DANISH MEDICAL JOURNAL

Original Article

Dan Med J 2020;67(7):A11190617

Validating the 7-item Eustachian Tube Dysfunction Questionnaire in Danish

Lars Juul Hansen[1], Henrik Glad[2], Andreas Jørkov[2], Kira Lundin[1] & Malene Kirchmann[1]

1) Department of ENT Head & Neck Surgery, Nordsjaellands Hospital, Hilleroed, 2) Department of Otorhinolaryngology and Maxillofacial Surgery, Zealand University Hospital, Koege, Denmark

Dan Med J 2020;67(7):A11190617

ABSTRACT

Introduction: Eustachian tube dysfunction (ETD) may result in hearing loss, chronic otitis and cholesteatoma. With advances in treatment options, the identification of patients with obstructive ETD is becoming increasingly important. The objective of this study was to validate a Danish translation of the 7-item Eustachian Tube Dysfunction Questionnaire (ETDQ-7).

Methods: All participants underwent tympanometry, otomicroscopy and completed the ETDQ-7. We included 34 ears from patients with obstructive ETD who had abnormal tympanometry curves but no history of cholesteatoma or adhesive otitis. As a control group, 48 otherwise healthy ears with a normal tympanometry curve were included from patients with known sensorineural hearing loss or normal hearing.

Results: A Cronbach's alpha of 0.77 indicated a good internal consistency reliability of the questionnaire. The mean ETDQ-7 score in the obstructive ETD group was 31 versus 13.5 in the control group (p = 0.00). A receiver operating characteristics analysis produced an area under the curve of 94%, showing excellent discriminatory abilities between the groups.

Conclusions: The ETDQ-7 has previously been validated in English, German, Dutch and Portuguese, demonstrating good clinical relevance. The Danish translation of the ETDQ-7 has produced similar results and may be valuable in diagnosing obstructive ETD and in monitoring the effect of balloon dilation of the Eustachian tube.

Funding: none.

The study was approved by the Danish Data Protection Agency (VD-2018-33, I-Suite 6229).

The Eustachian tube (ET) is anatomically and physiologically connected to the middle ear. Through an osseous lateral part, the ET connects the middle ear with the nasopharynx where it opens in a cartilaginous part. In adults, it is approx. 37 mm long, with the cartilaginous part constituting two thirds of the length [1]. The ET serves as a pressure

regulator of the middle ear and drains fluid via muco-ciliary transport [2]. Eustachian tube dysfunction (ETD) is a common problem in children and the condition may persist into adulthood, affecting around 1-5% of adults [3, 4]. In normal conditions, the middle ear pressure is continuously depleted, which is counterbalanced by intermittent ET openings offering gas to the middle ear [5] or by using Valsalva's manoeuvre. It has been shown that gas is delivered to the middle ear through short unconscious reflex-like openings [6]. However, ETD due to chronic infection, allergy, laryngeal reflux, primary mucosal pathology, anatomical obstruction or a dysfunctional dilation mechanism can prevent this gas exchange, resulting in middle ear under pressure [3]. Symptoms include aural fullness, affected hearing and pain [7]. ETD is likely one of the most important pathogenetic factors in the development of chronic middle ear diseases like chronic otitis media, retracted tympanic membrane, membrane perforations [8] and probably cholesteatoma.

ET function has been tested objectively using tubomanometry [9, 10], Eustachian Tube Score [9, 11], endoscopic video analysis [12], tympanometry [7] and pure-tone audiometry. There is no consensus regarding the optimal ET function test [13]. This underlines the anatomical complexity and probably also the limited knowledge about ET pathology. In 2012, the 7-item Eustachian Tube Dysfunction Questionnaire (ETDQ-7) was designed and validated by McCoul et al [14]. The ETDQ-7 estimates the severity of symptoms experienced by the patient with obstructive ETD. The ETDQ-7 is considered a valuable tool for diagnosing obstructive ETD and monitoring the effect of balloon dilation of the ET. It has subsequently been translated and validated for use in other languages [15-17]. The questionnaire consists of seven questions related to ET function. Each question is scored on a seven-level Likert scale where 1 indicates no problem and 7 indicates the worst possible symptoms. The sum of all scores determines how severe the ET dysfunction is (range: 7-49) with a score of ≥ 14.5 indicating ET dysfunction [14]. The ETDQ-7 does not discriminate well between obstructive ETD and a patulous Eustachian tube (PET) [15].

This study aimed to validate a Danish translation of the ETDQ-7 score in a Danish population comparing questionnaires from ETD patients and controls from two tertiary ear, nose and throat clinics.

METHODS

Translation from English into Danish

The translation from English into Danish was done by an experienced English speaker. The translation was reassessed by the author group. The final translation is listed in **Table 1**.

TABLE 1 / Danish translation of the 7-item Eustachian Tube Dysfunction Questionnaire.

Question no.	In Danish	In English
1	Trykken i ørerne?	Pressure in the ears?
2	Smerter i ørerne?	Pain in the ears?
3	Klokkefornemmelse eller følelse af at være under vand?	A feeling that your ears are clogged or "under water"?
4	Symptomer fra ørerne når du er forkølet eller har bihulebetændelse?	Ear symptoms when you have a cold or sinusitis?
5	Knitrende eller bloppende lyde i ørerne?	Crackling or popping sounds in the ears?
6	Ringen for ørerne?	Ringing in the ears?
7	Fornemmelse af at hørelsen er dæmpet?	A feeling that your hearing is muffled?

Subjects

Subjects were included from two tertiary care centres. Patients with obstructive ETD had been referred for balloon dilation of the ET. Controls had normal hearing or had been referred with a sensorineural hearing loss for a conventional hearing aid. All subjects were adults (age > 18 years).

Otomicroscopy, pure-tone audiometry and tympanometry were performed on all patients and controls.

The inclusion criteria for the obstructive ETD group were:

obstructive ETD symptoms for ≥ 1 month

abnormal tympanogram curve (b, c1 or c2)

an intact eardrum

Both normal and retracted eardrums as well as fluid-filled middle ears were included in the study.

Any patient with acute upper airway and/or ear infection, extensive middle ear pathology or cholesteatoma was excluded from the study. Controls were recruited among patients with sensorineural hearing loss or normal hearing, a normal tympanogram curve (a) and an air-filled middle ear. A total of 17 of the patients with sensorineural hearing loss also complained of tinnitus.

In all, 34 patients (16 females and 18 males) with obstructive ETD completed the ETDQ-7 of whom nine had bilateral ETD. A total of 48 controls (21 females and 27 males) completed the ETDQ-7 of whom 39 contributed with both ears. The mean age was 49 years in the obstructive ETD group and 70 years in the control group. The mean pure tone average (500; 1,000; 2,000 and 3,000 Hz) was 30 dB in the obstructive ETD group (n = 27 patients) and 32 dB in the

control group (n = 36 controls; in the remainder of obstructive ETD patients and controls, the hearing level at 3,000 Hz was not tested).

Statistical analysis

Statistical analysis was performed, and p-values of 0.05 were considered statistically significant. Where data from both ears were obtained, the mean ETDQ-7 score was calculated for both sides, showing no statistically significant difference between the right and left ear in either the obstructive ETD group (p = 0.9, Wilcoxon signed rank test) or the control group (p = 0.4, Wilcoxon signed rank test). Only the right ear was included in the statistical analysis when bilateral data existed. An abnormal tympanogram (b, c1 or c2) was used as a gold standard test of ETD. Internal consistency reliability was established through a Cronbach's alpha > 0.70.

Ethics

The study was approved by the Danish Data Protection Agency. Individual informed consent was obtained and signed by each patient.

Trial registration: Danish Data Protection Agency (VD-2018-33, I-Suite 6229).

RESULTS

A Cronbach's alpha of 0.77 was found in the obstructive ETD group, suggesting good internal consistency reliability of the questions in the Danish version of the ETDQ-7. Examining the sections of the analysis, we found that question four was less consistent with the overall questionnaire than the remaining questions, and our analysis even suggests that the Cronbach's alpha would be higher if the question was omitted (Cronbach's alpha = 0.8).

The mean ETDQ-7 score among patients with obstructive ETD was 31 (n = 34) compared to 13.5 among controls (n = 48) (p = 0.00, Mann-Whitney U test) (**Table 2** and **Table 3**). Furthermore, an ETDQ-7 score of ≥ 14.5 (cut-off value) was significantly more frequent in the obstructive ETD group than in the healthy control group (p = 0.00, Pearson's χ^2 test) (**Figure 1**).

TABLE 2 / Eustachian Tube Dysfunction Scores in the obstructive Eustachian tube dysfunction group (N = 34).

EDTQ-7 item no.	Min.-max.	Mean ± standard deviation
1	1-7	4.47 ± 1.83
2	1-7	3.00 ± 1.89
3	1-7	4.24 ± 2.18
4	1-7	5.15 ± 1.76
5	1-7	4.50 ± 1.71
6	1-7	3.56 ± 2.02
7	1-7	5.91 ± 1.71

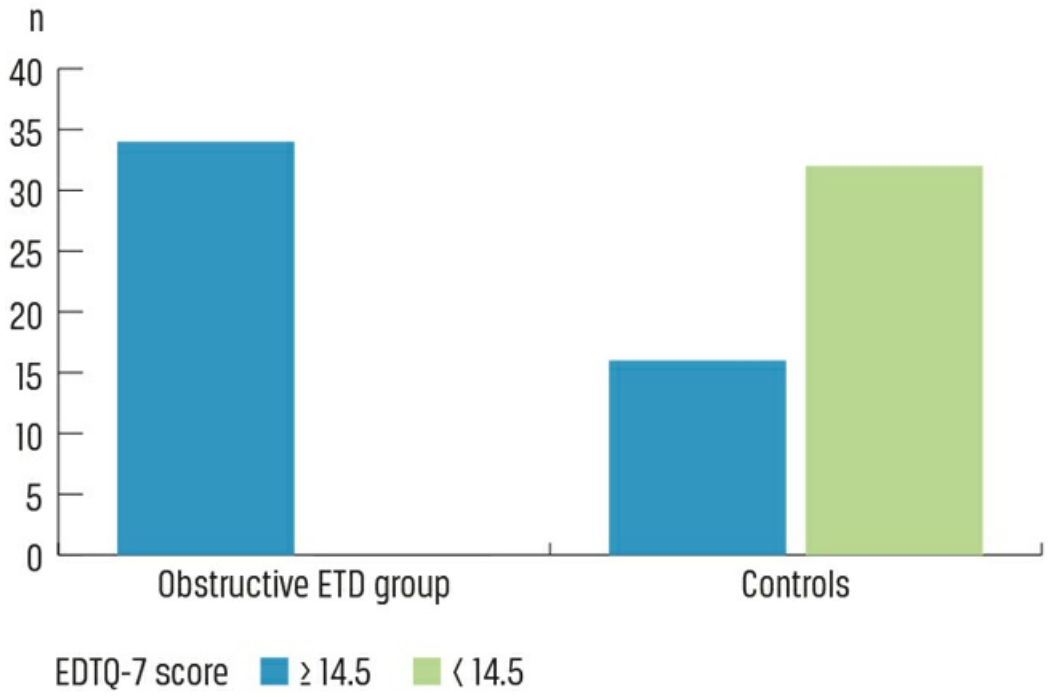
ETDQ-7 = 7-item Eustachian Tube Dysfunction Questionnaire.

TABLE 3 / Eustachian Tube Dysfunction Scores in the control group (N = 48).

EDTQ-7 item no.	Min.-max.	Mean ± standard deviation
1	1-6	1.50 ± 1.167
2	1-5	1.25 ± 0.812
3	1-5	1.56 ± 1.090
4	1-7	1.81 ± 1.497
5	1-7	1.54 ± 1.368
6	1-7	2.40 ± 1.783
7	1-7	3.44 ± 1.809

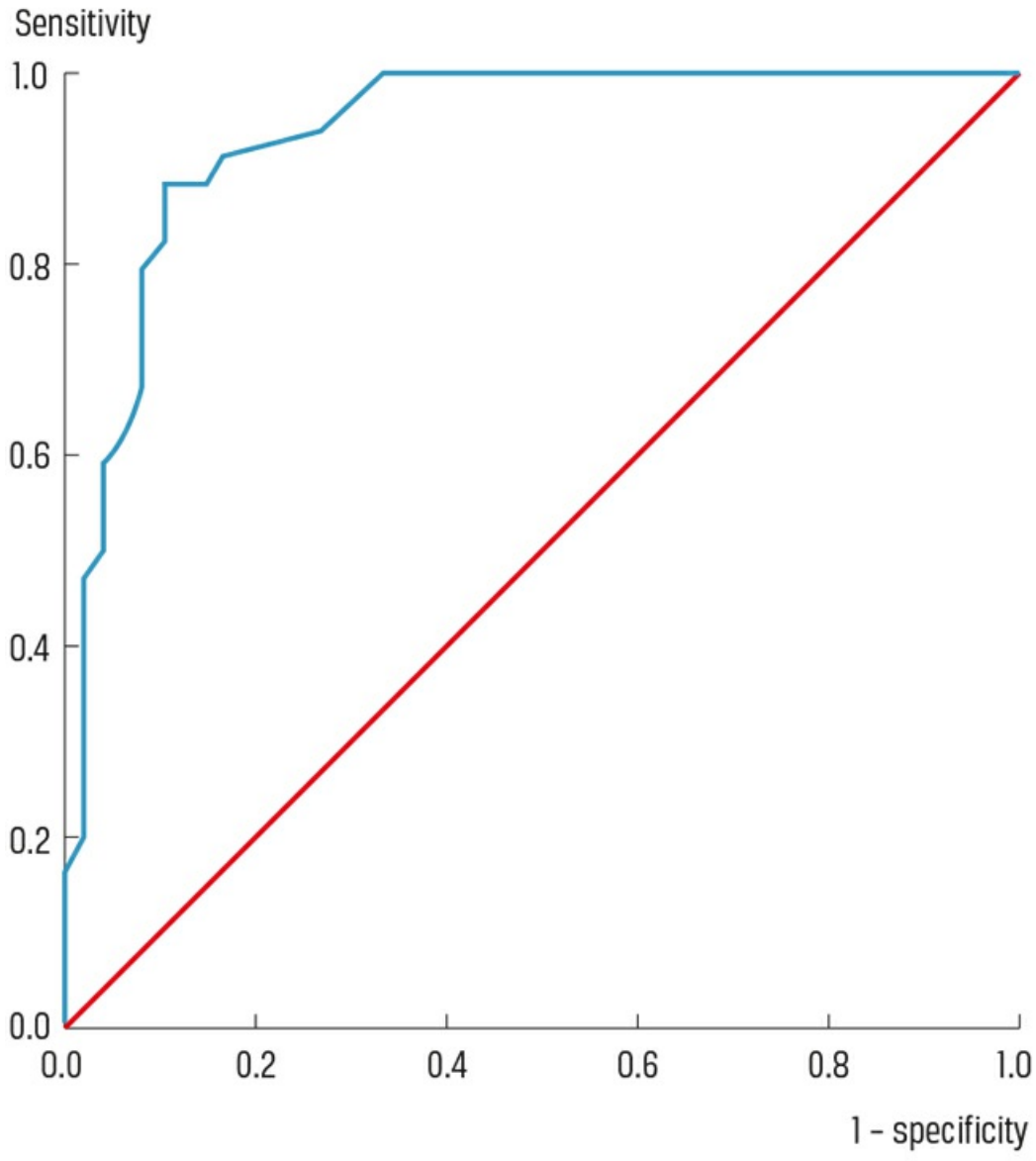
ETDQ-7 = 7-item Eustachian Tube Dysfunction Questionnaire.

FIGURE 1 / 7-item Eustachian Tube Dysfunction Questionnaire (ETDQ-7) scores in the obstructive Eustachian tube dysfunction (ETD) group (n = 34) and the control group (n = 48), showing the distribution of scores above and below a cut-off value of 14.5. A positive outcome (≥ 14.5) was significantly more likely in the obstructive ETD group (p = 0.00, Pearson's χ^2 test).



The sensitivity of the ETDQ-7 was 100% (95% confidence interval (CI): 90-100%) and the specificity was 67% (95% CI: 52-80%) when the ETDQ-7 cut-off value for obstructive ETD was set at ≥ 14.5. The likelihood ratio of a positive test result was three (sensitivity/(1–specificity)). A receiver operator characteristic (ROC) analysis revealed an area under the curve of 94% (95% CI: 89-99%), showing excellent discriminatory abilities between patients with obstructive ETD and healthy controls (**Figure 2**).

FIGURE 2 / Receiver operating characteristic (ROC) curve for the Danish translation of the 7-item Eustachian Tube Dysfunction Questionnaire. Diagonal segments are produced by ties.



DISCUSSION

An early diagnosis of obstructive ETD is important to take preventative measures against potentially severe middle ear pathology. In the absence of a compelling diagnostic test, the ETDQ-7 offers an alternative patient-reported outcome measure. We translated the ETDQ-7 into Danish and validated its applicability in a Danish population. In order to avoid falsely

inflating our numbers, only the right-sided ears were analysed when data from both ears were available. The mean ETDQ-7 scores between left and right ears were not significantly different, and the selection of one side was made randomly. When analysing the pooled data from both sides, we found very similar results to the ones presented here. However, two ears from the same participant cannot be considered statistically independent. Calculating the mean value from a set of ears was considered, but that approach poses a problem when testing the internal consistency reliability of a Likert scale like the ETDQ-7. We found good internal consistency reliability with a Cronbach's alpha of 0.77 in the obstructive ETD group. Question four showed a lower inter-item correlation than the remaining questions and would produce a slightly higher Cronbach's alpha if deleted (0.80). Upon analysing these results, we found no evidence that this is related to the translation. Question four regarding symptoms from the ears when suffering from a cold or sinusitis does have a slightly higher mean score than the remaining except for question 7 (Table 2). However, the overall internal consistency reliability is good, and a larger sample size would possibly improve the single-item correlation.

We found significantly higher ETDQ-7 scores in the obstructive ETD group than in the healthy control group. With a cut-off ETDQ-7 score of 14.5, the sensitivity was excellent (100%), and our ROC analysis produced an area under the curve of 94% which is slightly lower than but largely in line with previous studies (Van Roeyen et al: 95% and Schröder et al: 98.8% and Gallardo et al: 98%) [15-17]. In the studies by Van Roeyen et al and Schröder et al, cut-off values of 14.5 were also used, whereas Gallardo et al found that a cut-off value of 14 improved their results. The specificity in the present study was lower than the specificity reported in the study by McCoul et al [14]. One possible explanation of this is that our controls were recruited among patient with known sensorineural hearing loss and in some cases complaints of tinnitus. Our control group often reported ringing in the ears and a feeling that their hearing was muffled (ETDQ-7 questions six and seven). This indicates that these symptoms are related to hearing loss in general and are not specific symptoms of obstructive ETD. Changing the cut-off value [17] would rapidly reduce our sensitivity and thereby the questionnaire's value as a diagnostic and monitoring tool.

Patients diagnosed with unilateral obstructive ETD tended to score their "healthy" ear higher than the healthy controls did. This might be due to early symptoms on the contralateral "healthy" ear, or that patients generally find it difficult to separate the two ears when completing the ETDQ-7. However, the accompanying tympanometry allowed us to identify the diseased ears.

Overall, our results support the diagnostic properties of the ETDQ-7 but also underline that the questionnaire cannot stand alone but should be used as an aid in the diagnosis of obstructive ETD along with otomicroscopy and tympanometry. The inability of the questionnaire to discriminate between obstructive ETD and PET underlines this fact. In cases

of known obstructive ETD, the ETDQ-7 could be a valuable tool to monitor the effect of treatments like balloon dilation of the ET.

CONCLUSIONS

In the absence of a compelling diagnostic test of obstructive ETD, the ETDQ-7 may be a valuable aid in the diagnosis of this disease, and it shows promise as a monitoring tool in the treatment of obstructive ETD. The Danish translation can satisfyingly distinguish between obstructive ETD and healthy controls in the data presented here.

Correspondence: *Lars Juul Hansen*. E-mail: larsjuulhansen@gmail.com

Accepted: 6 April 2020

Conflicts of interest: none. Disclosure forms provided by the authors are available with the full text of this article at Ugeskriftet.dk/dmj

LITERATURE

1. Leuwer R, Koch U. Anatomie und Physiologie der Tuba auditiva. HNO 1999;47:514-23.
2. Bluestone CD, Doyle J. Anatomy and physiology of eustachian tube and middle ear related to otitis media. J Allergy Clin Immunol 1988;81:997-1003.
3. Swarts JD, Bluestone CD. Eustachian tube function in older children and adults with persistent otitis media. Int J Pediatr Otorhinolaryngol 2003;67:853-9.
4. Browning GG, Gatehouse S. The prevalence of middle ear disease in the adult British population. Clin Otolaryngol Allied Sci 1992;17:317-21.
5. Doyle WJ. A formal description of middle ear pressure-regulation. Hear Res 2017;354:73-85.
6. Gaihede M, Padurariu S, Jacobsen H et al. Eustachian tube pressure equilibration. Temporal analysis of pressure changes based on direct physiological recordings with an intact tympanic membrane. Hear Res 2013;301:53-9.
7. Mccoul ED, Anand VK. Eustachian tube balloon dilation surgery. Int Forum Allergy Rhinol 2012;2:191-8.
8. Bluestone CD. Pathogenesis of otitis media: role of eustachian tube. Ped Infec Dis J 1996;15:281-91.
9. Ockermann T, Reineke U, Upile T et al. Balloon dilatation eustachian tuboplasty: a clinical study. Laryngoscope 2010;120:1411-6.
10. Schröder S, Lehmann M, Korbmacher D et al. Evaluation of tubomanometry as a routine diagnostic tool for chronic obstructive Eustachian tube dysfunction. Clin Otolaryngol 2015;40:691-7.
11. Schröder S, Lehmann M, Sauzet O et al. A novel diagnostic tool for chronic obstructive eustachian tube dysfunction-the eustachian tube score. Laryngoscope 2015;125:703-8.
12. Poe DS, Abou-Halawa A, Abdel-Razek O. Analysis of the dysfunctional eustachian tube by video endoscopy. Otol Neurotol 2001;22:590-5.
13. Wendell Todd N. There are no accurate tests for eustachian tube function tasting instilled otologic drops is not a reliable test of eustachian tube function. Head Neck 2009;126:1041-2.

14. McCoul ED, Anand VK, Christos PJ. Validating the clinical assessment of eustachian tube dysfunction: The Eustachian Tube Dysfunction Questionnaire (ETDQ-7). Laryngoscope 2012;122:1137-41.
15. Van Roeyen S, Van De Heyning P, Van Rompaey V. Value and discriminative power of the seven-item eustachian tube dysfunction questionnaire. Laryngoscope 2015;125:2553-6.
16. Schröder S, Lehmann M, Sudhoff H et al. Assessment of chronic obstructive eustachian tube dysfunction. HNO 2013;62:160-4.
17. Gallardo FP, Onishi ET, Lira FI et al. Translation, validation and cultural adaptation of "The Eustachian Tube Dysfunction Questionnaire-7" (ETDQ-7) to Brazilian Portuguese (BR). Braz J Otorhinolaryngol 2019;85:456-64.