

Translation and Validation of the Eustachian Tube Dysfunction Questionnaire (ETDQ-7) into the Malay Language

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ABSTRACT

Introduction: Chronic Eustachian tube dysfunction (ETD) is the pathophysiologic basis of many middle ear diseases. Unfortunately, there is a lack of diagnostic tools for this condition. The ETDQ-7 is basically a 7-item questionnaire that has been consistently studied and proven to be reliable and valid for the evaluation and diagnosis of Eustachian tube dysfunction. We aim to translate the ETDQ-7 into a Malay language version and determine its validity. **Methods:** This cross-sectional study was carried out in the Department of Otorhinolaryngology, Head and Neck Surgery, University Sains Malaysia, from March 2020 until January 2021. A translated Malay language version of the ETDQ-7 (BM-ETDQ-7) was produced following rigorous forward and backward translation. The BM-ETDQ-7 underwent face validity (FV) testing in 10 patients. Following a satisfactory (0.83) FV index, 126 participants were recruited to complete the BM-ETDQ-7, including 60 participants with ETD and 66 healthy control participants. Participants grouped in ETD were those who had positive ETD complaints and abnormal tympanograms. A subset of participants from both groups repeated the BM ETDQ-7 within a time frame of 2 weeks. **Results:** Internal consistency testing of the translated ETDQ-7 yielded a Cronbach α value of 0.878. Test-retest reliability showed a good ICC coefficient (>0.9), and a good correlation ($r > 0.8$). The BM-ETDQ-7 showed good discrimination between both groups with a significantly higher total mean score (SD) of 26.12 (6.17) in the ETD group as compared to 11.94 (3.83) in the non-ETD group. A score of 17.5 was found to be the optimal value to differentiate both groups. **Conclusion:** The present study showed good reliability and validity of the BM-ETDQ-7 when applied to both ETD and healthy participants. We recommend the use of the BM-ETDQ-7 in clinical practice among the Malay language-speaking population.

KEYWORDS: Eustachian tube dysfunction, ETDQ-7, translation, Malay Language, validation

INTRODUCTION

The eustachian tube (ET) plays an important role to maintain the equilibrium of the pressure of the middle ear (ME) with regard to environmental pressure changes. The (adult) human ET measures about 3-4 cm and can be divided into the bony part and fibrocartilaginous part [1]. Basic functions of the Eustachian tube are pressure equalization and ventilation of the middle ear, mucociliary clearance of secretions from the middle ear, and protection of the middle ear from sounds, pathogens, and secretions from the nasopharynx. [2].

Eustachian tube dysfunction (ETD) affects roughly up to 1-5% of the adult population and this condition can significantly impact the quality of life [3]. Participants may present with a wide variety of symptoms such as aura fullness, tinnitus, popping discomfort and occasionally ear pain and discomfort, autophony and muffled hearing.

The clinical assessment of participants with suspected ET dysfunction is subjective based on a wide variety of clinical complaints, physical examination, and some ancillary tests such as tympanometry, tuning

fork test, pure tone audiometry and nasopharyngoscopy. A recent consensus by Schilder et al. regarding ETD agreed that individual signs and symptoms cannot be used reliably to diagnose ETD [4]. Only by using a combination of clinical symptoms and signs supported by ancillary tests are clinicians able to diagnose and classify the subtypes of ETD. Tympanometry is a good tool to demonstrate ETD by revealing a negative ME pressure or Jerger type C pattern. However, it should be noted that this test is made at a single point, and a normal ME pressure may not exclude obstructive or patulous ETD [5]. Furthermore, tympanometry is not a tool that is readily available in primary care.

Nasopharyngoscopy are helpful in the case of inflammatory or dilatory ET dysfunction, where examination may reveal an inflamed Eustachian tube orifice or obstructive masses in the area of the ET as in the case of nasopharyngeal carcinoma, enlarged adenoid tissues or other tumours encroaching the tubal orifice. Again however, this tool is not readily available in primary care settings. Imaging techniques such as Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) are not recommended for routine use for diagnosing ETD outside of research settings [6].

ETD can negatively affect a person's quality of life and have financial repercussions. The symptoms of ETD, such as ear pain, hearing loss, and dizziness, can affect a person's ability to communicate, focus, and perform everyday activities. Additionally, anxiety, depression, and social isolation can result from these conditions. ETD can result in side effects like repeated ear infections, which may necessitate medical attention and time away from work or school. Direct medical expenses as well as indirect costs like lost output and reduced earning potential may result from this. Furthermore, there may be related costs, such as medication and healthcare expenditures, with ETD treatments like nasal sprays, decongestants, and surgery. As a consequence, ETD can significantly affect a person's quality of life and result in financial hardships. Seeking early medical care and successful treatment can help to mitigate these impacts.

ETD can significantly impact a person's quality of life, and diagnosis is typically made through clinical assessment. New techniques such as eustachian tuboplasty or balloon dilatation are emerging for the

treatment of ETD. To assess symptoms related to ETD, Mc Coul et al. developed a questionnaire known as the Eustachian Tube Dysfunction Questionnaire-7 (ETDQ-7). The questionnaire consists of 7 items related to symptoms of ETD and a scale of response ranging from 1 to 7, with "7" corresponding to maximum symptom severity. The questionnaire is modelled on other popular questionnaires such as the Otitis Media 6-Item Quality-of-Life Survey (OM-6) and 20-Item Sino-Nasal Outcomes Test (SNOT-20). The author has found that the total item score cut point of ≥ 14.5 versus < 14.5 or a mean score of ≥ 2.1 (for categorizing a participant as having ETD) provided 100% sensitivity and 100% specificity of differentiating participant with or without ETD.

ETDQ-7 has been extensively validated not only in another English study [8] but has also been translated and validated in other languages such as German [9], Brazil [3], Turkish [10], Danish [11] and Portuguese [12]. All these studies reported a valid and reliable tool after translation.

The main advantage of ETDQ-7 is that it allows for quantitative measurement of symptoms rather than getting a clinical history alone. Quantification of symptom score allows for assessment of disease severity, follow-up, and monitoring of treatment outcome. As the questionnaire was originally published in English, there is a need to translate it into Bahasa Malaysia (Malay language) so that it can be culturally adapted to our country and the translated questionnaire can be used with the existing standards for diagnosing ETD which is via a combination of history, clinical examination and supportive ancillary test [4]. The translated and validated Malay language version of ETDQ-7 will facilitate early detection and treatment to help prevent the sequelae of ETD, and it should be readily available to be used not only by the otorhinolaryngologists (ORL) specialists, but even the general practitioners and the medical supporting staff, i.e., staff nurses and medical assistants.

MATERIALS AND METHODS

Sample size calculation

Face validity testing was used as the choice of our initial pilot testing, with a minimal sample size of 10 participants based on a study by Yusof MSB et al. [13].

For internal consistency testing, minimal sample size calculations were based on the general rule-of-thumb of 10 subjects per variable [14]. Minimal sample size in our 7-item questionnaire was 70 samples. For discriminant validity testing, minimal sample size taken were based on sensitivity and specificity formula [15] for obtaining a Receiver Operator Curve (ROC). We estimated a sensitivity and specificity of are 0.950 and 0.950, respectively. Local study on the prevalence of otitis media effusion is 18.3% were taken to reflect the prevalence of ET dysfunction in our local area [16]. When Type I error probability and precision were taken as 0.05 and 0.1, with an additional 20% dropout rate, the minimal sample size was 125 samples. Preceding translational studies of ETDQ-7 [7,10,11,12] used sample sizes ranging from 30-50 subjects in the ETD group and 20-60 in the control group. We used a minimal sample size of 50 for both groups. Therefore, a minimal sample of 125 is required for sensitivity and specificity testing. We believe the minimal sample size incorporating the prevalence of disease into the sample size calculation for sensitivity and specificity, as proposed by Bruderer et al., should be used. [15] We have chosen a minimal sample size based on this formula since the other minimal sample sizes calculated for other objectives of study are relatively smaller in number.

The sensitivity and specificity discriminatory study of the ROC analysis and determining the area under curve (AUC) is the most important part of our project, as it not only correlates with clinical confirmation of ETD, but also to estimate a sensitive and specific cut-off point between ETD vs non-ETD groups in our local setting.

Subjects, Location and Time

Participants were prospectively enrolled from the Otorhinolaryngology Clinic in Hospital Universiti Sains Malaysia. All subjects recruited presented to the clinic from March 2020 till January 2021. Participant recruitment was determined by randomly recruiting 10 Malay-speaking natives in the outpatient clinic, followed by a complete protocol of physical examination, otoscopy, nasoendoscopy, tympanometry, and answering the Malay language ETDQ-7. All data was collected and keyed into a "Pro-Forma" document,

and further confirmed by the attending otorhinolaryngologist.

Inclusion and Exclusion Criteria

For inclusion criteria, all participants in this study were at least 18 years old and were able to read in the Malay language. They are included into 2 groups (ETD and non-ETD). Participants included in the ETD group were those who presented with a history of at least two of the following symptoms in one or both ears over the previous 1 month period: aural fullness or pressure, a sensation of clogged or muffled hearing, recurrent or persistent middle ear effusion (defined as an effusion present on examinations at least 1 month apart), or the inability to rapidly self-equilibrate middle ear pressure following changes in ambient atmospheric pressure and had a retracted or poorly mobile tympanic membrane on pneumatic otoscopy. This group must have abnormal tympanograms. Another group of participants who did not fulfil the inclusion criteria for the ETD group are those who presented to the clinic with complaints not related to the ET. They were enrolled as a non-ETD group. The non-ETD group are participants who do not present with symptoms pertaining to ET dysfunction and must have a normal otoscope, nasoendoscopic finding and normal tympanogram. Participants excluded from the study are those who have had recent surgery of the head or neck within the last 3 months; history of radiotherapy at the head and neck region; evidence of acute upper respiratory infection, including uncontrolled allergic rhinitis, acute sinusitis, acute otitis media, or active chronic suppurative otitis media; cleft palate or history of cleft palate repair; or craniofacial syndrome, including Down syndrome.

Procedures: Translation of ETDQ-7 into Malay Language

Forward translation from English to Malay language was done by a professional translator from the School of Languages, Literacy and Translation USM. The forward Malay language draft was then back translated to English by a different professional translator from School of Languages, Literacy and Translation USM. The forward and backward translated draft were reviewed by a panel of experts consisting of a Rhinologist, Otologist and Audiologist and reconciled before producing the final translation of ETDQ-7 (Table 1).

Table 1 The original English version and the Malay language version of ETDQ-7

Item No.	Original English Version	Final Malay Language Version
	During the past 1 month, how much of a problem were each of the following?	Dalam masa sebulan , sebanyak mana skor masalah yang anda hadapi?
Item 1.	Pressure in the ear?	Rasa tekanan dalam telinga?
Item 2.	Pain in the ear?	Rasa sakit dalam telinga?
Item 3.	A feeling that your ears are clogged or “underwater”	Rasa telinga dimasuk air atau tersumbat?
Item 4.	Ear problems when you have a cold or sinusitis?	Ada masalah telinga apabila selsema atau resdung?
Item 5.	Crackling or popping sounds in the ear?	Bunyi “pop” atau “keretakan” (ranting kayu patah) dalam telinga?
Item 6.	Ringing in the ears?	Bunyi berdengung dalam telinga?
Item 7.	A feeling that your hearing is muffled?	Pendegaran sayup (tidak jelas)?
	Do you get these symptoms in one ear only or both ears?	Adakah anda mengalami gejala ini di sebelah ataupun kedua-dua belah telinga?

Grouping Criteria

Participants included in the ETD group are those that have positive ETD complaints as previously described, with objective signs of ET dysfunction based on otoscopic or nasoendoscopic findings and supported by abnormal tympanogram either Types B or C. The non-ETD group are participants who do not present with symptoms pertaining to ETD dysfunction as previously described and must have a normal otoscope and nasoendoscopic finding and must have normal tympanogram. All grouping between ETD and non-ETD participants in the study was consulted with the attending Otorhinolaryngologist.

Participants grouped for the test-retest reliability were those who agreed to withhold their medication such as usage of antihistamine, nasal decongestants such as oxymetazoline, nasal douching for a duration of two weeks. All participants who failed

to complete the questionnaire in the two weeks' duration were excluded from this analysis.

Statistical analysis

The statistical calculation and evaluation were performed via IBM SPSS version 26 (IBM, Armonk, NY, USA). Descriptive statistics were employed for selected variables. The findings were presented based on the types and distribution of the data. Categorical data were presented as frequencies and percentages, while numerical data were presented as means and standard deviations or as medians and interquartile ranges if not normally distributed.

Face validity testing of the translated questionnaire was adapted from another study of similar design by Zakaria et al. [17]. A face validity questionnaire was distributed to 10 participants who were fluent in the Malay language. Feedback was obtained as a score of 1 to 4 regarding clarity and

comprehension of the questionnaire with a higher score indicating questions with increasing clarity and comprehension. The face validity index for Item and Scale (I-FVI and S-FVI) were calculated respectively. The acceptable index cut-off point was 0.83 based on a study by Mohamad et al. [18]. Participants for the face validity test were randomly recruited from among native Malay language speakers from the outpatient clinic (6 females and 4 males). Face validation was performed after forward and backward translation, but before the discriminatory study as the result of face validity was a pilot project to test the clarity of the language and sentence structure. After obtaining a satisfactory Face Validity Index, the 10 patients were not further included in the discriminatory study phase.

Internal consistency reliability was assessed by calculating Cronbach α value. Internal consistency was generally considered adequate if Cronbach α was above 0.7.

Test-retest reliability, respondents for the questionnaire were followed up in a time frame of two weeks to reassess the symptoms score. The analysis was performed using the Intraclass Correlation Coefficient (ICC) as well as Pearson Correlation Coefficient. All probability values are two-sided, and a level of significance of less than 0.05 were considered as statistically significant.

For discriminant validity, the difference in mean scores of each item and difference in mean total scores between the ETD and non-ETD groups were compared using independent sample T-tests and a level of significance of less than 0.05 were considered as statistically significant.

Estimates of sensitivity and specificity were measured using a ROC curve with the larger AUC indicating better sensitivity and specificity. Optimal score cut-off point differentiating ETD and non-ETD groups were then analysed.

Content validation was not done in this study in view of the fact that content validity was already undertaken in the original study itself by McCoul [7]. We also noted that other translational studies did not include content validity results in their studies [8, 9, 10, 11].

RESULTS

Subject Demography

Demographic characteristics of participants for the study were presented in Table 2. A total of 126 participants were enrolled for the discriminant validation study. Of the 126 participants, 60 were diagnosed with ETD while 66 were in the non-ETD group. The ETD group consisted of 37 (61.7%) females and 23 (38.3%) males, while the non-ETD group consisted of 39 (59.1%) females and 27 (40.9%) males. The mean age in the ETD group was 39 ± 14 years while the mean age in the non-ETD group was 44 ± 16 years. In the ETD group, 37 participants (61%) have type B tympanogram while 23 participants (39%) have type C tympanogram. All non-ETD participants (100%) have type A tympanogram.

Table 2 Demographic data of participants recruited

Variables	ETD (Total= 60)	Non-ETD (Total = 66)
Gender, n (%)		
Male	23 (38.3%)	27 (40.9%)
Female	37 (61.7%)	39 (59.1%)
Age (years), (mean \pm SD)	39 ± 14	44 ± 16
Tympanometry, n (%)		
A	0	66 (100%)
B	37 (61%)	0
C	23 (39%)	0
2-week retest score, mean (SD)*	37 (61%)	25 (38%)

*number of samples for test-retest are ET=37 vs non-ET=25

Face Validity

A total of 10 recruits were enrolled for Face Validity testing. They were aged between 35 to 66 years (6 females and 4 males). The I-FVI (Table 3) for ETDQ-7 were found to range from 0.90 to 1.00. Of the 7 items in the translated ETDQ-7 questionnaire, 6 items rated 1.00 while only 1 item rated 0.90 for I-FVI. The S-FVI/Average is 0.98.

Table 3 Face Validity Testing of Bahasa Malaysia Eustachian Tube Questionnaire

Item	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10	Rater in Agreement	I-FVI
Q0	4	4	3	3	3	3	3	4	3	3	10	1
Q1	3	4	4	3	4	3	3	4	4	4	10	1
Q2	4	4	4	3	4	3	3	4	4	4	10	1
Q3	4	4	2	3	4	3	3	4	3	4	9	0.9
Q4	3	4	4	3	4	3	3	3	4	4	10	1
Q5	3	4	4	3	4	3	3	3	4	3	10	1
Q6	4	4	4	3	4	3	3	4	4	4	10	1
Q7	4	4	4	3	4	3	3	4	4	4	10	1
S-FVI/Average											0.98	

Reliability Testing

Internal consistency testing of translated ETDQ-7 yielded a Cronbach α value of 0.878 (very high) for the entire study with an intraclass correlation coefficient (ICC) value of 0.878 (95% CI 0.842-0.908).

For test-retest reliability, a total of 66 participants fulfilled our criteria as suitable for withholding medication and were followed up in 14 days. However, 4 participants who did not fulfil the 14-

day timeline were excluded from this part of analysis. A final total of 62 participants were included in the statistical analysis. Of these participants, 37 were in the ETD group, while 25 were in the non-ETD group for the retest (Table 2). The ICC coefficient value of all items were scored above 0.9. Strong correlation between the first and second evaluations for each item of the questionnaire was shown by Pearson correlation coefficient above 0.80; $p < 0.001$ in Table 4.

Table 4 Test-retest reliability - Intraclass correlation and Pearson Correlation Coefficient for each item

ITEMS	ICC Coefficient	95% Confidence Interval	Pearson Correlation	p
Item 1- retest item 1	0.974	0.957 - 0.984	0.950	< .001
Item 2- retest item 2	0.916	0.861 - 0.949	0.845	< .001
Item 3 - retest item 3	0.972	0.953 - 0.983	0.946	< .001
Item 4 - retest item 4	0.947	0.911 - 0.968	0.901	< .001
Item 5 - retest item 5	0.953	0.922 - 0.972	0.911	< .001
Item 6 - retest item 6	0.932	0.888 - 0.959	0.877	< .001
Item 7 - retest item 7	0.960	0.933 - 0.976	0.922	< .001
Test - Retest total	0.988	0.981 - 0.993	0.978	< .001

Discriminant Validity

Mean score and the total mean score for the ETD group versus the non-ETD group were generally significantly different, as shown in Table 5. Those in the ETD group scored higher with the average difference between the two groups ranging from 6.27 to 15.25 for total mean score and the differences were statistically significant ($p < 0.001$). The BM-ETDQ-7 showed good discrimination between both groups with a significantly

higher total mean score of 26.12 (6.17) in the ETD group as compared to 11.94 (3.83) in the non-ETD group.

ROC analysis shown in Figure 1 shows AUC of 97.3% (95% CI= 0.943-1.00); $p < 0.001$. The accepted cut-off point of 14.5 in the original study only yielded a sensitivity of 96.5% and specificity of 72.5% in our study. A more optimal cut-off point was found at 17.5 with a sensitivity of 96.5% and specificity of 84.1% (Table 6).

Table 5 Comparison of Mean Score for Individual Items and Total Score between ETD and non-ETD groups

Items	ETD group	Non-ETD group	t	p
	(n = 60)	(n = 66)		
	Mean (SD)	Mean (SD)		
Item 1	4.02 (1.44)	1.74 (0.98)	10.23	< 0.001
Item 2	2.98 (1.48)	1.58 (0.96)	6.27	< 0.001
Item 3	3.95 (1.50)	1.68 (0.98)	9.94	< 0.001
Item 4	3.53 (1.54)	1.91 (1.25)	6.48	< 0.001
Item 5	2.97 (1.48)	1.21 (0.48)	8.75	< 0.001
Item 6	4.58 (1.48)	1.89 (1.10)	11.51	< 0.001
Item 7	4.08 (1.61)	1.92 (1.28)	8.28	< 0.001
Test Total	26.12 (6.17)	11.94 (3.83)	15.25	< 0.001

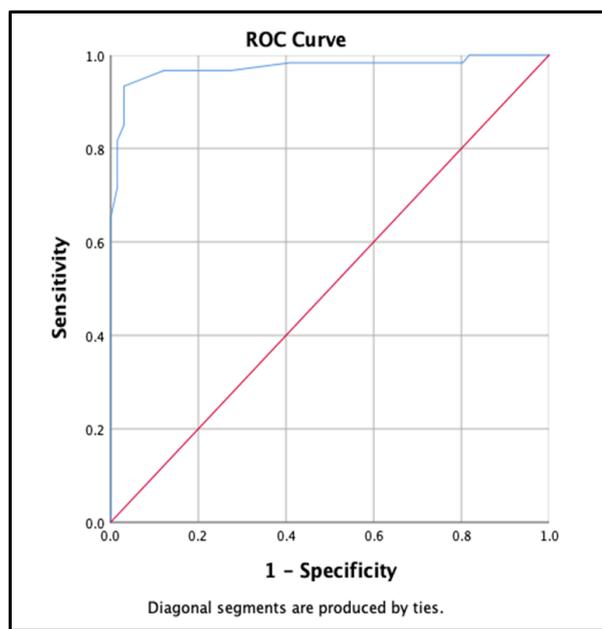


Figure 1 Receiver operating characteristic (ROC) curve for the translated ETDQ-7 in detecting eustachian tube dysfunction. Area under curve = 97.3% ($p < 0.001$)

Table 6 Comparison of Mean Score for Individual Items and Total Score between ETD and non-ETD groups

Interest Cut-off Score	Sensitivity	Specificity
6	1	0
7.5	1	0.182
8.5	0.983	0.197
9.5	0.983	0.288
10.5	0.983	0.379
11.5	0.983	0.515
12.5	0.983	0.591
13.5	0.967	0.727
<u>14.5</u>	<u>0.967</u>	<u>0.758</u>
15.5	0.967	0.803
16.5	0.967	0.864
17.5	0.967	0.879
18.5	0.933	0.97
19.5	0.883	0.97
20.5	0.85	0.97
21.5	0.817	0.985
22.5	0.717	0.985
23.5	0.65	1
24.5	0.583	1
25.5	0.517	1
26.5	0.45	1
27.5	0.367	1
28.5	0.3	1
29.5	0.283	1
30.5	0.233	1
31.5	0.183	1
32.5	0.117	1
34.5	0.1	1
38	0.033	1
41.5	0.017	1
44	0	1

DISCUSSION

This work described the process of translation and validation of the ETDQ-7 into the Malay language, the lingua franca of Malaysia. ETDQ-7 remains as the only validated disease-specific instrument for ETD used worldwide that was founded by Mc Coul et al. [7]. There remains a notable need to translate this tool in our local setting in the absence of a compelling diagnostic test as an alternative participant-reported outcome measure of ETD. An early diagnosis of ETD potentially prevents severe middle ear pathology.

Previous studies on translation and validation of the ETDQ-7 had been undertaken into the German, Turkish, Portuguese and Danish languages and all yielded results similar to the original North American version. Hence the ETDQ-7 is now widely used as an adjunct method for the diagnosis and management of ETD patients and is recommended as pre- and post-operative assessment of patients undergoing tuboplasty [9]. We followed the method of translation used in other similar local translational and validation studies [19] and similar guidelines [20] for medical questionnaires using forward and backward translation with a panel of expert review.

Face validity as a form of response process validation is a systematic and evidence-based approach [13]. The overall I-FVI of 0.90 and S-FVI of 0.98 reflects high clarity rating judged by individual raters. This form of face validation has also been adopted in other local studies as an alternative for measuring content validity [17]. Of note, we could only perform quantitative assessment as the qualitative assessment was not recorded.

We found good internal consistency with a Cronbach α value of 0.878 with an ICC of 0.878 (95% confidence interval of 0.842 to 0.908). The Cronbach alpha could suggest that questions are interrelated, and the overall construct is homogeneous. Similar high internal consistency has also been reported in other studies [9-12]. Test-retest reliability of the Malay language ETDQ-7 demonstrated excellent ICC above 0.9 between repeated measurements after 14 days. The duration of 14 days was chosen as it is similar to that of other translational studies [10,12] to enable making a comparison. We also adopted the protocol from the original study where only participants who did not

receive any medical or surgical intervention were chosen for retest as we believed that continuing symptomatic relief medication could improve the score, especially in the ETD group. It is arguable that a time frame of two weeks could provide a possibility of modification status between two evaluations; however, our study showed that the mean test- and retest score were not found to be significantly different.

Overall individual items for translated ETDQ-7 score and total score were significantly higher in the ETD than the non-ETD group, reflecting consistency with the overall construct of this questionnaire. Of note, item 1 which translated for "*Rasa tekanan dalam telinga?* (Pressure in the ear?)" and item 6 for "*Bunyi berdengung dalam telinga?* (Ringing in the ears?)" also known as tinnitus were found to have significantly higher mean scores (10.23 and 11.51 respectively; Table 5) in the ETD group compared to the non-ETD group, which may imply that these two symptoms were more often experienced in ETD participants.

The original English study by Mc.Coul et al. yielded an AUC of 100% and a German translation study also showed a good AUC of 98.8% [9]. We demonstrated an AUC of 97.3% providing outstanding discrimination score. The generally accepted cut-off points of 14.5 in other studies showed a 100% sensitivity and 100% specificity [7,9]. In our study, this cut-off point yielded a sensitivity of 96.5% but a specificity of 72.5%. A cut-off point of ≥ 17.5 was found to provide a better balance of sensitivity (96.5%) and specificity (84.1%) in the Malay language ETDQ-7 (Table 6). The specificity in our present study was lower than the specificity reported by Mc Coul et al. and these findings were also similarly reported by Hansen et al. [11]. The author proposed that this low specificity could be due to recruitment of patients with known sensorineural hearing loss in the control group which in some cases complaints of Ringing in the ears (Tinnitus) in item 6.

While the ETDQ-7 was initially developed for patients who have undergone tuboplasty, it can also be used to assess the severity of symptoms in patients who have undergone other forms of medical treatment for ETD. The questionnaire asks about symptoms such as ear fullness, popping or clicking sounds, and changes in hearing, which are common symptoms of ETD

regardless of the type of treatment received. However, it is important to note that the ETDQ-7 is not a diagnostic tool and should be used in conjunction with a thorough medical evaluation by a healthcare professional. A healthcare professional can determine the appropriate treatment for ETD based on the patient's symptoms, medical history, and physical examination.

Some limitations to the ETDQ-7 are worth mentioning. Age limits include patients over 18 years old are due to their maturity and ability to understand the questionnaire better, as well as their better cooperation to participate in the full data collection procedure such as otoscopic examination, nasoendoscopy, and tympanometry. Response items are focused on the severity of the symptoms. The nature of the events whether it is intermittent, continuous or worsens during a certain time of day are not represented in the questionnaire. We have also not assessed the concurrent validity with other questionnaires such as the SNOT-22 as was done by Mc Coul et al. because a local Malay language version is yet to be adapted.

CONCLUSION

In conclusion, this study found the translated the Malay language version of ETDQ-7 is reliable and valid. The Malay language version of ETDQ-7 can provide a simple and valuable alternative for screening ETD participants in our primary health care setting and is useful for screening and guiding appropriate intervention. The Malay language version of ETDQ-7 may perhaps be utilised further in assessment of intervention outcomes.

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Ethical approval

The study protocol was approved by the Human Research Ethics Committee of Universiti Sains Malaysia (USM/JEPeM/20010027) and written informed consent was obtained from all participants.

Conflict of interest

Authors declare none.

Author contributions

RRR, YWL and NANO designed the study and the data collection methods. RRR and YWL analyzed and interpreted the data, provided logistical support, and conducted the final review of the results. RRR and YWL wrote the initial and RRR wrote the final draft of the article. All authors have critically reviewed and approved the final draft and are responsible for the content and similarity index of the manuscript.

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