Accuracy of the ETDQ-7 for Identifying Persons with Eustachian Tube Dysfunction

Miriam S. Teixeira, MD, PhD¹, J. Douglas Swarts, PhD¹, and Cuneyt M. Alper, MD¹,²

Abstract

Objective. To compare the accuracy of the Eustachian Tube Dysfunction Questionnaire (ETDQ-7) in identifying people with eustachian tube (ET) dysfunction based on symptoms and an objective ET function test.

Study Design. Cross-sectional study.

Setting. Tertiary referral center.

Subjects and Methods. Fifty-five subjects with and without symptoms suggestive of ET dysfunction completed the ETDQ-7 and had their ET function evaluated by the percentage of middle ear pressure equilibrated after 5 swallows (PEq5) either during a pressure chamber test (intact tympanic membranes) or by the inflation-deflation test (nonintact tympanic membranes). ETDQ-7 score ≥14.5 and PEq5 <60% were used to define ET dysfunction, and sensitivity, specificity, and receiver operating characteristic curves were used to assess the level of association between ETDQ-7 scores and PEq5.

Results. Twenty-five asymptomatic subjects (group 1 = 15 females, 15 white; mean ± SD age, 32 ± 12.8 years) and 30 subjects with ET dysfunction symptoms (group 2 = 17 females, 25 white; age, 27 ± 16.3 years) were included in the analysis. ETDQ-7 sensitivity and specificity regarding correct group assignment were 70% and 100%, respectively, and with respect to predicting PEq5<60%, 54% and 78%. An area under the curve (AUC) of 0.68 (95% CI, 0.53-0.83) at the participant level and 0.64 (95% CI, 0.50-0.77) at the ear level indicated a moderate level of association that was lower, though not statistically significant, for nonintact tympanic membranes (AUC = 0.63 at the participant level and AUC = 0.49 at the ear level).

Conclusion. The ETDQ-7 score had a higher correlation with the ET dysfunction symptoms than with an objective measure of ET function.

Keywords
ETDQ-7, eustachian tube, otitis media, pressure chamber test, inflation-deflation test, percentage pressure equilibrated

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The preservation of middle ear (ME) health and normal hearing requires that ME pressure be maintained at near-ambient levels, which is achieved by transient, muscle-assisted dilations of the eustachian tube (ET) lumen. Although ET dysfunction (ETD) is mainly regarded as the inefficiency to properly open to equalize pressure between the ME and the nasopharynx, it also comprises ears with a continuously open, patulous ET. Various methods are described to assess ET function: sonotubometry,²⁻⁴ forced response test,⁵ ⁹-step test,⁴ tubomanometry,⁶,⁷ nasopharyngeal maneuvers,⁵,⁸ videendoscopy,⁹,¹⁰ pressure chamber test,¹¹⁻¹⁴ and inflation-deflation test.¹⁵ Two of these can create consistent and reproducible ME-nasopharyngeal under- and overpressure gradients: the pressure chamber test, used for intact tympanic membranes, and the inflation-deflation test, used for nonintact tympanic membranes.⁵,⁸,¹⁵ At the standard under- or overpressure condition, a maneuver that results in ET opening (eg, swallowing) is performed to attempt equilibrating the pressure differential. The percentage of pressure equilibrated (PEq) after each swallow can then be used to quantify ET function.⁵,¹³⁻¹⁵ The advantages of PEq are that it can be used for intact and nonintact tympanic membranes, it can be expressed as a continuous-interval measure, and it assesses the most important functional aspect of the ET—its efficiency for ME pressure regulation.

Yet, the use of ET function tests is limited by the need for high-cost equipment and trained personnel, which are mostly available in specialized centers. Therefore, a simple
tool such as a questionnaire that could reliably identify people with ETD would be a valuable instrument for in-office use. About 5 years ago, the Eustachian Tube Dysfunction Questionnaire (ETDQ-7) was introduced as a new score system for quantitative assessment of ETD-related symptoms, with a possible score ranging from a minimum of 7 to a maximum of 49 points (Table 1). Receiver operating characteristic (ROC) curve analysis of the ETDQ-7 identified a cut-point total score \( \geq 14.5 \) (mean score \( \geq 2.1 \)) with perfect 100% sensitivity and 100% specificity for categorizing a patient as having ETD. To avoid recall bias, the ETDQ-7 includes only the symptoms that were present in the past month.16

The ETDQ-7 has been translated into German17 and Dutch18 and used for clinical evaluation of ETD18-20 and as an objective measure of surgical procedure outcomes, such as balloon dilation of the ET.20-22 Due to the increasing interest in a reliable score system that could help identify people with ETD, we designed a study to evaluate the accuracy of the ETDQ-7 for categorizing people with and without ETD based on symptoms and an objective measure of the ET function, the PEq.

**Methods**

This cross-sectional study was approved by the Institutional Review Board at the University of Pittsburgh, and written informed consent was obtained from all participants.

**Study Population**

Seventy-six generally healthy subjects participating in studies at the Middle Ear Physiology Laboratory and patients evaluated at the Eustachian Tube Dysfunction Clinic at the Children’s Hospital of Pittsburgh of UPMC had a detailed medical, ears, nose, and throat history, followed by otolaryngology examination, pneumatic otoscopy, and tympanometry measurements (sound frequency = 226 Hz; Titan, Interacoustics USA, Eden Prairie, Minnesota).

Subjects were classified as controls (group 1) if they had no history of ear disease or symptoms related to ETD and had normal otoscopy and pneumatic otoscopy and type A tympanograms. Controls could have a unilateral tympanostomy tube inserted by us if they were participating in studies at the Middle Ear Physiology Laboratory that required a nonintact tympanic membrane to perform ET function tests. The symptomatic group (group 2) consisted of people (1) with a history of chronic or recurrent otitis media or ME effusion, with or without the need for tympanostomy tubes and with or without a residual tympanic membrane perforation; or (2) with symptoms suggestive of ETD such as persistent ear pressure, popping and crackling sounds, or fullness/otalgia due to rapid barometric changes that are not alleviated by swallowing, yawning, or Valsalva maneuver. Each group was stratified as subgroup A, if the tympanic membrane was nonintact due to the presence of a tympanostomy tube or perforation and subgroup B, if the tympanic membrane was intact.

If signs of acute upper respiratory infection or nasal allergy, acute otitis media, ME fluid, otorrhea, or type B tympanogram was present on the testing day, the subjects were dismissed and the testing session postponed until the acute problem was resolved. Subjects were excluded if they had a history of cleft palate, a suspicion of submucous cleft, a craniofacial malformation, a history of ossicular chain reconstruction, or an inability to perform the tests.

**ETDQ-7**

All participants were instructed to answer the ETDQ-7 based on their symptoms present in the previous month (Table 1).16 Whenever necessary, children had the help of their caregivers to explain and answer the questionnaire. A total score \(< 14.5\) or a mean score \(< 2.1\) was considered normal.

**ET Function Tests**

The test chosen to drive ME over- and underpressures relative to ambient and evaluate ET function depended on the tympanic membrane status: a pressure chamber was used for intact tympanic membranes and the inflation-deflation

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**Table 1. ETDQ-7 Questions Related to Eustachian Tube Dysfunction Symptoms Present in the Past Month and the Scoring System from 1 to 7.a**

<table>
<thead>
<tr>
<th>Question</th>
<th>No Problem</th>
<th>Moderate Problem</th>
<th>Severe Problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>Over the Past 1 Month, How Much Has Each of the Following Been a Problem</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>for You?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Pressure in the ears?</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2. Pain in the ears?</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3. A feeling that your ears are clogged or “under water”?</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4. Ear symptoms when you have a cold or sinusitis?</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5. Crackling or popping sounds in the ears?</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6. Ringing in the ears?</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7. A feeling that your hearing is muffled!</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

Abbreviation: ETDQ-7, Eustachian Tube Dysfunction Questionnaire.

Pressure Chamber Test. The pressure chamber used was a HyperTec hyperbaric chamber (5100; HyperTec, Olney, Texas) modified during construction for hypo- and hyperbaric applications. The subject entered the pressure chamber with a technician, who performed tympanometry measurements at specific time points. A staff member located outside controlled the chamber pressures and recorded the tympanometry readings. During the test, subjects performed commanded swallows with 1-mL aliquots of water from a 5-mL plastic syringe. The protocol for all experiments consisted of the following: (1) baseline tympanometry at ambient pressure and repeated tympanometry after 1 and 5 swallows; (2) chamber pressure increased at a rate of approximately 10 daPa/s to achieve a target ME pressure between −90 and −250 daPa (pressure chamber around 250 daPa and adjusted as necessary); (3) tympanometry before and after 1 and 5 swallows; (4) chamber pressure returned to ambient; and (5) tympanometry before and after 1 and 5 swallows—end of the test.

Inflation-Deflation Test. The inflation-deflation test instrument was developed by us and consists of an ear canal probe coupled serially via tubing to an SDX01D4 differential pressure transducer (Honeywell, Morristown, New Jersey) through a 3-way valve to a flow sensor (Respiratory Flowhead 1L MTL11; AD Instruments, Dunedin, New Zealand) and a third 3-way valve to a syringe. The transducer signals were routed via a PowerLab 4/35 data acquisition system (PL3504) to a personal computer running LabChart 7.3.6 software (AD Instruments) for real-time display of ear pressures and data storage. The ear probe was sealed into the test ear and ME pressure zeroed to ambient. ME pressure was then increased to 150 daPa above ambient and the valve closed to reduce the system volume. The subject was asked to swallow 5 times at about 4-second intervals while the residual ME pressure values were recorded. Then, ME pressure was zeroed to ambient and the procedure repeated at a ME pressure of −150 daPa. After 5 swallows, the ME pressure was zeroed and the ear probes removed.

For this study, only the subject’s ability to equalize relative negative ME pressure was used in the analysis because it mimics the normal pathophysiology of ETD and ME disease. That condition corresponds to the deflation part of the inflation-deflation test and the 250 daPa segment in the pressure chamber test. Only tests in which both left and right ME pressures reached a minimum of −90 daPa were considered evaluable and included in the analysis. The parameter for analysis was the percentage of ME underpressure equilibrated after 5 swallows (ie, after 5 attempts to open the ET). PEq after 5 swallows (PEq5) was calculated as the difference in ME-gauge pressures before and after 5 swallows divided by the pre-swallow ME pressure times 100. The PEq5 could not be calculated, and tests were excluded from the analysis if the paired tympanograms for a test sequence had either a flat tracing (type B) or an otherwise nonmeasurable compliance peak. On average, the percentage of negative ME-nasopharyngeal PEq5 in the control population was 75%. To be more conservative, in this analysis we chose <60% as the cutoff value to classify ears as having decreased ET function.

During both test protocols, input from submucosal surface electrodes (Noraxon Dual Electrodes; Noraxon USA Inc, Scottsdale, Arizona) placed over the anterior belly of the digastric muscle was continuously monitored for confirmation and timing of the commanded swallows.

Data Analysis
Sensitivity and specificity for group 1 and 2 assignment were computed with an ETDQ-7 score ≥14.5 and PEq5 <60% as an indication of ETD. The ETDQ-7 does not discriminate if symptoms come from left, right, or both ears, so to avoid assumptions that could create a selection bias, the primary PEq5 statistical analysis was done at the participant level using the lowest PEq5 for 2 ears and at the ear level using the same ETDQ-7 for both ears.

For participant-level analysis, ETDQ-7 and PEq5 scores were compared between the symptomatic and control groups with the 2-sample Wilcoxon test (proc npar1way, SAS 9.4; SAS Institute, Cary, North Carolina). Exact 95% Clopper-Pearson confidence intervals were obtained for sensitivity and specificity (proc freq, SAS 9.4), and Fisher exact test was used for comparing sensitivity or specificity between subgroups of patients.

Kendall correlation coefficient was used to test the association between the PEq5 and ETDQ-7 scores (proc corr, SAS 9.4). Association of ETDQ-7 scores with the inadequate PEq5<60% as well as with group assignment was assessed with the empirical area under the receiver operating characteristic curve. At ear-level data, statistical analysis (including evaluating Kendall coefficient and area under the curve [AUC]) was performed with the nonparametric bootstrap confidence interval for clustered data with the participant as a resampling unit, based on 10,000 bootstrap samples.

Results
From the initial 76 subjects evaluated, 17 were excluded because only data from 1 ear were available, and 4 were excluded because the ME pressure gradient did not reach a minimum of −90 daPa for the PEq5 calculations.

Of the 55 remaining subjects, 25 were classified as group 1, consisting of 15 females and 10 males (15 white, 9 black, and 1 other race; mean ± SD age, 32 ± 12.8 years). Thirty were included in group 2, consisting of 17 females and 13 males (25 white, 4 black, and 1 other race; age, 27 ± 16.3 years). Of the 110 tested ears, 30 had tympanostomy tubes (group 1A = 6 [due to participation in studies at the Middle Ear Physiology Laboratory], group 2A = 24); 4 had residual perforation due to recurrent ME infections and/or tympanostomy tube insertion (group 2A = 4); and 76 had intact tympanic membranes (group 1A = 6, group 1B = 38, group 2A = 6, group 2B = 26).

Table 2 shows the distribution of ETDQ-7 scores for each question and the total and mean scores and standard
error for the ETDQ-7 and PEq5 in each of the 4 groups. Controls had ETDQ-7 total scores ranging from 7 to a maximum of 12, while in the symptomatic group the scores went from 7 to 41. Interestingly, 9 symptomatic subjects had scores \( \leq 14.5 \) (5 had bilateral long-term tympanostomy tubes; 1 had unilateral perforation; and 3 had bilateral intact tympanic membranes), and 24 ears had PEq5 \( \leq 60\% \) (8 non-intact and 16 intact tympanic membranes). Among controls, there were 9 ears with PEq5\( \leq 60\% \), 3 with tympanostomy tubes and 6 with intact tympanic membranes.

**Association with the Group Assignment**

The total ETDQ-7 score was significantly higher in the symptomatic group than in the control group (21.6 vs 8.1, \( P < .0001 \)). The difference stemmed primarily from participants with intact membranes (26.1 vs 7.7, \( P < .0001 \)), whereas participants with nonintact membranes had a relatively small difference (18.1 vs 9.2, \( P = .95 \)). Sensitivity and specificity of ETDQ-7 with respect to group 1 and 2 classification were correspondingly 70\% (95\% CI, 0.51-0.85) and 100\% (95\% CI, 0.86-1.00) with an AUC of 0.89 (95\% CI, 0.80-0.98), indicating a high correlation with group assignment. Sensitivity level appeared to be higher, albeit not statistically significant, for participants with intact membranes than for those with nonintact membranes (77\% vs 65\% respectively, \( P = .6908 \)).

The PEq5 score was significantly lower in the symptomatic group than in the control group (0.39 vs 0.69, \( P = .0027 \)). The difference stemmed from participants with intact (0.51 vs 0.74, \( P < .1715 \)) and nonintact tympanic membranes (0.29 vs 0.53, \( P = .1201 \)). Sensitivity and specificity of PEq5 with respect to

### Table 2. ETDQ-7 Scores and PEq5 Values for Participants in Control and Symptomatic Groups.*

<table>
<thead>
<tr>
<th>Question</th>
<th>Control</th>
<th>Symptomatic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group 1A (n = 6)</td>
<td>Group 1B (n = 19)</td>
</tr>
<tr>
<td>Question 1</td>
<td>Mean 1.50</td>
<td>1.11</td>
</tr>
<tr>
<td></td>
<td>SE 0.22</td>
<td>0.07</td>
</tr>
<tr>
<td>Question 2</td>
<td>Mean 1.00</td>
<td>1.00</td>
</tr>
<tr>
<td></td>
<td>SE 0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>Question 3</td>
<td>Mean 1.33</td>
<td>1.05</td>
</tr>
<tr>
<td></td>
<td>SE 0.21</td>
<td>0.05</td>
</tr>
<tr>
<td>Question 4</td>
<td>Mean 1.83</td>
<td>1.37</td>
</tr>
<tr>
<td></td>
<td>SE 0.40</td>
<td>0.11</td>
</tr>
<tr>
<td>Question 5</td>
<td>Mean 1.00</td>
<td>1.11</td>
</tr>
<tr>
<td></td>
<td>SE 0.00</td>
<td>0.07</td>
</tr>
<tr>
<td>Question 6</td>
<td>Mean 1.33</td>
<td>1.00</td>
</tr>
<tr>
<td></td>
<td>SE 0.21</td>
<td>0.00</td>
</tr>
<tr>
<td>Question 7</td>
<td>Mean 1.17</td>
<td>1.11</td>
</tr>
<tr>
<td></td>
<td>SE 0.17</td>
<td>0.07</td>
</tr>
<tr>
<td>ETDQ-7 total score</td>
<td>Mean 9.17</td>
<td>7.74</td>
</tr>
<tr>
<td></td>
<td>SE 0.70</td>
<td>0.25</td>
</tr>
<tr>
<td>ETDQ-7 score ( \geq 14.5 )</td>
<td>Rate 0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>PEq5 (worst ear)</td>
<td>Mean (%) 53</td>
<td>74</td>
</tr>
<tr>
<td></td>
<td>SE (%) 17</td>
<td>7</td>
</tr>
<tr>
<td>PEq5 ( \leq 60% )</td>
<td>Rate 0.50</td>
<td>0.16</td>
</tr>
</tbody>
</table>

Abbreviations: ETDQ-7, Eustachian Tube Dysfunction Questionnaire; PEq5, pressure equilibrated after 5 swallows.

*Groups 1A and 2A: nonintact tympanic membranes. Groups 1B and 2B: intact tympanic membranes.
group 1 and 2 classification were correspondingly 73% (95% CI, 0.54-0.88) and 76% (95% CI, 0.55-0.91).

Association between ETDQ-7 and PEq5
With respect to predicting PEq5 ≤ 60%, ETDQ-7 had sensitivity and specificity of 54% and 78%, respectively, at the participant level. Also at the participant level, the ETDQ-7 and the lowest PEq5 scores were not significantly correlated (Kendall correlation, −0.18; P = .0689). With respect to predicting PEq5 < 60%, ETDQ-7 had an AUC of 0.68 (95% CI, 0.53-0.83), indicating a moderate level of association (Figure 1A). The level of association appeared to be lower, albeit not statistically significant, for participants with nonintact tympanic membranes (AUC = 0.63, 95% CI, 0.40-0.87; Figure 1B) than for participants with intact membranes (AUC = 0.72, 95% CI, 0.54-0.91; Figure 1C).

At the ear level, the ETDQ-7 and ear-specific PEq5 scores remained at approximately the same low and statistically nonsignificant level (Kendall coefficient, −0.13; 95% CI, −0.31 to 0.05). With respect to predicting PEq5 < 60%, ETDQ-7 had an AUC of 0.64 (95% CI, 0.50-0.77), indicating a moderate level of association (Figure 2A). The association appeared to be weaker, albeit not statistically significant, for ears with nonintact tympanic membranes (AUC = 0.49, 95% CI, 0.29-0.71; Figure 2B) than for ears with intact membranes (AUC = 0.72, 95% CI, 0.53-0.87; Figure 2C).

Discussion
Previous studies reported sensitivities of 91% to 100%,16,17 specificities of 95% to 100%,16,17 and AUCs from 0.95 to 1.0 (95% CI, 0.874-1.00)16,18 to the accuracy of the ETDQ-7 to discriminate people with ETD, but none of them based their results on an objective assessment of the ET function.

In the first part of the analysis, we used the participants’ perception and report of their symptoms to assign them to group 1 or 2. As expected, the ETDQ-7 showed 100% specificity for this group assignment, as none of the 25 controls reported complaints related to ETD or had scores > 12. The lower sensitivity found in our study (70%) derived from the 9 people in group 2 who had scores < 14.5: 5 had bilateral tympanostomy tubes (scores: 7, 7, 7, 8, 9); 1 had unilateral perforation (score: 9); and 3 had bilateral intact tympanic membranes (scores: 9, 13, 13). We believe that these lower scores were due to the tubes and tympanic membrane perforations temporarily bypassing ET problems or to the intermittent nature of the symptoms that failed to be captured by the 1-month time frame of the questionnaire.

On the second part of the analysis, instead of symptoms, we evaluated the ETDQ-7 accuracy for categorizing ETD based on an objective measure of the ET function. With respect to predicting PEq5 < 60%, ETDQ-7 had a sensitivity and specificity of 54% and 78%, respectively, and AUCs of 0.68 (95% CI, 0.53-0.83) at the participant level (Figure 1A) and 0.64 (95% CI, 0.50-0.77) at the ear level (Figure 2A), indicating only a moderate level of association. As shown in Figures 1B and 2B, the association was weaker, although not statistically significant, in ears with nonintact tympanic membranes (AUCs = 0.63 and 0.49 at the participant and ear levels, respectively). Nine ears in the control group with no reported history of ME disease or ETD had PEq5 ≤ 60%, and 24 ears in the symptomatic group had PEq5 ≥ 60%, showing that symptoms alone are not sufficient to assess the level of ET function. Subjects with patulous ETs were tested but did not meet the study inclusion criteria, because they could not hold changes in ME pressure during the pressure chamber test or inflation-deflation test. However, in the study conducted by Van Roeyen et al, the ETDQ-7 failed to differentiate between obstructive and patulous types of ETD.18 Together, all these factors have important implications if the ETDQ-7 is used as the only method to assess ETD for indications of surgical procedures. For example, patients with symptoms but normal ET function will not benefit or might even
become patulous if subjected to the balloon dilation of the ET, while a patient with an already patulous ET has the risk of worsening the problem.

Regarding the ETDQ-7 questions, symptoms such as ear pain, tinnitus, and muffled hearing can be present in a series of trigeminal nerve and inner ear pathologies, so these questions do not help differentiate cases not related to ETD. Muffled hearing and clogged ears are very similar symptoms, which introduces redundancy to the questionnaire and scoring system. In this study, 6 children were between 6 and 11 years old, and despite the help of their caregivers in explaining the questionnaire and the scoring system, we found it difficult for children <12 years old to consistently assess their symptoms, which restricts the use of the ETDQ-7 in this age group.

In conclusion, our results show that although the ETDQ-7 had high correlation with symptoms, it was only moderately associated with an objective measure of the ET function. The scoring system also appears less reliable when applied to people with nonintact tympanic membranes. Further studies on the validation of the ETDQ-7 are necessary and should include test-retest reliability, assessment of the placebo effect on the scoring system, and evaluation of accuracy for categorizing ETD based on other modalities of ET function tests. Despite these refinements, it seems improbable that symptoms alone will supplant the information derived from objective ET function tests.26

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Author Contributions

Miriam S. Teixeira, study design, data acquisition and analysis, paper draft and final approval and agreement to be accountable for all aspects of the work; J. Douglas Swarts, study design, data acquisition and analysis, paper review and final approval and agreement to be accountable for all aspects of the work; Cuneyt M. Alper, study design, data acquisition and analysis, paper review and final approval and agreement to be accountable for all aspects of the work.

Disclosures

Competing interests: None.

Sponsorships: No role in the study design, analysis, writing of manuscript approval.

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