



The Italian Version of ETDQ-7 in Patients with Eustachian Tube Dysfunction

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Received: October 24, 2024

Published: November 30, 2024

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Abstract

Object: Validation of the Italian version of the EDTQ-t questionnaire for the evaluation of Eustachian Tube Dysfunction in comparison with tympanometry test.

Materials and Methods: Validation of the ETDQ-7. Prospective study with 21 patients with symptoms compatible with Eustachian Tube Dysfunction and 20 controls. The Italian version of the ETDQ-7 was administered after translation and back-translation. Internal consistency and reliability were established, as well as a useful evaluation of tympanometry and ETDQ-7 in the study of Eustachian tube dysfunction was carried out.

Results: The Italian adaptation of the ETDQ-7 showed high reliability and internal consistency. The alpha Cronbach it was 0,9359, that is bigger than 0.70. The ROC curve Tympanometry and ETDQ-7 showed the same validity.

Conclusion: The Italian adaptation of the ETDQ-7 is valid, reliable and can be used in a clinical setting to quantify the impact and severity of the Eustachian Tube dysfunction. A new test combining ETDQ-7 and tympanometry could be suggested as a routine test in the diagnosis of Eustachian tube dysfunction.

Keywords: Eustachian Tube Dysfunction; Validation; Questionnaire ETDQ-7; Tubal Diagnosis

Abbreviations

ETDQ-7: Eustachian Tube Dysfunction Questionnaire-7; ET: Eustachian Tube; ETD: Eustachian Tube Dysfunction; NH: Normal Hearing; SNHL: Sensorineural Hearing Loss

Introduction

Middle ear diseases are strongly connected with the functionality of the Eustachian tube (ET), which plays a central role in its well-being. The incidence of obstructive ET dysfunction is estimated to be 4% in children and 1% in adults. ET dysfunction can result in chronic otitis media, tympanic atelectasis, and even the onset of cholesteatoma. ET dysfunction is a common entity in daily practice in ENT clinics. Its symptoms include: sensation of ear fullness, tinnitus, clogged ears or inability to rapidly equilibrate middle ear pressure [1].

The clinical evaluation of these symptoms is subjective and based essentially on patients' complaints, as well as on physical examination and some ancillary tests, such as tympanometry or pneumatic otoscopy, as there is no specific and sensible tool to provide objective measurement of symptom intensity and morbidity, or to allow comparisons before and after clinical or surgical treatments [2].

The Eustachian Tube Dysfunction Questionnaire (ETDQ-7), published by McCoul, et al. in 2012, quantifies the patients' symptoms based on the Eustachian tube obstruction and represents an improved data collection compared to the traditional clinical history. Tympanometry was used for the external validation of the test in patients with tube dysfunction [3]. In addition to that, the use

of symptoms self-assessment questionnaires has shown to be of great effectiveness. The seven-item Eustachian tube dysfunction questionnaire (ETDQ-7) is a disease-specific questionnaire for the evaluation of symptoms of ET obstructive dysfunction and treatment outcome.

It has subsequently been translated and validated for use in other languages [4-7].

The ETDQ-7 does not discriminate well between obstructive ETD and a patulous Eustachian tube (PET), however a study reported the results of only eight patients with PET [8].

The aim of this study was to present the Italian adaptation of the ETDQ-7 and its validation as a routine tool in combination with tympanometry, in order to evaluate patients with chronic ET dysfunction and to establish the degree of severity of chronic Eustachian tube dysfunction.

Methods

The study was approved by the Institutional Ethics Committee (University Hospital of Palermo number 02/2022, date 15.02.2022).

Patients were referred to ENT clinics by their primary care physicians and assigned to one of two studies groups.

- A group of patients diagnosed with middle ear disease consistent with tympanic perforation, middle ear atelectasis, cholesteatoma, or symptoms consistent with obstructed

ears (recurrent serous otitis media, full ear feeling, tinnitus, difficulty in hearing pressure balance).

- Another group of patients with nasal involvement consisting of septal deviation, inferior turbinate hypertrophy, sinonasal polyposis, or nasal respiratory syndrome.

Data from 41 patients were entered. The sample was determined by estimating the prevalence of ET dysfunction in the general population [9,10]. Of this number, 21 were patients with ear involvement and 20 were control patients with nasal involvement. Both ears of all patients were evaluated.

All patients underwent a specialist ENT examination with specialist otoendoscopy and hearing tests, Valsalva maneuver, nasal endoscopy, rhinomanometry and tympanometry, and they also completed the questionnaire during the consultation with the doctor.

Procedure for the italian adaptation of the questionnaire

A translation of the questionnaire from English into Italian was carried out by qualified bilingual professionals, followed by a translation from Italian into the original language, and eventually revised by two ENT doctors with good knowledge of the English language on the basis of the article published by McCoul, *et al.* describing the original version of the ETDQ-7. The final version of the validated translation of the questionnaire, called the Eustachian Tube Dysfunction Questionnaire (ETDQ-7), is presented in this publication (Table 1, 2).

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	Ringling 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

Table 1

In the last month, how much did each of the following problems represent a problem for you?		No discomfort		Moderate discomfort			Severe discomfort	
1	Pressure in the ears?	1	2	3	4	5	6	7
2	Ear pain?	1	2	3	4	5	6	7
3	Feeling like your ears are clogged or “under water”?	1	2	3	4	5	6	7
4	Ear symptoms like when you have a cold or sinusitis?	1	2	3	4	5	6	7
5	Creaking or popping sounds in your ears?	1	2	3	4	5	6	7
6	Ringling or ringing in your ears?	1	2	3	4	5	6	7
7	Feeling of muffled hearing?	1	2	3	4	5	6	7

Table 2: Italian version to the Eustachian tube dysfunction questionnaire.

Evaluation scales

The questionnaire consists of 7 items, with a minimum score of 7 points and a maximum of 49 points (Table 1, 2). At the end of the translation, the recruiting phase began. The 41 patients were evaluated in an observational, descriptive, analytical and cross-sectional study conducted at the Otolaryngology and Audiology Unit of the Military Sovereign Order of Malta in Rome, from March 2022 to December 2022.

Statistical analysis

The statistical analysis addressed the issue of confirming the overall diagnostic performance of EDTQ-7 in an Italian language setting. Descriptive statistics were provided. Internal consistency was assessed by calculating Cronbach alpha for the entire instrument. Cronbach alpha was considered if bigger than 0.70.

The point biserial statistics was estimated and tested to explore the correlation between EDTQ-7 and Eustachian tube dysfunction status.

A T test, adjusted according to Satterthwaite because of the lack of homoscedasticity, was carried out to assess the discriminant validity of EDTQ-7, detecting a difference between the group affected by ETD vs the control group.

Estimates of sensitivity and specificity at the optimal score cut-point, area under the curve (AUC), and an ROC curve were calculated.

The ETDQ-7 test was studied adding up as covariates age and sex to assess its invariance or dependence on them. Logit adjusted score was built up. Model fitting was assessed exploiting the Loglikelihood ratio test. The corresponding AUC statistics of the previous test based only on EDTQ7 score against the new score -

adjusted according to sex and age - were compared. The analysis ended up comparing the diagnosis based on Tympanometry (left/right) and the ETDQ-7 test based diagnosis. In order to carry out the comparison, a Tympanometry logit model score was set.

The analysis was carried out using the statistical software STATA (StataCorp LLC StataCorp), version 17.

Results

The sample selected for this study consisted of 41 individuals, 21 (51.0%) patients and 20 (49.0%) controls (Table 3), divided by sex as follows: 22 men and 19 women. The patients’ group included 11 (52.0%) men and 10 (48.0%) women. Their mean age was 43 years, ranging from 18 to 76 years, with a standard deviation of 16.2 years. As regards tympanometry curve tracing, type B was observed in 12 patients (60%) and type C, in 9 patients (40.0%). The control group consisted of 11 (60 %) men and 9 (40%) women. Their mean age was 41.5 years, ranging from 28 to 76 years, with a standard deviation of 13.8 years. All subjects in this group had bilateral type A or As tympanometry curve tracings. The validation of the ETDQ-7 (The Seven-item Eustachian Tube Dysfunction Questionnaire) was the main research target of this study.

The ETDQ-7 test was studied adding up as covariates age and sex, in order to assess its invariance or dependence on them and no difference was found.

The EDTQ-7 score performs differently according to the Eustachian tube dysfunction. Internal consistency was assessed by calculating Cronbach alpha for the entire tool. The value is higher than 0.70, which is usually considered good.

Cronbach’s alpha was used to assess the questionnaire internal consistency, considering all questions together and excluding items one-by-one (figure 1): internal consistency resulted to be adequate when grouping patients and controls (Cronbach’s $\alpha = 0.9359$).

Cronbach alpha of: edtq1 edtq2 edtq3 edtq4 edtq5 edtq6 edtq7

Test scale = mean (unstandardized items)
 Average interitem covariance: 2.271951
 Number of items in the scale: 7
 Scale reliability coefficient: 0.9359

The questionnaire’s discriminatory validity of the overall score between patient and control - measured at the first moment - was evaluated through the Receiver Operating Characteristic (ROC) Curve (Figure 1). The overall score ≥ 18 (cutoff point) showed an important discriminatory power between patients and controls.

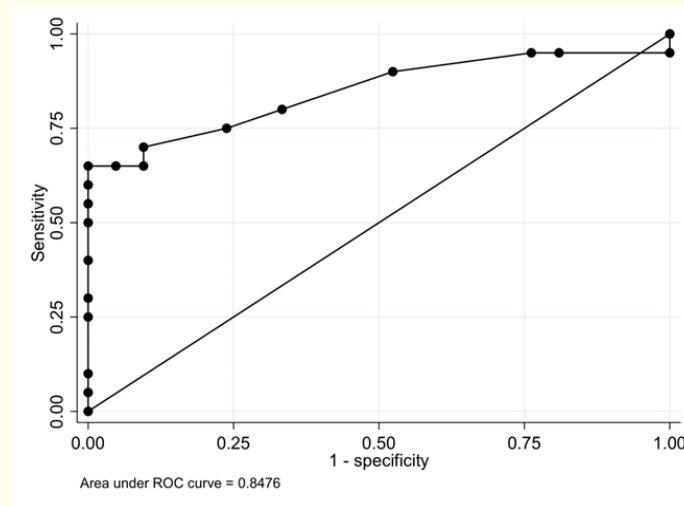


Figure 1

The AUC refers to the performance of EDTQ-7 questionnaire used to assess the ETD status. The area under the ROC curve (AUC) The test has an AUC statistic of 84.8%, with a standard error of 6%, cut-off=18, sens=65%, specificity=95.24%.

Classification variable choosing the cut-off (Youden) 18.

A further comparison between the outcomes of the questionnaire and the tympanometry test for both ears was made.

The analysis of the ROC comparison shows that there is no statistically significant difference between the AUCs. Therefore, the AUC for the tympanometry-based ETD test is 86%, which is comparable with the preceding EDTQ-7 based test. The logistic model shows for both the left and right examination a statistically significant positive predictive power of ETD occurrence.

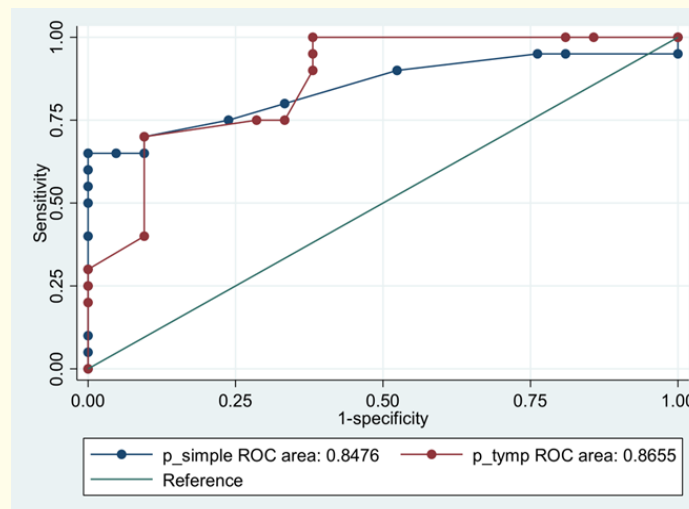


Figure 2

Study of the comparison of the diagnosis based on Tympanometry (left/right) and the ETDQ-7 test based diagnosis.

Discussion

McCoul, *et al.* (2012) developed the ETDQ-7, a new questionnaire which could be used to diagnose and assess ET dysfunction [3]. Several studies have demonstrated that ETDQ-7 is very reliable and is valid to clinically assess ET function [5]. However, it only focuses on subjective complaints of patients and does not include any objective data. In addition, since the questionnaire has only seven levels for each symptom, it is difficult to evaluate it on the basis of subtle changes after operation.

The ETDQ-7 has been translated, validated and adapted to German, Turkish and Brazilian Portuguese, Danish, Spanish, also with similar results to the original North-American version, and it is strongly suggested as an adjunct method for the diagnosis and management of patients with chronic ETD [7,11,14-16]. The current study aimed to translate, validate and culturally adapt the ETDQ-7 questionnaire into Italian.

The ETDQ-7 is a reliable tool in the pre/postoperative evaluation and follow-up after miniinvasive treatment such as balloon dilation Eustachian tuboplasty (BET) [17,19,20] for obstructive ET dysfunction if the patients have been diagnosed, even using the classification of its severity with HDS-it score, with definite obstructive ET dysfunction. The Eustachian tube score (ETS) has also been reported as a valid and reliable method in patients with chronic obstructive ET function [17]. They include clinical symptoms (clicking sound when swallowing and positive Valsalva maneuver) and tubomanometry results. Its sensitivity has been reported at 96% and its specificity at 96%. This study also revealed that it is mandatory to discriminate between obstructive ET dysfunction and PET before applying the ETDQ 7, as the questionnaire was not able to discriminate between the two conditions. Therefore, it can also be applied after tubal and middle ear operations, in order to evaluate patients in long-term follow up.

In 2016, van Roeyen, *et al.* applied the ETDQ-7 questionnaire to 11 patients with symptoms compatible with ET dysfunction relating to atmospheric pressure changes, but with no abnormalities on otoscopy or tympanometry [13].

The studies carried out by Sudhoff demonstrated how this test can be administered to all the patients, especially in the post-operative control: this is in our opinion its most auspicious use in

the future because of the difficulties to assess tubal function due to poor sensitivity and specificity using the state of art diagnostic tools available [12].

The results were compared with those of 22 controls. Both the score checked with the Mann-Whitney U test and the ROC curves showed statistically significant differences in comparison to the control group. It was also applied to the 11 patients with Eustachian tube dysfunction relating to atmospheric pressure changes and treated with balloon dilatation tuboplasty with an estimated success rate of 70% [13].

Out of the 11 patients, 8 were operated in both ETs and 3 were operated with tubal balloon dilation unilaterally. The mean score prior to the surgery was 26 and 16 after the surgery. Even so, the limitation of this study is the sample size and absence of a gold standard for comparison. They conclude that this study should be applied pre-operatively and post-operatively in patients with patulous ET. Furthermore, it should be possible to distinguish whether the condition is unilateral or bilateral.

An Italian novel device called Molecular Vaporizer (MV) has a very promising application to medicate and treat ET dysfunction, because of the capability to produce very small drops gas-like (200/300 nm in diameter), about 50 times smaller than aerosol, able to completely fill the rhino-pharynx and homogeneously penetrate inside the tube [21]. Italian version of ETDQ-7 will be a very reliable, simple and fast tool to compare evolution of the ETD during medical treatment administered via MV, in order to discriminate which patients could be successfully treated with medical therapies or need surgical procedure such as BET.

Conclusions

The ETDQ-7 was translated, validated and adapted to the Italian reality. A standardized symptom score system can improve clinical care, stressing the impact of chronic ETD on the patients' life and guiding adequate patient management. It would be of high importance to introduce this questionnaire to control outcomes in post-operative ETD in the patient's native language, as well as to report about such outcomes and to publish further research, comparing the different interventions made in patients with ETD.

Conflict of Interest Statement

The authors declare no conflict of interest.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Author Contributions

PMP: ideation, methodology, draft, supervision and review; PMP, GR: data collection and processing, analysis, literature review, writing, editing; SS, MC: assisted in data management; JG, ARF: critical review. All authors read and approved the last version of the manuscript.

Ethical Consideration

This study was approved by the Institutional Ethics Committee (Azienda Ospedaliera Universitaria di Palermo nr: 02/2022 del 15.02.2022).

The research was conducted ethically, with all study procedures being performed in accordance with the requirements of the World Medical Association's Declaration of Helsinki.

Written informed consent was obtained from each participant/patient for study participation and data publication.

Disclosure Statement

The authors declare no conflict of interest.

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