

REVIEW

Predictive value of the Eustachian Tube Dysfunction Questionnaire-7 for identifying obstructive Eustachian tube dysfunction: A systematic review

Nicholas S. Andresen MD¹  | Jeffrey D. Sharon MD² |
Carrie L. Nieman MD, MPH^{1,3}  | Stella M. Seal MLS⁴ | Bryan K. Ward MD¹ 

¹Department of Otolaryngology—Head and Neck Surgery, Johns Hopkins University School of Medicine, Baltimore, Maryland, USA

²Department of Otolaryngology—Head and Neck Surgery, University of California—San Francisco, San Francisco, California, USA

³Cochlear Center for Hearing and Public Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, USA

⁴Welch Medical Library, Johns Hopkins University School of Medicine, Baltimore, Maryland, USA

Correspondence

Nicholas S. Andresen, MD, Johns Hopkins Outpatient Center, Department of Otolaryngology—Head and Neck Surgery, 601 N. Caroline Street, 6th Floor, Baltimore, MD 21287, USA.
Email: nandres1@jhmi.edu

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Abstract

Objective: To perform a systematic review to determine if a total score of ≥ 14.5 (mean score ≥ 2.1) on the ETDQ-7 accurately identifies patients with obstructive Eustachian tube dysfunction (OETD) on impedance tympanometry (peak compliance < 0.2 mL or middle ear pressure of -100 daPa) or other objective measures of OETD.

Methods: A systematic review without a meta-analysis was performed of studies in four electronic databases (Pubmed, Embase, Web of Science, and Scopus) that used the ETDQ-7 and at least one objective measure of OETD.

Results: Six-hundred and fifty-two studies were identified in the initial literature search. Abstracts from 337 studies were screened, followed by full-text review of 61 studies, and qualitative synthesis of 12 studies. Tympanometry was used as an objective measure in ten studies. Eight of the 12 included studies had patient cohort selection bias. Eight studies administered the ETDQ-7 in cohorts of patients with or without OETD, already confirmed on tympanometry, and found a sensitivity of 91%-100% and specificity of 67%-100%. Four studies administered the ETDQ-7 to patients who had not previously undergone objective testing and found a sensitivity of 49%-80% and specificity of 24%-78%.

Conclusions: The ETDQ-7 is an important patient-reported outcome measure. However, based upon existing literature, the ETDQ-7 appears limited as a diagnostic tool for OETD or as an objective measure of Eustachian tube function.

KEYWORDS

ETDQ-7, Eustachian tube, Eustachian tube dysfunction, Eustachian Tube Dysfunction Questionnaire-7, patient-reported outcomes

1 | INTRODUCTION

The Eustachian tube connects the middle ear to the nasopharynx and is important for the maintenance of middle ear health. Proper function

of the Eustachian tube allows for pressure equalization and ventilation of the middle ear, mucociliary clearance of secretions from the middle ear, and protection of the middle ear from sounds and pathogens from the nasopharynx.¹ Patients with obstructive Eustachian tube

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dysfunction (OETD) experience symptoms such as ear pain, fullness, pressure, or hearing difficulty and have evidence of abnormal Eustachian tube function on otoscopy or tympanometry.² Eustachian tube dysfunction includes three distinct clinical subtypes (obstructive, patulous, baro-challenge induced) and may affect as many as 11 million Americans.³

The Eustachian Tube Dysfunction Questionnaire (ETDQ-7) is a seven-question survey that was developed in 2012 as a patient-reported outcome measure to assess the severity of Eustachian tube dysfunction (ETD) symptoms and measure treatment response.⁴ Since its development, the ETDQ-7 has been translated into at least nine languages⁵⁻¹² and used extensively in the assessment of clinical response to balloon dilation of the Eustachian tube (BDET).¹³ ETDQ-7 scores improve with BDET¹³ and may also improve following sinus surgery.^{14,15} However, the degree to which patient symptoms and ETDQ-7 scores predict objective measures of Eustachian tube function, such as tympanometry, remains unknown.

When developed by McCoul et al,⁴ ETDQ-7 was administered to a group of 50 patients with OETD confirmed by the presence of symptoms for longer than 1 month and abnormal impedance audiometry, and was compared to asymptomatic controls with normal tympanograms. Among this cohort of patients, a total ETDQ-7 score of ≥ 14.5 had 100% sensitivity and 100% specificity for predicting OETD. Similarly designed studies used to validate translated^{5,6,8-12} versions of ETDQ-7 have found the ETDQ-7 to have a sensitivity and specificity of $>90\%$, often approaching 100%. However, a recent study by Teixeira et al¹⁶ found that a total score of ≥ 14.5 on the ETDQ-7 had a sensitivity and specificity of 54% and 78%, respectively, for predicting OETD identified by pressure chamber and inflation-deflation testing. Additional studies have similarly called into question the sensitivity and specificity of the ETDQ-7¹⁷⁻¹⁹ and studies of BDET have shown large numbers of patients with abnormal ETDQ-7 scores, but normal tympanograms.²⁰⁻²³ There is a lack of a consensus regarding the ability of ETDQ-7 to predict OETD and the degree to which ETDQ-7 could substitute for objective measures of ET function and the diagnosis of OETD.

The primary aim of this systematic review was to determine if a total score of ≥ 14.5 (mean score ≥ 2.1) on the ETDQ-7 accurately identifies patients with OETD on impedance tympanometry (peak compliance <0.2 mL or middle ear pressure of -100 daPa) among a cohort of patients presenting with possible OETD. Other objective measures of OETD were considered when available.

2 | METHODS

2.1 | Search strategy

A systematic review was performed using four electronic databases (Pubmed, Embase, Web of Science, and Scopus) for articles published before 31 July 2020 in English language publications. Search terms included "Eustachian Tube Dysfunction Questionnaire," "Eustachian Tube Dysfunction Questionnaire-7," "ETDQ-7," and "(Eustachian tube dysfunction OR Eustachian tube balloon dilation OR Eustachian

tube disorder) AND (questionnaire OR survey OR tool)" (Table S1). A university informationist (SMS) oversaw the literature search and Covidence systematic review software²⁴ was used for reference management. The following PICO model was utilized:

- Patient: individuals presenting to an otolaryngology office with otologic symptoms.
- Intervention: ETDQ-7 total score of ≥ 14.5 (mean item score ≥ 2.1).
- Comparison: abnormal impedance tympanometry (peak compliance <0.2 mL or middle ear pressure of -100 daPa) or other objective measures (when tympanometry is not used).
- Outcome: sensitivity and specificity of a total ETDQ-7 score of ≥ 14.5 (mean item score ≥ 2.1) for detecting abnormal impedance tympanometry or other objective measures.

This study was conducted in accordance with PRISMA guidelines and a PRISMA checklist was completed.²⁵ The Cochrane Risk of Bias assessment tool was used to evaluate all studies with a reported sensitivity and specificity.²⁶

2.2 | Inclusion criteria

Following the removal of duplicate references, one author (Nicholas S. Andresen) assessed studies for eligibility. The abstracts of all studies were reviewed and those that met inclusion criteria underwent full-text review. Studies were included for full-text review if they included adult participants greater than 18 years old, were published in full-text format in English, and included both ETDQ-7 scores and objective measures of middle ear function. Observational and interventional studies with a cross-sectional, case-control, cohort, or randomized design were included. Measures of middle ear function sufficient for study inclusion were otoscopy, tympanometry, audiometry, and Valsalva maneuver, as well research-based measurements such as the pressure-chamber test and inflation test. When multiple objective measures Eustachian tube function were used, tympanometry was used as the primary measure of middle ear function, with a type B tympanogram defined as compliance of less than

TABLE 1 Characteristics of included studies (n = 12)

Study design	
Cross-sectional	12
Objective measures of ETD	
Tympanometry	10
Otoscopy	8
Valsalva maneuver	8
Tubomanometry	4
Pressure chamber test	1
Inflation-deflation test	1
Sonotubometry	1
Toynbee maneuver	1

0.2 mL and type C defined as middle ear pressure of less than -100 daPa.²⁷ In order to be consistent with the ETDQ-7 scores in the cohort reported by McCoul et al.,⁴ mean item scores were used instead of total ETDQ-7 scores for cross-study comparisons. If mean

item scores were not reported by the authors, single-item ETDQ-7 scores were averaged. In studies, where the ETDQ-7 was administered multiple times, the scores from the first administration of the survey were used for analysis. Given the limited number and

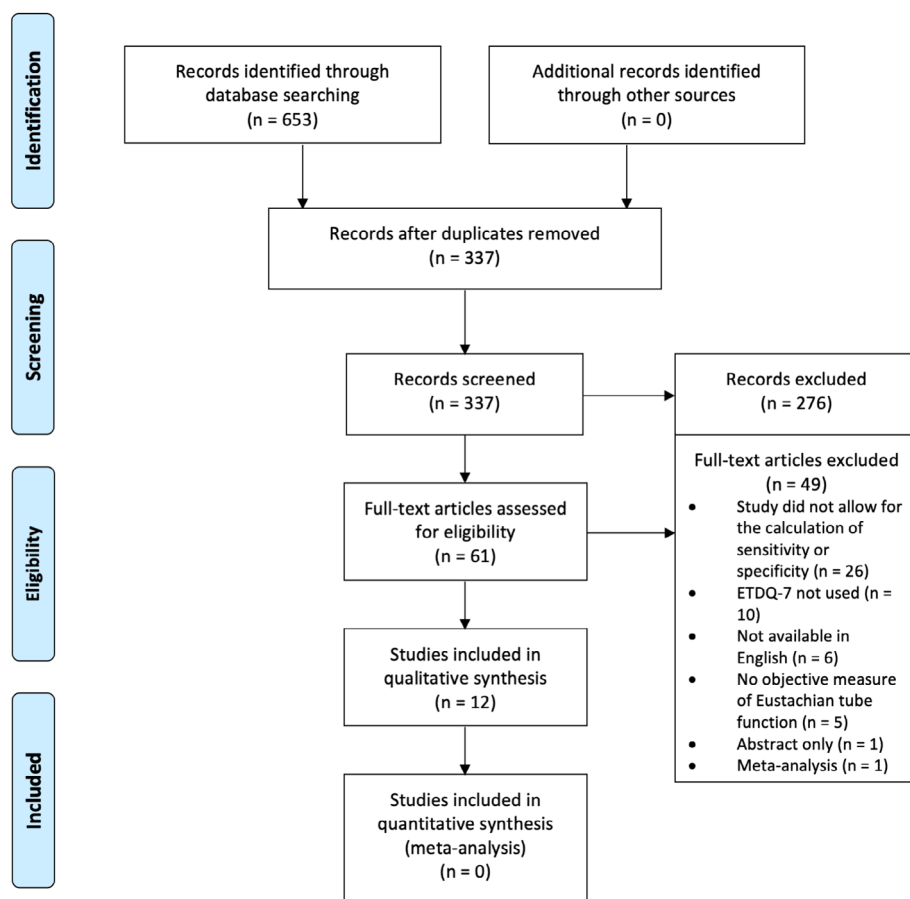


FIGURE 1 PRISMA diagram of search strategy

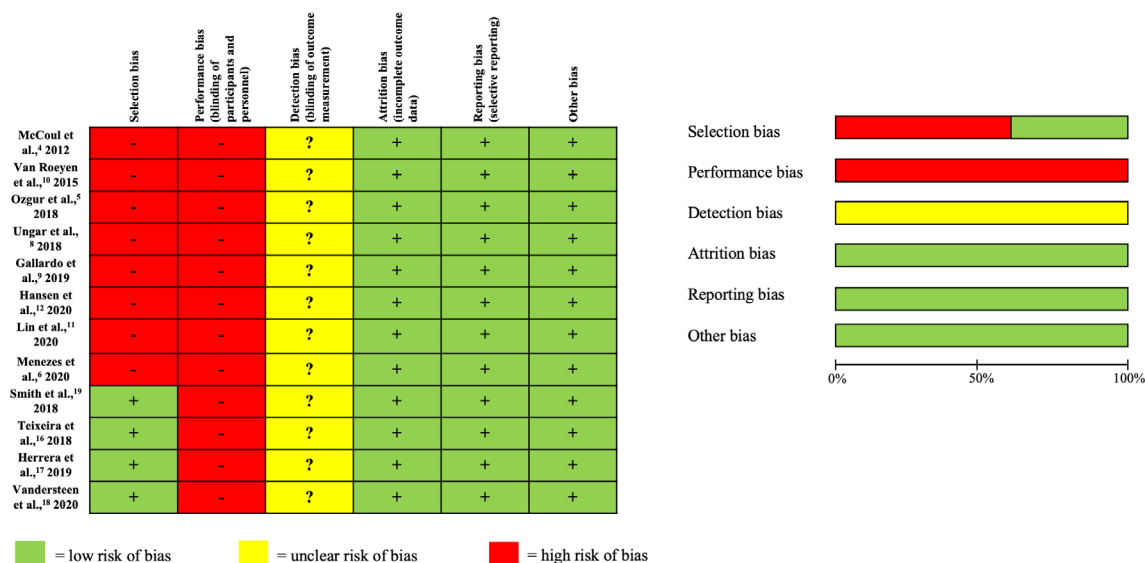


FIGURE 2 Risk of bias assessment for all studies reporting a sensitivity and specificity. “+” indicates high risk of bias; “-” indicates low risk of bias; “?” indicates unclear risk of bias

heterogeneous nature of the studies reviewed, a meta-analysis was not performed.

3 | RESULTS

Six-hundred and fifty-three references were identified in the initial literature search, from which 316 duplicate references were removed. The title and abstract of the remaining 337 studies were reviewed for use of the ETDQ-7 and at least one objective measure of Eustachian tube function. Two-hundred and seventy-six were excluded, leaving 61 studies that underwent full-text review. Forty-nine studies were excluded after full text review. Twenty-six studies were excluded because they did not allow for a determination of the sensitivity or specificity of the ETDQ-7, 15 for using the wrong outcome measure (ie, no objective measure of OETD), six for not being available in full-text format in English, one for wrong study design (meta-analysis), and one for being available only as an abstract (conference preceding). Twelve studies that included use of the ETDQ-7 and at least one objective measure of Eustachian tube function were included in this review. The review process is summarized in Figure 1. All 12 of the included studies were cross-sectional (Table 1). Tympanometry was used as an objective measure of ET function in 10 studies and other methods consisted of otoscopy, Valsalva maneuver, tubomanometry, pressure chamber testing, inflation-deflation testing, sonotubometry, and the Toynbee maneuver (Table 1). Eight studies showed selection bias on risk of bias assessment (Figure 2).

Studies that administered the ETDQ-7 to individuals with or without OETD, as determined by the presence or absence of symptoms and tympanometry prior to administration of the survey, showed ETDQ-7 scores of ≥ 14.5 (mean score ≥ 2.1) to be highly sensitive and specific for OETD. Eight studies designed in this manner were identified, including the first description of the ETDQ-7 by McCoul et al,⁴ as well as studies aiming to validate the ETDQ-7 in Brazilian Portuguese,⁹ Chinese,¹¹ Danish,¹² Dutch,¹⁰ European Portuguese,⁶ Hebrew,⁸ and Turkish.⁵ Within these studies, all control patients were asymptomatic with normal tympanometry and all OETD patients were symptomatic with abnormal tympanometry. Among these studies, the ETDQ-7 was found to have a sensitivity of 91%-100% and specificity of 67%-100% using an overall score cut-off of ≥ 14.5 (Table 2).

Studies that have administered the ETDQ-7 to individuals who have not already undergone objective testing for OETD have found much lower rates of sensitivity and specificity (Table 3). In contrast to the studies above, Herrera et al¹⁷ tested a Spanish version of ETDQ-7 among patients who had not undergone tympanometry or objective testing for OETD, and found a much lower sensitivity and specificity. In their study, Herrera et al¹⁷ administered ETDQ-7 to 75 individuals with symptoms of OETD and 50 asymptomatic controls, none of which had previously undergone tympanometry or other testing prior to completing the ETDQ-7. All subjects then underwent tympanometry and receiver operating curve analysis was performed, which showed an optimal cut-off for the Spanish version of the

TABLE 2 Summary of studies validating translated versions of the ETDQ-7 to groups of patients with or without ETD that have already undergone objective assessments of Eustachian tube function

References	Language of translation (if applicable)	Number of participants with ETD	Number of control participants	ETD ETDQ-7 mean item score	Control ETDQ-7 mean item score	AUC	Sensitivity	Specificity
McCoul et al ⁴	English (original version of survey)	50	25	4.0 \pm 1.1	1.3 \pm 0.3	1	100%	100%
Van Roeyen et al ¹⁰	Dutch	47 (39 obstructive, 8 patulous)	22	Obstructive: 3.7 Patulous: 3.9	1.4	Obstructive: 0.95 Patulous: 0.96	N/A	N/A
Ozgur et al ⁵	Turkish	40	40	4.1	1.2	1 ^a	100% ^a	100% ^a
Ungar et al ⁸	Hebrew	24	119	3.8	1.5	0.96	91.9%	87.5%
Gallardo et al ⁹	Brazilian Portuguese	20	20	3.8	1.3	0.98	95%	96%
Hansen et al ¹²	Danish	34	48	4.4	1.9	0.94	100%	67%
Lin et al ¹¹	Traditional Chinese	30	30	3.9 \pm 1.0	1.3 \pm 0.3	1	100%	99.9%
Menezes et al ⁶	European Portuguese	50	25	4.4	1.3	N/A	100% ^a	96% ^a

Abbreviations: ETD, Eustachian tube dysfunction; ETDQ-7, Eustachian Tube Dysfunction Questionnaire-7; AUC, area under the curve.

^aData extrapolated from study results.

TABLE 3 Summary of studies validating the ETDQ-7 among cohorts of patients that have not already undergone objective testing for Eustachian tube dysfunction prior to administration of the questionnaire

References	Objective measure of Eustachian tube function used	Number of participants	Total ETDQ-7 score ≥ 14.5	ETD on objective testing (by ear)	AUC	Sensitivity	Specificity
Smith et al ¹⁹	Expert panel consensus with tympanometry	119 (57 with OETD)	71% (82/116)	N/A	0.59	80%	24%
Teixeira et al ¹⁶	Pressure Chamber test or Inflation-Deflation test	55 (30 with ETD symptoms)	38% (21/55)	41% (45/110)	0.68	54%	78%
Herrera et al ¹⁷	Tympanogram (Valsalva and tubomanometry also performed)	125 (75 with ETD symptoms)	N/A	N/A	0.59	49%	67%
Vandersteen et al ¹⁸	Tubomanometry	129	47% (61/129)	50% (61/122, only patients with ETDQ-7 ≥ 14.5 tested)	N/A	N/A	N/A

Abbreviations: ETD, Eustachian tube dysfunction; ETDQ-7, Eustachian Tube Dysfunction Questionnaire-7; AUC, area under the curve.

ETDQ-7 was 17.5 (AUC 0.59), where the sensitivity and specificity of the survey were 49% and 67%, respectively. Smith et al¹⁹ assessed the predictive value of ETDQ-7 among a cohort of 116 patients, 57 of which had OETD diagnosed by expert panel consensus, and determined a sensitivity of 80% and specificity of 24%. Teixeira et al¹⁶ conducted a cross-sectional study of 30 patients with symptoms of ETD for >1 month or a history of chronic or recurrent otitis media and 25 controls. Participants underwent pressure chamber testing or inflation-deflation testing following completion of the ETDQ-7. ETDQ-7 scores ≥ 14.5 were 70% sensitive and 100% specific for group assignment, but only 54% sensitive and 78% specific for ETD measured on objective testing of ET function. Vandersteen et al¹⁸ conducted a prospective study, administering the ETDQ-7 to patients with chronic rhinosinusitis (CRS) and conducting several tests of ET function on those with mean ETDQ-7 scores ≥ 14.5 . Of the 64 patients with a score ≥ 14.5 , 64% had ETD on tubomanometry. Furthermore, there was little overlap between those participants with an ETDQ-7 score ≥ 14.5 and those with type B or C tympanograms, as 47% of the patients with CRS had a ETDQ-7 score ≥ 14.5 , but only 19% had a type B or type C tympanogram.

4 | DISCUSSION

The ETDQ-7 has become widely used to assess patient symptoms related to OETD and to evaluate the efficacy of BDET.¹³ The degree to which ETDQ-7 scores can predict OETD on tympanometry or other objective measures of Eustachian tube function remains unclear. This systematic review provides a comprehensive assessment of the literature to assess the ability of ETDQ-7 scores to predict objective measures of ETD. Thirty-eight studies were identified that used ETDQ-7 scores with at least one objective measure of Eustachian tube function. Twelve studies reported sensitivity and specificities for the ability of ETDQ-7 scores to predict OETD, of which eight studies demonstrated significant patient cohort selection bias (Figure 2).

Among the four studies that did not have patient cohort selection bias, ETDQ-7 scores ≥ 14.5 were 49%-80% sensitive and 24%-78% specific for predicting OETD based upon objective measures (Table 3). Due to significant heterogeneity among the studies identified, the authors did not feel it was appropriate to perform a meta-analysis and synthesis of data. Despite this, the authors accomplished the study objective of providing an estimate of the sensitivity and specificity of ETDQ-7 for predicting OETD from the best available evidence.

McCoul et al⁴ first validated the ETDQ-7 among a cohort of patients diagnosed with or without ETD on the basis of symptoms and tympanometry. The ETDQ-7 had both a sensitivity and specificity of 100% when using a total score cut-off of ≥ 14.5 among this cohort. Eight studies that were designed in a nearly identical manner, in order to validate the ETDQ-7 in different languages, have similarly shown a sensitivity and specificity of 91%-100% and 67%-100%, respectively.^{5,8-12,28} However, studies that have administered the ETDQ-7 to cohorts of symptomatic patients who have not previously undergone tympanometry or other objective testing have found much lower rates of sensitivity (49%-80%) and specificity of (24%-78%).¹⁶⁻¹⁸ Similarly, multiple studies using the ETDQ-7 to assess the efficacy of BDET have shown significant discordance between ETDQ-7 scores and tympanometry.^{15,20-23} When designing a study of diagnostic accuracy (determining test sensitivity and specificity), the test should be administered to a large population of individuals that are the same as that in which the test is intended to be used. Guidelines have been established for designing studies to determine the diagnostic accuracy of a test.²⁹ Knowledge of the diagnosis before administering the test can skew the results in favor of higher sensitivity, known as diagnostic review bias.³⁰ Furthermore, the demographics of the two groups used may differ in important ways that make generalizability impossible. These differences in study methodology should be carefully assessed when considering the utility of the ETDQ-7.

The study design used by McCoul et al⁴ and authors in subsequent similar studies to validate the ETDQ-7 by administering it to

cohorts of patients who have already undergone tympanometry limits their ability to assess the predictive power of the ETDQ-7. A diagnosis of OETD requires both patient reported symptoms (ear pain, fullness, pressure, etc.) for >1 month and evidence of OETD on otoscopy or tympanometry. Consequently, there are individuals who would not receive a diagnosis of ETD that either have symptoms but normal (type A) tympanometry or who have abnormal tympanometry (type B or type C) but are asymptomatic. When individuals in the control group are confirmed to both be asymptomatic and have normal tympanometry, a significant number of patients without ETD are excluded. The question of most interest to clinicians, and the focus of this review, is whether patients presenting with symptoms of ETD and a total score of ≥ 14.5 can be predicted to have evidence of ETD on tympanometry or other objective measures. Under these conditions, the ETDQ-7 performs much worse and demonstrates limited predictive value.

Studies that use the ETDQ-7 as a clinical assessment tool for treatment response for OETD further demonstrate its limitations as a diagnostic instrument. In our literature review, we identified 19 studies that used ETDQ-7 and tympanometry to assess for response to treatment for ETD, 14 of which assessed responses to BDET (Table S2). Five of these studies had cohorts with mean baseline ETDQ-7 scores ≥ 2.1 and 70% or more of patients with type A tympanograms.^{15,20-23} Twelve of these studies reported both improvements in ETDQ-7 score and an increased proportion of type A tympanograms after BDET.^{15,20,21,31-39} However, ETDQ-7 scores were not consistently associated with improved tympanometry following BDET. While the sensitivity and specificity of the ETDQ-7 cannot be inferred from these studies, the frequent discordance between ETDQ-7 scores and tympanometry is notable, and suggest they may measure different constructs.

This discordance between ETDQ-7 scores and objective measures of OETD highlights the complexity of diagnosis for OETD. Symptoms such as ear pain, fullness, and popping may present with a number of conditions such as migraine,⁴⁰ superior semicircular canal dehiscence, Meniere's disease, temporomandibular disorders (TMJ),⁴¹ sinus disease, sore throat, or dental pain that may be unrelated to Eustachian tube function. McCoul et al suggested that the presence of normal tympanometry with positive ETDQ-7 scores may be due to insensitivity of the currently accepted interpretation standards for tympanometry.⁴² It is an important point that objective measures of Eustachian tube function such as otoscopy, tympanometry, or tubomanometry are imperfect measures. However, given the number of conditions that may cause the relatively nonspecific symptoms of OETD and how hard it can be to exclude certain conditions, such as TMJ, objective measures of OETD such as tympanometry will always remain critical for accurate diagnosis.

There are several limitations of this review. There was significant selection bias in eight of the 12 included studies (Figure 2). Several studies used experimental or research-based clinical assessment tools (eg, tubomanometry, pressure chamber testing) rather than tympanometry, making it difficult to compare results across studies. The use of tympanometry as a clinical endpoint is also subject to limitations. Tympanometry testing uses variable pressure conditions with

the ear canal and a sound emitted by the tympanometer that vibrates the tympanic membrane. The tympanometer then measures the sound returned to the tympanometer to infer the compliance of the tympanic membrane and pressure within the middle ear. Consequently, tympanometry is an indirect rather than direct measure of Eustachian tube function. This measurement occurs at one point in time while the ETDQ-7 inquires about symptoms within the past month without specifying laterality. Based upon these differences, some degree of discordance between ETDQ-7 scores and tympanometry would be expected in individuals who have fluctuating Eustachian tube function.

Despite its limitations, the ETDQ-7 remains an important clinical assessment tool as a patient-reported measure related to ETD and response to treatment. The ETDQ-7 has proven a valuable method of objectively quantifying improvement in ETD-related symptoms following BDET.¹³ Future studies may allow us to more definitely state the predictive power of the ETDQ-7 in identifying individuals with ETD. The overwhelming majority of the presently reviewed literature on ETDQ-7, particularly studies that assess response to BDET, only report ETDQ-7 scores and tympanometry or other measures of Eustachian tube function for entire cohorts of patients. Understanding ETDQ-7 scores and tympanometry for a large cohort of individual patients presenting to an otolaryngology clinic would allow for a more robust assessment of the predictive power of ETDQ-7. However, based upon the currently available evidence, it is unlikely that future studies would support the use of ETDQ-7 scores as a substitute for tympanometry or other objective measures in diagnosing ETD.⁴³⁻⁴⁷

5 | CONCLUSION

The ETDQ-7 is a valuable patient-reported measure of OETD symptoms and important in assessing interventions for OETD. However, based upon the available literature, the ETDQ-7 appears limited as a diagnostic tool for OETD or as an objective measure of Eustachian tube function. Larger trials with ETDQ-7 measures collected prior to objective Eustachian tube function testing are needed to better understand the role ETDQ-7 should play in the assessment and management of patients presenting with suspected OETD.

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CONFLICT OF INTEREST

Carrie L. Nieman is a board member of the nonprofit Access HEARS and the Hearing Loss Association of America.

ORCID

Nicholas S. Andresen  <https://orcid.org/0000-0002-9753-0512>

Carrie L. Nieman  <https://orcid.org/0000-0002-5284-3785>

Bryan K. Ward  <https://orcid.org/0000-0001-5201-6117>

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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