Original Article / Çalışma - Araştırma

Evaluation of the Turkish version of the Eustachian Tube Dysfunction Questionnaire

Östaki Tüp Disfonksiyonu Anketinin Türkçe versiyonunun değerlendirmesi

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ABSTRACT

Objectives: This study aims to determine the value and discriminative power of the validated translation of the Eustachian Tube Dysfunction Questionnaire-7 (ETDQ-7) in a Turkish speaking population with and without Eustachian tube dysfunction (ETD).

Materials and Methods: The ETDQ-7 was completed by 38 patients with ETD and 47 healthy individuals. The internal consistency was evaluated using the Cronbach's alpha coefficient. The receiver operating characteristic (ROC) curve was determined as an accuracy measure.

Results: The Turkish version of the ETDQ-7's Cronbach's alpha value of 0.89. In the comparison of case and control groups, there was a significant change in the total scoring. There was a significant positive correlation between the test and retest using the Spearman's correlation test ($p<0.05$). In the discrimination of the ETD and control groups, curve area under 14, the highest cut-off value, was used. Sensitivity was 97.4%, positive predictive value was 88.1%, specificity was 89.4%, and negative predictive value was 97.7%.

Conclusion: The Turkish version of the ETDQ-7 demonstrated acceptable levels of reliability and validity to be used for Turkish speaking individuals with ETD. Test-retest reliability for the Turkish version of the ETDQ-7 was also excellent.

Keywords: Eustachian tube; eustachian tube dysfunction questionnaire-7; dysfunction; reliability.

ÖZ

Amaç: Bu çalışmada östaki tüp disfonksiyonu (ÖTD) olan ve olmayan Türkçe konuşan bir popülasyonda Östaki Tüp Disfonksiyonu Anketi-7'nin (ETDQ-7) doğrulanmış çevirisinin değeri ve ayırıcı gücü belirlendi.

Gereç ve Yöntemler: Östaki Tip Disfonksiyonu Anketi-7 38 ÖTD hastası ve 47 sağlıklı birey tarafından tamamlandı. İç tutarlılık Cronbach alfa katsayısı kullanılarak değerlendirildi. Alıcı işletim karakteristik (ROC) eğrisi, doğruluk ölçütü olarak belirlendi.

Bulgular: Türkçe ETDQ-7 versiyonunun Cronbach alfa değeri 0.89 idi. Olgu ve kontrol gruplarının karşılaştırılmasında, total puanlamada anlamlı değişim saptandı. Spearman korelasyon testi ile test ve yeniden test arasında anlamlı pozitif bir ilişki vardı ($p<0.05$). ÖTD ve kontrol gruplarının ayrımında, en yüksek kesme değeri 14 altındaki eğri alanı kullanıldı. Duyarlılık %97.4, pozitif öngörü değeri %88.1, özgüllük %89.4 ve negatif öngörü değeri %97.7 idi.

Sonuç: Türkçe ETDQ-7 versiyonu ÖTD'li Türkçe konuşan bireylerde kullanılmak üzere kabul edilebilir düzeyde güvenirlik ve geçerlilik göstermiştir. Türkçe ETDQ-7 versiyonunun test-yeniden test güvenirliği de mükemmel düzeyde idi.

Anahtar Sözcükler: Östaki tüpü; östaki tüp disfonksiyon testi-7; disfonksiyon; güvenirlik.

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Eustachian tube dysfunction (ETD), which causes inadequate ventilation of the middle ear has an estimated prevalence of 1% in the adult population.[1] It can be divided into three pathological processes: pressure dysregulation, impaired protective function, and diminished clearance. Symptoms of ETD include aural fullness or pressure, otalgia and tinnitus. Symptoms are often exacerbated with atmospheric pressure changes.[1,2] Patients may also experience pressure, clogged or under-water sensation, popping, ringing and crackling. Chronic ETD may result in variable middle ear pathologies, such as serous otitis media, chronic otitis media, tympanic membrane retractions, and cholesteatoma. Therefore, surgeons believe that eustachian tube (ET) function is important for the outcome of middle ear diseases.[3]

The lack of an objective gold standard diagnostic method makes it difficult to evaluate ETD patients.[2] During clinical assessment, the medical history of the patient with ETD is critical. The presence of symptoms is important to identify the severity of ETD. The use of questionnaires in daily clinical practice also plays an important role in understanding ETD. In 2012, Mc Coul et al.[3] developed the first disease-specific instrument for the assessment of ETD related symptoms, the Eustachian Tube Dysfunction Questionnaire (ETDQ-7). The questionnaire was validated and translated into several languages, such as German and Dutch.[4,5]

In this study, we aimed to identify the value and discriminative power of the validated translation of the ETDQ-7 in a Turkish speaking population with and without ETD. To prevent the potentially confusing distribution of recent questionnaires that are not comparable to those available in the literature, a rigorous adaptation process is required, and mere translation alone is not adequate. Therefore, we aimed to evaluate the reliability and validity of a Turkish-language, culturally adapted version of the ETDQ-7.

MATERIALS AND METHODS

Translation and cross-cultural adaptation

Two Turkish individuals who were fluent in English translated the ETDQ-7; a physician (as the informed translator) and a teacher (as the uninformed translator). Both were native language Turkish, and both were fluent in English. The translations were completed independently and both translations were then compared and reviewed by a bilingual individual who highlighted the conceptual errors or inconsistencies in the translations. When the Turkish translation was made, two native English speakers with a good command of Turkish independently back-translated the finalized Turkish translation into English. Both of these translators were blind to the purpose of the study and had no access to the original scale. The subsequent versions of the questionnaire were compared to the initial translation. A committee consisting of four translators compared the English re-translation with the initial Turkish translation before approving the Turkish version of the ETDQ-7 (Table 1).[6]

Participants

The study was approved by the institutional Ethics Committee (No: 2015/18/03, Date: November 23, 2015) and conducted according to the principles of the Declaration of Helsinki. Written informed consent was obtained from each participant. The ETDQ-7 was completed by 38 participants (mean age: 28.7±9.3 years) with ETD and 47 healthy individuals (control group) (mean age: 27.5±6.8 years). All participants were diagnosed as having ETD with pneumatic otoscopy, symptoms, type C or type B tympanogram and abnormal tympanometry with Valsalva and Toynbee maneuvers. The healthy individuals were the members of medical staff and hospital staff without any past medical history of ear disease and surgery of the ear.

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 22.0 software (IBM Corp., Armonk, NY, USA). Descriptive statistics were calculated for all variables. These included frequency counts and the percentage for nominal variables and measures of central tendency (means and medians) and dispersion (standard deviations and ranges) for continuous variables. The measurement properties analyzed in this study for the instruments included internal consistency, test-retest reliability, construct validity, and ceiling and floor effects.

The reliability of the scale scores was estimated using internal consistency method and test-retest method across repeated administrations. Internal

Table 1. Sociodemographic findings and Eustachian Tube Dysfunction Questionnaire (ETDQ-7) Turkish version results of individuals

	Patients group					Control group					
	n	%	Mean±SD	Median	Min-Max	n	%	Mean±SD	Median	Min-Max	*p*
Age (year)			28.7±9.3	28	11-56			27.5±6.8	26	19-41	0.480*
Gender											0.689†
Female	21	55.3				28	59.6				
Male	17	44.7				19	40.4				
Smoking	4	10.5				0	0.0				0.036†
Drinking	0	0.0				1	2.1				1.000†
Drug usage	6	15.8				3	6.4				0.161†
Duration of complaints			6.3±3.8	6	1-10						
Question 1			4.1±1.6	4	1-7			1.4±1.0	1	1-5	0.000‡
Question 2			2.7±1.6	2	1-7			1.2±0.8	1	1-6	0.000‡
Question 3			4.4±1.9	4	1-7			1.3±0.7	1	1-4	0.000‡
Question 4			4.1±2.1	4	1-7			1.8±1.6	1	1-7	0.000‡
Question 5			3.4±2.2	3	1-7			1.4±1.1	1	1-7	0.000‡
Question 6			3.6±2.0	4	1-7			1.5±1.0	1	1-5	0.000‡
Question 7			4.0±2.0	4	1-7			1.3±0.6	1	1-4	0.000‡
Total score			26.3±8.4	25	14-47			9.9±4.9	7	7-31	0.000‡

SD: Standard deviation; Min: Minimum; Max: Maximum; * t test; † Chi-square test; ‡ Mann-Whitney U test.

consistency was assessed using Cronbach's alpha.[6] Test-retest reliability, a measure of stability or reproducibility, represents the capability of a scale with consistent results, when administered on separate occasions. To minimize the risk of short-term clinical change, no treatments were provided during this period (ICC= 0.81-1.0, excellent; 0.61-0.80, very good; 0.41-0.60, good; 0.21-0.40, fair; and 0.00-0.20, poor).[7]

Validity is represented by the extent to which a score retains its intended meaning and interpretation. In our study, divergent validity was assessed. Tympanometry was accepted as the standard criterion to establish external validity, as it is the most useful objective measurement.[6] The evaluation of the ETDQ-7 was performed using receiver operating characteristic (ROC) curves. A value of the area equal to 1 indicates perfect discrimination, whereas a value equal to 0.5 indicates no discrimination.

RESULTS

There was no statistically significant difference in the age and gender of the individuals between the participant and control groups ($p>0.05$). Questions 1, 2, 3, 4, 5, 6, 7, and total scores in the participant group were higher than the control group ($p<0.05$) (Table 2).

The internal consistency of the Turkish version of the ETDQ-7 was strong with a Cronbach's alpha value of 0.89. There was a significant positive correlation between the test-retest Questions 1, 2, 3, 4, 5, 6, 7, and total scores ($p<0.05$) (Table 3).

In the discrimination of participant and control groups, significant event of the total score were observed ($p<0.05$) [0.964 (0.924-1.00)]. The discrimination of the ETD and control groups was the curve area under the highest cut-off value 14. Its sensitivity was 97.4%, positive predictive value was 88.1%, specificity was 89.4%, and negative predictive value was 97.7% (Table 4). The ROC analysis also supported the excellent

Table 2. Correlation of test retest results of Eustachian Tube Dysfunction Questionnaire-7 (ETDQ-7) Turkish version

	Question 1	Question 2	Question 3	Question 4	Question 5	Question 6	Question 7	Total score
Test-retest								
r	0.607	0.730	0.750	0.829	0.722	0.737	0.722	0.537
p	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001

Table 3. Discriminative validity and cut off point of the Eustachian Tube Dysfunction Questionnaire-7 (ETDQ-7) Turkish version

	%	UCA	95% CI	*p*
Score		0.964	0.924-1.000	0.000
Cut-off 14		0.934	0.874-0.994	0.000
Sensitivity	97.4			
Positive predictivity	88.1			
Specificity	89.4			
Negative predictivity	97.7			
ROC curve				

UCA: Under curve area; CI: Confidence interval; ROC: Receiver-operating characteristic.

discriminate validity of the ETDQ-7 using an optimal total item score cut point of 14 (Figure 1).

DISCUSSION

The ET is an osteocartilaginous canal allowing the middle ear to communicate with the nasopharynx. The ET plays important roles for functional balance of the middle ear. The essential functions of the ET are ventilation of middle ear, mucociliary clearance of middle ear secretions and protection of the middle ear from excess noise, pathogens, and nasopharyngeal secretions.[8] The precise mechanism by which the ET opens remains a current and controversial topic. However, it is suggested that the levator veli palatini, the tensor veli palatini, and the salpingopharyngeus muscles are all required in opening the ET.[9] The physiological status of the ET becomes stable at the time of complete anatomical maturation. Hence, ETD is blamed for the development of chronic otitis media, tympanic membrane retraction, and progression of the latter to chronic cholesteatomatous otitis media[10-13] and might affect the success rate of middle ear surgery.[14] Vila et al.[15] reported that ETD is associated with 2 million visits per annum among those >20 years of age and 2.6 million visits among those <20 years. The cited authors revealed that the related diagnoses of ETD have a significant economic burden, and adequate knowledge of the pathophysiology of ETD and its suitable treatment may decrease the resource-intensive and significant economic burden.

Eustachian tube dysfunction represents a spectrum of symptoms for which diagnosis was made based on medical history and physical examination. Although the importance of the intact ET for the ventilation and health of the middle ear mucosa has been known for many centuries, no diagnostic gold standard tool for ET diseases is currently available.[2] Identification of ETD is difficult, and a recent systematic review identified wide variations in the diagnostic criteria employed.[16] In recent years, new therapeutic approaches for chronic obstructive ETD have been developed in several countries. However, a need has arisen for a practical method to follow the results of these approaches. In this context, the ETDQ-7 is used as a valid, safe, easy-to-use method for identifying of ETD-related symptoms in affected patients. Because this questionnaire is not meant for evaluation of ET symptoms that increase

Table 4. Turkish Version of the Eustachian Tube Dysfunction Questionnaire

1. Pressure in the ears?	Kulaklarınızda basınç hissi var mı?
2. Pain in the ears?	Kulaklarınızda ağrı hissi var mı?
3. A feeling that your ears are clogged or "under water"?	Kulaklarınızda tıkanıklık veya sesler suyun altından geliyormuş gibi hissediyor musunuz?
4. Ear symptoms when you have a cold or sinusitis?	Nezle veya sinüzit olduğunuzda kulaklarınızda herhangi bir şikayet oluyor mu?
5. Crackling or popping sounds in the ears?	Kulaklarınızda çatırdama veya patlama sesi oluyor mu?

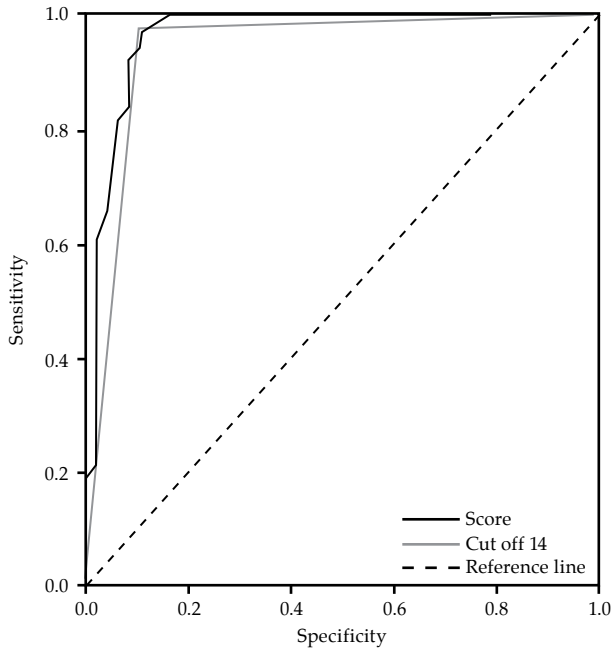

Figure 1. *Receiver operating characteristic analysis of the Eustachian Tube Dysfunction Questionniare-7 Turkish version.*

such conditions as acute upper tract infections or neoplastic process, participants with these conditions were excluded from the study group.

In 2012, Mc Coul et al.[3] developed ETDQ-7 as an optimal tool for clinical and research classification of the severity of ETD. This test is important as it is a disease-specific instrument for ETD. The authors reported a cut-off value for the diagnosis of ETD of ≥14.5 at 100% sensitivity and 100% specificity.[3] However, it has some limitations, firstly that ETDQ-7 is primarily concerned with the severity of disease, while it lacks the timing of symptoms. Second, recall time period and different pressures may produce different responses. On the other hand, it has standardized symptom severity and is easy to answer for respondents.[3]

The systematic questionnaire is needed, but it must be translated and culturally adapted before a questionnaire can be used in a community. Additionally, the psychometric properties of the translated version of the questionnaire need to be assessed and compared to those of the original version. The ETDQ-7 has seven basic questions and has several advantages for both patients and researchers. It can be easily applied and is available for ear, nose, and throat specialists in the primary setting. However, there is no available tests that can be applied to Turkish ETD patients. Therefore, there was a need for a Turkish version of the ETDQ-7. In the present study, we translated and culturally adapted the ETDQ-7 into the Turkish language and aimed to provide reliability and validity data for the translated version based on a sample of Turkish-speaking participants with ETD. Combining subjective and objective tests gives a horizon for a predictive function of ET. We used tympanometry and pneumatic otoscopy as objective tests, while ETDQ-7 is subjective. Based on our sample, the Turkish version of the ETDQ-7 demonstrated acceptable levels of reliability and validity to be used for Turkish speaking individuals with ETD. Internal consistency of the Turkish version using Cronbach alpha was 0.89. Test-retest reliability for the Turkish version of the ETDQ-7 was also excellent and comparable to what has been previously reported in the literature. The ROC analysis also confirmed that the ETDQ-7 produced excellent discrimination between participants with ETD and controls. The highest cut-off value was 14. Its sensitivity was 97.4%, positive predictive value was 88.1%, specificity was 89.4%, and negative predictive value was 97.7%. To the best of our knowledge, no prior study has focused on the translation and cultural adaptation of the ETDQ-7 into the Turkish language. Thus, we believe that this is the first such report.

In another study, Roeyen et al.[5] translated this questionnaire into Dutch and assessed its validity. They found an area under the curve in the ROC analysis for the obstructive ET group of 95%, confirming its excellent discriminant validity for the healthy control group; however, it was unable to discriminate the pathology of ET obstructive or patulous.[5] In addition, Schroder et al.[4] published the German version of the ETDQ-7. The authors evaluated 100 healthy subjects and 43 patients with chronic obstructive tube dysfunction. The mean total point value of the ETDQ-7 was 8.67 in the healthy controls and 24.7 in the patient group. They also found a sensitivity of 90.7 and specificity of 95.

Furthermore, the ETDQ-7 has some merits, compared to conventional history taking. First, the questionnaire includes a symptom score that allows more precise severity grading of

the disease. Second, it provides a formal and validated documentation of the history, leading to improved follow up.[5] However, this subjective method must be supported with objective evaluation methods. Duration of symptoms, timing of worsening symptoms with associated diseases such as rhinosinusitis or reflux should be assessed with the medical history. Roeyen et al.[17] assessed patients with baro-challenge-induced ETD and healthy controls using the ETDQ-7. The authors reported that ETQD-7 was useful in the diagnosis of baro-challenge-induced ETD dysfunction. Nonetheless, the major limitation of our study is its small sample size, although the results of our study confirm the usefulness of ETDQ-7 in the diagnosis of adults with obstructive ETD.

In conclusion, ETD is a debilitating condition, as the ET is not only a static pipe, but also a dynamic organ. Based on our study results, the ETDQ-7 is a valuable and practical instrument for grading the severity of disease. It is also useful for monitoring new treatment outcomes of ETD. Therefore, we recommend using the Turkish version of the ETDQ-7 in clinical practice.

Declaration of conflicting interests

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