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# Clinical Predictors of Symptom Improvement Following Eustachian Tube Balloon Dilation

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## Abstract

**Objective:** This study aims to identify clinical predictors of treatment response to Eustachian Tube Balloon Dilation (ETBD) as measured by changes in Eustachian Tube Dysfunction Questionnaire-7 (ETDQ-7) scores.

**Methods:** One hundred thirteen patients who underwent ETBD at an institution from 2017 to 2021 completed ETDQ-7 pre- and post-operatively. We conducted multivariable regression analyses with ETDQ-7 normalization (<2.1 post-op), minimum clinically important difference (MCID) (>0.5 pre-op – post-op), and quantitative improvement in ETDQ-7 score as outcome variables. Pre-operative ETDQ-7 score, tympanogram type, chronic otitis media, chronic rhinosinusitis (CRS), inferior turbinate hypertrophy, deviated septum, allergic rhinitis, and rhinorrhea were included as covariates. Models controlled for age, sex, ethnicity, prior ear or sinus surgery, and follow-up duration.

**Results:** The mean age was 49 years old. 51% were females, and all patients had pre-operative ETDQ-7 above 2.1. After a mean follow-up period of 13 months, 77% achieved MCID and 37% had normalized. Higher pre-operative ETDQ-7 score was associated with greater ETDQ-7 score improvement ( $B=0.60$ , 95% CI=[0.37, 0.83]) and greater odds of achieving MCID (aOR=1.65; 95% CI=[1.06, 2.59]). A history of CRS improved chances of achieving MCID (aOR=4.53; 95% CI=[1.11, 18.55]) and a history of chronic otitis media predicted increased odds of ETDQ-7 normalization (aOR=2.88; 95% CI=[1.09, 7.58]).

**Conclusions:** Our findings suggest that ETBD was highly effective among patients with pre-operative ETDQ-7 above 2.1. Furthermore, higher pre-operative ETDQ-7 score, CRS, and chronic otitis media predicted more favorable symptomatic benefit from ETBD. These factors may be important to consider when counseling potential candidates for this procedure.

## Keywords

Eustachian tube, chronic rhinosinusitis, otitis media, ETDQ-7, Eustachian tube balloon dilation

## Introduction

Obstructive Eustachian Tube Dysfunction (ETD) is a prevalent disorder (4.6%) in the United States associated with symptoms of ear fullness, crackling, and popping sounds.<sup>1-4</sup> Although ETD accounts for over 2 million medical visits annually, its diagnostic criteria are not well defined.<sup>5</sup> In 2012, the Eustachian Tube Dysfunction Questionnaire-7 (ETDQ-7) was published as a validated scoring tool to assess clinical symptoms and treatment outcomes among patients with suspected ETD.<sup>6-8</sup>

First-line medical therapy for ETD involves intranasal and/or systemic steroids.<sup>9-11</sup> In refractory cases, Eustachian tube balloon dilation (ETBD) has emerged as a promising surgical treatment.<sup>6,12-18</sup> Although prior randomized controlled trials have demonstrated the safety and efficacy of ETBD, little is known about factors predicting treatment success.<sup>6,12-14,18</sup> The identification of such predictive

variables may provide important implications in the selection of appropriate candidates for ETBD.

ETBD is indicated for patients with history and physical exam consistent with ETD, workup that rules out other causes of aural fullness, and who exhibit persistent ETD symptoms despite completing appropriate medical therapy.<sup>19,20</sup> At our institution, patients with clinical evaluations consistent with

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ETD first undergo medical therapy with a topical nasal steroid spray and/or oral steroids for at least 4 weeks, as recommended by previous studies.<sup>13,14</sup> If symptoms persist despite medical therapy, they were offered ETBD. The purpose of this study is to determine whether ETBD was effective in alleviating patients' symptoms and to identify baseline clinical factors that may predict successful symptom mitigation following ETBD as measured by change in ETDQ-7 scores.

## Materials and Methods

### Data Collection and Inclusion Criteria

This study was reviewed and approved by the UCLA Institutional Review Board (IRB#18-001094 and IRB#19-001580). From October 2017 to October 2021, a retrospective review was performed of 113 patients who underwent ETBD. All patients had a history consistent with ETD and were initially treated with at least 4 weeks of consistent medical therapy with a topical nasal steroid spray and/or oral steroids as recommended by previous studies.<sup>13,14</sup> If patients had a mean ETDQ-7 score greater than 2.1 following the medical trial, they were offered ETBD. All patients also underwent nasal endoscopy as well as audiogram with tympanometry preoperatively. Dilations were performed with either 6 × 16 mm Aera (Acclarent, Irvine, CA) or 6 × 20 mm Xpress Balloon (Entellus, Plymouth, MN). Data regarding age, sex, ethnicity, co-morbidities, tympanometry findings, as well as pre-operative ETDQ-7 scores were collected. Post-operative ETDQ-7 scores were also obtained after at least 3 months of follow-up.

### Variable Characterization

The primary dependent variable of interest was change in ETDQ-7 score, a validated instrument to assess symptoms and treatment outcomes of ETBD.<sup>6,7</sup> ETDQ-7 is a 7-item questionnaire that assesses the severity of patients' ETD-related symptoms. Each item has 7 levels of severity, with 1 being "no problem" and 7 being "severe problem."<sup>6</sup> A final ETDQ-7 score was calculated by averaging the reported severity rating across 7 items. A final score of 2.1 or higher is considered consistent with ETD.<sup>7</sup> Pre-operative ETDQ-7 was recorded at consult visits prior to ETBD. Post-operative ETDQ-7 was collected at follow-up visits or self-reported by patients on an electronic survey form at least 3 months after their ETBD procedures.

Three outcome variables characterizing change in ETDQ-7 score pre- and post-ETBD were calculated: normalization, achievement of minimum clinically important difference (MCID), and quantitative score improvement. Normalization is a binary variable that indicates whether a patient's ETDQ-7 score, which was higher than 2.1 prior to

ETBD, reaches below 2.1 at follow-up. MCID was a binary variable that indicates whether a patient achieved MCID in ETDQ-7 score from pre- to post-ETBD, which was defined by Poe et al<sup>13</sup> as 0.5. Quantitative improvement in ETDQ-7 score was a continuous variable calculated by subtracting post-operative ETDQ-7 score from pre-operative ETDQ-7 score.

We selected several clinically relevant variables that were felt to be important as independent variables of interest, including pre-operative tympanogram type, pre-operative ETDQ-7 score, preoperative rhinorrhea, history of chronic otitis media, allergic rhinitis, CRS, deviated septum, and inferior turbinate hypertrophy. All patients with CRS met the diagnostic criteria outlined in the American Academy of Otolaryngology–Head and Neck Surgery Foundation clinical practice guideline for adult CRS.<sup>21</sup>

### Statistical Analysis

We used a paired samples *t*-test to compare pre-operative ETDQ-7 score and post-operative ETDQ-7 score for the overall sample. Additionally, we built 3 separate multivariable models for the 3 outcome variables of interest. Specifically, a logistic regression model with MCID as the outcome variable, a logistic regression model with normalization in ETDQ-7 score as the outcome variable, and a linear regression model with quantitative improvement in ETDQ-7 score as the outcome variable were constructed. All independent variables of interest were incorporated as covariates into the multivariable models.

Age, sex, ethnicity, follow-up length, prior ear or sinus surgery, and type of ETBD device (Aera or Xpress) were also included in these models as control measures. Since concurrent procedures could potentially influence patients' experiences, we evaluated concurrent ESS and septoplasty as covariates in separate regression models for the 3 outcome variables measuring ETDQ-7 score improvement. If either concurrent procedure was found to significantly impact patient outcomes, it would also be directly controlled for in the respective model. Statistical significance was assessed at 2-tailed,  $\alpha = .05$ . All statistical analyses were conducted with IBM SPSS, Version 27.

## Results

### Study Cohort Characteristics

A summary of study population characteristics is presented in Table 1. The mean age at time of surgery was 49 years with a standard deviation of 16 years (range 13-77). Mean follow-up period was 13 months with a standard deviation of 9 months (range 3-50 months). Sample proportions of females and males were relatively equal

**Table 1.** Summary of Patient Characteristics and ETDQ-7 scores.

|                                     | Count | Proportion (%) | Mean Preoperative ETDQ-7 Score | Mean Postoperative ETDQ-7 Score |
|-------------------------------------|-------|----------------|--------------------------------|---------------------------------|
| Overall                             | 113   | 100            | 4.67                           | 2.87                            |
| Age                                 |       |                |                                |                                 |
| 18-39                               | 37    | 32.7           | 4.65                           | 2.83                            |
| 40-64                               | 57    | 50.4           | 4.73                           | 2.94                            |
| 65+                                 | 19    | 16.8           | 4.54                           | 2.75                            |
| Sex                                 |       |                |                                |                                 |
| Female                              | 58    | 51.3           | 4.83                           | 3.14                            |
| Male                                | 55    | 48.7           | 4.51                           | 2.59                            |
| Ethnicity                           |       |                |                                |                                 |
| Hispanic or Latino                  | 10    | 8.8            | 5.19                           | 3.64                            |
| Non-Hispanic or Latino              | 103   | 91.2           | 4.62                           | 2.79                            |
| Pre-operative tympanogram           |       |                |                                |                                 |
| Type A                              | 61    | 54.0           | 4.60                           | 2.81                            |
| Type B                              | 19    | 16.8           | 4.96                           | 3.21                            |
| Type C                              | 33    | 29.2           | 4.64                           | 2.80                            |
| Chronic otitis media                |       |                |                                |                                 |
| Yes                                 | 35    | 31.0           | 4.84                           | 2.72                            |
| No                                  | 78    | 69.0           | 4.60                           | 2.94                            |
| Allergic rhinitis                   |       |                |                                |                                 |
| Yes                                 | 50    | 44.3           | 4.64                           | 2.81                            |
| No                                  | 63    | 55.8           | 4.70                           | 2.92                            |
| Chronic rhinosinusitis              |       |                |                                |                                 |
| Yes                                 | 34    | 28.8           | 4.87                           | 2.85                            |
| No                                  | 79    | 66.9           | 4.59                           | 2.88                            |
| Rhinorrhea                          |       |                |                                |                                 |
| Yes                                 | 55    | 49.1           | 4.87                           | 3.21                            |
| No                                  | 57    | 50.9           | 4.49                           | 2.55                            |
| Deviated septum                     |       |                |                                |                                 |
| Yes                                 | 48    | 42.9           | 4.55                           | 2.86                            |
| No                                  | 65    | 57.1           | 4.80                           | 2.88                            |
| Inferior turbinate hypertrophy      |       |                |                                |                                 |
| Yes                                 | 86    | 76.1           | 4.55                           | 2.86                            |
| No                                  | 27    | 23.9           | 5.06                           | 2.92                            |
| Prior ear or sinus surgery          |       |                |                                |                                 |
| Yes                                 | 54    | 47.8           | 4.69                           | 2.75                            |
| No                                  | 59    | 52.2           | 4.66                           | 2.99                            |
| Concurrent endoscopic sinus surgery |       |                |                                |                                 |
| Yes                                 | 48    | 42.90          | 4.77                           | 3.16                            |
| No                                  | 65    | 57.10          | 4.58                           | 2.64                            |
| Concurrent septoplasty              |       |                |                                |                                 |
| Yes                                 | 55    | 49.11          | 4.49                           | 2.64                            |
| No                                  | 57    | 50.89          | 4.83                           | 3.08                            |

(51% vs 49%, respectively). Of the 113 ETBD surgeries analyzed, 45% (n=51) were operated on both sides, 29% (n=33) were operated on the right side, and 26% (n=29) were operated on the left side. Additionally, 39% (n=44) of procedures were dilated with Xpress and 61% (n=69) were dilated with Aera. Finally, 49% (n=55) of patients underwent concurrent septoplasty and 43% of patients underwent concurrent ESS (n=48).

Most patients exhibited type A tympanograms prior to ETBD (54%), followed by type C tympanograms (29%),

and type B tympanograms (17%). All patients who had type A tympanograms reported a history of baro-challenge. Approximately a third of all patients had a history of chronic otitis media (31%), 29% had a history of CRS, and 44% had a reported history of allergic rhinitis. Nearly half of patients in our sample had prior ear or sinus surgery (48%). At the preoperative consult visit, 49% (n=55) of patients reported rhinorrhea, 50% (n=56) were diagnosed with deviated septum, and 76% (n=86) were diagnosed with inferior turbinate hypertrophy.

**Table 2.** Multivariable Logistic Regression Models Assessing Minimum Clinically Important Difference and Normalization of ETDQ-7 Scores (N = 113).

|                                | Outcome = MCID |                           |             | Outcome = Normalization |                          |             |
|--------------------------------|----------------|---------------------------|-------------|-------------------------|--------------------------|-------------|
|                                | Log-odds       | aOR [95% CI]              | P           | Log-odds                | aOR [95% CI]             | P           |
| Follow-up duration             | 0.04           | 1.04 [0.97, 1.12]         | .23         | 0.01                    | 1.01 [0.96, 1.06]        | .79         |
| Age                            | 0.01           | 1.01 [0.98, 1.04]         | .57         | -0.01                   | 0.99 [0.96, 1.02]        | .38         |
| Sex                            |                |                           |             |                         |                          |             |
| Male                           | Reference      |                           |             |                         |                          |             |
| Female                         | 0.36           | 1.43 [0.51, 4.03]         | .50         | -0.59                   | 0.56 [0.23, 1.36]        | .20         |
| Ethnicity                      |                |                           |             |                         |                          |             |
| Non-Hispanic or Latino         | Reference      |                           |             |                         |                          |             |
| Hispanic or Latino             | -1.19          | 0.30 [0.05, 1.84]         | .19         | -0.30                   | 0.74 [0.14, 3.86]        | .72         |
| ETDB device                    |                |                           |             |                         |                          |             |
| Aera                           | Reference      |                           |             |                         |                          |             |
| Xpress                         | 0.34           | 1.41 [0.46, 4.33]         | .55         | 0.46                    | 1.59 [0.64, 3.91]        | .32         |
| Prior ear or sinus surgery     |                |                           |             |                         |                          |             |
| No                             | Reference      |                           |             |                         |                          |             |
| Yes                            | -0.05          | 0.95 [0.30, 2.99]         | .94         | 0.07                    | 1.07 [0.39, 2.91]        | .89         |
| Preoperative ETDQ-7 Score      | <b>0.50</b>    | <b>1.65 [1.06, 2.59]</b>  | <b>.028</b> | <b>-0.40</b>            | <b>0.67 [0.46, 0.98]</b> | <b>.041</b> |
| Preoperative tympanogram       |                |                           |             |                         |                          |             |
| Type A                         | Reference      |                           |             |                         |                          |             |
| Type B                         | -0.94          | 0.39 [0.09, 1.62]         | .20         | -0.01                   | 0.99 [0.28, 3.53]        | .98         |
| Type C                         | 0.21           | 1.24 [0.35, 4.33]         | .74         | 0.32                    | 1.38 [0.50, 3.82]        | .53         |
| Chronic otitis media           |                |                           |             |                         |                          |             |
| No                             | Reference      |                           |             |                         |                          |             |
| Yes                            | 0.82           | 2.28 [0.67, 7.78]         | .19         | <b>1.06</b>             | <b>2.88 [1.09, 7.58]</b> | <b>.033</b> |
| Allergic rhinitis              |                |                           |             |                         |                          |             |
| No                             | Reference      |                           |             |                         |                          |             |
| Yes                            | 0.71           | 2.03 [0.65, 6.36]         | .23         | 0.33                    | 1.39 [0.53, 3.64]        | .50         |
| Chronic rhinosinusitis         |                |                           |             |                         |                          |             |
| No                             | Reference      |                           |             |                         |                          |             |
| Yes                            | <b>1.51</b>    | <b>4.53 [1.11, 18.55]</b> | <b>.036</b> | 0.20                    | 1.22 [0.46, 3.28]        | .69         |
| Deviated septum                |                |                           |             |                         |                          |             |
| No                             | Reference      |                           |             |                         |                          |             |
| Yes                            | 0.26           | 1.30 [0.41, 4.12]         | .66         | 0.27                    | 1.31 [0.49, 3.53]        | .59         |
| Inferior turbinate hypertrophy |                |                           |             |                         |                          |             |
| No                             | Reference      |                           |             |                         |                          |             |
| Yes                            | 1.07           | 2.91 [0.77, 10.96]        | .11         | -0.21                   | 0.81 [0.27, 2.42]        | .71         |
| Rhinorrhea                     |                |                           |             |                         |                          |             |
| No                             | Reference      |                           |             |                         |                          |             |
| Yes                            | -0.97          | 0.38 [0.11, 1.24]         | .11         | -0.56                   | 0.57 [0.23, 1.43]        | .23         |

Bold indicates statistical significance ( $P < 0.05$ ).

### Improvement in ETDQ-7 Score

The mean pre-operative ETDQ-7 score was 4.67 with a standard deviation of 1.24 and the mean post-operative ETDQ-7 score was 2.87 with a standard deviation of 1.48. Paired sample *t*-test revealed that ETDQ-7 score significantly decreased from pre to post-ETBD ( $P < .001$ , Cohen's  $d = 1.52$ ). Additionally, ETD symptoms in the ETDQ-7 were normalized among 37% ( $n = 42$ ) of all patients, and MCID was achieved among 77% ( $n = 87$ ) of all patients. Details regarding ETDQ-7 scores stratified by independent variables of interest are presented in Table 1.

### Predictors of Treatment Outcomes

Concurrent septoplasty (aOR = 1.52, 95% CI = [0.62, 3.73]) and ESS (aOR = 0.54, 95% CI = [0.22, 1.31]) both did not significantly influence patients' odds of reaching MCID. Multivariable analysis revealed that a higher pre-operative ETDQ-7 score was independently predictive of higher rates of MCID. Specifically, each 1-point increase in pre-operative ETDQ-7 score was associated with a 1.7-fold increase in odds of achieving MCID (aOR = 1.65, 95% CI = [1.06, 2.59]), Table 2. Notably, 100% of patients with a pre-operative ETDQ-7 score above 6 reached MCID. Additionally, a

history of CRS was independently associated with a 4.5-fold increase in odds of achieving MCID (aOR=4.53, 95% CI=[1.11, 18.55]), Table 2.

Concurrent septoplasty (aOR=1.74, 95% CI=[0.80, 3.79]) and ESS (aOR=0.69, 95% CI=[0.31, 1.53]) both did not significantly influence the likelihood of ETDQ-7 normalization. Multivariable analysis demonstrated that a history of chronic otitis media was independently associated with a 2.9-fold increase in odds of ETDQ-7 normalization (aOR=2.88; 95% CI=[1.09, 7.58]). Furthermore, a higher pre-operative ETDQ-7 score was independently predictive of lower rates of ETDQ-7 normalization (aOR=0.67, 95% CI=[0.46, 0.98]), Table 2.

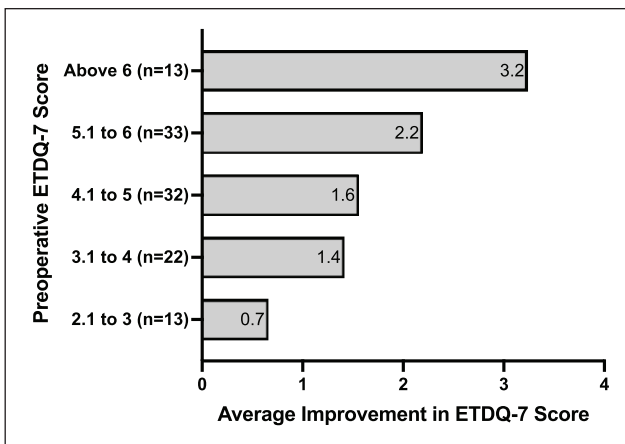
Concurrent septoplasty ( $B=0.12$ , 95% CI=[-0.45, 0.69]) and ESS ( $B=-0.32$ , 95% CI=[-0.90, 0.26]) both did not significantly influence patients' quantitative improvement in ETDQ-7 score. Multivariable linear regression revealed that a higher pre-operative ETDQ-7 score was independently predictive of higher quantitative improvement in ETDQ-7 score from pre- to post-ETBD, Figure 1. Specifically, each 1-point increase in pre-operative ETDQ-7 score was associated with a 0.6-point increase in improvement of ETDQ-7 score from pre- to post-ETBD ( $B=0.60$ ; 95% CI=[0.37, 0.83]), Table 3.

## Discussion

Our results suggest that ETBD was highly effective among patients whose pre-operative ETDQ-7 scores were above 2.1. Furthermore, higher pre-operative ETDQ-7 score was associated with higher likelihood of achieving the MCID and greater quantitative improvement in ETDQ-7. Additionally, a history of CRS was predictive of greater odds of reaching MCID and a history of chronic otitis media was predictive of greater odds of ETDQ-7 normalization, even after controlling for follow-up duration, demographic variables, and clinically relevant factors.

The demographic characteristics of our patient population are 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.<sup>10</sup> Consistent with prior studies, our population of patients had a high rate of otologic and nasal pathologies related to ETD, including history of chronic otitis media, prior ear or sinus surgery, rhinorrhea, and deviated septum.<sup>3,22,23</sup> Patients in our sample also had high rates of allergic rhinitis, which is also consistent with the literature.<sup>24-28</sup>

ETBD has been associated with improvement in subjective and objective treatment outcome measures, including the ETDQ-7 survey.<sup>14,16,18</sup> A previous multicenter randomized controlled trial of ETBD among 60 patients reported a pre-operative ETDQ-7 average of 4.6 and postoperative ETDQ-7 of 2.1 among those who underwent ETBD.<sup>14</sup>



**Figure 1.** Relationship between pre-operative ETDQ-7 score and quantitative improvement in ETDQ-7 score from pre- to post-ETBD.

While our average pre-operative ETDQ-7 score of 4.7 is consistent with the baseline value of this study, our post-operative average of 2.9 appears to be higher than the previously reported average of 2.1 at follow-up. We suspect that this is due to the inherently more complex pathologies of patients in our cohort from a tertiary care center. Nevertheless, since we observed significant improvement in ETDQ-7 score from pre- to post-ETBD, our data supports the consensus in the literature that there is a significant symptomatic benefit of ETBD.<sup>14,16,18</sup>

Few to no studies have investigated predictors of ETBD outcomes. The most similar study we could identify in the literature was a small-scale comparative analysis of ETDQ-7 score before and after functional endoscopic sinus surgery among 60 patients with CRS.<sup>29</sup> This study found high preoperative ETDQ-7 scores ( $\geq 4$ ) to be independently associated with ETDQ-7 normalization ( $< 2.1$ ) in patients undergoing endoscopic sinus surgery.<sup>29</sup> No patients underwent ETBD.

To the best of our knowledge, the present study is the first to explore predictors of ETBD treatment response. We found that higher preoperative ETDQ-7 was associated with higher rates of achieving the MCID and greater quantitative improvement in ETDQ-7 score. This suggests that patients with more severe ETD symptoms at baseline experienced quantitatively greater benefit from ETBD in symptom mitigation compared to those with less severe ETD symptoms at baseline. Patients with more severe ETD symptoms at baseline have more room to detect discernable improvement from ETBD, which may explain why the degree of improvement is positively associated with pre-operative ETDQ-7 score. In our cohort, all patients with a pre-operative ETDQ-7 score of 6 or greater reached MCID. Therefore, ETDQ-7 administered preoperatively appears to be a reliable predictor of treatment success and should be considered when counseling patients prior to ETBD.



**Table 3.** Multivariable Linear Regression Model Assessing Quantitative Improvement in ETDQ-7 Scores From Pre- to Post-ETBD.

|                                | Outcome = ETDQ-7 score difference from pre- to post-ETBD |                     |             |                 |
|--------------------------------|--|---------------------|-------------|-----------------|
|                                | B  | 95% CI              | t-statistic | P               |
| Follow-up duration             | 0.01   | [-0.03, 0.04]       | 0.39        | .70             |
| Age                            | 0.003  | [-0.01, 0.02]       | 0.33        | .74             |
| Sex                            |  |                     |             |                 |
| Male                           | Reference  |                     |             |                 |
| Female                         | -0.31  | [-0.87, 0.24]       | -1.12       | .27             |
| Ethnicity                      |  |                     |             |                 |
| Non-Hispanic or Latino         | Reference  |                     |             |                 |
| Hispanic or Latino             | -0.63  | [-1.62, 0.37]       | -1.25       | .21             |
| ETDB device                    |  |                     |             |                 |
| Aera                           | Reference  |                     |             |                 |
| Xpress                         | 0.21   | [-0.36, 0.77]       | 0.72        | .47             |
| Prior ear or sinus surgery     |  |                     |             |                 |
| No                             | Reference  |                     |             |                 |
| Yes                            | 0.07   | [-0.55, 0.69]       | 0.22        | .83             |
| Preoperative ETDQ-7 score      | <b>0.60</b>  | <b>[0.37, 0.83]</b> | <b>5.20</b> | <b>&lt;.001</b> |
| Preoperative tympanogram       |  |                     |             |                 |
| Type A                         | Reference  |                     |             |                 |
| Type B                         | -0.35  | [-1.16, 0.45]       | -0.87       | .39             |
| Type C                         | 0.05   | [-0.59, 0.69]       | 0.15        | .88             |
| Chronic otitis media           |  |                     |             |                 |
| No                             | Reference  |                     |             |                 |
| Yes                            | 0.45   | [-0.16, 1.05]       | 1.46        | .15             |
| Allergic rhinitis              |  |                     |             |                 |
| No                             | Reference  |                     |             |                 |
| Yes                            | 0.20   | [-0.39, 0.78]       | 0.67        | .50             |
| Chronic rhinosinusitis         |  |                     |             |                 |
| No                             | Reference  |                     |             |                 |
| Yes                            | 0.11   | [-0.50, 0.73]       | 0.36        | .72             |
| Deviated septum                |  |                     |             |                 |
| No                             | Reference  |                     |             |                 |
| Yes                            | 0.03   | [-0.57, 0.63]       | 0.10        | .92             |
| Inferior turbinate hypertrophy |  |                     |             |                 |
| No                             | Reference  |                     |             |                 |
| Yes                            | 0.12   | [-0.58, 0.82]       | 0.33        | .74             |
| Rhinorrhea                     |  |                     |             |                 |
| No                             | Reference  |                     |             |                 |
| Yes                            | -0.41  | [-0.98, 0.17]       | -1.40       | .16             |

Bold indicates statistical significance ( $P < 0.05$ ).

We also found that a history of CRS was predictive of higher likelihood of achieving MCID. The association between CRS and ETD has been previously established, with 50% of CRS patients reporting ETDQ-7 scores consistent with ETD.<sup>2,3,30,31</sup> It has been postulated that upper airway inflammation and thickened mucus driven by CRS may predispose patients to ETD.<sup>31</sup> A recent study found that ETDQ-7 scores for patients with CRS improved significantly after functional endoscopic sinus surgery (FESS), suggesting that addressing one pathology often results in symptomatic improvement of the

other.<sup>31</sup> Similarly, a subsequent meta-analysis involving 1336 consecutive patients concluded that patients with both CRS and ETD who underwent FESS experienced similar improvement in ETDQ-7 score compared to patients with ETD alone who underwent ETBD.<sup>30</sup> Our current study indicates that patients with both CRS and ETD are more likely to experience significant improvement in ETDQ-7 score following ETBD compared to patients with ETD without CRS. Therefore, ETBD may be a promising treatment option for patients with both CRS and ETD.

Finally, a history of otitis media was independently predictive of higher rates of ETDQ-7 normalization, even after accounting for pre-operative ETDQ-7 score. Although this finding has not been previously reported due to limited literature on this topic, ETD is known to predispose patients to higher risks of otitis media. Specifically, when the Eustachian Tube is obstructed for a prolonged period, middle ear effusion can increase the risk of otitis media.<sup>32</sup> Therefore, a history of chronic otitis media may be associated with obstructive ETD, explaining the increased likelihood of symptom resolution from ETBD among patients with this risk factor.

We did not find pre-operative tympanogram type (types A, B, C) to be a reliable predictor of ETBD treatment response. ETBD elicited symptom improvement regardless of pre-operative tympanogram type. These findings suggest that patients without retracted tympanic membranes or normal tympanometry can also benefit from ETBD. This is consistent with prior findings on the baro-challenged subtype of ETD, in which otoscopic and tympanometry demonstrate normal findings.<sup>33</sup> Although this subtype of ETD does not lead to negative pressure or lack of tympanometric peak pressure as denoted by type C and type B tympanograms, prior research has shown that ETBD can safely and effectively treat this subtype of ETD.<sup>34</sup> Similar to prior studies, it appears that pre-operative tympanogram may not be able to identify ETD patients who will reliably respond to ETBD. Instead, a high pre-operative ETDQ-7 score, and a history of chronic otitis media and CRS may be more informative.

Our study has several limitations that should be noted. Since this is a retrospective chart review, demographics and prior history included in our dataset were limited by those described in the chart. Furthermore, the primary measure of symptom resolution was a self-reported survey of patients' symptoms (ETDQ-7). Therefore, our findings regarding ETBD outcomes are mostly applicable to patients' subjective experiences. Although this measure is subjective, it is one of the few currently available tools to assess ETD symptoms and has been validated as effective and useful in evaluating baseline ETD symptom and treatment outcomes.<sup>6,7,20</sup> Moreover, the follow-up length among patients ranged from 3 to 13 months, which could have served as a confounding variable during between subject comparisons. However, follow-up length was accounted for in multivariable analysis and was shown to not significantly influence the major findings of this study. Finally, a portion of patients underwent concurrent sinonasal procedures, which may have potentially influenced their treatment outcomes. However, our analyses accounted for concurrent procedures and showed that they did not significantly affect the findings of our study. Despite these limitations, this study, to our knowledge, is the first to investigate predictors of symptom improvement following ETBD. With a large, diverse, multiyear sample, we present several important predictors

of ETBD outcomes that may help guide clinical practice in terms of candidate selection.

## Conclusion

Our analysis showed that ETBD led to significant symptom mitigation as measured by ETDQ-7, with almost 80% of patients achieving the MCID in ETDQ-7 scores. Furthermore, our findings suggest that a high pre-operative ETDQ-7 score, a history of CRS, and a history of chronic otitis media are potential clinical predictors of successful symptom improvement following ETBD. These factors may be important to note when considering ETBD as a treatment option and counseling prospective patients.

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## References

1. Shan A, Ward BK, Goman AM, et al. Prevalence of Eustachian tube dysfunction in adults in the United States. *JAMA Otolaryngol Head Neck Surg.* 2019;145(10):974-975.
2. Fischer JL, Riley CA, Hsieh MC, Marino MJ, Wu XC, McCoul ED. Prevalence of Eustachian tube dysfunction in the US elderly population. *Otolaryngol Head and Neck Surg.* 2020;163(6):1169-1177.
3. Tangbumrungham N, Patel VS, Thamboo A, et al. The prevalence of Eustachian tube dysfunction symptoms in patients with chronic rhinosinusitis. *Int Forum Allergy Rhinol.* 2018;8(5):620-623.
4. Randrup TS, Ovesen T. Balloon Eustachian tuboplasty: A systematic review. *Otolaryngol Head Neck Surg.* 2015;152(3):383-392.
5. Vila PM, Thomas T, Liu C, Poe D, Shin JJ. The burden and epidemiology of Eustachian tube dysfunction in adults. *Otolaryngol Head Neck Surg.* 2017;156(2):278-284.
6. McCoul ED, Anand VK. Eustachian tube balloon dilation surgery. *Int Forum Allergy Rhinol.* 2012;2(3):191-198.
7. McCoul ED, Anand VK, Christos PJ. Validating the clinical assessment of eustachian tube dysfunction: the Eustachian tube dysfunction questionnaire (ETDQ-7). *Laryngoscope.* 2012;122(5):1137-1141.
8. Teixeira MS, Swarts JD, Alper CM. Accuracy of the ETDQ-7 for identifying persons with Eustachian tube dysfunction. *Otolaryngol Head Neck Surg (United States).* 2018;158(1):83-89.



9. Gluth MB, McDonald DR, Weaver AL, Bauch CD, Beatty CW, Orvidas LJ. Management of Eustachian tube dysfunction with nasal steroid spray: a prospective, randomized, placebo-controlled trial. *Arch Otolaryngol Head Neck Surg.* 2011;137(5):449-455.
10. Froehlich MH, Le PT, Nguyen SA, McRackan TR, Rizk HG, Meyer TA. Eustachian tube balloon dilation: a systematic review and meta-analysis of treatment outcomes. *Otolaryngol Head Neck Surg.* 2020;163(5):870-882.
11. Adil E, Poe D. What is the full range of medical and surgical treatments available for patients with Eustachian tube dysfunction? *Curr Opin Otolaryngol Head Neck Surg.* 2014;22(1):8-15.
12. Silvola J, Kivekäs I, Poe DS. Balloon dilation of the cartilaginous portion of the Eustachian tube. *Otolaryngol Head Neck Surg.* 2014;151(1):125-130.
13. Poe D, Anand V, Dean M, et al. Balloon dilation of the Eustachian tube for dilatatory dysfunction: a randomized controlled trial. *Laryngoscope.* 2018;128(5):1200-1206.
14. Meyer TA, O'Malley EM, Schlosser RJ, et al. A randomized controlled trial of balloon dilation as a treatment for persistent Eustachian tube dysfunction with 1-year follow-up. *Otol Neurotol.* 2018;39(7):894-902.
15. Huisman JML, Verdam FJ, Stegeman I, de Ru JA. Treatment of Eustachian tube dysfunction with balloon dilation: a systematic review. *Laryngoscope.* 2018;128(1):237-247.
16. Schröder S, Lehmann M, Ebmeyer J, Upile T, Sudhoff H. Balloon Eustachian tuboplasty: a retrospective cohort study. *Clin Otolaryngol.* 2015;40(6):629-638.
17. Anand V, Poe D, Dean M, et al. Balloon dilation of the Eustachian tube: 12-month follow-up of the randomized controlled trial treatment group. *Otolaryngology Head Neck Surg.* 2019;160:687-694.
18. Xiong H, Liang M, Zhang Z, et al. Efficacy of balloon dilation in the treatment of symptomatic Eustachian tube dysfunction: one year follow-up study. *Am J Otolaryngol Head Neck Med Surg.* 2016;37(2):99-102.
19. Micucci S, Keschner DB, Liang J. Eustachian tube balloon dilation: emerging practice patterns for a novel procedure. *Ann Otol Rhinol Laryngol.* 2018;127(11):848-855.
20. Tucci DL, McCoul ED, Rosenfeld RM, et al. Clinical consensus statement: balloon dilation of the Eustachian tube. *Otolaryngol Head Neck Surg.* 2019;161(1):6-17.
21. Rosenfeld RM, Andes D, Bhattacharyya N, et al. Clinical practice guideline: adult sinusitis. *Otolaryngol Head Neck Surg.* 2007;137(3 Suppl. 1):S1-S11.
22. Chao WY, Tseng HZ, Chang SJ. Eustachian tube dysfunction in the pathogenesis of cholesteatoma: clinical considerations. *J Otolaryngol.* 1996;25(5):334-338.
23. Stoikes NF, Dutton JM. The effect of endoscopic sinus surgery on symptoms of Eustachian tube dysfunction. *Am J Rhinol.* 2005;19(2):199-202.
24. Lazo-Sáenz JG, Galván-Aguilera AA, Martínez-Ordaz VA, Velasco-Rodríguez VM, Nieves-Rentería A, Rincón-Castañeda C. Eustachian tube dysfunction in allergic rhinitis. *Otolaryngol Head Neck Surg.* 2005;132(4):626-629.
25. Juszczak HM, Loftus PA. Role of allergy in Eustachian tube dysfunction. *Curr Allergy Asthma Rep.* 2020;20(10):54.
26. Ma Y, Liang M, Tian P, et al. Eustachian tube dysfunction in patients with house dust mite-allergic rhinitis. *Clin Transl Allergy.* 2020;10(1):30.
27. Bowles PFD, Agrawal S, Salam MA. Eustachian tube dysfunction in chronic rhinosinusitis: pre- and post-operative results following endoscopic sinus surgery, a prospective study. *Rhinology.* 2019;57(1):73-77.
28. Parsel SM, Unis GD, Souza SS, et al. Interpretation of normal and abnormal tympanogram findings in Eustachian tube dysfunction. *Otolaryngol Head Neck Surg (United States).* 2021;164(6):1272-1279.
29. Higgins TS, Cappello ZJ, Wu AW, Ting JY, Sindwani R. Predictors of Eustachian tube dysfunction improvement and normalization after endoscopic sinus surgery. *Laryngoscope.* 2020;130(12):E721-E726.
30. Chen T, Shih MC, Edwards TS, et al. Eustachian tube dysfunction (ETD) in chronic rhinosinusitis with comparison to primary ETD: a systematic review and meta-analysis. *Int Forum Allergy Rhinol.* 2022;12:942-951.
31. Wu AW, Walgama ES, Higgins TS, et al. Eustachian tube quality of life and severity of disease in patients with chronic rhinosinusitis. *Am J Rhinol Allergy.* 2020;34(4):532-536.
32. Fireman P. Otitis media and Eustachian tube dysfunction: connection to allergic rhinitis. *J Allergy Clin Immunol.* 1997;99(2):S787-S797.
33. Schilder AG, Bhutta MF, Butler CC, et al. Eustachian tube dysfunction: consensus statement on definition, types, clinical presentation and diagnosis. *Clin Otolaryngol.* 2015;40(5):407-411.
34. Utz ER, LaBanc AJ, Nelson MJ, Gaudreau PA, Wise SR. Balloon dilation of the Eustachian tube for baro-challenge-induced otologic symptoms in military divers and aviators: A Retrospective analysis. *Ear Nose Throat J.* Published online 5 July 2020.