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**VALUE AND DISCRIMINATIVE POWER OF THE 7-ITEM EUSTACHIAN TUBE
DYSFUNCTION QUESTIONNAIRE.**

Obstructive or patulous Eustachian tube?

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ABSTRACT

Objective: Obstructive Eustachian tube (ET) dysfunction is a common condition associated with various otologic symptoms. The current lack of a diagnostic gold standard makes diagnosis and evaluation at follow-up difficult. The aim of the study was to determine the value and discriminative power of the 7-item Eustachian Tube Dysfunction Questionnaire (ETDQ-7) in patients with obstructive ET dysfunction and patulous ET.

Study design: Diagnostic test study.

Methods: The ETDQ-7 was completed by 39 patients with obstructive ET dysfunction, 8 patients with patulous ET and 22 healthy controls. The internal consistency was evaluated using Cronbach's alpha coefficient. Receiver-operator characteristics (ROC) were determined as an accuracy measure.

Results: The mean ETDQ-7 total score was 9.91 in the control group, 25.77 in the patients with obstructive ET dysfunction and 27 in the patulous ET group. The Cronbach's alpha coefficient was 0.795 in the obstructive ET group and 0.72 in the patulous ET group, demonstrating adequate reliability. The area under the curve in ROC analysis for the obstructive ET group was 95% and 96% for the patulous ET dysfunction group, which confirms its excellent discriminant validity towards the healthy control group. However, the ETDQ-7 cannot discriminate between obstructive ET dysfunction and patulous ET.

Conclusions: The ETDQ-7 can be a useful disease-specific rating scale for ET dysfunction but unable to discriminate between patients with obstructive ET dysfunction and patulous ET.

Key Words: Eustachian tube, questionnaires, Eustachian Tube Dysfunction Questionnaire-7

Level of evidence: 3b

INTRODUCTION

The Eustachian Tube (ET) is a narrow canal of approximately 3.5 - 3.7 cm, which courses from the middle ear cavity to the nasopharynx. (1) The ET consists of an osseous and a cartilaginous portion. The osseous part constitutes approximately one-third of the entire length and is patent at all times in contrast to the fibrocartilaginous portion, which is closed at rest and opens during swallowing, yawning or when forced open by performing the Valsalva manoeuvre. (1-3) Obstructive ET dysfunction is the failure of the ET to adequately ventilate the middle ear. Obstructive ET dysfunction is common, with an estimated incidence of 1% in the adult population and produces symptoms of aural fullness, otalgia, tinnitus and hearing loss, often exacerbated or precipitated by atmospheric pressure changes. (1-3) Obstructive ET dysfunction may also result in other middle ear pathologies such as serous otitis media, tympanic membrane retractions and cholesteatoma. (4) Patulous ET is a condition defined as the patency of the ET, which can generate loud and disturbing autophony and aural fullness. Many patients will report a 'blocked' ear, which makes it difficult to distinguish patulous ET from obstructive ET dysfunction. (1)

Many methods have been reported for measuring ET function, including impedance audiometry (5), otoscopic appearance (6), visual grading of endoscopic findings (7), Eustachian Tube Score (ETS) (8), tympanometry (4,9), Valsalva manoeuvre (6,8,9) and pure-tone audiometry. The complexity of the functional anatomy and physiology of the ET are reasons why there is no specific test capable of fulfilling all diagnostic needs. (10,11)

In 2012 McCoul et al. developed the 7-Item Eustachian Tube Dysfunction Questionnaire (ETDQ-7). The ETDQ-7 is a disease-specific instrument for the assessment of symptoms related to obstructive dysfunction of the ET and treatment outcome. The ETDQ-7 consists of 7 questions and a seven-item Likert scale, with a response of "1" indicating no problem and "7" indicating a severe problem. The total score is divided by the number of items (7) to give

an overall score ranging from 1.0 to 7.0. The need for a validated, disease-specific instrument for ET dysfunction is particularly notable because of the lack of a widely accepted objective measure of the presence and severity of this disorder. (12)

The aim of the study was to determine the value and discriminative power of the validated translation of the ETDQ-7 in a Dutch-speaking population with and without ET dysfunction.

MATERIALS AND METHODS

Ethics. The study was designed and conducted according to the Declaration of Helsinki (1996). Ethic committee approval was obtained.

Development of the Dutch version of the ETDQ-7. The ETDQ-7 was translated from English to Dutch and back translated by a native English speaker from Dutch to English. The assessment of the correlation between the original and the final English version was again achieved with item-by-item assessment. No divergence between the original and translated items was found. The final version of the Dutch ETDQ-7 is shown in Table 1.

Subjects. The ETDQ-7 was completed by 39 patients with obstructive ET dysfunction (table 2) and 8 patients who were diagnosed with patulous ET (table 3) at a tertiary referral academic hospital. Patients presenting with symptoms related to obstructive ET dysfunction, type C tympanogram or abnormal nine-step tympanometry or tubomanometry were included in the obstructive ET group. Patients with autophony symptoms consistent with patulous ET, disappearing when in supine position or when placing the head into a dependent position, tubomanometry or breath-synchronous fluctuations on impedance tympanometry, were included in the patulous ET group. Temporal bone CT was performed in the latter group to exclude a dehiscent superior semicircular canal.

The ETDQ-7 was also completed by a random control group of 22 persons without symptoms that could be related to ET dysfunction and patulous ET (table 4).

Validation measures. Internal consistency reliability was assessed by calculating Cronbach α for the entire instrument. Internal consistency was considered adequate if Cronbach α was $\geq .70$, coefficients $\geq .80$ were defined as good. The data were analysed using SPSS (SPSS Inc. Chicago, IL, USA).

Accuracy testing. Accuracy was determined using area under the curve (AUC) in the Receiver-Operating-Curves (ROC) analysis. AUC exceeding 0.9 was defined as excellent, 0.8-0.9 as good, 0.7-0.8 as fair, 0.6-0.7 as poor and 0.5-0.6 as failed.

RESULTS

Patients in the obstructive ET dysfunction group and patulous ET group had a mean age of 45 years and 32 years respectively. The control group had a mean age of 36 years. The ages ranged from 21 to 86 in the obstructive ET dysfunction group, from 17 to 44 in the patulous ET group and from 21 to 59 in the healthy control group. The obstructive ET group contained 26 (67%) men and 13 (33%) women, the patulous ET group contained 2 (25%) men and 6 (75%) women and the control group contained 8 men (36%) and 14 women (64%) The average total value of the ETDQ-7 in the control group was 9.91, in the obstructive ET group 25.77 and in the patulous ET group 27.

The Cronbach's alpha value of the obstructive ET group and patulous ET group was 0.795 and 0.72 respectively, meaning the internal consistency of the Dutch translation of ETDQ-7 was adequate in both groups of patients.

The overall scores of the obstructive ET dysfunction group and patulous ET group were compared separately with the healthy control group (Mann-Whitney U), which resulted in a p value of less than 0.001 in both analyses. The overall ETDQ-7 score among the 39 patients in the obstructive ET dysfunction group and the 8 patients in the patulous ET group was significantly greater than the score among the 22 patients in the control group. When comparing the obstructive ET dysfunction and patulous ET group, no statistically significant difference could be observed (Mann-Whitney U, p value 0.47).

The AUC in the ROC analysis demonstrated excellent accuracy both for the obstructive ET and patulous ET group when compared to the healthy control group. (Figure 1 -2).

DISCUSSION

With an incidence of 1% in the adult population, obstructive ET dysfunction implies a significant burden on the health system. Numerous diagnostic tools have been proposed in an attempt to measure ET function. The clinical utility of these ET function tests is currently limited. None are uniformly able to determine the adequacy of tubal function. The current lack of a diagnostic gold standard for obstructive ET dysfunction makes it difficult to identify patients who will benefit from treatment. Evaluation of baseline symptoms and treatment outcome is difficult because there is no pre-existing standard for the assessment of obstructive ET dysfunction symptoms. In the absence of objective diagnostic methods for ETD, the diagnosis is often based on clinical history. Patient reported outcome measures have gained importance to assess the impact of disease and treatment on health-related quality of life. Because clinical assessment of symptoms is a subjective process, McCoul et al. developed a symptom score as a reliable, disease-specific measure of obstructive ET dysfunction symptoms. The ETDQ-7 has several advantages over the traditional clinical history: a symptom score provides a more precise estimate of disease burden and produces formal and validated documentation of the patients' history. (12) Therefore we translated this questionnaire into Dutch and made an assessment of its validity. The internal consistency reliability of the ETDQ-7 was adequate in patients with obstructive ET dysfunction and patulous ET, meaning that all questions were close to measuring the same underlying concept. Our ROC analysis confirmed that the ETDQ-7 produces excellent discrimination between patients with obstructive ET dysfunction or patulous ET dysfunction and the control group. (12,13) In our opinion, an area under the curve of 95% might be a more realistic value for testing discriminant validity than the 100% of McCoul et al. (12) or the 64% reported by Schröder et al. while analysing their German translation of the ETDQ-7. (8,14) However, the

ETDQ-7 cannot discriminate between patients with obstructive or patulous ET dysfunction even while the ETDQ-7 does not include a question on autophony (Figure 3).

The Eustachian Tube Score 7 (ETS-7) has been reported as a promising diagnostic tool for obstructive ET dysfunction. (14) An advantage of the ETS-7 is the inclusion of objective and subjective elements including tubomanometry, tympanometry and objective Valsalva. Both instruments probably serve a different cause and are therefore complementary: the ETDQ-7 provides a disease-specific rating scale, while the ETS-7 combines subjective and objective elements to support the suspected diagnosis at presentation. Further research is needed to determine the responsiveness to change after treatment of both tools.

The major limitation of our study is mainly its small sample size. In our opinion, our results confirm the usefulness of ETDQ-7 in the diagnosis of patients with obstructive ET dysfunction.

CONCLUSION

This study demonstrates that the ETDQ-7 is a precise measure of symptoms in patients with obstructive ET dysfunction and therefore a valuable instrument. However, the ETDQ-7 cannot discriminate between patients with obstructive ET dysfunction and patulous ET. Its responsiveness to change after treatment of these patients remains to be studied.

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FIGURE LEGENDS

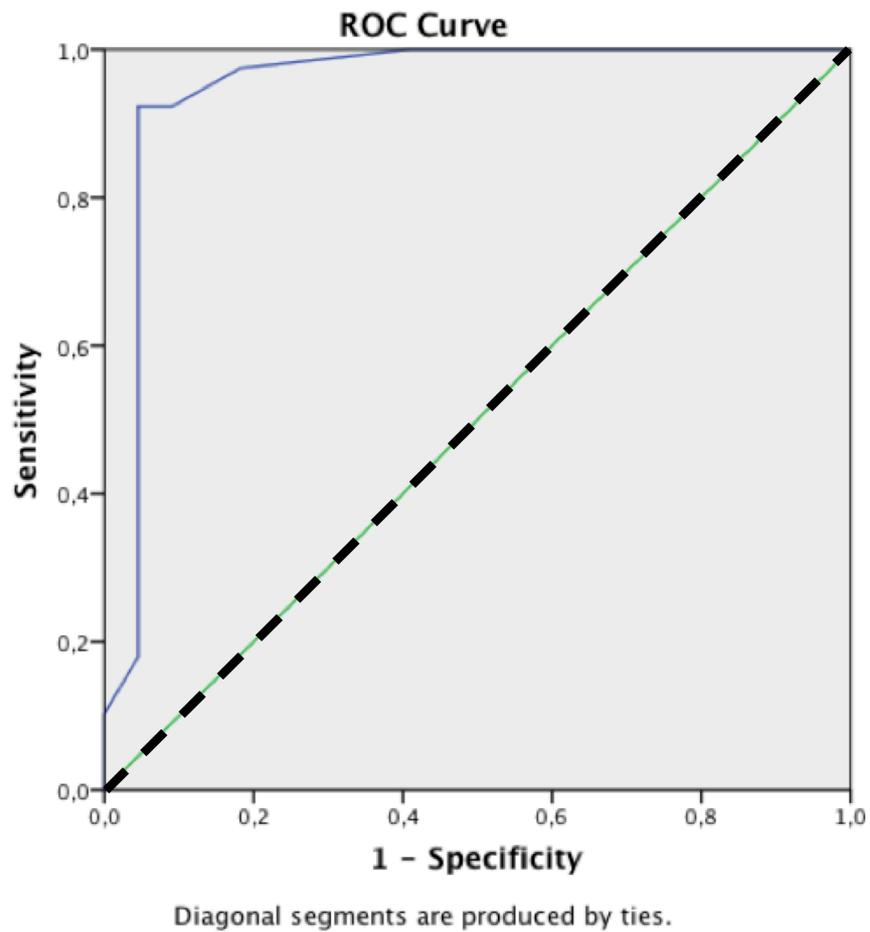


Figure 1. Receiver operating characteristic curve for the ETDQ-7 in detecting Eustachian tube dysfunction. Area under the curve = 95% with a confidence interval of 0.874-1.00. Dotted = diagonal reference line. Solid = ROC curve.

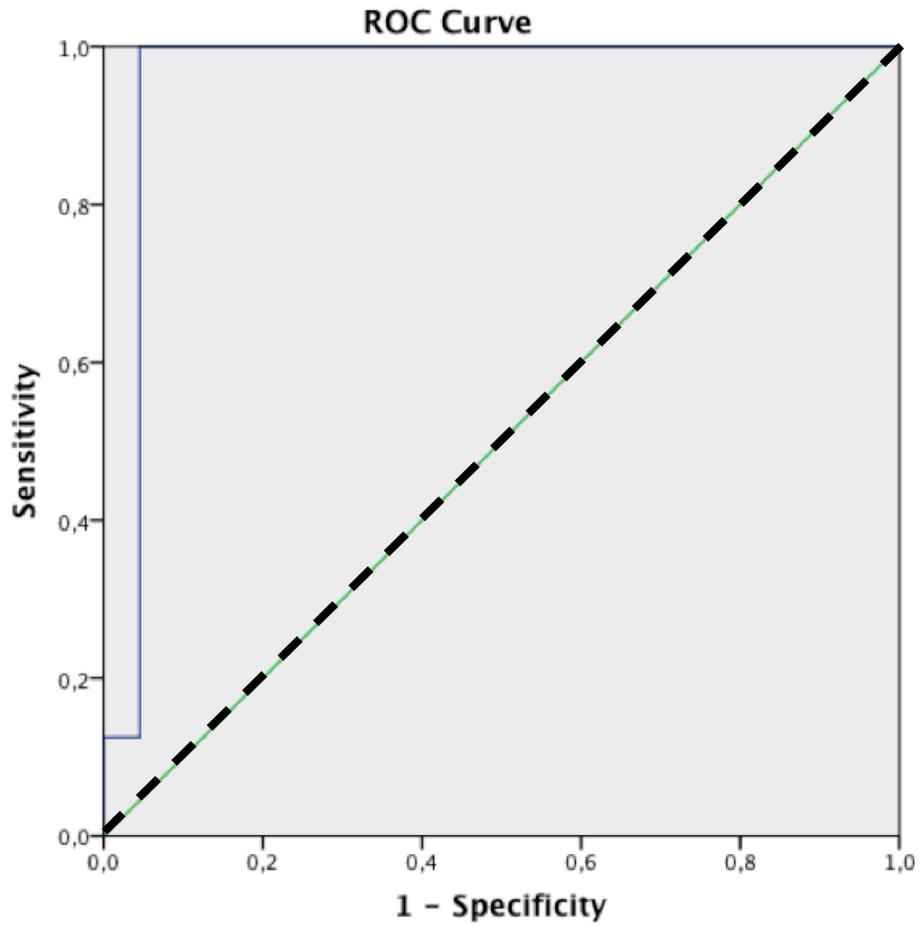


Figure 2. Receiver operating characteristic curve for the ETDQ-7 in detecting patulous ET.

Area under the curve = 96% with a confidence interval of 0.883-1.00. Dotted = diagonal reference line. Solid = ROC curve.

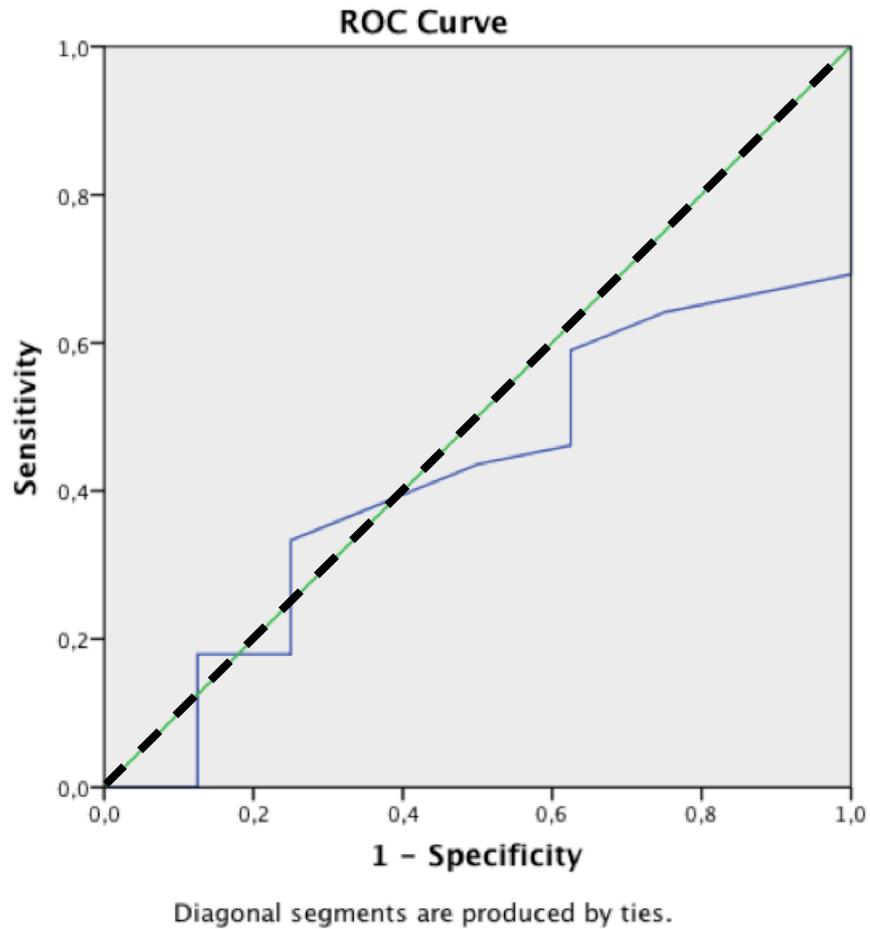


Figure 3. Receiver operating characteristic curve for the ETDQ-7 in detecting obstructive ET dysfunction from patulous ET. Area under the curve = 41,8% with a confidence interval of 0.227-0.610. Dotted = diagonal reference line. Solid = ROC curve.