Predictors of Eustachian Tube Dysfunction Outcomes after Balloon Dilation

Vivian Wung, BA; Jose E. Alonso, MD; Akira Ishiyama, MD; Quinton Gopen, MD; Connie Ho, BS; Marilene Wang, MD; Jeffrey Suh, MD; Christine Wells, PhD; Jivianne T. Lee, MD

Background

The eustachian tube is responsible for pressure regulation, protection of the middle ear from the nasopharynx, and clearance of the middle ear space.[1] Eustachian tube dysfunction (ETD) is a prevalent disorder in the United States that is associated with complaints of fullness, crackling and popping sounds, ear pain, and muffled hearing, among other symptoms. Patients with ETD have been reported to have higher rates of chronic rhinitis, chronic sinusitis, allergic rhinitis, acute sinusitis, among other pathologies.[2] The condition accounts for over 2 million medical visits annually.[3] Although prevalent, ETD is not well defined. In 2012, the ETDQ-7 was published as a validated scoring tool to better objectively assess clinical symptoms and treatment outcomes.[4–6]

Although common, obstructive ETD can be challenging to treat. First line therapy involves medical treatment including intranasal and/or systemic steroids.[7–9] With refractory cases, eustachian tube balloon dilation (ETBD) has emerged as a promising surgical treatment for the management of ETD.[4,10–16] In addition, patients with a history of recurrent barochallenge may improve following ETBD.[17,18] Although recent randomized clinical trials have demonstrated its efficacy in comparison to medical therapy, factors associated with favorable clinical outcomes are less understood.[4,10–12,16] The identification of predictive variables may have important implications in the selection of appropriate candidates for ETBD. Our study aims to identify such demographic or medical factors by comparing pre- and postoperative ETDQ-7 outcomes among patients.

Methods

Selection of Patients, Collection and Analysis of Data

This study was reviewed and approved by the UCLA Institutional Review Board (IRB no. IRB#18-001094 and IRB#19-001580) and was completed in accordance with the Helsinki Declaration. 110 patients with ETD were treated with ETBD between March 2017-November 2019 with the Aera (Acclarent, Irvine, CA) or XprESS Balloon (Entellus, Plymouth, MN), identified by CPT code of all procedures during this time interval. 70 patients were treated using the Aera device while 40 patients were treated with the Entellus balloon. Medical records were reviewed for patient demographics, history of head or ear trauma, chronic otitis externa, chronic otitis media, tympanic membrane perforation, prior ear surgery, allergies, allergic rhinitis, chronic rhinitis, nasal congestion, history of sinusitis, postnasal drip, rhinorrhea, nasal trauma, hyposmia, nasal obstruction, deviated septum, prior sinus surgery, and prior ETBD. Preoperative consult notes were reviewed for completion of the ETDQ-7, a validated instrument to assess symptoms and treatment outcomes.[4,5] A total of 73 patients were identified who had completed the preoperative questionnaire. At least six months after surgery, patients were contacted over the phone, completed an oral consent and the ETDQ-7, and asked whether they would refer a friend with similar symptoms, whether they would do the surgery again, and the most difficult parts of side effects from the dilation over the phone. In total, 59 patients completed the postoperative ETDQ-7; the remainder of patients were unable to be reached over the phone due to change in number or lack of response. 55 patients completed both pre- and postoperative ETDQ-7. (Figure 2).

Clinically relevant variables were selected from the collected data, including preoperative ETDQ-7 score, prior history of otologic surgery, presence of negative preoperative tympanogram, and type of device. These variables were compared using Pearson's correlation. All demographics data and medical history collected in this study were incorporated into the model as predictor variables. Statistical tests were two-sided and an alpha level of 0.05 was set *a priori*. Significant p-value was determined to be p=0.013 after Bonferroni correction. All statistical analyses were performed in SPSS Version 24.0 (IBM, Armonk, NY, USA). Statistical analysis was reviewed by an independent statistician (C.W.).

Age	Years
Mean	47.6
Min	16
Max	86
Characteristic	Percentage (n)
Sex	
Female	48.2% (53)
Male	51.8% (57)
Balloon Type	
Aera (Acclarent)	63.6% (70)
XprESS (Entellus)	36.4% (40)
ETDQ-7 Score	Score
Preoperative Score	
Mean	4.6
Min	1.1
Max	7
SD	1.3
Postoperative Score	
Mean	2.6
Min	1
Max	6.4
SD	1.4
Difference: Pre- and Postoperative Score	
Mean	1.9
Min	-3.3
Max	5.0
SD	1.5

Results

Patient Demographics, Past Medical History

The mean age at time of surgery was 47.6 years with a standard deviation of 16.6 years (range 16-86). Average duration of follow-up was 12.8 months with a standard deviation of 6.0 months (range 2-27 months). Of the total sample of 110 patients, 51.8% (n=57) were male and 48.2% (n=53) were female. (**Table 1**)

On a review of prior otologic history, 34.5% had prior history of chronic otitis media (n = 38) and 41.8% had prior history of prior ear surgery (n=46). When reviewing rhinologic history, 48.2% had prior history of environmental allergies (n=53), and 30.0% of patients had history of allergic rhinitis (n=33) and 39.1% had a history of nonallergic sinusitis n=43). Most common rhinologic symptoms included congestion (77.3%, n=85), and postnasal drip (40.0%, n=44). A significant group had prior history of sinus surgery (31.0%, n=34), and 9.1% reported prior eustachian tube balloon dilation (n=10). 33 of 53 patients reported they would get the procedure again and 36 said they would refer the procedure to their friends. When asked about the most difficult part of their recovery, 43 patients stated the recovery was well-tolerated with minimal problems, and 16 reported there was minimal improvement in their symptoms after their surgery. A total of 48 patients had preoperative tympanograms in their medical record, with 75.0% (n=36) Type A tympanograms, 8.3% (n=4) Type B tympanograms, and 16.7% (n=8) Type C tympanograms. Of all these, 56.3% (n=27) had negative peak pressures. (**Table 2.**)

Preoperative and Postoperative ETDQ-7 Outcomes

Among these 110 patients, 73 completed a preoperative questionnaire, 59 completed a postoperative ETDQ-7, and 55 completed both. The mean preoperative ETDQ-7 Score was 4.6 with a standard deviation of 1.3 (range 1.1-7, n=73). Postoperative ETDQ-7 Score was 2.6 with a standard deviation of 1.4 (range 1-6.4, n=59). (**Table 1**.) Average difference in postoperative and preoperative ETDQ-7 scores was 1.9 with a standard deviation of 1.5 (n=55, 95% confidence interval of 1.42-2.28, p<.001) as measured by a paired samples t-test.

Statistical Analysis

We examined clinically relevant variables: preoperative ETDQ-7 score, prior history of otologic surgery, presence of negative peak pressure preoperative tympanogram, and type of device. These variables were used as predictors for postoperative ETDQ-7 scores and overall improvement after ETBD. Our analyses showed patients with negative peak pressure preoperative tympanogram were more likely to have a lower postoperative ETDQ-7 (Pearson correlation coefficient -0.392, p=0.009, n=43). When comparing mean postoperative outcomes between the two groups, patients with negative preoperative tympanograms had an average score of 1.97+/-0.93 while patients with positive preoperative tympanograms had an average score of 2.91+/-1.35. Although negative pressure preoperative tympanograms were associated with a lower postoperative ETDQ-7 raw score, they were not associated with greater degree of improvement in postoperative ETDQ-7.

Higher preoperative ETDQ-7 resulted in higher postoperative ETDQ-7 (Pearson correlation coefficient 0.420, p=0.003, n=49) but greater improvement in ETDQ-7 (Pearson correlation coefficient 0.439, p=0.001, n=51). Prior history of ear surgery and type of device (Aera vs Entellus) were not significantly associated with postoperative changes in ETDQ-7. (**Table 3.**)

A one-way analysis of variance was conducted to evaluate the null hypothesis that there is no difference in postoperative ETD-7 or improvement in ETDQ-7 between preoperative tympanogram type (A, B, C) which served as the three independent groups. There was no significant difference in postoperative ETDQ-7 score or postoperative change in ETDQ-7 score to reject the null hypothesis.

Prior Medical History		
	Percentage (n)	Total
History of Prior Head or Ear Trauma	5.4 (6)	110
Chronic Otitis Externa	1.8 (2)	110
Chronic Otitis Media	34.5 (38)	110
Tympanic Membrane Perforation	18.2 (20)	110
Prior History of Ear Surgery	41.8 (46)	110
Environmental Allergies	48.2% (53)	110
Allergic Rhinitis	30.0 (33)	110
Nonallergic Rhinitis	39.1 (43)	110
Nasal Congestion	77.3 (85)	110
Sinusitis	29.1 (32)	110
Postnasal Drip	40.0 (44)	110
Rhinorrhea	29.0 (32)	110
Nasal Trauma	3.6 (4)	110
Hyposmia	7.3 (8)	110
Nasal Obstruction	81.8 (90)	110
Deviated Septum	42.7 (47)	110
Negative Pressure Preop Tympanogram	56.3 (27)	48
Type A Preop Tympanogram	75.0 (36)	48
Type B Preop Tympanogram	8.3 (4)	48
Type C Preop Tympanogram	16.7 (8)	48
Postoperative Opinions		
	Percentage (n)	Total
Prior history of sinus surgery	31.0 (34)	110
Prior history of ET dilation	9.1 (10)	110
Would they get the procedure again?	61.8 (34)	55
Would they refer a friend?	67.3 (37)	55
Well-tolerated recovery	78.2 (43)	55
Minimal or no improvement	29.1 (16)	55

Discussion

ETD is a relatively common disorder in the general population with a prevalence of roughly 1%.[19] The demographics of our patient population is highly reflective of the general ETD population as described by a recent meta-analysis reporting an average age of 47.6 years old and a rate of 57% males.[8] As expected, our population of patients has a high rate of otologic and nasal pathologies related to ETD, including history of chronic otitis media, prior ear surgery, prior sinus surgery, environmental allergies, allergic rhinitis, chronic rhinitis, nasal congestion, sinusitis, postnasal drip, rhinorrhea, and deviated septum.[20–22]

In the literature, ETBD has been associated with improvement in subjective and objective treatment outcome measures, including the ETDQ-7 Survey. In fact, our average preoperative ETDQ-7 score of 4.6 +/-1.3 is consistent with the previously reported baseline reported by Meyer et. al of 4.6+/-1.1.[12] Similarly, our postoperative average of 2.6+/-1.4 is similar to the follow-up average of 2.1 across all time points.[12] As all postoperative surveys were administered at least six months postoperatively, our population also supports the consensus in the literature that there exists a lasting long-term benefit of ETBD for patients with ETD.[12,15,16]

Currently, ETBD is indicated for patients who a have history and physical exam consistent with ETD, workup that rules out other causes of aural fullness, and have failed medical therapy.[17,23] At our institution, patients undergo at least four weeks of consistent medical therapy with a topical nasal steroid spray and/or prior course of oral steroids. Patient-reported symptom scores alone are not enough to diagnose ETD. However, patients with persistent symptoms upon barochallenge despite medical therapy may improve following ETBD.[17,18] Although ETBD is growing in popularity as surgical treatment for ETD and a number of patients meet these indications for treatment, little is known about factors predicting treatment success.

Of the 55 patients with preoperative and postoperative ETDQ-7 information, our study found higher preoperative ETDQ-7 was associated with greater improvement in ETDQ-7, but also higher overall postoperative score. These findings expand upon those in a recent study by Higgins et. al in which high preoperative scores (≥4) were independently associated with ETDQ-7 normalization (<2.1) in patients undergoing endoscopic sinus surgery.[24] In our study, higher preoperative ETDQ-7 scores appear to be associated with a greater degree of ETDQ-7 improvement, suggesting patients do experience benefit in ETD symptoms from dilation. However, higher preoperative ETDQ-7 score was correlated with higher postoperative ETDQ-7 score suggesting that although they experienced a greater degree of improvement, they may have a lower rate of resolution compared to patients with lower preoperative ETDQ-7 scores. Overall, preoperative and postoperative ETDQ-7 were significantly different by an average of 1.9 +/- 1.45 points.

Our study also found negative peak pressure preoperative tympanograms were significantly correlated with lower postoperative ETDQ-7 scores (p=0.009). In a study by Meyer et al, patients with retracted tympanic membranes on examination benefited from ETBD with improvement of postoperative ETDQ-7 from baseline.[12] When looking at average postoperative scores, patients with negative preoperative tympanograms had an average score of 1.97+/-0.9, reflecting normalization of ETD, while patients with positive preoperative tympanograms had an average score of 2.91+/-1.35 reflecting sustained presence of ETD.[5] Our findings suggest that ETDQ-7 and preoperative tympanogram peak pressure may be useful to identify patients who will experience ETD resolution after ETBD.

In the literature, Type B or C tympanograms have been shown to be associated with obstructive ETD and is listed as an indication for ETBD.[25] However, our analyses did not find evidence for difference in postoperative ETDQ-7 and improvement in ETDQ-7 between tympanogram type (A, B, C). One reason for this may be the limited sample size, as only 43 patients had preoperative tympanograms, preoperative and postoperative ETDQ-7 scores for analysis. Of these, only 34 had Type A, 3 had Type B, and 6 had Type C preoperative tympanograms. Our smaller sample size likely affected our lack of significance. As a tertiary referral center, many patients receive tympanometry at outside institutions. All available tympanometries were included in our study. We welcome larger studies to further assess whether preoperative tympanogram type is predictive of postoperative outcomes.

The two other clinically relevant variables, prior history of otologic surgery and type of dilation device, were not found to be significant predictors of lower postoperative ETDQ-7 score or improvement in score from baseline. Prior history of otologic surgery was selected as ETD has been shown to be a risk after cholesteatoma surgery.[20] However, our study found no association with prior history of otologic surgery and postoperative differences in ETDQ-7 scores. Analyses regarding revision balloon dilation were not performed due to small sample size (n=10). Consensus guidelines are currently inconclusive with regards to the benefit of repeat balloon dilations.[17]

There are currently two dilation devices available for ETD: the AERA (Acclarent, Inc.) and XprESS Dilation systems (Entellus Medical Inc.). The AERA dilation system consists of a 6x16 mm noncompliant flexible balloon catheter at a 55 degree angle, and is held at the inflated position for 2 minutes at 12 ATM.[26] Similarly, the XprESS Dilation system is comprised of a 6x20mm balloon with a malleable seeker. Inflation to 12 ATM is also performed and held for 2 minutes. [27] Both systems are similar in profile, balloon compliance, and measurements.[28] To our knowledge, this is the only study comparing outcomes between the two devices. In our retrospective chart review, we found 70 patients were treated with the Aera dilation device while 40 were treated with the Entellus device. No significant differences in outcomes were found between the two dilation devices.

	Postoperative ETDQ-7			Difference between preoperative and postoperative ETDQ-7		
	Pearson Correlation	Sig. (2-tailed)	N	Pearson Correlation	Sig. (2-tailed)	N
Prior Ear Surgery	0.151	0.254	59	-0.243	0.073	55
Nonallergic Rhinitis	-0.118	0.374	59	0.272	0.044	55
Use of Aera or XprESS dilation systems	0.113	0.394	59	0.068	0.621	55
Negative Preoperative Tympanogram	-0.392**	0.009	43	0.085	0.592	42
Preoperative ETDQ-7	0.420**	0.003	49	0.439**	0.001	51

Limitations

Limitations of this study include all those associated with a retrospective chart review. Demographics and prior history included in our dataset were limited by those described in the chart. Although patients were assured their participation would not affect their care and they could decline at any time, survey administration was performed over the phone which could have affected responses compared to if the patient were self-reporting on a written survey. To control survey administration, the surveys were administered by the first author who was blinded to preoperative ETDQ-7 scores. In addition, subgroup analysis comparing preoperative tympanograms and ETBD outcomes may not have been sufficiently powered to reach statistical significance. Follow-up times ranged from 6 to 39 months, which may have also resulted in a wider range of postoperative outcomes. Finally, initial study design intended for comparison of pre- and postoperative tympanograms, but limitations of patient care during the severe acute respiratory syndrome coronavirus 2 pandemic prevented patients from completing these studies.

Conclusion

Higher preoperative ETDQ7 scores were significantly correlated with lower postoperative ETDQ-7 and greater postoperative improvement in ETDQ-7, while negative peak pressure preoperative tympanograms were significantly correlated with lower postoperative ETDQ-7 score. History of otologic surgery or type of balloon dilation device also did not affect surgical outcomes. Further studies are needed to determine which additional factors are associated with better response rates to balloon dilation for ETD.

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