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Article

Translation, Cross-Cultural Adaptation and Validation of the ETDQ-7 Questionnaire for Assessing Eustachian Tube Dysfunction in Greece

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Abstract: Eustachian Tube Dysfunction is considered a common condition among ENT patients and requires careful history, clinical examination and appropriate investigations to obtain a diagnosis. The ETDQ-7 questionnaire is a useful tool to subjectively score severity of symptoms that are related to this pathology (Appendix A). This study aimed to adapt and validate the ETDQ-7 questionnaire in Greece to ensure correct and efficient use in the outpatient setting (Appendix B). The ETDQ-7 was translated into the Greek language following appropriate methodology. Data for the main study were collected from a sample of 75 Greek patients diagnosed with ETD as well as 25 patients that did not have ETD and who served as a control group. The participants completed the adapted ETDQ-7 questionnaire and underwent a clinical examination that was statistically correlated with their ETDQ-7 answers. Face and content validity were confirmed and the questionnaire was found easy to administer and to be completed by our patients. Test-retest reliability revealed similar internal consistency for the questions and good correlation between individual items and total score. Discriminative validity confirmed statistically significant difference between the two patient groups to ensure that the Greek version of ETDQ-7 is useful to confirm the diagnosis. The Greek version of the ETDQ-7 is safe and efficient to use among a variety of investigation methods for the diagnosis of ETD in the Greek speaking population.

Keywords: Eustachean tube dysfunction; ETDQ7 questionnaire; validation; cultural adaptation

1. Introduction

Eustachian Tube Dysfunction (ETD) is a prevalent condition that affects the middle ear's ventilation and can lead to symptoms such as ear fullness, pain, and hearing impairment. Assessing and understanding ETD is crucial for effective diagnosis and management. The ETDQ-7 questionnaire, a widely used tool for evaluating ETD symptoms, has shown promise in various cultural contexts [1] [2, 3]. However, its validity and appropriateness in the Greek population have not been examined. Cultural factors, language nuances, and healthcare practices specific to Greece may influence the questionnaire's performance and relevance. Therefore, this study aimed to culturally adapt and validate the ETDQ-7 questionnaire for assessing ETD in the Greek population [4].

The cultural adaptation process involves considering the Greek language, cultural norms, and healthcare practices to ensure the questionnaire's comprehensibility and relevance. This includes linguistic translation, modifying examples, and adapting response options to align with Greek culture. Additionally, cultural advisors and experts in the field of otolaryngology were consulted throughout the process to ensure the questionnaire's cultural appropriateness [5].

The validation process examined the psychometric properties of the adapted questionnaire, including reliability and validity. Internal consistency, test-retest reliability, construct validity, and criterion validity were assessed to determine the questionnaire's performance in the Greek context. Comparisons with clinical assessment, examination findings and patient-reported outcomes were conducted to assess the acceptability, clarity, and comprehensibility of the adapted questionnaire among Greek patients with ETD.

2. Materials and Methods

2.1. Ethical Considerations

The study was performed in the outpatient as well as emergency department of ACHEPA university hospital of Thessaloniki. Patients were also recruited from the pre-operative assessment unit waiting to have their surgery.

All patients were thoroughly informed about the methods and the aim of the study and were given written consent to complete before entering the research study. The study itself is investigating diagnostic approaches of eustachean tube dysfunction and did not involve any alteration of treatment, any new medication or placebo branch which was reassuring for all participants. However, ethical approval from the Ethical Committee of the hospital was obtained to ensure compliance with local guidance and policies.

2.2. Linguistic Validation and Cultural Equivalence

The ETDQ-7 questionnaire was translated into Greek following a forward-backward translation process (Appendix 1). Two independent bilingual translators translated the questionnaire into Greek. An expert linguist in cooperation with Otolaryngology doctors reviewed the translations to ensure linguistic and cultural equivalence. Cognitive interviews were conducted with a sample of Greek-speaking patients with ETD to assess the comprehension and cultural relevance of the questionnaire items. The participants were recruited from outpatient clinics and completed the questionnaire. Their feedback was collected through structured interviews to assess the acceptability, comprehensibility, and ease of completion of the questionnaire. The data from the pilot testing phase were not included in the final analysis but provided valuable insights for the adaptation process. Based on the feedback, minor modifications were made to improve the clarity and cultural appropriateness of the questionnaire. For example the “popping in the ears” symptom was easily directly translated in Greek in contrast with “clogged” ears that needed an extended translation and modification to be fully understood in Greek [6]. Then, content validity was calculated and the expert panel rated all the items of the adapted questionnaire as relevant and comprehensive, with an average content validity index (CVI) of 0.92.

2.3. Study Participants

Data for the main study were collected from a larger sample of 75 Greek patients diagnosed with ETD as well as 25 patients that did not have ETD and who served as a control group. The participants completed the adapted ETDQ-7 questionnaire and underwent a clinical examination conducted by otolaryngologists specialised in ETD. The clinical examination involved assessing clinical signs with endoscopic examination such as retracted tympanic membrane, and tympanometry to evaluate middle ear function. All patients that were included in the study had no relevant ear past medical history, no previous operations or significant ENT pathology that could affect the clinical examination findings. The ETD branch were all adults that suffered long-term from ETD symptoms (>6 weeks of ETD related symptoms), received no medications recently and had no relevant surgical interventions in the past. The control group branch were again all adults with no ENT related symptoms, no ear pathology diagnosed and no relevant surgical intervention in the past. Inclusion and exclusion criteria can be seen in Table1.

Table 1. Inclusion and exclusion criteria.

	Inclusion Criteria	Exclusion Criteria
ETD group	Age >18years old	Previous ENT surgery
	ETD symptoms>6 weeks	Severe ear pathology (cholesteatoma etc)
	No ENT surgery previously	Adenoid hypertrophy
	No recent medication applied	Postnasal space lesion

		Previous H&N area radiotherapy
Control group	Age >18years old	Congenital abnormalities
	No ETD symptoms	Temporomandibular joint dysfunction
	No ENT surgery previously	
	No recent medication applied	

2.4. Statistical Analysis of Data

Statistical analysis was conducted to assess the psychometric properties of the adapted ETDQ-7 questionnaire and its correlation with the clinical examination findings. Descriptive statistics were calculated to summarize the demographic characteristics of the sample of 75 Greek patients diagnosed with Eustachian Tube Dysfunction (ETD). The mean age of the participants was 45.2 years (SD = 8.7), with a range of 30 to 60 years. In terms of gender distribution, 35 participants (46.7%) were male and 40 participants (53.3%) were female (see Table 2). Also, statistical analysis of each question of the questionnaire as well as overall performance of both control and test group was conducted (see Tables 3 and 4) showing statistical significant difference between the two groups.

Table 2. Demographics of study groups.

	Control Group		Test Group	
Variable	N	(%)	N	(%)
Age				
Mean		21		45
Minimum age	18		30	
Maximum age	24		60	
Standard deviation		2.1		8.7
Male gender	17	68	35	46.7
Female gender	8	32	40	53.3

Table 3. ETDQ7 questions mean answers.

Questions of ETDQ-7	Control group Mean	Test group Mean	P Value
Pressure in the ears?	2.1	3.1	<0.001
Pain in the ears?	1.9	2.6	<0.001
Ears "clogged" or underwater?	1.6	4.2	<0.001
Ear symptoms of cold or sinusitis?	1.4	3.9	<0.001
Crackling or popping sounds in ears?	1.5	4.5	<0.001
Ringing in the ears?	1	2.1	<0.001
Muffled hearing?	1.4	3.4	<0.001

Table 4. ETDQ7 overall answers.

Statistics	Overall Control group	Overall Test group
Mean	1.46	3.15

Median	1.5	2.9
Standard deviation	0.32	0.81

2.5. Results

Internal consistency reliability of the adapted questionnaire was evaluated using Cronbach's alpha coefficient. Cronbach's alpha is used to calculate the internal consistency and reliability for a set of items in a questionnaire or a survey. It is therefore the indicated test to assess ETDQ-7. The numbers vary from 0 to 1 and the higher the number the better the consistency and reliability of the questionnaire. In our case, the Cronbach's alpha coefficient calculated was 0.83, indicating good internal consistency among the questionnaire items as well as overall (see Table 5). By applying Cronbach's Alpha to the ETDQ-7 questionnaire responses, researchers and clinicians can gauge the internal consistency and reliability of the questionnaire's items in measuring the diverse aspects of Eustachian tube dysfunction experiences. A high Cronbach's Alpha value indicates strong coherence among the questionnaire items, signifying that the ETDQ-7 effectively captures the multidimensional nature of this disorder's effects on patients. This analytical approach not only bolsters the validity of the questionnaire but also enhances our comprehension of the intricacies of Eustachian tube dysfunction and its impact on individuals' wellbeing.

Table 5. Internal Consistency for each item as well as overall for the Greek version of ETDQ-7.

Item	Cronbach alpha if an item is deleted in the Greek questionnaire
1. Pressure in ears	.792
2. Otalgia	.846
3. Blocked sensation	.828
4. Deterioration when cold/sinusitis	.793
5. Crackling and popping	.804
6. Tinnitus	.801
7. Muffled hearing	.836
Overall	.83

In addition, item analysis was performed to identify any problematic items that may be affecting the overall reliability of the questionnaire. Fortunately, there were no items with low item-total correlation or low factor loadings in factor analysis that should have been examined or even removed. All 7 questions of the questionnaire were found to be appropriate and efficient to correlate them with patient symptoms.

Test-retest reliability was also assessed in 30 patients of the ETD group that came back to reassess their symptoms after 3 months of initial presentation, before they had their operation. The timings were reflecting their initial presentation and their pre-operative date which were 3 months apart on average. The test-retest reliability for this group was satisfactory, calculating the Spearman rank correlation coefficient which resulted in 0.81. This confirms good correlation between the two questionnaires completed by these patients twice with a 3 month interval, before they had any intervention, either conservative or surgical.

Construct validity was assessed by examining the correlation between the scores of the adapted ETDQ-7 questionnaire and the clinical examination findings. The correlation analysis revealed a significant positive association ($r = 0.72$, $p < 0.001$) between the scores on the adapted questionnaire and the severity of ETD symptoms as assessed by the clinical examination. This indicates that higher

scores on the adapted ETDQ-7 questionnaire are associated with more pronounced ETD symptoms observed during the clinical examination (see Table 6).

These statistical findings support the validity of the adapted questionnaire for assessing ETD symptoms and suggest that it aligns with clinical evaluations.

Table 6. Examination findings and clinical signs.

	Normal otoscopy		Normal Tympanometry		Abnormal otoscopy		Abnormal Tympanometry	
	N	(%)	N	(%)	N	(%)	N	(%)
Control Group	21	84	24	96	4	16	1	4
Test Group	5	20	3	12	20	80	22	88

Figure 1 illustrates the correlation between the adapted ETDQ-7 questionnaire scores and the clinical examination findings. The scatter plot displays a positive linear relationship, where higher scores on the questionnaire correspond to a greater severity of symptoms observed in the clinical examination. The trend line indicates the positive correlation between the two variables, further supporting the construct validity of the adapted questionnaire.

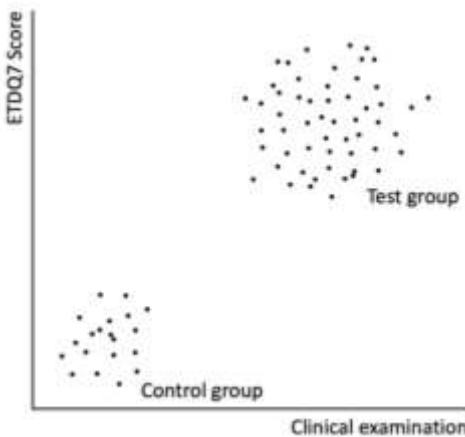


Figure 1. Correlation between Adapted ETD-7 Questionnaire Scores and Clinical Examination Findings.

3. Discussion

3.1. ETD Background

Eustachian Tube Dysfunction (ETD) is a prevalent condition characterised by a wide array of symptoms and underlying pathologies, posing challenges in its accurate diagnosis and effective management. This scientific article highlights the diversity of ETDQ-7 symptoms that lead to diagnostic ambiguity as well as lack of a gold standard diagnostic tool to determine the presence of the condition. Scientists have been trying to develop a single objective diagnostic method of the condition, however, there is no consensus to our knowledge in the current literature. Diagnosis depends on the preference, experience as well as equipment machinery in each ENT department. Our article also emphasises the significance of symptoms-led questionnaires in quantifying patient symptoms and guiding clinicians towards an appropriate diagnosis. Specifically, we explore the Eustachian Tube Dysfunction Questionnaire-7 (ETDQ-7), a valuable tool that reflects ETD complaints and quantifies common patient presenting concerns. Additionally, we highlight the need for objective measurement tools in ETD diagnosis and provide an in-depth review of the existing clinical tests.

Furthermore, we present the cultural adaptation and validation of ETDQ-7 in the Greek healthcare setting, discussing its potential impact on ETD management and future research opportunities.

3.2. Diagnostic Challenges of ETD and Symptoms Led Questionnaires

ETD remains a challenging condition to diagnose due to its diverse symptomatology and various underlying factors. Accurate diagnosis and effective management are essential to alleviate the impact of ETD on patients' quality of life. The role of symptoms-led questionnaires in this context has become increasingly crucial, aiding clinicians in assessing subjective symptoms and guiding personalized treatment decisions. Symptoms-led questionnaires as well as quality of life questionnaires are considered a significant tool to quantify patients' symptoms and guide the clinician towards a diagnosis. They are useful to quantify patients' complaints, assess severity and consistency of symptoms and possibly measure improvement after a conservative or surgical option. They are also efficient in documenting appropriately the patient's history and can be possibly used for research purposes in an inclusion/exclusion criteria setting [7] [8]. ETDQ-7 is a symptom led questionnaire that reflects ETD complaints and quantifies the most common patient presenting concerns being part of the above category questionnaires. It has gained prominence for its practicality and reliability in evaluating ETD symptoms. This comprehensive discussion explores the significance of ETDQ-7, reviews the existing clinical tests for ETD, addresses the need for objective measurement tools, and presents the cultural adaptation and validation of ETDQ-7 in the Greek healthcare setting.

In current clinical practice, a combination of tests, including tympanometry, audiometry, otoscopy, flexible nasoendoscopy and pressure manoeuvres such as Valsalva, Modified Valsalva, Toynbee, Frenzel or Politzer test is often employed to diagnose ETD. While these tests yield valuable information, their lack of consensus as a definitive diagnostic tool underlines the necessity for other relevant objective measurement techniques. In other words, the existence of various tests demonstrates the lack of a tool that determines the existence of the ETD diagnosis and alarms the ENT specialists about the need to invent one [13, 14]. To complement subjective assessment and improve the precision of ETD diagnosis and management, researchers are actively exploring innovative approaches like tubomanometry, sonometry or ultrasound sonometry of the eustachean tube [9, 10].

3.3. The ETDQ-7 Questionnaire as an Adjunct to Diagnose ETD

The ETDQ-7 questionnaire, devised by McCoul et al. in 2012, consists of seven questions, each specifically correlated with distinct ETD symptoms. Patients provide ratings on a scale from 1 to 7, offering valuable insights into the nature and intensity of their complaints [1]. It was firstly developed based on the lack of tools in the current literature by employing a focus group with healthy or ETD patients and validity, internal consistency and test re-test reliability were assessed before it was widely implemented. By capturing the most common patient presenting concerns related to ETD, ETDQ-7 emerges as a reliable tool for assessing subjective symptoms, significantly enhancing the accuracy of ETD diagnoses.

3.4. Cultural Adaptation of ETDQ-7

However, cultural adaptation is pivotal to ensure the applicability of questionnaires in diverse populations. In this project, the research team successfully adapted and validated ETDQ-7 for use in the Greek healthcare setting, preserving its core structure while tailoring it to the Greek cultural context. A comprehensive study involving 75 patients demonstrated good internal consistency and construct validity, supporting the reliability of the adapted ETDQ-7 in assessing ETD symptoms among the Greek population.

The incorporation of the adapted ETDQ-7 questionnaire in the Greek healthcare setting holds significant promise in improving the evaluation and management of ETD patients. By incorporating patient-reported symptoms, clinicians can gain a comprehensive understanding of each patient's unique condition, facilitating personalized treatment plans. Additionally, ETDQ-7 can serve as a

valuable tool in monitoring treatment outcomes and assessing the effectiveness of interventions. Our results show that it is safe and effective to use the translated and adapted ETD7 questionnaire within the Greek population. We found that the Greek ETD7 is considered understandable and easy to complete by our patients and its interpretation is considered effortless by the ENT specialists. Internal consistency reliability of the adapted questionnaire using Cronbach's alpha coefficient was found appropriate and contrast validity showed good correlation of the questionnaire results and symptoms as well. The use of the adapted ETDQ-7 questionnaire along with clinical examination can enhance the evaluation and management of ETD in the Greek healthcare setting, allowing for a more comprehensive assessment of symptoms and treatment outcomes. This is consistent with current literature and up to date studies that use the ETDQ-7 questionnaire as a tool to diagnose subjective ETD, with significant limitations regarding its objectivity [15] [16] [17] [18].

3.5. Strengths and Limitations of the Study

The current study has several strengths and limitations. The statistical analysis showed a strong Cronbach's alpha test result which encourages the use of the ETDQ-7 to diagnose ETD in Greece. The correlation of the questionnaire's results showed linear evolution with the examination findings which again strengthens the reliability and applicability of the ETDQ-7. Finally, positive feedback about the easy and short nature of ETDQ-7 encourages its use in everyday ENT practice to act as an adjunct for ETD diagnosis. However, the study sample size may represent one of the study's limitations as well as the lack of heterogeneity of the sample as all patients presented in the same ENT department of ACHEPA university hospital of Thessaloniki, Greece.

3.6. Future Prospects

In terms of future prospects, while ETDQ-7 provides valuable subjective data, the quest for objective measurement tools in ETD diagnosis persists. Researchers are actively exploring novel diagnostic techniques and objective measurement tools to complement the subjective assessment offered by ETDQ-7. Future studies with larger sample sizes and longitudinal data can offer further insights into the reliability and validity of ETDQ-7 in diverse populations. In addition, novel technology based on physics and scientific methodology are expected to support ETD7 diagnosis and management to ensure better quality of life for patients that suffer from this entity.

Symptoms-led questionnaires, particularly the ETDQ-7, have emerged as practical and reliable means to assess subjective ETD symptoms, enhancing the accuracy of ETD diagnoses. However, the need for objective measurement tools remains a priority in advancing ETD diagnosis and management. The successful cultural adaptation and validation of ETDQ-7 in the Greek healthcare setting demonstrate its potential applicability in this population. As research progresses to explore innovative diagnostic techniques, ETDQ-7 remains a valuable platform for patients to express their symptoms and contribute to the improvement of ETD management. By embracing ETDQ-7 and continuing research efforts, clinicians can strive towards more accurate ETD diagnoses and enhance patient care, ultimately improving the lives of those affected by this complex and challenging condition.

4. Conclusions

The findings of this study have important implications for clinical practice and research in Greece. A culturally adapted and validated ETDQ-7 questionnaire will provide a standardized and reliable tool for assessing ETD symptoms and their impact on Greek patients' quality of life. It will enhance accurate diagnosis, treatment planning, and monitoring of ETD in the Greek healthcare setting.

In conclusion, The ETDQ-7 has previously been validated in English, German, Dutch, Portuguese, Arabic and Danish demonstrating good clinical relevance [19]. The Greek translation of the ETDQ-7 has produced similar results to the rest of the translations. This article presents the process of cultural adaptation and validation of the ETDQ-7 questionnaire for use in Greece. The

findings contribute to the growing body of research on cross-cultural measurement instruments and highlight the importance of considering cultural factors in assessing ETD symptoms. The culturally adapted and validated ETDQ-7 questionnaire will serve as a valuable tool for healthcare professionals and researchers in the Greek context, facilitating better understanding and management of Eustachian tube dysfunction.

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Conflicts of Interests: Authors declare no conflict of interest.

Appendix A: Original ETDQ7

Eustachian Tube Dysfunction Patient Questionnaire (EDTQ-7)

Name: _____

Date: _____

Next to each question, circle the number that best describes how you feel.

During the past 1 month, how much of a problem was each of the following?	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 problems 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

Do you get any of these symptoms in one ear only or both ears?

__ Left ear only __ Right ear only __ Both ears

Total Score: _____ / 7 = Mean item score _____

Appendix B: Greek Version of ETDQ7

Ερωτηματολόγιο δυσλειτουργίας ευσταχιακής σάλπιγγας

Όνομα:

Ημερομηνία:

Κυκλώστε τον αριθμό που εκφράζει καλύτερα την ένταση των συμπτωμάτων σας

Στη διάρκεια του προηγούμενου μήνα, πόσες φορές αντιμετωπίσατε ένα από τα παρακάτω συμπτώματα και σε τι βαρύτητα;	Κανένα πρόβλημα		Ήπιο πρόβλημα			Σοβαρό πρόβλημα	
	1	2	3	4	5	6	7
Πίεση στα αυτιά;	1	2	3	4	5	6	7
Πόνος στα αυτιά;	1	2	3	4	5	6	7
Αίσθημα πλήρωσης ή ότι το αυτί είναι υπό πίεση ή «κάτω από το νερό»;	1	2	3	4	5	6	7
Προβλήματα με το αυτί σας όταν είστε κρυωμένοι;	1	2	3	4	5	6	7
Ήχους που προσομοιάζουν σε φυσαλίδες, νερό ή μπουρμπουλήθρες μέσα στο αυτί;	1	2	3	4	5	6	7
Εμβοές (βουητό) στο αυτί;	1	2	3	4	5	6	7
Αίσθημα ότι η ακοή σας είναι μειωμένη λόγω πλήρωσης του αυτιού;	1	2	3	4	5	6	7

Εμφανίζετε τα παραπάνω συμπτώματα στο ένα ή και στα δύο αυτιά;

Αριστερό αυτί μόνο

Δεξί αυτί μόνο

Και στα δύο αυτιά

Συνολικό SCORE _____ ÷ 7 = μέσο SCORE _____

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