Scientific Research Publishing

International Journal of Otolaryngology and Head & Neck Surgery, 2026, 15(6), 410-427
https://www.scirp.org/journal/ijohns
ISSN Online: 2168-5460
ISSN Print: 2168-5452

Validation of the Eustachian Tube Dysfunction Questionnaire-7 in Diagnosing Patients with Eustachian Tube Dysfunction in Mulago National Referral Hospital

Yvonne Nabachwa Kuteesa[1], Fiona Kabagenyi[1], Amina Seguya[2], Julius Mwangi[2], Sandra Petit Anena[1], Isaiah Kalinge[1], Andrew Twineamatsiko[3]

[1]Department of Ear, Nose and Throat, School of Medicine, College of Health Sciences, Makerere University, Kampala, Uganda
[2]Department of Ear, Nose and Throat, Mulago National Referral Hospital, Kampala, Uganda
[3]Seed Global Health, Kampala, Uganda
Email: kuteesayvonne@gmail.com

How to cite this paper: Kuteesa, Y.N., Kabagenyi, F., Seguya, A., Mwangi, J., Anena, S.P., Kalinge, I. and Twineamatsiko, A. (2026) Validation of the Eustachian Tube Dysfunction Questionnaire-7 in Diagnosing Patients with Eustachian Tube Dysfunction in Mulago National Referral Hospital. *International Journal of Otolaryngology and Head & Neck Surgery*, **15**, 410-427.
https://doi.org/10.4236/ijohns.2026.156037

Received: October 23, 2026
Accepted: November 22, 2026
Published: November 25, 2026

Copyright © 2026 by author(s) and Scientific Research Publishing Inc.
This work is licensed under the Creative Commons Attribution International License (CC BY 4.0).
http://creativecommons.org/licenses/by/4.0/

Open Access

Abstract

Introduction: Eustachian tube dysfunction is the failure of the eustachian tube to maintain pressure equalization or mucociliary clearance of the middle ear. Subjective and objective methods are clinically utilized to assess ETD. These include otoscopy, tubomanometry, tympanometry, nasopharyngoscopy and the Eustachian Tube Dysfunction Questionnaire-7. The ETDQ-7 remains underutilized and lacks validation in numerous countries, including Uganda. However, validating its accuracy could enhance patient diagnosis and management by fostering patient engagement and adherence to treatment protocols. **Objective:** This paper aims to determine the accuracy of ETDQ-7 in diagnosing patients with ETD based on tympanometry as an objective test in Mulago National Referral Hospital. **Methods:** This was a cross-sectional diagnostic accuracy study of 182 consecutive adults attending the ENT clinic. Tympanometry (the reference standard) was performed first, and the ETDQ-7 (the index test) was then administered by interviewers who were unaware of the tympanometry results. A participant was classified as reference-positive if either ear showed a Type B or Type C tympanogram on the baseline (pre-Valsalva) recording; the ETDQ-7 score was not part of the reference definition. An ETDQ-7 score of ≥14.5 was considered positive. Sensitivity, specificity, predictive values and likelihood ratios with exact 95% confidence intervals (CIs) were calculated using STATA version 14.0, and internal consistency was assessed with Cronbach's alpha. **Results:** Thirty-five of the 182 participants (19.2%) were reference-positive. The ETDQ-7 had a sensitivity of 80.0% (95%

CI: 63.1 - 91.6), a specificity of 97.3% (95% CI: 93.2 - 99.3), a positive predictive value of 87.5% (95% CI: 71.0 - 96.5), a negative predictive value of 95.3% (95% CI: 90.6 - 98.1), a positive likelihood ratio of 29.4 (95% CI: 11.0 - 78.4) and a negative likelihood ratio of 0.21 (95% CI: 0.11 - 0.40). Seven of the 35 reference-positive participants (20%) were not identified by the questionnaire. Internal consistency was good (Cronbach's alpha = 0.827). **Conclusion:** Against an imperfect tympanometric reference standard in this referral-clinic sample, the ETDQ-7 showed high specificity and moderate sensitivity. It may serve as a useful clinical adjunct for identifying ETD where tympanometry is unavailable, but a negative score does not reliably exclude ETD, and further validation in primary-care and other settings is needed before it can be recommended as a stand-alone diagnostic tool in Uganda.

Keywords

Eustachian Tube Dysfunction, ETDQ-7, Tympanometry, Diagnostic Accuracy, Sensitivity and Specificity

1. Introduction

Eustachian tube dysfunction (ETD) is the failure of the eustachian tube to maintain pressure equalization or mucociliary clearance. The eustachian tube is a 36 mm long tube connecting the middle ear to the postnasal space [1]. Its functions include clearance of mucus from the ear, pressure equalization, and protection of ear from loud sounds and pathogens. When it is blocked, aural symptoms such as ear blockage, aural fullness, and hearing loss may result [2]. Common risk factors for ETD include gastroesophageal reflux, rhinosinusitis, allergy, and recent upper respiratory diseases. Complications that may arise from ETD include otitis media with effusion, tympanic membrane atelectasis, cholesteatoma, and hearing difficulties [3]. Avoidance of these complications requires accurate diagnosis and subsequent application of appropriate medical or surgical treatments for ETD. Management options include medical interventions like nasal decongestants, antihistamines, nasal steroids, Valsalva and Toynbee maneuvers, and surgical procedures such as myringotomy, pressure equalization tubes and Eustachian tuboplasty [4].

Despite ETD being a common ENT condition, its global burden has not been clearly defined [5]. Available literature shows prevalence ranges from 0.9% - 49% among adults in the United States with little documentation from sub-Saharan Africa [4]. Anecdotal monthly findings from the ENT clinic in Mulago National Referral Hospital (MNRH) in Uganda indicate that 12/1000 patients are diagnosed with ETD. This was according to the Health Management Information System records from the ENT clinic between the months of January to June 2023.

Diagnosis of ETD can be made subjectively and objectively. Clinical identification of ETD can be based on clinical symptoms e.g. using the Eustachian Tube Dysfunction Questionnaire-7 (ETDQ-7), examination of the ear (otoscopy) and

nasopharynx (nasopharyngoscopy), tubomanometry and tympanometry [6].

Tympanometry is often used to measure middle ear compliance and pressure. Negative middle ear pressure signifies Eustachian Tube Dysfunction. It is a reliable method with a recorded sensitivity between 54% and 100% and specificity between 63.9% and 100% [6]. Tympanometry is widely used as an objective test for ETD, but it is an imperfect reference standard because it reflects middle-ear pressure at the time of testing rather than Eustachian tube function directly [2]. In addition, it is not readily available in all centers, requires expertise to operate and interpret and even at the facilities where it is available, it comes at a cost.

In resource-limited settings like Uganda, the challenges are even more pronounced due to the scarcity of advanced diagnostic equipment and specialized medical personnel. In Uganda, there are 16 regional referral hospitals which offer ENT services; however, only a few have functional tympanometers and audiometers. This creates a diagnostic dilemma for the facilities.

Current diagnostic methods, which often include nasopharyngoscopy, and subjective symptom assessment, frequently fail to independently provide comprehensive and definitive diagnoses [7]. This diagnostic ambiguity can lead to misdiagnosis or delayed treatment, exacerbating patient suffering and potentially resulting in chronic complications such as cholesteatoma, otitis media with effusion, retraction of the ear drum and chronic otitis media [8].

The ETDQ-7 is a subjective, symptom-based alternative for diagnosing ETD. It contains seven questions and yields a total score ranging from 7 to 49; a score of ≥14.5 indicates ETD. It is a validated, reliable, disease-specific measure for adults with ETD [9] [10] and assesses ear pressure, pain, worsening symptoms during a cold or sinusitis, a clogged sensation, popping sounds, tinnitus, and muffled hearing [11]. It is the only validated patient-reported outcome measure described in the literature for diagnosing ETD [2]. The ETDQ-7 is free, easy to administer and interpret, and requires no specialized expertise. Compared with tympanometry, it also provides more structured and validated documentation of the patient-reported history [3].

The ETDQ-7 score has been used and validated in several geographical areas with high sensitivity ranging between 71.4% and 100%, specificity; 84.4% to 100%, negative predictive value (NPV); 73.1% and 96.7% and positive predictive value (PPV) within 83.3% to 95% in Saudi Arabia, Middle East [12], Brazil in South America [13] and Türkiye [14]. However, there is paucity of data of its use diagnosis of ETD in sub-Saharan African countries, including Uganda. This tool has also not been validated in in sub-Saharan Africa or in any low- or middle-income countries.

Across multiple studies, a cutoff score between 13 and 14.5 is frequently used to distinguish between ETD patients and controls; this study therefore adopted 14.5 as a cut off.

Therefore, the aim of this study was to assess the diagnostic accuracy of the Eustachian Tube Dysfunction Questionnaire-7 (ETDQ-7) in identifying patients

with Eustachian Tube Dysfunction at Mulago National Referral Hospital with the ultimate goal of improving ease in the diagnosis and therefore subsequent management of Eustachian Tube Dysfunction in clinical settings.

2. Methods

2.1. Study Design and Setting

A cross-sectional diagnostic accuracy study design was used to achieve the study objectives.

This study was conducted at Ear, Nose and Throat (ENT) clinic of Mulago National Referral Hospital (MNRH). As one of the National Referral Hospitals in Uganda, MNRH doubles as the teaching hospital for Makerere University College of Health Sciences as well. The hospital is located on Mulago hill, approximately 5 kilometers, Northeast of Kampala's central business district. The hospital has an estimated bed capacity of approximately 1800 beds and provides both general and specialized medical and surgical services. The ENT clinic in MNRH is located on level 5 block G. It receives about 800 - 1000 patients monthly, and the ENT clinic receives about 240 patients of which 8 to 12 have a diagnosis of ETD.

The study was conducted between January and April 2024.

2.2. Study Population

The study population were patients attending the ENT clinic in Mulago National Referral Hospital between January 2024 and April 2024.

2.2.1. Inclusion Criteria

- Patients above 18 years of age;
- Patients with ability to consent;
- Patients who attend ENT clinic at Mulago National Referral Hospital.

2.2.2. Exclusion Criteria

- Patients with pus in the ear;
- Patients with perforation of the ear drum;
- Patients with impacted wax in the ear;
- History of ear surgery;
- History of radiation in the head and neck region;
- Craniofacial anomalies;
- Gross sinonasal and oral masses.

2.3. Sample Size and Sampling Strategy

The sample size was estimated using the Kish and Leslie formula (1965)

$$N = \left(\frac{Z^2 p(1-p)}{d^2} \right)$$

N is required sample size.

d is precision (tolerable sampling error) = 5%.

p is estimated proportion of ETD in the public at 12.2 based on a study Almutairi *et al*. [15].

Z is the standard normal value at 95% confidence level = 1.96.

N = 165;

Considering 10% non-response = 17 participants;

Therefore, the study interviewed 182 participants.

Consecutive sampling technique was used till the required sample size was realized.

Because the calculation above estimates a single proportion, the adequacy of the sample for the diagnostic-accuracy objective was additionally assessed using Buderer's method [16], which relates the number of participants required to the desired precision of sensitivity (Se) and specificity (Sp) and to the expected prevalence (P) of the target condition:

$$n_{Se} = \frac{Z^2 \times Se \times (1 - Se)}{d^2 \times P}$$

$$n_{Sp} = \frac{Z^2 \times Sp \times (1 - Sp)}{d^2 \times (1 - P)}$$

where d is the desired half-width of the 95% confidence interval. Assuming a sensitivity of 80% and a specificity of 95% (within the ranges reported in previous ETDQ-7 validation studies [12]-[14]), a prevalence of reference-positive ETD of 20%, and a precision of ±15% for sensitivity and ±5% for specificity, the required sample sizes are 137 and 92 participants, respectively. The 182 participants recruited therefore exceeded the larger of these requirements.

2.4. Reference Standard and Index Test Definitions

For the diagnostic accuracy analysis, ETD was defined by tympanometry alone; the ETDQ-7 score was not part of the reference definition. Each ear was classified according to the Jerger classification [17] as Type A (a single peak with middle-ear pressure greater than −100 daPa), Type B (a flat tracing with no identifiable peak) or Type C (a peak with middle-ear pressure of −100 daPa or less). Both Type B and Type C tympanograms were considered positive for ETD. Classification was made at the participant level: a participant was considered reference-positive if at least one ear showed a Type B or Type C tympanogram, irrespective of the findings in the contralateral ear, and reference-negative only if both ears showed Type A tympanograms. A participant with discordant findings between the two ears (one abnormal and one normal ear) was therefore classified as reference-positive. For descriptive reporting, a participant with a Type B tympanogram in one ear and a Type C tympanogram in the other would have been categorised as Type B; no such participant was observed.

The ETDQ-7 was scored at the participant level, because its items refer to symptoms in either ear. A total score of ≥14.5 was considered positive, and a score below 14.5 was considered negative.

2.5. Data Collection

Data was collected by two study assistants and the principal investigator. The study assistants are trained and qualified ENT clinical officers licensed by Allied Health Professionals Council.

Participants' age and sex was captured. The PI did tympanometry on all study participants. A well calibrated Titan tympanometer (Interacoustics) was used for this study. A probe tip of the tympanometry was placed in the ear canal where 226Hz was administered producing a tympanogram. The tympanogram has values of compliance, ear canal volume and middle ear pressure. Each ear was classified as Type A, B or C, and each participant was classified as reference-positive or reference-negative, as defined in Section 2.4. Tympanometry was done in a quiet room of about 30 - 40 decibels (dB). The participants were instructed not to cough, talk, or chew during the procedure to avoid wrong measurements. The procedure took approximately five minutes to complete.

All study participants had an interviewer administered ETDQ-7. The ETDQ-7 has seven parameters each scoring between 1 and 7 depending on the severity of the symptoms. Participants got a minimum total score of 7 and maximum total score of 49. A participant with a score of ≥14.5 was diagnosed with ETD on an ETDQ-7 and a participant with less than 14.5 was considered not to have ETD. The questionnaire took approximately 15 minutes to complete. Participants who were found to have ETD were scheduled for review in the otology clinic.

The data collection process is summarized in **Figure 1**. Tympanometry was performed first by the PI. The ETDQ-7 was then administered by a study assistant who was not informed of the tympanometry results, and participants were not told their tympanometry results until after the questionnaire had been completed. The PI classified the tympanograms without knowledge of the ETDQ-7 responses. Diagnostic classification was based on the baseline tympanogram recorded before the Valsalva manoeuvre; the post-Valsalva recording was not used to classify participants.

2.6. Data Management and Analysis

The data entry form was checked daily for completeness and correctness to check if data on all the specified variables was extracted. All data entry forms were stored in a password protected mobile gadget accessible to only members of the study team. Data entry was done using ODK software for data collection. The data was cleaned and exported to STATA version 14.0 (STATA Corp, College Station, TX) for analysis.

Descriptive analysis was used to summarize participant demographic characteristics. These were presented in tables and figures. Diagnostic accuracy was determined by measuring sensitivity, specificity, negative predictive values, positive predictive values, positive and negative likelihood ratios. Ninety-five percent confidence intervals were calculated from the unrounded cell counts using the exact (Clopper-Pearson) binomial method for sensitivity, specificity and predictive val-

ues [18] and the log method for likelihood ratios [19]; reported values were rounded only after calculation. Analyses stratified by the laterality of reported symptoms were exploratory because of the small subgroup sizes.

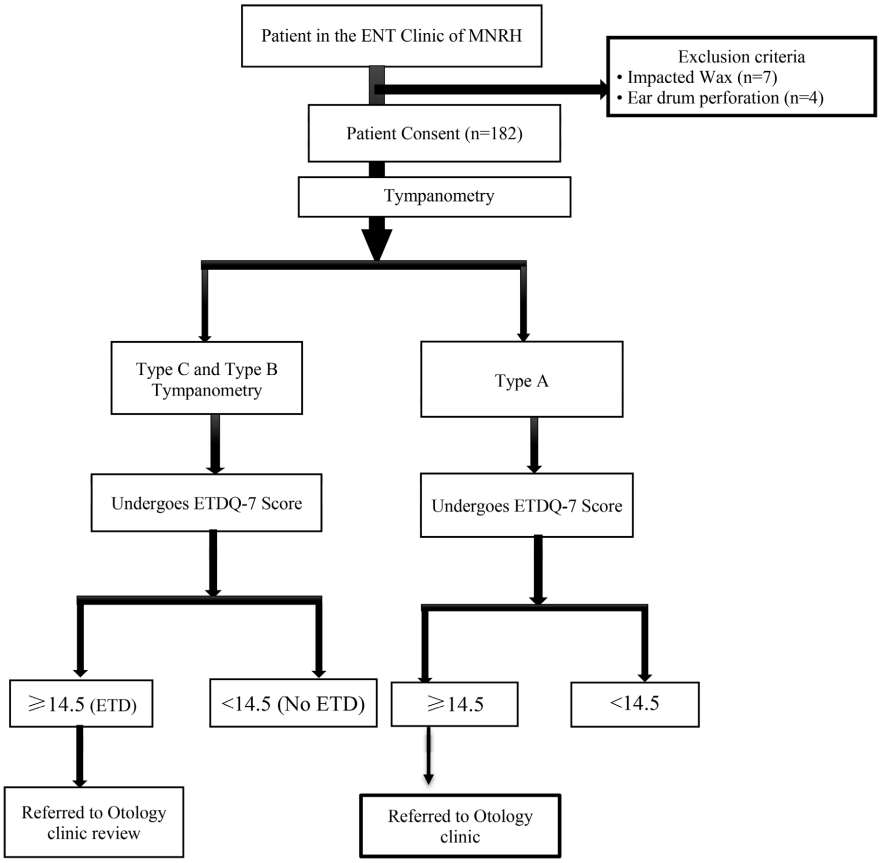


Figure 1. Data collection flowchart.

Sensitivity was determined as $\left(\frac{a}{a+c}\right)*100\%$

Specificity was determined as $\left(\frac{d}{b+d}\right)*100\%$

Positive predictive value was determined as $\left(\frac{a}{a+b}\right)*100\%$

Negative predictive value was determined as $\left(\frac{d}{c+d}\right)*100\%$

Positive Likelihood Ratio = Sensitivity/(1 − Specificity)

Negative Likelihood ratio = (1 − Sensitivity)/Specificity

Whereby: *a* refers to True positives

b refers to False positives

c refers to False negatives

d refers to True negatives

Internal consistency of the seven ETDQ-7 items was assessed using Cronbach's alpha coefficient (range 0 - 1); values above 0.7 were considered acceptable. Inter-

nal consistency indicates the extent to which the items measure a common construct.

2.7. Quality Control

The study assistants were trained on how to use the tympanometer, daily calibration as well as how to fill in the ETDQ-7 questionnaire in order to ensure completeness of the data. This was done to ensure consistency and reliability of the data collected.

A well calibrated Titan tympanometer (Interacoustics) was used for this study. The test was performed by the PI under the supervision of an Audiology technician. For validity and accuracy, the audiology technician randomly selected patients for retesting to ensure retest reliability in the same sitting. A Valsalva maneuver was performed during the procedure for the participants to improve sensitivity of the results. This maneuver was particularly relevant for detecting subtle changes in middle ear compliance and eustachian tube patency, thereby improving the diagnostic accuracy of the test. The Valsalva manoeuvre was performed only after the baseline tympanogram had been recorded, and diagnostic classification used the baseline (pre-Valsalva) tympanogram.

2.8. Ethical Considerations

Permission to conduct the study was sought from the ENT Department of College of Health Sciences, Makerere University as well as administrative clearance was also sought from MNRH Ethical approval was sought from the School of Medicine Research Ethics Committee (SOMREC) of Makerere University with an approval number of Mak-SOMREC-2023-756. A written informed consent was sought from the study participants before recruitment into the study. For confidentiality reasons, identities of study patients were not included in the study data.

3. Results

3.1. Baseline Characteristics

The study screened 193 participants and recruited 182. Eleven patients were excluded; four were due to tympanic perforation, and seven due to wax impactions. Of the 182 participants the median age was 36 years (IQR: 25 – 50 years). Most participants were female (57.1%). The most reported aural symptom was ringing in the ears followed by muffled hearing (see Table 1).

Table 1. 2 × 2 analysis matrix.

		Tympanometry		
		Type B & C	Type A	
ETDQ-7	≥14.5	a	b	a + b
	Less than 14.5	c	d	c + d
		a + c	b + d	N

Table 2. Baseline characteristics of the study participants.

	Frequency (N = 182)	Percentage (%)
Age in Years		
Median IQR	36 (25 - 50)	
18 - 39	107	58.8
40 - 59	53	29.1
60+	22	12.1
Sex		
Female	104	57.1
Male	78	42.9
ETDQ-7 symptoms reported		
Pressure in the ears	30	16.5
Pain in the ears	21	11.5
Clogged ears	35	19.2
Ear problems when you have a cold or sinusitis	33	18.1
Crackling or popping sounds in the ear	35	19.2
Ringing in the ears	51	28.0
Muffled hearing	40	22.0

3.1.1. Tympanometry Results

27 (14.8%) participants had Type C tympanometry in at least one ear, 8 (4.4%) had Type B and 147 (80.8%) had Type A tympanograms in both ears (Figure 2). Of the 35 participants with an abnormal tympanogram, 30 had an abnormal finding in one ear only (14 left, 16 right) and 5 had abnormal findings in both ears (Table 2); all 35 were classified as reference-positive.

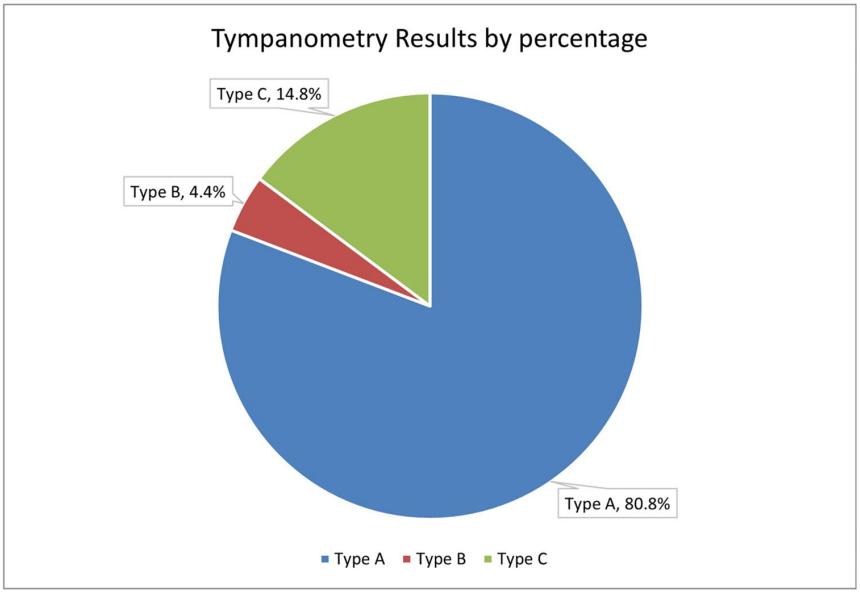


Figure 2. Tympanometry results.

3.1.2. Tympanometry Results Based on Each Ear

Majority of the participants had type A tympanograms in both left and right ears. The right ear had more type C tympanograms as compared to the left ear. On tympanometry, the left ear only had 5 (1.4%) participants with type B, 9 (2.5%) with type C while 168 (46.2%) had type A. In the right ear only 2 (0.5%) had type B,14 (3.8%) had type C and 166 (45.6%) had type A. In both ears, 147 (40.2%) had type A, 1 (0.3%) had type B and 4 (1.1%) had type C (see Table 3).

Table 3. Tympanometry results based on each ear.

	Type A (N = 364) N (%)	Type B (N = 364) N (%)	Type C (N = 364) N (%)
Left ear only	168 (46.2%)	05 (1.4%)	09 (2.5%)
Right ear only	166 (45.6%)	02 (0.5%)	14 (3.8%)
Both ears	147 (40.2%)	01 (0.3%)	04 (1.1%)

3.1.3. Diagnosis of ETD Based on ETDQ-7 Results

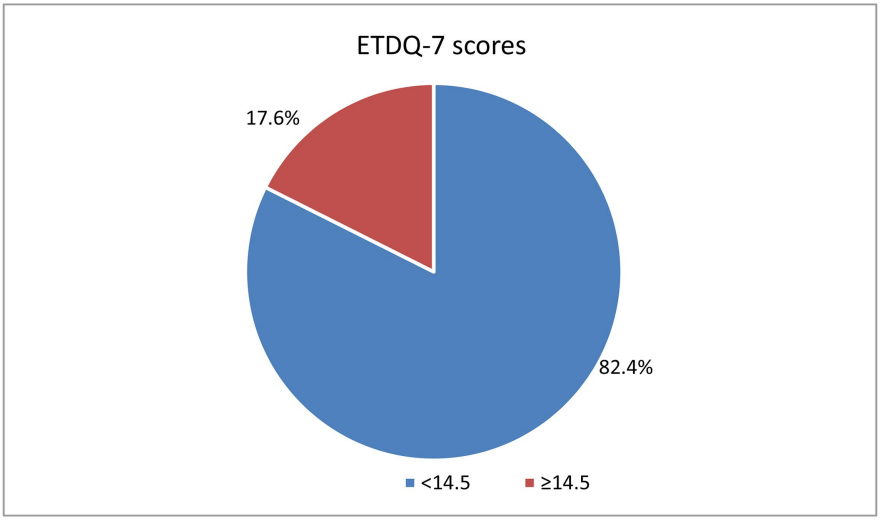


Figure 3. ETDQ-7 classification.

32 (17.6%) of the participants had a score ≥ 14.5 and therefore were diagnosed as having ETD based on ETDQ-7 while 150 (82.4%) had less than 14.5 and hence had no ETD as per the ETDQ-7. The median ETDQ-7 score was 7 (Figure 3).

Based on the ETDQ-7 score, 86.8% reported symptoms in both ears while 6% reported in left ear only and 7.1% reported symptoms in right ear only (Table 4).

Table 4. ETDQ-7 symptoms on either ear.

Symptoms in one ear only or both ears	Number	Percentage
Both ears	158	86.8
Left ear only	11	6
Right ear only	13	7.1

3.2. Sensitivity and Specificity of Eustachian Tube Dysfunction Questionnaire-7

A total of 28 (15.4%) patients were classified as having ETD by both tympanometry and the ETDQ7, and 143 (78.6%) were negative on both; there were 4 false-positive and 7 false-negative results (Table 5 and Figure 4). Participants were classified on tympanometry and on the ETDQ-7. The sensitivity of the ETDQ-7 was 80.0% (28/35; 95% CI: 63.1 - 91.6) and the specificity was 97.3% (143/147; 95% CI: 93.2 - 99.3). Thus, 7 of the 35 reference-positive participants (20%) were not identified by the questionnaire.

Table 5. A contingency table showing the sensitivity and specificity of the ETDQ-7.

		Tympanometry	
	Overall (N = 182)	**NO ETD (N = 147) N (%)**	**ETD (n = 35) N (%)**
ETDQ7 (overall N = 182)	NO ETD	143 (78.6%)	7 (3.8%)
	ETD	4 (2.2%)	28 (15.4%)
ETDQ-7 Both Ears (N = 158)	NO ETD	134 (84.8%)	3 (1.9%)
	ETD	3 (1.9%)	18 (11.4%)
ETDQ-7 Left Ear only (N = 11)	NO ETD	6 (54.5%)	2 (18.2%)
	ETD	0 (0%)	3 (27.3%)
ETDQ-7 Right ear only (N = 13)	NO ETD	3 (23.1%)	2 (15.4%)
	ETD	1 (7.7%)	7 (53.8%)

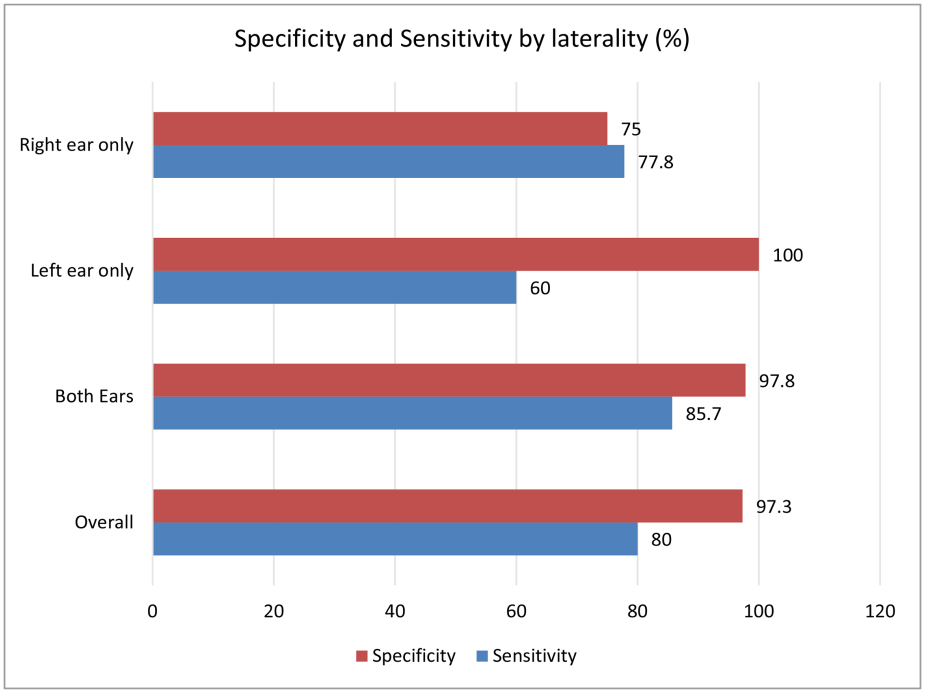


Figure 4. Sensitivity and specificity by laterality.

3.3. Positive and Negative Likelihood Ratios of Eustachian Tube Dysfunction Questionnaire-7

The positive likelihood ratio was 29.4 (95% CI: 11.0 - 78.4) and the negative likelihood ratio was 0.21 (95% CI: 0.11 - 0.40) (Table 6). In exploratory subgroup analyses, the positive likelihood ratio was highest in participants with symptoms in both ears (39.1; 95% CI: 12.6 - 121.5), with wide confidence intervals.

Table 6. Diagnostic accuracy estimates of the ETDQ-7 with 95% confidence intervals (overall, N = 182).

Overall (N = 182)	Value	95% CI
Sensitivity (%)	80.0	63.1 - 91.6
Specificity (%)	97.3	93.2 - 99.3
Positive predictive value (%)	87.5	71.0 - 96.5
Negative predictive value (%)	95.3	90.6 - 98.1
Positive likelihood ratio	29.4	11.0 - 78.4
Negative likelihood ratio	0.21	0.11 - 0.40

3.4. Positive and Negative Predictive Values of ETDQ-7

The positive predictive value (PPV) of the ETDQ-7 was 87.5% (28/32; 95% CI: 71.0 - 96.5) and the negative predictive value (NPV) was 95.3% (143/150; 95% CI: 90.6 - 98.1) (Table 6). These values correspond to the 19.2% prevalence of reference-positive ETD in this sample; in settings with a lower prevalence, the PPV would be lower and the NPV higher. In exploratory subgroup analyses, the PPV was highest among participants with symptoms in the left ear only (100%, 3/3) and lowest among those with symptoms in right ear only (85.7%, 18/21) (Figure 5).

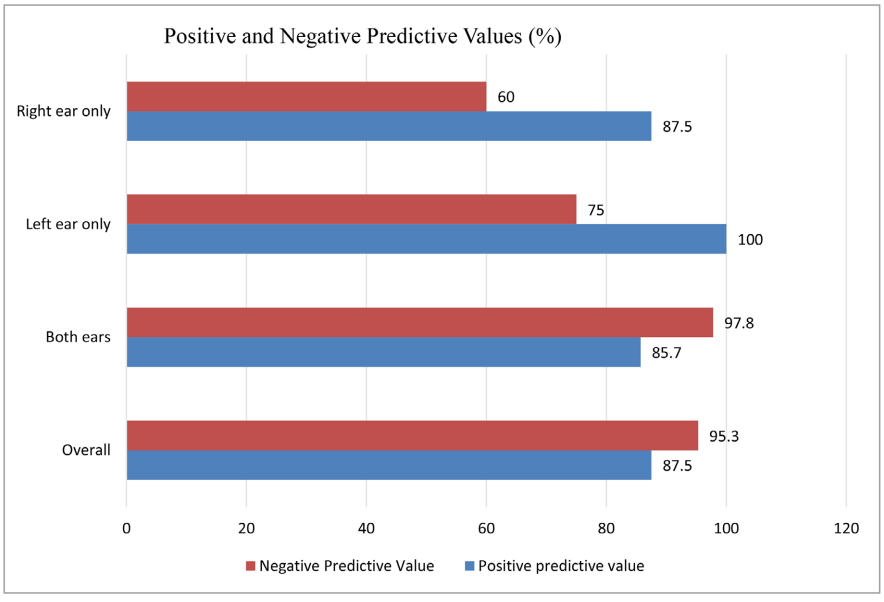


Figure 5. Negative and positive predictive values.

3.5. Internal Consistency of the ETDQ-7

The seven ETDQ-7 items showed good internal consistency (Cronbach's alpha = 0.827), indicating that the items measure a common symptom construct. This result reflects internal consistency only.

4. Discussion

4.1. Sensitivity and Specificity

Our study determined that the ETDQ-7 questionnaire has a sensitivity of 80% and specificity of 97.3%, highlighting its strong diagnostic performance in identifying Eustachian Tube Dysfunction (ETD) among the 182 participants. These findings suggest that the ETDQ-7 is a reliable tool for improving clinical decision-making and patient management.

However, variations in sensitivity and specificity observed in other studies across different populations highlight the importance of considering contextual factors.

For instance, Gallardo *et al*. (2019) reported higher sensitivity (95%) and specificity (96.7%) in a Brazilian Portuguese-speaking population [13], potentially due to their use of a lower ETDQ-7 cutoff score of 14.

Similarly, McCoul *et al*. (2012) achieved 100% sensitivity and specificity in a pioneer validation study using Tympanometry as the gold standard. Their case-control design with matched cases and controls and inclusion of a larger proportion of ETD patients likely contributed to these results [11].

In a study to identify the value and discriminative power of 7- item ETDQ among 39 patients with obstructive ETD in Edegem, Belgium, revealed a sensitivity of 95% and specificity of 96% [3], also a study in Taiwan revealed the sensitivity and specificity of ETDQ-7 score to be 100% and 99.9% respectively, this being a case control study with matched sex and age may have increased the diagnostic accuracy to near 100% [20].

In contrast, studies such as Wee *et al*. (2023) in Malaysia demonstrated lower specificity (72.5% with a cutoff of 14.5), which increased to 84.1% with a cutoff of 17.5 [21]. This discrepancy was attributed to the inclusion of patients with sensorineural hearing loss and tinnitus in the control group, potentially inflating ETDQ-7 scores among controls. Other studies, like Parsel *et al*. (2021), reported even lower specificity (53.2%) due to considering both Type C and Type B patients as ETD cases and employing a different scoring cutoff of >2.1 [22].

Likewise, some studies have indicated a slightly lower specificity and sensitivity values, these include a systematic review study to assess the predictive value of obstructed ETDQ-7 that found a sensitivity of 54% and specificity of 78%, which resulted in lack of consensus on whether it can correctly diagnose obstructive ETD [23]. A study by Alkholaiwi *et al*. mentioned earlier, also had slightly lower sensitivity of 71.4% and specificity of 84.4% but concluded that the ETDQ-7 indeed was able to differentiate between those with and without ETD based on higher AUC. The difference in these values could be attributed to usage of a different cut

off value of 13 or even the fact that cases and controls were matched for age and sex accordingly [12].

4.2. Likelihood Ratios

The positive likelihood ratio of 29.4 (95% CI: 11.0 - 78.4) in our study supports the ETDQ-7's ability to rule in ETD, as a positive likelihood ratio > 10 is generally regarded as strong evidence for ruling in a condition. In contrast, the negative likelihood ratio of 0.21 (95% CI: 0.11 - 0.40) indicates only a moderate ability to rule out ETD, because values below 0.1 are usually required for confident exclusion; a negative ETDQ-7 score should therefore not be used on its own to exclude ETD. Our positive likelihood ratio was higher than that reported in a Danish validation study, which reported a positive likelihood ratio of 3 [24]. The differences in likelihood ratios across studies may arise from sample size, differences in population demographics, or variations in diagnostic criteria and reference standards.

4.3. Predictive Values

Our findings demonstrated a positive predictive value (PPV) of 87.5% (95% CI: 71.0 - 96.5) and a negative predictive value (NPV) of 95.3% (95% CI: 90.6 - 98.1). These results are broadly comparable to those reported by Gallardo *et al*. (2019), who observed a PPV of 95% and NPV of 96.7% [13]. However, Alkholaiwi *et al*. (2022) in Saudi Arabia reported lower PPV (83.3%) and NPV (73.1%) [12], potentially reflecting differences in population characteristics or case-control matching. Similarly, Parsel *et al*. (2021) observed a PPV of 99% but an NPV of 40.9%, likely due to differences in scoring thresholds and case definitions [22]. Because predictive values depend on prevalence, the NPV observed here (at a reference-positive prevalence of 19.2%) may not apply to settings with a different prevalence of ETD.

Anatomical differences, variations in ETD severity between ears, or uneven sample distributions could explain these discrepancies. Future research focusing on these factors could yield valuable data for refining diagnostic approaches.

4.4. Clinical Implications

The performance of the ETDQ-7 against tympanometry in this referral-clinic sample suggests that it may be a useful clinical adjunct for identifying ETD, especially in resource-limited settings where tympanometry may be unavailable. A positive score makes ETD likely; however, because approximately one in five reference-positive patients was missed, a negative score should not be relied on to exclude ETD, and patients with persistent symptoms should still be referred for objective assessment where possible. Its simplicity and non-invasive nature make it accessible, although its performance in primary-care populations, whose case mix differs from that of a national referral clinic, has not been evaluated.

In regions with diverse demographic profiles, adopting population-specific cut-off values may optimize diagnostic performance. Additionally, using the ETDQ-

7 alongside clinical examination could support decision-making where objective testing is not available.

4.5. Limitations of the Study

- The tool was not able to differentiate between patulous and obstructive ETD.
- The score is based on patient description of their symptoms; this subjectivity may have response bias.
- The Questionnaire was not translated to local languages and hence patients speaking other languages other than English could experience differences in translation of the items.
- The study did not match cases and controls; this could have increased the diagnostic accuracy.
- Tympanometry is an imperfect reference standard for ETD: it reflects middle-ear pressure at the time of testing rather than Eustachian tube function directly, and a Type B tympanogram may indicate middle-ear effusion from other causes. Misclassification by the reference standard may have biased the accuracy estimates.
- The study was conducted in a single national referral clinic; the spectrum of patients may differ from that in primary-care settings, which limits generalizability.
- Only 35 participants were reference-positive, so the sensitivity estimate is imprecise, and the laterality subgroup analyses are exploratory.
- Test-retest reliability of the ETDQ-7 was not assessed.

5. Conclusion and Recommendations

5.1. Conclusion

The ETDQ-7 showed good internal consistency (Cronbach's alpha = 0.827). Against an imperfect tympanometric reference standard in this referral-clinic sample, it showed a high specificity (97.3%) and a moderate sensitivity (80.0%), so that one in five reference-positive patients was not identified. The ETDQ-7 may therefore serve as a practical clinical adjunct for identifying ETD where tympanometry is unavailable, but it should not be used on its own to rule out ETD. Further validation in primary-care and other populations is required.

5.2. Recommendations

Clinical use: The ETDQ-7 may be considered as an adjunct to clinical assessment of ETD in ENT clinics, particularly where tympanometry is unavailable, with objective testing retained for patients who have negative scores but persistent symptoms.

Clinicians may also consider using the tool to monitor symptoms following treatment.

Conduct longitudinal studies to evaluate the ETDQ-7's sensitivity to changes in symptoms following treatment [25].

Translate and culturally adapt the ETDQ-7 into local languages, assessing its reliability and validity across diverse linguistic and cultural contexts.

Design comparative studies to explore the diagnostic performance of the ETDQ-7 between matched case-control groups.

Validate the ETDQ-7 in primary-care and regional referral settings, using a reference standard that combines tympanometry with other measures of Eustachian tube function where feasible.

Acknowledgements

The authors thank the staff and participants at the ENT Clinic, Mulago National Referral Hospital, for their support during data collection.

Author Contributions

Conceptualization, Y.N.K.; methodology, Y.N.K.; formal analysis, Y.N.K.; investigation, Y.N.K.; writing original draft preparation, Y.N.K., S.P.A., I.K.; writing review and editing, F.K., A.S., J.M., and A.T; supervision, F.K., A.S. and J.M.; manuscript drafting, Y.K.N., A.T. All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

References

[1] Alshehri, K.A., Saggaf, O.M., Alshamrani, H.M., Alnefaie, A.M. and Alghamdi, K.B. (2020) Prevalence of and Factors Associated with Eustachian Tube Dysfunction among the Public in Jeddah, Saudi Arabia: Cross-Sectional Survey-Based Study. *Interactive Journal of Medical Research*, **9**, e14640. https://doi.org/10.2196/14640

[2] Schilder, A.G.M., Bhutta, M.F., Butler, C.C., Holy, C., Levine, L.H., Kvaerner, K.J., *et al*. (2015) Eustachian Tube Dysfunction: Consensus Statement on Definition, Types, Clinical Presentation and Diagnosis. *Clinical Otolaryngology*, **40**, 407-411. https://doi.org/10.1111/coa.12475

[3] Van Roeyen, S., Van de Heyning, P. and Van Rompaey, V. (2015) Value and Discriminative Power of the Seven-Item Eustachian Tube Dysfunction Questionnaire. *The Laryngoscope*, **125**, 2553-2556. https://doi.org/10.1002/lary.25316

[4] Shan, A., Ward, B.K., Goman, A.M., Betz, J.F., Reed, N.S., Poe, D.S., *et al*. (2019) Prevalence of Eustachian Tube Dysfunction in Adults in the United States. *JAMA Otolaryngology—Head & Neck Surgery*, **145**, 974-975. https://doi.org/10.1001/jamaoto.2019.1917

[5] Vila, P.M., Thomas, T., Liu, C., Poe, D. and Shin, J.J. (2017) The Burden and Epidemiology of Eustachian Tube Dysfunction in Adults. *Otolaryngology—Head and Neck Surgery*, **156**, 278-284. https://doi.org/10.1177/0194599816683342

[6] Wuraola, O.A., Afolabi, A.O. and Ologe, F.E. (2023) Tympanometry and Endoscopic Diagnosis of Eustachian Tube Dysfunction in Patients with Chronic Rhinosinusitis. *Nigerian Postgraduate Medical Journal*, **30**, 126-131. https://doi.org/10.4103/npmj.npmj_31_23

[7] Smith, M.E., Takwoingi, Y., Deeks, J., Alper, C., Bance, M.L., Bhutta, M.F., *et al*. (2018) Eustachian Tube Dysfunction: A Diagnostic Accuracy Study and Proposed Diagnostic Pathway. *PLOS ONE*, **13**, e0206946. https://doi.org/10.1371/journal.pone.0206946

[8] Bluestone, C.D. (2005) Eustachian Tube: Structure, Function, Role in Otitis Media. PMPH-USA.

[9] Teixeira, M.S., Swarts, J.D. and Alper, C.M. (2018) Accuracy of the ETDQ-7 for Identifying Persons with Eustachian Tube Dysfunction. *Otolaryngology—Head and Neck Surgery*, **158**, 83-89. https://doi.org/10.1177/0194599817731729

[10] Ungar, O.J., Cavel, O., Golan, G.S., Oron, Y., Wasserzug, O. and Handzel, O. (2018) The Hebrew Version of the Eustachian Tube Dysfunction Questionnaire-7. *Hearing Balance and Communication*, **16**, 114-119. https://doi.org/10.1080/21695717.2018.1463756

[11] McCoul, E.D., Anand, V.K. and Christos, P.J. (2012) Validating the Clinical Assessment of Eustachian Tube Dysfunction: The Eustachian Tube Dysfunction Questionnaire (ETDQ-7). *The Laryngoscope*, **122**, 1137-1141. https://doi.org/10.1002/lary.23223

[12] Alkholaiwi, F., Alnatheer, A.M., Theyab, R.S., Alyousef, M., Aldrees, T., Dahmash, A.B., *et al*. (2022) Cross-Cultural Adaptation, Validation, and Arabic Translation of the Eustachian Tube Dysfunction Questionnaire (ETDQ-7). *International Archives of Otorhinolaryngology*, **26**, e636-e642. https://doi.org/10.1055/s-0041-1740161

[13] Gallardo, F.P., Onishi, E.T., Lira, F.I., Suzuki, F.B. and Testa, J.R.G. (2019) Translation, Validation and Cultural Adaptation of "The Eustachian Tube Dysfunction Questionnaire-7" (ETDQ-7) to Brazilian Portuguese (BR). *Brazilian Journal of Otorhinolaryngology*, **85**, 456-464. https://doi.org/10.1016/j.bjorl.2018.03.010

[14] Özgür, E., Bilgen, C. and Cengiz Özyurt, B. (2018) Turkish Validity and Reliability of Eustachian Tube Dysfunction Questionnaire-7. *Brazilian Journal of Otorhinolaryngology*, **84**, 435-440. https://doi.org/10.1016/j.bjorl.2017.05.001

[15] Almutairi, A., Alharbi, B.A., Alharbi, M.T., Al-Sowinea, A.F., Alshammakhi, A.M., Munhish, F.A., *et al*. (2024) Symptoms and Factors Associated with Eustachian Tube Dysfunction among the Population of Qassim, Saudi Arabia. *Cureus*, **16**, e61087. https://doi.org/10.7759/cureus.61087

[16] Buderer, N.M.F. (1996) Statistical Methodology: I. Incorporating the Prevalence of Disease into the Sample Size Calculation for Sensitivity and Specificity. *Academic Emergency Medicine*, **3**, 895-900. https://doi.org/10.1111/j.1553-2712.1996.tb03538.x

[17] Jerger, J. (1970) Clinical Experience with Impedance Audiometry. *Archives of Otolaryngology—Head and Neck Surgery*, **92**, 311-324. https://doi.org/10.1001/archotol.1970.04310040005002

[18] Clopper, C.J. and Pearson, E.S. (1934) The Use of Confidence or Fiducial Limits Illustrated in the CASE of the Binomial. *Biometrika*, **26**, 404-413. https://doi.org/10.1093/biomet/26.4.404

[19] Simel, D.L., Samsa, G.P. and Matchar, D.B. (1991) Likelihood Ratios with Confidence: Sample Size Estimation for Diagnostic Test Studies. *Journal of Clinical Epidemiology*, **44**, 763-770. https://doi.org/10.1016/0895-4356(91)90128-v

[20] Lin, W., Chou, Y., Sun, C., Lin, C., Hsu, C. and Wu, H. (2020) Evaluation of Thirty Patients with Eustachian Tube Dysfunction in Taiwan Region by Questionnaire Survey. *JFMA*, **119**, 621-626. https://doi.org/10.1016/j.jfma.2019.08.017

[21] Wee, L.Y., Ramli, R.R., Nik Othman, N.A. and Redzyque Ramza Ramli, R.R. (2023) Translation and Validation of the Eustachian Tube Dysfunction Questionnaire (ETDQ-7) into the Malay Language. *Journal of Clinical and Health Sciences*, **8**, 35-45. https://ir.uitm.edu.my/id/eprint/83263

[22] Parsel, S.M., Unis, G.D., Souza, S.S., Bartley, H., Bergeron, J.M., Master, A.N., *et al*. (2021) Interpretation of Normal and Abnormal Tympanogram Findings in Eustachian Tube Dysfunction. *Otolaryngology—Head and Neck Surgery*, **164**, 1272-1279. https://doi.org/10.1177/0194599820965236

[23] Andresen, N.S., Sharon, J.D., Nieman, C.L., Seal, S.M. and Ward, B.K. (2021) Predictive Value of the Eustachian Tube Dysfunction Questionnaire-7 for Identifying Obstructive Eustachian Tube Dysfunction: A Systematic Review. *Laryngoscope Investigative Otolaryngology*, **6**, 844-851. https://doi.org/10.1002/lio2.606

[24] Hansen, L.J., Glad, H., Jørkov, A., Lundin, K. and Kirchmann, M. (2020) Validating the 7-Item Eustachian Tube Dysfunction Questionnaire in Danish. *Danish Medical Journal*, **67**, A11190617. https://ugeskriftet.dk/dmj/validating-7-item-eustachian-tube-dysfunction-questionnaire-danish

[25] Van Roeyen, S., Van de Heyning, P. and Van Rompaey, V. (2016) Responsiveness of the 7-Item Eustachian Tube Dysfunction Questionnaire. *The Journal of International Advanced Otology*, **12**, 106-108. https://doi.org/10.5152/iao.2016.2086