Received: 1 April 2022 | Revised: 11 June 2022 | Accepted: 13 June 2022

DOI: 10.1002/lio2.842

ORIGINAL RESEARCH

Laryngoscope Investigative Otolaryngology

Comparison of outcomes for balloon dilation of the Eustachian tube under local vs general anesthesia

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Abstract

Objective: To compare the effectiveness of balloon dilation of the Eustachian tube (BDET) under local versus general anesthesia in the treatment of obstructive Eustachian tube dysfunction (OETD).

Study Design: Retrospective review.

Methods: Consecutive patients ages ≥18 with persistent OETD having failed adequate medical therapy underwent BDET between 2013 and 2018 under local or general anesthesia. Inclusion criteria were persistent type B or C tympanograms with symptoms or type A with symptoms upon barochallenge. Objective outcome measures were tympanometry, otoscopy and the need for additional subsequent intervention (revision dilation and tympanostomy tube). Primary outcome (failure) was defined as no change or worse in tympanogram.

Results: The 191 patients (332 ETs), ages 18–88 years (mean 58.0) underwent BDET. The 112 patients (59%) were female. The 107 procedures (32%) were performed under local anesthesia. Mean duration of follow-up was 3.1 years (SD 1.9). Tympanograms improved to type A in 88% for BDET under local and 74% for general anesthesia at 12 months. Probability of being failure-free at 5 years was 70% (95% confidence interval [CI]: 52%–82%) in the local anesthesia group versus 65% (95% CI: 55%–73%) in the general anesthesia group. Risk of failure did not significantly differ between the groups (HR = 0.60; 95% CI: 0.27–1.31; $p = .20$).

Conclusion: BDET under local anesthesia is effective in treating OETD and results in sustained improvements over 2 years. The procedure was successfully performed in all but one case utilizing a precise anesthesia protocol, and results are comparable with the procedure performed under general anesthesia.

Level of evidence: 4

KEYWORDS
balloon dilation, Eustachian tube, in-office balloon dilation, local anesthesia

1 | INTRODUCTION

Functions of the Eustachian tube (ET) include regulating middle ear pressure, clearance of secretions and protecting the middle ear from reflux of material and sounds.[1] ET dysfunction (ETD) includes a spectrum of failure of the functional valve. Obstructive ETD (OETD) is the inability of the ET to sufficiently open in order to ventilate the middle ear. Patulous dysfunction is at the opposite end of the spectrum with a loss of competence of the valve resulting in autophony. Patients who experience difficulty ventilating their ears when subjected to rapid changes in ambient pressure (barochallenge), have a lesser degree of OETD in which the valve opens adequately under normal circumstances.

With an estimated prevalence of 4.6% in the general population, ETD[2] is a major health care problem accounting for over two million visits annually in both pediatric and adult populations[3] and direct costs averaging $4 billion annually in the US.[4]

The most common cause of obstruction is mucosal inflammation within the cartilaginous ET.[5–7] Balloon dilation of the cartilaginous ET (BDET) has been used as a treatment for chronic OETD since 2009, initially being done under general anesthesia.[8] However, interest in performing BDET in an office setting under local anesthesia has grown and feasibility has been reported in small cohorts with varying local anesthesia protocols, but with recommendations for improvements.[9–12] Efficacy comparing the procedure under local and general anesthesia has only been reported in one recent retrospective study of 49 patients. Intraoperative pain in the local anesthesia group was reported as moderate and was greatest during the inflation of the balloon. At 52 weeks follow-up, normalization of ETDQ-7 symptom scores in the local anesthesia group trended lower, but did not reach statistical significance. Ability to perform a Valsalva maneuver was lower in the local anesthesia group.[12]

The purpose of this study is to compare the results of BDET performed under general and local anesthesia with the hypothesis of achieving similar results, using a refined topical anesthesia protocol and presenting longer term follow-up data. A concern for local anesthesia is that patient tolerance might limit the extent of treatment such as reduced inflation pressure or duration of inflation, as has been previously reported.

2 | MATERIALS AND METHODS

The study was approved by the Institutional Review Board at the participating sites. Retrospective review was done of consecutive adult patients ages ≥18 with persistent OETD (having failed adequate medical therapy) who underwent BDET between 2013 and 2018, either under general or local anesthesia, at an academic-affiliated specialty private practice. All operations were performed by the second author. Indications for surgery were persistent symptoms of aural fullness and hearing loss with type B or C tympanograms or consistent symptoms of aural fullness with pain when barochallenged with type A for over 3 months despite medical therapy for at least 4 weeks. Medical therapy included a trial of nasal steroid spray unless medically contraindicated. Additionally, if there was evidence of allergic rhinitis (clear rhinorrhea, pale mucosa, itchy eyes etc., exacerbated by exposure to

TABLE 1 Characteristics of patients who underwent balloon dilation of the Eustachian tube (BDET) under local versus general anesthesia (a total of 332 BDET procedures in 191 patients)

	BDET under local anesthesia	BDET under general anesthesia
Patient characteristic		
Number of patients	($n = 58$)	($n = 133$)
Sex		
Female	34 (58.6%)	78 (58.7%)
Male	24 (41.4%)	55 (41.3%)
Age (years), mean (SD)	57.2 (±14.2)	58.3 (±16.5)
Comorbidities		
Chronic rhinosinusitis	41 (70.7%)	41 (30.8%)
Allergies	26 (44.8%)	64 (48.1%)
GERD	16 (27.6%)	39 (29.3%)
Asthma	6 (10.3%)	10 (7.5%)
Side		
Bilateral	49 (84.5%)	92 (69.2%)
Unilateral	9 (15.5%)	41 (30.8%)
Procedures		
Number of procedures	($n = 107$)	($n = 225$)
Indication		
COM	86 (80.4%)	200 (88.9%)
COM, ROM	8 (7.4%)	4 (1.8%)
Barochallenge	13 (12.2%)	21 (9.3%)
Adjunctive procedures		
None	17 (15.9%)	128 (56.9%)
Sinus balloon	88 (82.2%)	11 (4.9%)
Sinus balloon, R patch	1 (0.9%)	—
FESS	—	54 (24.0%)
FESS, M&T	—	2 (0.6%)
FESS, septoplasty	—	1 (0.3%)
Septoplasty	—	3 (1.3%)
M&T	1 (0.9%)	4 (1.8%)
Tympanoplasty	—	9 (4.0%)
Tympanoplasty, OCR	—	4 (1.8%)
Myringotomy	—	1 (0.4%)
Myringoplasty	—	3 (1.3%)
RW	—	2 (0.9%)
Adenoidectomy	—	1 (0.4%)
Tube removal	—	1 (0.4%)
Tube removal, myringoplasty	—	1 (0.4%)
Follow-up duration (years), mean (SD)	3.6 (±2.0)	2.9 (± 1.7)

certain environments, i.e., seasons, cedar etc.) or laryngopharyngeal reflux (edematous uvula, cobblestoning in the pharynx, and pachydermia/posterior commissure hypertrophy with symptoms such as dysphagia, cough, hoarseness, globus, etc.) antihistamines or proton pump inhibitors (PPIs) were given for at least 4 weeks if indicated. If symptoms were not controlled the patient was referred for additional testing. All patients with type A tympanograms and normal otoscopy had significant and consistent barochallenge complaints. To be indicated for surgery, all patients had to have inflammatory pathology including edema or lymphoid hyperplasia (mild 2–severe 4) as described by Kivekas et al.[13] seen in the cartilaginous portion of the ET on preoperative transnasal endoscopy.

Objective outcome measures were tympanometry, otoscopy, and the need for additional subsequent intervention (ie. revision dilation, tympanostomy tube). The decision to perform the procedure under local or general anesthesia was made depending on the requirements of an adjunctive procedure, patient and surgeon preferences, and financial considerations. Adjunctive procedures were performed when indicated, most commonly balloon dilation of the paranasal sinuses in the local anesthesia group and functional endoscopic sinus surgery (FESS) in the general anesthesia group (Table 1). Adjunctive sinus surgery was offered for failure of appropriate medical management. Indications for sinus surgery included SNOT-22 scores ≥20 and significantly restricted or obstructed outflow tract/ostium along with associated changes in the affected sinus on CT scan of the sinuses.

Primary outcome (failure) was defined as no change or worse in tympanogram. Patients with a minimum of 6 months of follow-up and type B or C tympanogram preoperatively were included. Secondary outcome was defined as persistence or worsening of effusion/significant non-fixed retraction. We also evaluated the need for any additional surgical intervention on the Eustachian tube or ear due to inability to satisfactorily resolve the initial symptoms or findings. In the event of failure, revision surgery was considered after 6 months from the primary surgery. Indications for revision were the same as for primary surgery and additionally, there must have been significant improvement achieved with the primary surgery, either: (a) symptoms and findings had resolved, but returned or (b) symptoms and findings had improved, but not to the patients' satisfaction.

2.1 | Local anesthesia protocol

The protocol and surgical techniques employed were previously reported along with an accompanying video.[14] Preoperatively, patients were medicated with 10 mg of diazepam or less depending on comorbid conditions, age and size. Oxymetazoline 4% solution was sprayed into each nostril for decongestion. Topical anesthesia was placed onto the tympanic membrane as pain due to pressure changes in the middle ear has been reported during insertion of the balloon.[10] Five drops of 7% tetracaine/7% lidocaine compounded into an otic solution was placed onto the ipsilateral intact tympanic membrane. Cottonoids with 2% tetracaine solution were placed along the nasal floor bilaterally for 10 min, then removed and 0.5 cc of compounded 7% tetracaine/7% lidocaine cream was applied to the ET orifice through a Weiss catheter (Grace Medical, Memphis, TN). The tetracaine-soaked cottonoids were then replaced for an additional 10–15 min.

Procedures were performed with a 45-degree 2.7 mm diameter endoscope (Karl Storz, Tuttlingen, Germany). Prior to 2016, balloon dilation was performed with a 6 mm diameter sinuplasty balloon with 70° guide (off-label use, Acclarent, Irvine, CA) and after FDA approval in 2016, with the Acclarent Aera balloon (6 mm dia., Acclarent, Irvine, CA). The balloon was inserted into the ET orifice under direct endoscopic view to avoid mucosal trauma or false passage. After advancement to the isthmus, indicated by meeting resistance with the balloon catheter and with the yellow mark in the catheter still visible outside the ET orifice, the balloon was inflated at 1 atm per second to 12 atm, maintained for 2 min, deflated, and slowly retracted back into the guide catheter to avoid mucosal excoriation.

For patients undergoing general anesthesia, laryngeal mask or endotracheal intubation was utilized depending on anesthesiologist preference. Oxymetazoline 4% solution was applied 30 min prior to the procedure, then cocaine 4% pledgets prior to the procedure, but nothing into the ET. Procedures were otherwise carried out identically.

2.2 | Statistical analysis

We examined any change in the outcome between preoperative period and postoperative period using the mixed effects regression model. A three-level random-effects model was used to account for the correlations between repeated measures over time and between each pair of ears. The mixed effects logistic regression model was used to examine the postoperative changes in otomicroscopic findings and tympanogram. Patients with intact healthy/healthy graft or type A tympanogram at preoperative period were not included in the analysis. The linear mixed effects model was used for audiogram. Kaplan–Meier survival plots were constructed to examine the failure-free probability. Cox proportional hazards model with frailty term was used to compare the risk of failure between BDET under local anesthesia versus general anesthesia. The log-normal distribution was specified for the frailty term, which accounts for the correlation between paired ears. Hazard Ratio (HR) and 95% confidence interval (CI) were estimated. All analyses were conducted using SAS version 9.4.

3 | RESULTS

A total of 332 BDETs were performed in 191 patients (58 local anesthesia and 133 general anesthesia). Mean age at surgery was 58.0 years (SD 15.8; range 18–88 years). Of the BDET procedures, 107/332 (32.2%) were performed under local anesthesia and 225/332 (67.8%) under general anesthesia (Table 1). Adjunctive

TABLE 2 Pre and postoperative outcomes after BDET under local versus general anesthesia

	Preop	1 month	3 months	6 months	1 year	2 year	3 year	4 year	5 year	*p* value
BDET under local anesthesia										
Tympanogram	(*n* = 50)	(*n* = 21)	(*n* = 9)	(*n* = 7)	(*n* = 17)	(*n* = 16)	(*n* = 6)	(*n* = 16)	(*n* = 13)	
A	0 (0%)	15 (71%)	6 (67%)	5 (71%)	15 (88%)	13 (81%)	4 (67%)	5 (83%)	10 (77%)	<.001
B	13 (26%)	1 (5%)	2 (22%)	2 (29%)	1 (6%)	2 (13%)	1 (17%)	1 (17%)	1 (8%)	
B/graft	—	—	—	—	—	—	—	—	—	
B/perforated	3 (6%)	—	—	—	—	—	—	—	—	
B/tube	1 (2%)	1 (5%)	—	—	—	—	—	—	—	
C	33 (66%)	4 (19%)	1 (11%)	—	1 (6%)	1 (6%)	1 (17%)	—	2 (15%)	
Otomicroscopy	(*n* = 31)	(*n* = 23)	(*n* = 14)	(*n* = 21)	(*n* = 20)	(*n* = 18)	(*n* = 6)	(*n* = 2)	(*n* = 10)	
Intact healthy /healthy graft	0 (0%)	21 (91%)	14 (100%)	19 (90%)	18 (90%)	18 (100%)	5 (83%)	2 (100%)	6 (75%)	.01
Retracted	25 (81%)	—	—	—	—	—	—	—	1 (12%)	
Perforated	3 (10%)	1 (4%)	—	1 (5%)	—	—	1 (17%)	—	—	
Tube	1 (3%)	1 (4%)	—	1 (5%)	2 (10%)	—	—	—	—	
Effusion	1 (3%)	—	—	—	-	—	—	—	1 (12%)	
Retracted, effusion	1 (3%)	—	—	—	—	—	—	—	—	
Graft	—	—	—	—	—	—	—	—	—	
Valsalva	(*n* = 75)	(*n* = 35)	(*n* = 24)	(*n* = 26)	(*n* = 30)	(*n* = 19)	(*n* = 10)	(*n* = 16)	(*n* = 17)	
Positive	0 (0%)	31 (89%)	20 (83%)	25 (96%)	30 (100%)	17 (89%)	10 (100%)	16 (100%)	15 (88%)	.28
Audiogram	(*n* = 16)	(*n* = 9)	—	—	(*n* = 3)	(*n* = 2)	—	—	(*n* = 6)	
Air-bone gap	10 (9)	12 (7)	—	—	1 (1)	23 (6)	—	—	5 (6)	
Air conduction	30 (13)	32 (10)	—	—	31 (14)	54 (2)	—	—	27 (8)	
Bone conduction	20 (8)	20 (4)	—	—	30 (15)	31 (4)	—	—	21 (6)	
BDET under general anesthesia										
Tympanogram	(*n* = 164)	(*n* = 114)	(*n* = 83)	(*n* = 90)	(*n* = 96)	(*n* = 42)	(*n* = 23)	(*n* = 14)	(*n* = 6)	
A	0 (0%)	75 (64%)	60 (72%)	54 (60%)	71 (74%)	32 (76%)	19 (83%)	9 (64%)	4 (67%)	<.001
B	49 (30%)	15 (13%)	9 (11%)	11 (12%)	14 (15%)	2 (5%)	2 (9%)	2 (14%)	1 (17%)	
B/graft	1 (1%)	—	5 (6%)	3 (3%)	2 (2%)	1 (2%)	1 (4%)	1 (7%)	1 (17%)	
B/perforated	9 (5%)	4 (4%)	4 (5%)	4 (4%)	1 (1%)	2 (5%)	1 (4%)	1 (7%)	—	
B/tube	10 (6%)	7 (6%)	2 (2%)	3 (3%)	—	—	—	—	—	
C	95 (58%)	15 (13%)	3 (4%)	15 (17%)	8 (8%)	5 (12%)	—	1 (7%)		
Otomicroscopy	(*n* = 121)	(*n* = 98)	(*n* = 81)	(*n* = 80)	(*n* = 85)	(*n* = 57)	(*n* = 40)	(*n* = 21)	(*n* = 15)	<.001
Intact healthy /healthy graft	0 (0%)	88 (89%)	69 (85%)	71 (89%)	72 (85%)	50 (88%)	33 (83%)	17 (81%)	12 (80%)	
Retracted	72 (60%)	—	2 (2%)	—	6 (7%)	2 (4%)	4 (10%)	2 (10%)	2 (13%)	

(Continues)

TABLE 2 (Continued)

	Preop	1 month	3 months	6 months	1 year	2 year	3 year	4 year	5 year	*p* value
Perforated	10 (8%)	5 (5%)	4 (5%)	4 (5%)	3 (4%)	4 (7%)	2 (5%)	1 (5%)	–	
Tube	10 (8%)	5 (5%)	2 (2%)	3 (4%)	2 (2%)	–	–	–	–	
Effusion	13 (11%)	–	–	–	1 (1%)	–	–	–	–	
Retracted, effusion	15 (12%)	–	–	–	–	–	–	–	–	
Graft	1 (1%)	–	4 (5%)	2 (3%)	1 (1%)	1 (2%)	1 (3%)	1 (5%)	1 (7%)	
Valsalva	(*n* = 152)	(*n* = 86)	(*n* = 63)	(*n* = 68)	(*n* = 51)	(*n* = 28)	(*n* = 19)	(*n* = 16)	(*n* = 7)	
Positive	0 (0%)	68 (79%)	49 (78%)	57 (84%)	44 (86%)	25 (89%)	15 (79%)	13 (81%)	4 (57%)	<.001
Audiogram	(*n* = 87)	(*n* = 54)	(*n* = 20)	(*n* = 5)	(*n* = 8)	(*n* = 9)	–	–	–	
Air-bone gap	13 (12)	10 (9)	14 (13)	7 (3)	8 (7)	4 (4)	–	–	–	.04
Air conduction	42 (16)	41 (17)	43 (14)	48 (25)	33 (13)	24 (9)	–	–	–	
Bone conduction	28 (14)	31 (15)	30 (15)	42 (25)	25 (9)	20 (8)	–	–	–	

Note: *p* value based on any change in the outcome between preoperative period and postoperative period (months of follow-up as a continuous variable) using the mixed effects regression model.

procedures were performed in 84.1% in BDET under local versus 43.1% under general anesthesia. The mean duration of follow-up was 3.1 years (SD 1.9; range 6 months to 6.6 years). One patient under local anesthesia had abortion of the procedure due to significant discomfort during inflation of the balloon. The dilation was later performed under general anesthesia without difficulty. There were no other adverse effects experienced in the local group and specifically, there were no vasovagal, respiratory or cardiac complaints. All patients in the local anesthesia group were asked if they would choose to have the procedure in the office again and all patients stated that they would.

Among patients who had type B or C tympanogram preoperatively, tympanograms significantly improved to type A in 88% for BDET under local anesthesia versus 74% for BDET under general anesthesia at 12 months (Table 2, Figure 1). During the study period, 14 failures (no change or worse in tympanogram) occurred in 50 BDETs under local anesthesia and 49 failures occurred in 164 BDET under the general anesthesia (Table 3). Risk of failure did not differ between the two groups after accounting for age, sex, comorbidities, and adjunctive procedures in the multivariable Cox model (adjusted HR = 0.60; 95% CI: 0.27–1.31; $p = .20$; Table 3 and Figure 2). The probability of being failure-free at 5 years was 70% (95% CI: 52%–82%) in the local anesthesia group versus 65% (95% CI: 55–73%) in the general anesthesia group.

Among patients who had abnormal tympanic membrane preoperatively, significant improvements in otomicroscopic findings were observed (Table 2). The tympanic membrane was healthy in 90% of cases for BDET under local versus 85% for BDET under general anesthesia at 12 months. There were two ears with persistence or worsening of effusion/retraction in 31 BDET under local anesthesia and 8 in 121 BDET under general anesthesia (Table 3). Risk of persistence or worsening of effusion/retraction did not differ between local versus general anesthesia (adjusted HR = 0.15; 95% CI: 0.02–1.41; $p = .10$).

There were 33 patients (40 ears) who underwent a second procedure (26 underwent re-dilation, 11 tympanostomy tube placement, two tympanoplasties, and one myringoplasty). There were 13/107 failures in the local (12%) versus 27/225 in the general anesthesia (12%) groups. Risk of revision surgery did not differ between local versus general anesthesia (adjusted HR = 0.77; 95% CI: 0.30–2.01; $p = .60$).

Significant improvements were also observed in the ability to perform Valsalva maneuver in the local anesthesia group and the general anesthesia group (Table 2). A/B gap closure was also observed in both groups.

In a subgroup analysis, the risk of failure (no change or worse in tympanogram) did not differ between the two groups of patients without adjunctive procedures (4/17 under local vs. 28/128 general anesthesia; adjusted HR = 1.05; 95% CI: 0.33, 3.33; $p = .93$; Figure 3). The risk of failure also did not differ between the groups with adjunctive procedures (10/90 under local vs. 26/97 general anesthesia; adjusted HR = 0.47; 95% CI: 0.17–1.30; $p = .15$). For BDET without adjunctive procedures, there was no significant

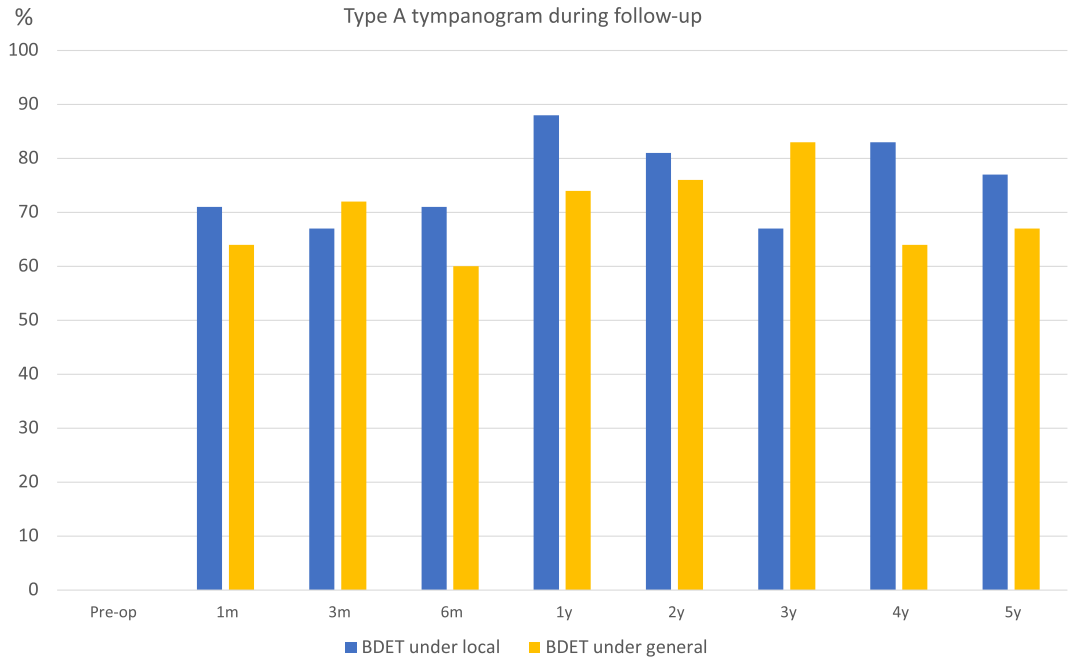

FIGURE 1 Percentage of patients with type A tympanogram preoperatively and during follow-up.

TABLE 3 Risk of failure in patients who underwent BDET under local versus general anesthesia

	Total failures /n. at risk	1-year failure-free probability (95% CI)	2-year failure-free probability (95% CI)	5-year failure-free probability (95% CI)	Adjusted HR (95% CI)	*p*
Tympanogram[a]						
BDET under local anesthesia	14/50	88% (75%–94%)	80% (65%–89%)	70% (52%–82%)	0.60 (0.27–1.31)	.20
BDET under general anesthesia	49/164	76% (69%–82%)	73% (65%–79%)	65% (55%–73%)	Reference	
Otomicroscopy[b]						
BDET under local anesthesia	2/31	100% (100%–100%)	100% (100%–100%)	75% (32%–93%)	0.15 (0.02–1.41)	.10
BDET under general anesthesia	8/121	98% (93%–99%)	96% (90%–99%)	89% (77%–94%)	Reference	

Note: Adjusted hazard ratio (HR) and 95% confidence interval (CI) were based on the Cox proportional hazards model with frailty term that accounts for pairs of ears. Multivariable model includes age, gender, comorbidities, and adjunctive procedures.
[a]Primary outcome (failure) was defined as no change or worse in tympanogram. Patients who had type B or C tympanogram preoperatively included.
[b]Secondary outcome (failure) was defined as persistence or worsening of effusion/significant non-fixed retraction. Patients who had abnormal tympanic membrane.

difference in improvements in tympanograms and otomicroscopic findings between the local versus general anesthesia groups at 24 months follow-up (type A tympanogram: 75% vs. 88%; $p = .10$; and intact healthy tympanic membrane or healthy graft: 100% vs. 97%; $p = .97$). However, in the group of patients who underwent adjunctive procedures, the local anesthesia group had greater improvements in tympanograms than the general anesthesia group at 24 months (type A tympanogram: 88% vs. 56%, $p = .03$; and intact healthy tympanic membrane or healthy graft: 100% vs. 67%, $p = .98$).

4 | DISCUSSION

BDET was introduced as a procedure done under general anesthesia, but local anesthesia has been demonstrated to be feasible[9,10,12] and can be well tolerated with a precise anesthesia method. Careful patient selection is necessary to identify candidates who are likely to do well with local anesthesia (Table 4). Informed, consenting patients have realistic expectations for what will happen during the procedure that will optimize their cooperation and minimize their anxiety. In the current study, one patient out of 107 did not tolerate the procedure due to discomfort during inflation of the balloon. For the remaining local anesthesia patients, no compromises of balloon inflation time nor inflation pressure were necessary.

Advantages of performing BDET under local anesthesia include improved patient safety, convenience for the patient and reduced treatment costs. Local anesthesia alternatives have been studied especially in older adults due to their high prevalence of co-morbidities and a higher risk for postoperative complications.[15] Patient satisfaction may be increased with an option for local

anesthesia as it may be perceived to be safer[16] and more reassuring, giving a sense of maintaining some control in allowing for communication and maintaining their own airway.[17] Locke et al. compared the costs of procedures performed under local versus general anesthesia and found that the use of general anesthesia resulted in an average increase in costs of 243% compared to local anesthesia.[18] The cost of time in the OR has been estimated to be approximately $37 per minute.[19]

We noted no statistically significant difference in the need for additional interventions between the local and general anesthesia groups. Both groups showed statistically significant improvements in otoscopy findings, tympanogram and the ability to perform a Valsalva maneuver, however there were more significant improvements in tympanogram and otoscopy in patients undergoing adjunctive procedures under local anesthesia compared to general after both 1 and 2 years. Selection bias may have influenced this difference as patients with more severe pathology were directed toward the OR. In addition, when FESS with ethmoidectomy or tympanic membrane repair were performed, patients were asked to refrain from Valsalva or nose-blowing for 2 weeks, which might affect the early aeration of the ET.[20]

Prior studies have reported limitations in performing BDET due to pain. Catalano et al[9] was the first to report performing BDET in an office setting. Using oxymetazoline and lidocaine sprays to the nose and lidocaine gel topically in the ET lumen in 37 patients, pain limited the inflations to between 6 and 8 atm over 10 and 30 s.

Luukkainen et al. studied the feasibility of BDET (Acclarent Aera) with topical anesthesia in conjunction with monitored anesthesia care (MAC) compared with endoscopic sinus surgery (ESS).[10] They concluded that the procedure was feasible, although it caused more pain than ESS, most significantly occurring during balloon insertion. In a second study comparing two balloon devices (TubaVent and TubaVent short, both 3 mm dia, Spiggle & Theis Medizintechnik, Overath,

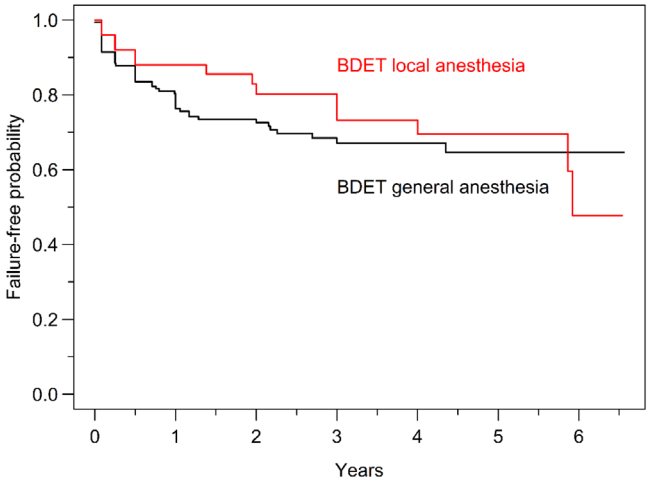

FIGURE 2 Kaplan Meier curve for failure-free probability comparing patients who underwent balloon dilation of the Eustachian tube (BDET) under local versus general anesthesia. Risk of failure was defined as no change or worse in tympanogram. Patients who had type B or C tympanogram preoperatively included.

TABLE 4 Characteristics for potential candidacy for local anesthesia

Diagnostic endoscopy was well tolerated and easily performed
Straightforward intranasal anatomy, including minimal to no septal deviation along with adequate nasal cavity dimensions to accommodate procedure
Absence of medical conditions that might become exacerbated by either medications or portions of the procedure such as unstable cardiac or pulmonary conditions, bleeding diathesis, and uncontrolled hypertension
Absence of severe obstructive sleep apnea if sedation is intended
Appropriate body habitus for in office procedures

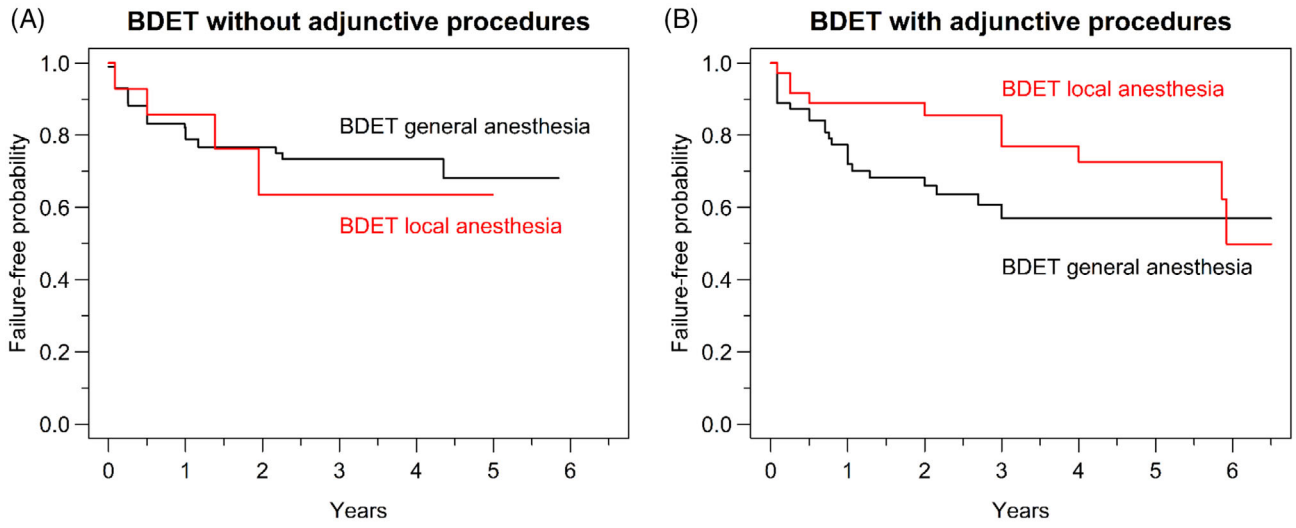

FIGURE 3 Failure-free probability comparing balloon dilation of the Eustachian tube (BDET) under local versus general anesthesia in groups with and without adjunctive procedures.

Germany) the procedure was feasible completing 2 min of dilation with 12 atm pressure in all patients despite the fact that the procedure caused discomfort.[21] 83% of the patients would choose local anesthesia and MAC over general anesthesia if they needed reoperation.

In a study by Chen et al.[12] 25 patients underwent BDET under local anesthesia and evaluated the pain during the procedure utilizing the visual analog scale (VAS) from 0 to 10. The mean VAS score was 5.4 during insertion of the balloon, 6.1 when the balloon was inflated, 4.9 during the maintenance of the 10 bar pressure and returned to 0.4 1 hour postoperatively. 96% (24/25) would choose local anesthesia over general anesthesia if a BDET procedure was needed again. When comparing the efficacy of the procedure under local or general anesthesia, improvements in ETDQ-7 symptom scores were similar between groups. They reported significant increases in blood pressure under local anesthesia and recommended monitoring during procedures.

In-office anesthesia protocols routinely used for sinonasal procedures do not necessarily provide sufficient pain management for BDET.[9,10] One reason for this may be barometric challenges presented to the middle ear. Sudhoff et al.,[22] reported on middle ear pressures during BDET (3 mm dia balloon, no lumen in the catheter to release backpressure) and the mean increase during insertion and inflation was +58 daPa, and the mean decrease was −90 daPa during deflation and retraction. Pain and discomfort can be generated from mucosal sensory, mechanical or stretch receptors within the lumen of the cartilaginous ET, TM or middle ear. This neuronal reflex arc also has the potential to trigger vasovagal responses.[23] As a result, we recommend the rate of inflation not exceed 1 atm/s. The senior author has performed concurrent endoscopy of the TM during insertion of an ET balloon catheter (Acclarent), which has a lumen in the catheter, under general anesthesia. Lateral excursion of the TM was observed during advancement of the balloon catheter through the lumen of the ET, presumably due to obstruction of the lumen by folds of mucosa building up in advance of the balloon tip and progressing as a wave that compressed air proximally into the middle ear. Once reaching the isthmus, the lumen of the catheter should theoretically vent any overpressure and prevent further increases in air pressure with inflation.

The anesthesia method utilized in this study addressed the above issues with an effective topical anesthetic to ensure local pain management in the nose, nasopharynx, cartilaginous portion of the ET and tympanic membrane. In addition to giving adequate time for the anesthetic to be fully effective, it also addressed the sensations caused by pressure changes on the tympanic membrane.[22,24] Slow insertion of the balloon catheter into the ET under endoscopic view combined with slow dilation of the balloon should minimize the pain and vagal responses. Injected anesthetics were not required.

Our patients underwent adjunctive procedures if indicated, most commonly balloon dilation of the sinuses in the local anesthesia group and FESS in the general anesthesia group (Table 1). Although symptoms of obstructive ET dysfunction can improve with FESS,[25,26] studies by McCoul et al.[27] and Ashry et al.[28] demonstrated the use of adjunctive procedures with BDET resulted in equal improvements when compared with BDET without adjunctive procedures.

There are several limitations to this study. It suffers from the inherent biases of a retrospective review. There was no control group. Symptom scores such as ETDQ-7 questionnaire[29] were not used, but objective measures were instead employed in this study. The procedures were performed by a single surgeon and while this strengthens the internal validity, it may limit the external validity of the findings. A significant percentage of the patients in this study underwent adjunctive balloon dilation of the paranasal sinuses or FESS at the time of BDET, which has been shown to possibly improve middle ear function.[30] The reason for the high percentage of sinus procedures was due to the referral pattern to the operating surgeon's rhinology subspecialty practice in which a majority of patients had concomitant chronic rhinosinusitis and OME. Excluding patients who underwent adjunctive procedures showed no difference in the risk of failure. We had a substantial percentage of patients lost to follow-up by 1 year, and long-term follow-up studies are needed in the future.

5 | CONCLUSION

BDET under local anesthesia is effective in treating obstructive ETD and results were durable with mean follow-up of over two years. The surgeon was able to complete the full BDET protocol without alteration in all but one case with a precise anesthesia protocol that did not require an injected anesthetic. There was no statistically significant difference in the need for additional interventions after BDET between the local and general anesthesia groups.

FUNDING INFORMATION

The study has not received any financial support or funding.

CONFLICT OF INTEREST

Dr. Marc Dean is a consultant for Acclarent, Aerin Medical, Biosense Webster, Immertec, Stryker, and STStent. Dr. Dennis Poe is a consultant for Acclarent.

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How to cite this article: Toivonen J, Dean M, Kawai K, Poe D. Comparison of outcomes for balloon dilation of the Eustachian tube under local vs general anesthesia. *Laryngoscope Investigative Otolaryngology*. 2022;7(4):1120-1128. doi:10.1002/lio2.842