The Laryngoscope

Patulous Eustachian Tube Dysfunction Symptoms Following Balloon Dilation

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Objective: Clinicians increasingly perform balloon dilation of the Eustachian tube (BDET) to treat obstructive Eustachian tube dysfunction (OETD) refractory to medical management. Reported complications have been limited and include patulous Eustachian tube dysfunction (PETD). This multicenter study investigates the incidence of PETD and associated factors.

Methods: Consecutive patients at three academic centers undergoing BDET (January 2014–November 2019) for OETD refractory to medical therapy were included. PETD was diagnosed by patient-reported symptoms of autophony of voice and/or breathing. Associated factors studied include age, sex, comorbidities, balloon size, duration of inflation, repeat BDET, and adjunctive procedures.

Results: BDET procedures (n = 295 Eustachian tubes) were performed on 182 patients. Mean age was 38.4 years (SD 21.0; range 7–78) and 41.2% were female. Twenty cases of PETD (6.8% of procedures; 9.3% of patients) occurred following BDET. Risk of PETD did not vary by institution, comorbidities, or adjunctive procedure. Age ≤18 years (adjusted risk ratio [RR] = 3.26; 95% confidence interval [CI]: 1.24, 8.54; p = 0.02), repeat BDET (RR = 3.26; 95% CI: 2.15, 4.96; p < 0.001), and severe preoperative Eustachian tube inflammation (RR = 2.83; 95% CI: 1.10, 7.28; p = 0.03) were associated with increased risk of developing PETD in the multivariable model. Most symptoms were reported as mild or intermittent.

Conclusion: BDET caused PETD symptoms in approximately 7% of dilated Eustachian tubes in this study with increased risk for younger patients and those with severe inflammation or undergoing repeat dilations. Although most cases were self-limited, symptoms can persist. Awareness of risk factors may aid clinicians in limiting this complication.

Key Words: Eustachian tube, middle ear, otitis media, otology/neurotology, pediatric otology, pediatrics.

Level of Evidence: 4

***Laryngoscope*, 133:3152–3157, 2023**

INTRODUCTION

Eustachian tube dysfunction (ETD) is commonly encountered in Otolaryngology-Head and Neck Surgery clinics. ETD occurs when the normal functions of the Eustachian tube (ET), including pressure equalization, mucociliary clearance, and acoustic protection,[1] are disrupted. Symptoms are a result of the functional valve within the cartilaginous portion of the ET remaining either too closed or too open, with obstructive ETD (OETD) at one end of the spectrum and patulous Eustachian tube dysfunction (PETD) at the other. Symptoms of OETD can include aural fullness, hearing loss, and otalgia, and it can lead to developing otitis media, and, ultimately, cholesteatoma.[2] Management begins with medical interventions directed toward identified underlying etiologies of inflammation, such as allergies, smoking, laryngopharyngeal reflux, and rhinosinusitis. Refractory cases traditionally undergo tympanostomy tube (TT) placement. Balloon dilation of the Eustachian tube (BDET) has become an increasingly popular alternative to TT placement in medically refractory cases of OETD. Cadaveric studies demonstrated feasibility for balloon dilation of the cartilaginous ET,[3] whereas retrospective studies suggested that BDET is a useful tool for medically refractory OETD[4] with durable improvements.[5] Two prospective randomized-controlled clinical trials have demonstrated that BDET with medical management is superior to medical management alone for patients with refractory symptoms[6,7] and that the duration of symptom relief can last at least 2 years.[4] There is limited literature on the complications of BDET. Our experience suggests that this procedure is well tolerated, however, we have seen in our practices increasing numbers of patients who developed PETD symptoms after BDET. The aim of this study was to assess the prevalence of PETD after BDET in three academic centers.

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Editor's Note: This Manuscript was accepted for publication on March 01, 2023.

The authors have no funding, financial relationships, or conflicts of interest to disclose.

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DOI: 10.1002/lary.30659

METHODS

Patients

All consecutive patients undergoing BDET for refractory OETD were included in the clinical practices of 4 academic otologists between January, 2014 and November, 2019. After BDET, PETD was diagnosed based on patient-reported symptoms. Patients were routinely asked by the surgeon about postoperative symptoms, including whether they had any breath or voice autophony (i.e., hearing one's own nasal breathing or voice abnormally loudly) or aural fullness. Patient charts were reviewed manually for symptoms followed by keyword search ("autophony", "aural fullness") and by using an automated keyword chart review tool (Hound Dog, an in-house non-commercially available tool) at the largest center.

Patient characteristics assessed were age, sex, and preoperative diagnoses including laryngopharyngeal reflux (clinical diagnosis), environmental allergies (diagnosed via symptoms and/or testing), chronic rhinosinusitis, and ET mucosal inflammation score. Additional covariates included balloon diameter, duration of balloon inflation, laterality of dilation including unilateral/bilateral, repeat BDET, and adjunctive procedures including any concurrently performed head and neck interventions. The most commonly performed adjunctive procedures included adenoidectomy and other ear procedures. ET mucosal inflammation score was determined by each surgeon by performing nasopharyngoscopy in clinic. Scores were assigned ranging from 1 (normal) to 4 (severe) based on a previously validated scale.[8]

This study was approved by the Institutional Review Board at each institution: Boston Children's Hospital, Georgetown-Medstar University Hospital, and Johns Hopkins University.

Procedure

A 6 × 16 mm balloon was used in the majority of cases (AERA, Acclarent, Irvine, CA). Prior to FDA approval of balloon devices for the ET, off-label use of sinuplasty balloons with appropriate informed consent was performed on 26 procedures using 7 × 16 mm, 5 × 16 mm, and 3.5 × 12 mm balloons. Procedures using 5 × 16 mm and 3.5 × 12 mm balloons were performed mostly (17/18 cases) in pediatric patients (7–12 years of age). All procedures were performed under general anesthesia. The duration of balloon dilation was 2 min on average and ranged from 30 s to 4 min (Table I).

Statistical analysis

We examined the risk of developing PETD by patient and procedure characteristics. To examine predictors of PETD, we conducted a regression analysis using a generalized estimating equations approach to account for the correlation between each pair of ears. All analyses were performed with the ear as the unit of analysis. Laterality of symptoms was documented in the majority of patients who developed PETD (15/17 patients); however, laterality was unknown in two patients and they were included as probable unilateral PETD cases in the analysis. In a sensitivity analysis, we obtained essentially the same results when those cases were included as bilateral cases. Risk ratios (RRs) and 95% confidence intervals (CIs) were estimated from the binomial regression model with a log-link function or Poisson regression model. Predictors with $p < 0.20$ in univariate analyses were considered as candidates for the multivariable regression model. The multivariable regression model was built using backward selection criteria with $p < 0.05$ as the retention criteria. All analyses were performed using SAS version 9.4 (SAS Institute, NC).

TABLE I.
Baseline Characteristics of Patients Who Underwent balloon dilation of the Eustachian tube (BDET) Characteristic.

	n (%) or mean (SD)
Patient (*n* = 182 patients)	
Age (years), mean (SD)	38.4 (SD 21.0; range 7–78)
Gender, female	75 (41.2%)
Environmental allergy	99 (54.7%)
Laryngopharyngeal reflux	28 (15.6%)
Chronic rhinosinusitis	62 (34.3%)
Institution	
1	145 (79.7%)
2	22 (12.1%)
3	15 (8.2%)
Dilation	
Unilateral	84 (46.2%)
Bilateral	98 (53.8%)
Procedures (*n* = 295)	
Duration of BDET (minutes)	
Median (range)	2 min (0.5–4)
0.5 m	2 (0.7%)
1 m	41 (13.9%)
1.5 m	14 (4.7%)
2 m	201 (68.1%)
3 m	16 (5.4%)
4 m	2 (0.7%)
N/A	19 (6.4%)
Balloon size (mm)	
6 × 16	264 (89.5%)
5 × 16	11 (3.7%)
7 × 16	9 (3.1%)
3.5 × 12	7 (2.4%)
N/A	4 (1.4%)
Preoperative ET mucosal inflammation/ dilation score, median (range)	3 (1–4)
Adjunctive procedure	177 (60.0%)
Adenoidectomy	46 (15.6%)
Adenoidectomy, M/T	17 (5.8%)
Adenoidectomy, myringotomy	7 (2.4%)
Adenoidectomy, tympanoplasty	6 (2.0%)
M/T	30 (10.2%)
Myringotomy	12 (4.1%)
Tympanoplasty	7 (2.4%)
Others	52 (17.6%)
Repeat BDET procedures	15 (5.1%)

Note: A total of 295 procedures include 280 first BDET procedures and 15 repeat BDET procedures.
ET, Eustachian tube; M/T, Myringotomy and tympanostomy tube insertion; N/A, information not available.

RESULTS

A total of 295 BDET procedures were performed on 182 patients. The mean age at surgery was 38.4 years (SD 21.0; range 7–78 years) and 75 patients (41.2%) were female (Table I). Eighty-four patients (46.2%) underwent unilateral dilation and 98 patients (53.8%) underwent

TABLE II.
Patulous Eustachian tube dysfunction (PETD) in Patients Who Underwent balloon dilation of the Eustachian tube (BDET).

	Number of PETD cases/ number of procedures (%)	*p*-value
Overall	20/295 (6.8%)	
Institution		0.99
1	16/235 (6.8%)	
2	2/32 (6.3%)	
3	2/28 (7.1%)	
Age category		0.01
7–18 years	12/90 (13.3%)	
19–49 years	6/108 (5.6%)	
50–78 years	2/97 (2.1%)	
Gender		0.89
Female	9/128 (7.0%)	
Male	11/167 (6.6%)	
BDET procedure		<0.001
1 BDET	17/280 (6.1%)	
Repeat BDET	3/15 (20.0%)	
Duration of BDET (min)		0.12
0.5	0/2 (0%)	
1	1/41 (2.4%)	
1.5	1/14 (7.1%)	
2	15/201 (7.5%)	
3	2/16 (12.5%)	
4	0/2 (0%)	
Preoperative ET mucosal inflammation/dilation score		0.18
1	1/26 (3.9%)	
2	5/80 (6.3%)	
3	8/152 (5.3%)	
4	6/31 (19.4%)	
Preoperative severe ET mucosal inflammation/dilation score		0.007
1–3	14/258 (5.4%)	
4	6/31 (19.4%)	
Pre and post-operative change in ET mucosal inflammation/ dilation score		0.02
No change or increase	1/55 (1.8%)	
Decline (−1)	4/50 (8.0%)	
Decline (−2/−3)	5/42 (11.9%)	
Adjunctive procedure		0.41
Yes	14/177 (7.9%)	
No	6/118 (5.1%)	
Adjunctive adenoidectomy		0.02
Yes	12/96 (12.5%)	
No	8/199 (4.0%)	
Environmental allergy		0.45
Yes	13/164 (7.9%)	
No	7/129 (5.4%)	
Gastroesophageal reflux		0.18
Yes	6/49 (12.2%)	
No	14/243 (5.8%)	
Chronic rhinosinusitis		0.20
Yes	10/103 (9.7%)	
No	10/190 (5.3%)	

Note: *p*-value was based on the log-binomial regression model that accounts for the correlation between paired ears. Age and duration of BDET were evaluated as continuous variables. ET mucosal inflammation/dilation score was based on the ordered categorical variable. Pre and post-operative change in mucosal inflammation/dilation score was assessed in 147 procedures.

ET, Eustachian tube.

bilateral dilation. Adjunctive procedures were performed on 60.0% of procedures. Eleven patients (15 procedures; 5.1%) underwent 2 or more dilations for recurrent symptoms of OETD. Of 295 BDET procedures, 20 ears undergoing BDET developed symptoms of PETD (6.8%; Table II). Seventeen of 182 patients (9.3%) developed symptoms of PETD during the study period. The risk of developing PETD did not vary by institution. The risk of PETD was higher in pediatric patients (13.3%, age range 7–18) than in adult patients (5.6% in adults 19–49 years of age and 2.1% in adults >50 years of age; $p = 0.01$; Table II). Patients with repeat BDET were more likely to develop PETD than patients who underwent one BDET (20.0% vs. 6.1%; $p < 0.001$). The risk of developing PETD was also higher in patients with severe ET mucosal inflammation/dilation score preoperatively than in patients with less severe inflammation (score 4: 19.4% vs. score 1–3: 5.4%; $p = 0.007$). Increased duration of BDET dilation did not reach statistical significance for developing PETD (Table II). Comorbidities including a history of environmental allergies, gastroesophageal reflux, and chronic rhinosinusitis, were not associated with a risk of PETD.

Age ≤18 years (adjusted RR = 3.26; 95% CI: 1.24, 8.54; $p = 0.02$), repeat BDET (RR = 3.26; 95% CI: 2.15, 4.96; $p < 0.001$), and severe preoperative ET inflammation (RR = 2.83; 95% CI: 1.10, 7.28; $p = 0.03$) were significantly associated with increased risk of developing PETD in the multivariable model (Table III).

Fifteen of seventeen patients who developed PETD experienced the onset of symptoms within the first month after surgery. One patient developed symptoms 5 months after surgery, which subsequently improved during pregnancy, and one patient 14 months after surgery following significant weight loss. Four patients had symptoms that were limited to a few brief episodes (minutes in duration) and in two of those patients, symptoms were only instigated by auto-insufflation. Three patients had minutes of symptoms occurring sporadically, lasting up to 1 week after surgery. One patient had symptoms for a month after surgery, but only when exercising. Two patients had symptoms lasting 6 months. Seven patients (41%) had

TABLE III.
Predictors of patulous Eustachian tube dysfunction in Patients Who Underwent balloon dilation of the Eustachian tube (BDET).

Variables	Univariate RR (95% CI)	*p*	Multivariable-adjusted RR (95% CI)	*p*
Age ≤18 years (vs. >18 years)	3.13 (1.21, 8.10)	0.02	3.26 (1.24, 8.54)	0.02
Repeat BDET	2.62 (1.89, 3.52)	<0.001	3.26 (2.15, 4.96)	<0.001
Severe ET mucosal inflammation/ dilation (score 4)	3.57 (1.40, 9.07)	0.007	2.83 (1.10, 7.28)	0.03
Adjunctive adenoidectomy	3.11 (1.20, 8.08)	0.02	-	
Chronic rhinosinusitis	1.84 (0.72, 4.73)	0.20	-	
BDET duration ≥3 min	1.69 (0.44, 6.54)	0.45	-	

Note: Multivariable-adjusted RR based on the multivariable regression model that includes age, repeat BDET procedure, and mucosal inflammation/dilation score and accounts for the correlation between paired ears.
CI, confidence interval; ET, Eustachian tube; RR, risk ratio.

symptoms lasting greater than 6 months, one whose symptoms resolved after quitting caffeine, and one, as previously mentioned, associated with significant weight loss. Four patients reported symptoms of PETD as of their most recent visit (follow-up range 3 to 9 months). All cases of PETD after BDET were initially managed with observation or medical management (e.g., good hydration, topical drops with saline, hypertonic saline or diluted ascorbic acid). Two patients contemplated surgery for PETD during the study period, and one patient underwent mass loading of the tympanic membrane as treatment for symptoms of PETD. The surgery successfully alleviated symptoms of PETD.

DISCUSSION

OETD affects as many as 80% of patients during childhood, decreasing to a prevalence of around 5% of adults.[9,10] In the United States, there are an estimated 2 million yearly visits for ETD/otitis media with effusion (OME)/tympanic membrane retraction in patients under age 18 and an additional 2 million for patients above that age.[11] Symptoms and sequelae of OETD are varied and include aural pressure and pain, worsening hearing, and the development of OME and cholesteatoma. Generic medical management has not been shown to provide lasting correction of OETD although short-term symptomatic improvement may be achieved.[12] The standard of care for medically refractory symptomatic OETD has been TT placement. TTs do not address the underlying etiology, often need to be replaced[13] and can cause complications including non-healing tympanic membrane perforations, tympanosclerosis, and cholesteatoma.[14]

BDET is a newer procedure that has been approved by the US Food and Drug Administration (FDA) for the treatment of medically refractory OETD since 2016. Complications from the procedure have been documented in the literature and include epistaxis,[15] self-resolving subcutaneous emphysema,[16,17] otitis media,[18] mucosal laceration, and C6-C7 radiculopathy that was believed to be related to positioning.[19] Our experience with almost 300 dilations suggests that these complications are less common than the development of PETD symptoms. Although prior studies have reported a few cases of patients developing PETD after BDET, this complication has received little attention.

This study found that among the ears with OETD that underwent BDET, a significant rate (approximately 7%) developed PETD symptoms. This rate is much higher than the estimated natural prevalence of PETD.[20] The short duration between the procedure and symptom onset in most patients in this series suggests that PETD symptoms likely occurred as a complication of the BDET procedure.

Fortunately, when PETD occurred, it was usually transient, occurring in the immediate post-operative period. Our experience showed, however, that delayed presentation (2/17 or 12%) and persistent symptoms (7/17 or 41% with 6+ months of symptoms) are possible. Delayed presentation might reflect that some patients with OETD exist along a spectrum of ETD and may be prone to periods of oscillating between OETD and PETD. Caution is recommended when considering performing BDET in patients who report a history of episodes of voice or breath autophony and we recommend specifically questioning patients about autophony prior to surgery as they often do not volunteer such a history. In bilateral cases, the benefits of BDET should be considered in each ear individually.

Our data also suggests that young age (≤18 years), repeat dilation, and severe ET mucosal inflammation/ dilation score are associated with an increased risk of developing PETD following BDET. Surgeons should be cognizant that inflammation on the torus tubarius is not indicative of the status of the mucosa within the lumen of the ET. The functional valve is situated within the lumen and this is the portion of the ET that is subject to the dilation by the balloon. Decisions about the duration of balloon inflation should be based upon an assessment of the severity of mucosal inflammation within the lumen, the degree to which the lumen can dilate the valve during swallows and yawns, and the severity of patient's symptoms.

We hypothesize that the pediatric ET may be more responsive to dilation due to possible factors such as smaller pediatric ET anatomy relative to balloon diameter and greater sensitivity of the inflammatory processes to the mechanism of action. The increased risk of PETD was present in patients between 12 and 18 years of age when the ET should have achieved full adult dimensions. For pediatric patients, consideration should be made to decrease the duration of dilation. Our dilation times were

determined independently by the individual surgeons based on their personal experience, patient age, and patient symptom severity. The goal was to optimize a balance of achieving therapeutic benefits while mitigating the risk of PETD. Our data suggest a possible correlation between duration and effect, which did not reach statistical significance, but the study was not powered for this purpose and 68% of the dilations were done for 2 min as a standard. Additionally, the senior author noticed the incidence of PETD early in the author's own series after which a reduction in dilation time was made for pediatric patients and all patients with lower mucosal inflammation scores. Alternatively, decreasing the maximum inflation pressure might also be considered in such cases, but there is no data to date on effectiveness of variations in pressure. For younger pediatric patients, consideration for the use of a smaller balloon size might be beneficial should such devices become available and approved by the FDA.

Recurrence of OETD may develop following BDET, particularly if patients do not adhere to medical measures directed at treating their underlying inflammatory etiologies. Surgeons should be aware that repeat dilation carries an increased risk of developing PETD. Finally, it might seem paradoxical that severe preoperative inflammation scores were associated with an increase in risk for PETD. It could be that such inflammation is more sensitive to the mechanism of action of the balloon or that atrophy of mucosa/submucosa proximally within the valve may not have been recognized if there was significant inflammation at the tubal orifice. Allergic rhinitis is the leading co-morbidity in our series of PETD cases. Patchy atrophy of "burned-out" mucosa with loss of goblet cells and thinning of mucosa and submucosa are known to occur in nasal and sinus mucosa with chronic allergic disease and we have observed what appears to be atrophy within the valves of patulous ETs. Atrophy within the valve can occur despite even robust inflammation at the orifice, torus tubarius, and adenoid. It is possible that atrophy occurring proximally within the functional valve of the cartilaginous ET can be missed on endoscopy if the view is not adequately angled in line with the longitudinal axis of the tubal lumen. The ET takes a roughly 45-degree course superiorly and laterally from the choana and the lumen is not always adequately seen with a zero-degree rigid endoscope or a flexible scope that is not appropriately angled. Careful inquiry as to any past history of patulous symptoms might help reduce the risk of PETD by reducing the time of dilation. A thorough history and endoscopic examination prior to BDET are important to minimize the risk of post-operative PETD. Clinicians should make a risk assessment and counsel patients accordingly. Another consideration is that patients with severe inflammation were more likely to have associated adjunctive procedures such as adenoidectomy or turbinate reduction, but these have not been previously reported to be associated with the development of PETD.

As a result of the data from this study, we recommend reducing the maximum duration of inflation of the balloon during BDET in pediatric patients or any patient who has reported a significant history of patulous symptoms. We now use a maximum duration of 2 min in adults and a maximum of 1.5 min in patients <18 years of age or patients with a history of patulous symptoms. Further reduction to 1 min or less can be done commensurate with the degree to which autophony might have occurred in the past and for minimal inflammation within the lumen of the ET.

In our experience, PETD has been associated with chronic allergic rhinitis (49% of patients with PETD).[21] Therefore we have been especially careful to inquire about any history of even brief autophony. Additionally, during endoscopy of the ET, we inspect deeply into the lumen of the ET for any evidence of patches of mucosal or submucosal atrophy in the anterolateral wall that could predispose to PETD. It is possibly due to that diligence that the incidence of postoperative PETD did not show an association with chronic allergic rhinitis in this study.

This study has limitations as a retrospective study and with all of the inherent biases with respect to data collection. The providers at the three institutions see patients with PETD as part of their clinical practice and therefore routinely ask patients about PETD symptoms, however, standardized instruments were not used to collect data. As almost 70% of patients were dilated for 2 minutes, the effect of duration of BDET could not be sufficiently determined. Also, our study is heavily weighted to one high-volume center where 80% of the dilations took place. Nevertheless, PETD rates were similar among the institutions. Symptoms of PETD were self-reported via the proxy symptom of autophony leaving the possibility of a missed diagnosis and underreporting of PETD or conversely misattribution of symptoms. Finally, patient follow-up duration was highly variable, ranging from weeks to years. Although most patients developed transient symptoms beginning in the immediate post-operative period, some had delayed presentations which may therefore go unrecorded.

CONCLUSION

BDET is a generally well-tolerated procedure that has been shown to be effective in alleviating symptoms and improving ET function in patients with medically refractory obstructive ETD. Complications are rare but include development of a patulous ET. PETD following balloon dilation is functionally an overcorrection of the preoperative pathology and was more common in younger patients, in patients with severe ET inflammation, and in patients undergoing repeat balloon dilation procedures in this study. Patients should be counseled accordingly.

CONFLICT OF INTEREST STATEMENT

Poe-consultant w/ Acclarent. Receives reimbursement for time + expenses. No equity interest or royalties. Nieman-on board of Access HEARS and on board of the Hearing Loss Association of America.

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