8 ± 7.3	8.4 ± 1.7	19.09	<0.001

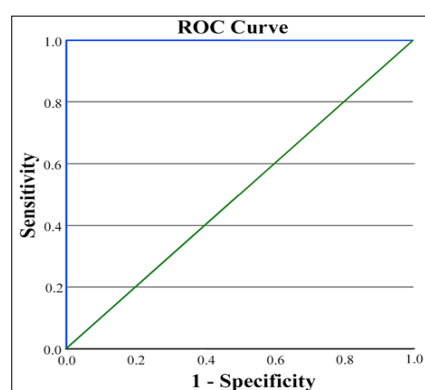and specificity of 100% respectively (Area under curve = 100%, p < 0.001). (Figure 1)

Figure 1. Receiver operating characteristic (ROC) curve for ETDQ-7(M) in determining ETD. Area under the curve = 100% (p < 0.001).

DISCUSSION

ETDQ-7 has undergone multiple validation studies with variable results. Smith et al. reported an excellent internal consistency reliability with Cronbach's alpha of 0.89. Discrimination between patients with ETD and healthy controls demonstrated sensitivity of 87% and specificity of 91% based on clinical diagnosis. However, the specificity dropped to 33% when compared with controls with otological symptoms, namely Meniere's disease and sensorineural hearing loss.[23] Teixeira et al. demonstrated a sensitivity of 70% and specificity of 100% to discriminate between patients with ETD and healthy controls based on clinical diagnosis. The lower sensitivity is postulated due to symptoms of ETD being negated in those with tympanostomy tube and tympanic membrane perforation.[7] Parsel et al. suggested that tympanometry alone, with sensitivity of 98.4% and specificity of 53.2%, may be insensitive to detect less severe ETD as documented by ETDQ-7 score.[24]

ETDQ-7 has been translated to nine other languages with good consistency and discriminant validity. (Table IV)[10-18] Our study has a comparable internal consistency reliability with other studies which reported Cronbach's alpha of 0.71–0.92. Other studies reported a cut-off point of 13.5–14.0 having excellent sensitivity of 90.7–100% and specificity of 67.0–99.9%.[9-18] This was similarly seen in our study.

ETDQ-7(M) reported an excellent predictive power for total score (AUC=1.0) suggesting that the Malay version of the ETDQ-7 is a reliable instrument with replicability and plausibility that can be used to evaluate any native Malay speaker regardless of nation. This is comparable to other studies which reported AUC ranging from 0.93 to 1.0 (Table V). [9-18]

A key limitation of our study is the lack of a universally accepted gold standard objective test to assess construct validity. Further studies are needed to identify a robust objective test which directly measures eustachian tube function. Additionally, as comparison was made between ETD patients and healthy controls, further studies are needed to determine its discriminative value among patients with otological conditions of similar non-specific symptoms, for example Meniere's disease, sensorineural hearing loss and superior semicircular canal dehiscence.

Allergic rhinitis, being a significant risk factor for ETD, has the highest incidence in children.[25] As ETDQ-7 was not designed for children, there is an absence of disease-specific patient-reported instrument in the management of ETD for paediatric age group. Further studies are needed to evaluate and adapt ETDQ-7 for application in the paediatric age group.

CONCLUSION

The ETDQ-7(M) is a validated instrument that has been culturally tailored for the Malay-speaking population. It is a solid and reliable complement to the management of ETD, both in establishing the diagnosis and monitoring the effectiveness of treatment.

DECLARATIONS

This manuscript has been presented at the 14th Malaysian International ORL-HNS Congress & 42nd Annual General Meeting of MSO-HNS and won the Best Presentation Award 2022.

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Table IV Comparison of different languages of ETDQ-7. ETD, eustachian tube dysfunction.

Study	Language	Number of Subjects		ETDQ-7 cut-off score	Cronbach's α	AUC (%)	Sensitivity (%)	Specificity (%)
		ETD	Control					
McCoul et al., 2012	English	50	25	14.5	0.711	100	100	100
Schröder et al., 2014	German	43	100	14.5	-	98.8	90.7	95
Van Roeyen et al., 2015	Dutch	47	22	14.5	0.795	95	-	-
Gunes et al., 2017	Turkish	38	47	14.0	0.89	93.4	97.4	89.4
Özgür et al., 2018	Turkish	40	40	14.5	0.714	-	-	-
Ungar et al., 2018	Hebrew	16	99	14.0	0.918	95.8	91.9	87.5
Gallardo et al., 2019	Brazilian Portuguese	20	30	14.0	0.762	98.0	95.0	96.7
Menezes et al., 2020	European Portuguese	50	25	14.5	0.896	-	-	-
Lin et al., 2020	Traditional Chinese	30	30	13.5	0.717	99.8	100	99.9
Hansen et al., 2020	Danish	34	48	14.5	0.77	94	100	67
Current study, ETDQ-7(M)	Malay	68	68	13.5	0.926	100	100	100

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