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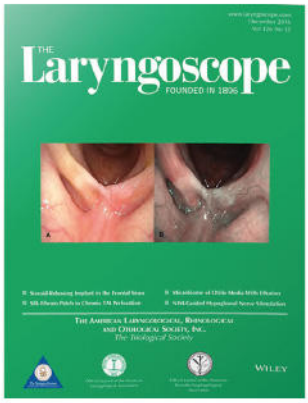

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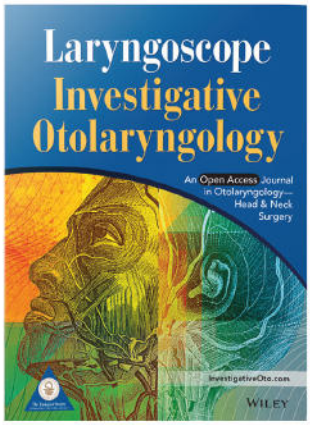

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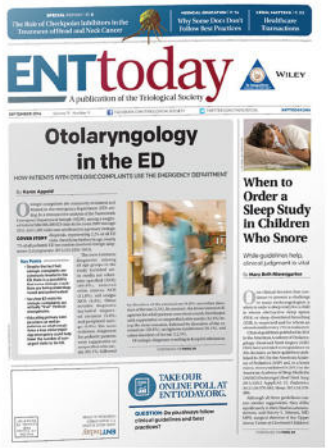

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ORIGINAL RESEARCH

Laryngoscope Investigative Otolaryngology

Balloon dilation of the Eustachian tube with a seeker-based device: A registry of 169 patients

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Abstract

Objective: To collect real-world data on the safety and effectiveness of balloon dilation of the Eustachian tube using a seeker-based device in patients with persistent/chronic symptoms of Eustachian tube dysfunction.

Methods: A multicenter, prospective, single-arm registry was conducted from June 2018 through August 2020 at 10 US centers, including tertiary care and private practices. Primary endpoints included mean change from baseline in the 7-item Eustachian Tube Dysfunction Questionnaire (ETDQ-7) and the serious related adverse event rate. Secondary endpoints include changes in middle ear assessments, surgical intervention rate, and changes in Sino-Nasal Outcome Test and Work and Activity Impairment (WPAI) questionnaires.

Results: A total of 169 participants were treated with balloon dilation of the Eustachian tube, with 166 and 154 participants completing the 6-week and 6-month follow-ups, respectively. Repeated measures analysis of the change in ETDQ-7 scores indicated statistically significant improvement (−2.1; 95% CI −2.40, −1.84; $P < .0001$) at 6-month follow-up. The minimum clinically important difference of improvement was achieved by 85% of participants at 6 months. Four nonserious adverse events were reported. Middle ear functional assessments were improved in the majority of participants with abnormal baseline findings. There were no statistically significant differences in the change from baseline ETDQ-7 scores between participants who had concurrent procedures and those who did not. WPAI scores demonstrated significant improvement.

Conclusion: Real-world evidence supports the clinical studies demonstrating that balloon dilation of the Eustachian tube with a seeker-based device is a safe and effective procedure to treat ETD symptoms.

Level of evidence: 3

KEYWORDS
barochallenge, ETDQ-7, Eustachian tube balloon dilation, Eustachian tube dysfunction

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1 | INTRODUCTION

Balloon dilation of the Eustachian tube (BDET) is an emerging treatment for obstructive Eustachian tube dysfunction (ETD). Obstructive ETD is understood as the most common Eustachian tube (ET) disorder, which may manifest with episodic or persistent symptoms. Barochallenge is a subclinical variant of obstructive ETD in which symptoms present only under conditions of atmospheric pressure changes (eg, scuba diving, flying).[1,2]

Abnormal pressure equalization in the middle ear is the hallmark of obstructive ETD, which can lead to fullness and pressure in the ear, dizziness, tinnitus, and pain or discomfort with barometric changes. Obstructive ETD can lead to tympanic membrane retraction, otitis media, cholesteatoma formation, and hearing loss.[3] This disease process is common, affecting over 11 million Americans, and carries a large economic burden.[4]

Historically, treatments have been directed toward management or prevention of otitis media, rather than correcting the dysfunction of the ET. These treatments include medical therapy, consisting of nasal steroids, nasal and oral antihistamines, and decongestants, as well as surgical interventions such as myringotomy and tympanostomy tube placement. Endoscopic transnasal dilation of the cartilaginous portion of the ET with a balloon was first published in 2010.[5] Since that time BDET has gained popularity with US Food and Drug Administration clearance of balloon devices to endoscopically treat persistent ETD.[6,7]To date, results from two randomized controlled trials[8,9,10,11] have demonstrated that BDET offers a safe and effective minimally invasive treatment for obstructive ETD. Although there is a relatively large body of single-arm studies evaluating wire-based balloon dilation devices, the literature on the seeker-based device is limited to one of the two randomized controlled studies that had strict enrollment criteria and procedures that may not be consistent with common practice. Therefore, the purpose of this study was to gather effectiveness and safety data for BDET using a seeker-based device in the real-world setting for patients with ETD symptoms. The enrollment of participants in this study was not constrained by prescribed parameters, but rather was meant to be more encompassing of all patients with ETD complaints to evaluate the effectiveness of this procedure in everyday clinical practice.

2 | MATERIALS AND METHODS

2.1 | Study design and population

This prospective, multicenter, interventional registry was conducted at 10 US investigational centers. The protocol was reviewed and approved for all centers by Western IRB (Puyallup, Washington; Protocol #20180869). All participants provided written informed consent before study participation. The study was registered at www.clinicaltrials.gov with the unique identifier NCT04136977.

Study enrollment was offered to consecutive patients who met inclusion and exclusion criteria. Participants were adults (≥18 years) who had ETD symptoms for 3 months or longer and who were undergoing BDET for any indication. Patients requiring concurrent ear surgery were excluded as were patients with patulous ET or carotid artery dehiscence. Concurrent nonotological surgical procedures were allowed, such as balloon sinus dilation (BSD), inferior turbinate reduction, septoplasty, and endoscopic sinus surgery. There were no minimum enrollment requirements for the 7-item Eustachian Tube Dysfunction Questionnaire (ETDQ-7) score.

All participants were scheduled to undergo unilateral or bilateral BDET with the commercially available XprESS ENT Dilation System (Stryker, Plymouth, Minnesota) in accordance with the manufacturer's Instructions for Use. Participants were scheduled to return for follow-up visits at 6 weeks and 6 months after treatment. All postprocedure care was provided per the sites' standard of care and was not prescribed by the study protocol.

2.2 | Assessments

At baseline and each follow-up visit, participants completed questionnaires, underwent middle ear functional assessment by tympanometry, and were assessed for adverse events and additional otological procedures. At the 6-week visit, participants were asked to report how long it took until they returned to normal daily activities after their procedure.

The primary effectiveness endpoint was the mean change in the ETDQ-7 score[12,13] between the baseline and follow-up assessments based on a repeated measures analysis. Secondary effectiveness endpoints included the 22-item Sino-Nasal Outcome Test (SNOT-22)[14] and the Work Productivity and Activities Impairment (WPAI)[15] scores. Middle ear assessments (tympanic membrane position, ability to perform a Valsalva maneuver, and tympanogram type) were collected at baseline and each follow-up visit. The number of revision dilation or additional ear surgeries was also collected.

The primary safety endpoint was the incidence of treatment-related serious adverse events (SAEs). Nonserious treatment-related adverse events (AEs) were also collected. Additional information was collected to elicit clinical practice patterns included procedural and diagnostic data.

2.3 | Statistical analysis

Summary statistics were calculated for all registry endpoints. Categorical variables were summarized using frequency distributions and continuous variables were summarized with either means and standard deviations for normally distributed data or medians and interquartile ranges (IQR) for non-normally distributed data. Confidence intervals (95% CI) were computed as appropriate.

Unless specified as mean individual item scores, all ETDQ-7 scores are reported as mean total scores, with a range from 1 to 7. The primary endpoint of the change from baseline for the total ETDQ-7 score was evaluated using a repeated measures linear regression analysis. Dunnett's test was used for the adjustment of multiple

comparisons with baseline. Secondary endpoints such as the change from baseline in individual ETDQ-7, SNOT-22, and WPAI items were tested using paired *t*-tests. Categorical changes in middle ear functional assessments were evaluated using the Wilcoxon's signed rank test. All tests were considered significant at a two-sided alpha level of 0.05.

Planned subgroup analyses of the ETDQ-7 scores included the following comparisons: ETD etiology (barochallenge vs functional/obstructive), concurrent procedures vs BDET only, and baseline ETDQ-7 scores. The baseline ETDQ-7 categories for the subgroup analysis were based on the interpretation of total ETDQ-7 scores as none/mild (<3), moderate (3–5), and severe (>5).[12]

All statistical analyses were performed by an independent statistician using SAS (version 9.4), unless otherwise noted.

3 | RESULTS

A total of 169 participants were enrolled at 10 US investigational sites from June 2018 through December 2019. Three participants withdrew before the 6-week visit. An additional 4 withdrew and 8 were lost to follow-up before the 6-month visit, resulting in a total of 154 participants (91.1%) with data available at the 6-month visit. Only one of the lost to follow-up participants reported an adverse event (acute otitis media). This participant and one discontinued participant did not achieve the MCID for the ETDQ-7 score at 6 weeks.

Demographic and baseline characteristics of the participants are presented in Table 1. The only statistically significant difference in baseline characteristics between participants undergoing BDET only (N = 38) compared with those undergoing concurrent procedures (N = 131) was the percent with chronic rhinosinusitis (31.6% vs 51.1%; $P = .042$).

TABLE 1 Demographics and baseline characteristics

Characteristic	All participants, N = 169
Age (years)	52.4 ± 14.2
Sex (male)	37.9% (64/169)
Race (White)	90.5% (153/169)
Ethnicity (non-Hispanic)	98.8% (167/169)
Mean total ETDQ-7 score	4.6 ± 1.1
Mean total SNOT-22 score	46.9 ± 23.8
Median duration of ETD (years)	3.5 [1.0, 17.5]
Primary type of ETD	
Barochallenged	27.2% (46/169)
Functional obstruction or dynamic dilatory dysfunction	16.0% (27/169)
Anatomic or obstructive dysfunction	56.8% (96/169)
Ear infections	95.3% (161/169)
Allergies	69.8% (118/169)
Tinnitus	49.1% (83/169)
Chronic or recurrent acute rhinosinusitis	46.7% (79/169)
Headaches	45.0% (76/169)
Hearing loss	43.2% (73/169)
Barotitis	36.1% (61/169)
Vertigo	27.2% (46/169)

Note: Results are presented as mean ± SD, median [IQR], or n (%).
Abbreviations: ETD, Eustachian tube dysfunction; ETDQ-7, 7-item Eustachian Tube Dysfunction Questionnaire; SNOT-22, 22-item Sino-Nasal Outcome Test.

TABLE 2 Diagnostic characteristics

Characteristic	All participants
Symptoms leading to diagnosis of ETD	
Aural fullness	79.3% (134/169)
Pressure in ears	76.3% (129/169)
Ear pain/discomfort/pressure	64.5% (109/169)
Ear popping/clicking	53.8% (91/169)
Muffled hearing	49.1% (83/169)
Pain with pressure changes	37.3% (63/169)
Ringing in ears	29.6% (50/169)
Other[a]	5.3% (9/169)
Assessments used to diagnose ETD symptoms with atmospheric pressure changes	47.9% (81/169)
Negative Valsalva maneuver	35.5% (60/169)
Tympanic membrane retraction	34.3% (58/169)
Negative tympanogram pressure	26.0% (44/169)
Symptom relief with tube placement	17.2% (29/169)
Inflammation of the ET orifice	16.6% (28/169)
Symptom relief with myringotomy	5.3% (9/169)
None	7.1% (12/169)
Other[b]	12.4% (21/169)
Medications used for ETD	
Topical steroid	79.9% (135/169)
Antihistamine/combo	66.3% (112/169)
Decongestant	52.1% (88/169)
Antibiotic	40.2% (68/169)
Oral steroid	29.0% (49/169)
Injected steroid	2.4% (4/169)
None	3.0% (5/169)
Other[c]	3.6% (6/169)

Note: Results are presented as % (n/N).
Abbreviations: ET, Eustachian tube; ETD, Eustachian tube dysfunction.
[a]Other symptoms include crackling; vertigo; itching; off balance, dizziness; lightheaded; ear drainage, echo, ears feel clogged; facial pain.
[b]Other assessments include: abnormal ETD function test, recurrent otitis media; persistent effusion; type B tympanograms; symptoms; recurrent infection and pain; lack of response to medical therapy; healing tympanoplasty; possible perforation; flat tympanic membrane; fluid in the ear; low compliance; stenotic ET orifice.
[c]Other medications include: sinus saline rinses; steroid/antibiotic ear drops; immunotherapy.

TABLE 3 Mean change in total ETDQ-7 score from baseline to follow-up—repeated measures

Follow-up period	Estimate at visit	Change from baseline estimate[a]	*P* value[b]
Baseline	4.6 ± 0.09 [4.41, 4.75]		
6 weeks	2.6 ± 0.11 [2.40, 2.82]	−2.0 ± 0.11 [−2.21, −1.72]	<.0001
6 months	2.5 ± 0.11 [2.24, 2.67]	−2.1 ± 0.12 [−2.40, −1.84]	<.0001

Note: Results are displayed as mean ± SE [95% CI].
[a]Least square means estimates from repeated measures linear regression model. Includes all available data.
[b]*P* values are from repeated measures linear regression model with multiple comparison adjustment based on the Dunnett-Hsu method.

Table 2 shows the participant-reported symptoms used to diagnose ETD in the study population, the most frequent being aural fullness (79.3%, 134/169), ear pressure (76.3%, 129/169), and ear pain/discomfort (64.5%, 109/169). Common comorbidities in the population were ear infections, allergies, tinnitus, and chronic rhinosinusitis. At baseline, 24.3% (73/300) ears had abnormal tympanic membrane position (retracted, bulging, or perforated), 20.1% (67/333) ears had type B or C tympanograms, and 39.5% (66/167) participants were unable to perform a Valsalva maneuver.

A majority of participants (77.5%, 131/169) underwent concurrent nonotologic procedures. The most common concurrent procedures were inferior turbinate reduction (62.7%, 106/169) and BSD (39.1%, 66/169). In-office procedures accounted for 53.8% (91/169) of the cases and 54.4% (92/169) received only local anesthesia. Bilateral procedures were planned in 82.2% (139/169) of participants and unilateral procedures in 17.8% (30/169). Procedures were completed in 306/308 ears (99.4%). Two procedures were not completed: 1 due to severe ET scarring on the right side and 1 due to poor visibility and bleeding on 1 side in a participant undergoing concurrent procedures. The median time participants reported for returning to normal activities was 2 days [IQR: 1.0, 7.0] for participants undergoing concurrent procedures and 1 day [IQR; 1.0, 4.0] for participants undergoing BDET only.

The changes from baseline in the ETDQ-7 using the repeated measures analysis are shown in Table 3 and Figure 1. The mean baseline total ETDQ-7 score of 4.6 indicates a moderate level of symptom severity at baseline for the study population. There were statistically significant improvements in the mean total ETDQ-7 scores at the 6-week and 6-month follow-up periods. The change from baseline for most participants was considerably larger than the predicted minimum clinical important difference (MCID) of a 0.5-point reduction, with 85.1% (131/154) of participants exceeding the MCID and 50.6% (78/154) having normalized total ETDQ-7 scores (≤2.1) at the 6-month follow-up. Mean scores for all individual ETDQ-7 items were significantly improved over baseline in the study population ($P < .0001$).

Subgroup analyses of the mean total ETDQ-7 scores found that there were no statistically significant differences in the changes from baseline between participants who had concurrent procedures and those who did not (6 months: −2.1 ± 1.6 vs −2.0 ± 1.5; $P > .05$). At 6 weeks post procedure, there was a statistically significant difference between the change in scores for participants with barochallenge vs functional/obstructive dysfunction (−1.5 ± 1.6 vs −2.0 ± 1.5; $P = .046$), although both groups demonstrated statistically significant improvements over baseline ($P < .0001$). There was no statistically significant difference at the 6-month period (−2.1 ± 1.3 vs −2.0 ± 1.6; $P > .05$). Additionally, there were statistically significant differences in the change from baseline based on the baseline total ETDQ-7 scores (<3 vs 3 to 5 vs >5) with higher baseline scores resulting in greater improvement at both follow-ups (6 months: −0.3 ± 1.2 vs -1.7 ± 1.3 vs −2.7 ± 1.5; $P < .0001$). Participants with baseline total ETDQ-7 scores<3 showed statistically significant improvement at 6 weeks (−0.8 ± 0.5; $P < .001$) but the improvement was lost by 6 months (−0.3 ± 1.2; $P > .05$) in this group.

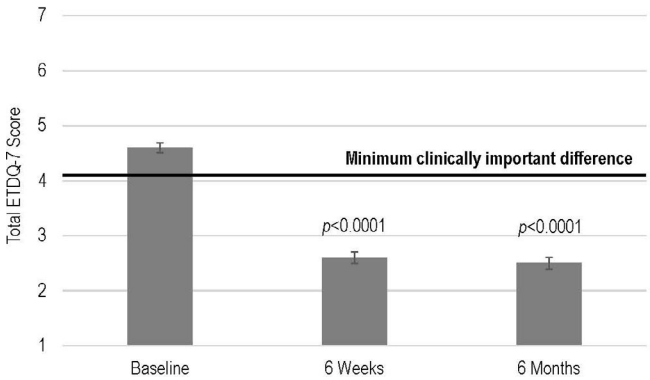

FIGURE 1 Change in total ETDQ-7 scores. Error bars indicate the SE of the estimate. *P* values are from repeated measures linear regression model with multiple comparison adjustment based on the Dunnett-Hsu method

Among participants with abnormal middle ear functional assessments at baseline, there were statistically significant improvements at both time periods (Table 4). At 6 months, tympanic membrane position was improved in 82.7%, Valsalva maneuver in 67.6%, and tympanogram type in 55.1% in participants who had abnormal assessments at baseline. Subgroup analysis was performed to determine the mean change from baseline in ETDQ-7 scores of baseline normal tympanic membranes (normal position and type A) vs baseline abnormal tympanic membranes (abnormal position and type B or C) (Table 5). No statistically significant difference in the mean change from baseline ETDQ-7 scores between the groups was found.

Fifteen participants (8.9%) underwent additional otological surgeries during the study period. Additional procedures occurred

TABLE 4 Change in middle ear functional assessments for ears with abnormal baseline assessments

Follow-up period	Outcome		95% CI of % improved	*P* value[a]
	Improved	No change		
Tympanic membrane position[b]				
6 weeks	67.1% (47/70)	32.9% (23/70)	56.1%, 78.1%	<.0001
6 months	82.7% (43/52)	17.3% (9/52)	72.4%, 93.0%	<.0001
Valsalva maneuver[c]				
6 weeks	60.2% (97/161)	39.8% (64/161)	52.7%, 67.8%	<.0001
6 months	67.6% (96/142)	32.4% (46/142)	59.9%, 75.3%	<.0001
Tympanogram type[d]				
6 weeks	43.5% (27/62)	56.5% (35/62)	37.6%, 62.4%	<.0001
6 months	55.1% (27/49)	44.9% (22/49)	47.6%, 74.9%	<.0001

Note: Numbers are presented as % (*n*/*N*). Unit of analysis is ear.
[a]*P* values are based on the Wilcoxon signed rank test.
[b]Improved tympanic membrane position = "Retracting," "Perforated," or "Bulging" to "Within normal limits."
[c]Improved Valsalva = negative to positive Valsalva.
[d]Improved tympanogram type = "Type B" or "Type C" to "Type A," or "Type B" to "Type C."

TABLE 5 Mean change in total ETDQ-7 score by normal/abnormal baseline tympanogram type and tympanic membrane position

Follow-up period	*N*	ETDQ-7 at baseline[a]	ETDQ-7 at follow-up	Change from baseline	Within group *P* value[b]	Between group *P* value[c]
Normal TM position and Type A tympanogram at baseline						
6-week	79	4.7 ± 1.0	2.8 ± 1.5	−1.9 ± 1.4	<.0001	.329
6-month	74	4.7 ± 1.0	2.6 ± 1.3	−2.1 ± 1.5	<.0001	.488
Abnormal TM position and Type B or C tympanogram at baseline						
6-week	74	4.4 ± 1.2	2.5 ± 1.3	−1.9 ± 1.5	<.0001	
6-month	67	4.3 ± 1.2	2.4 ± 1.4	−2.0 ± 1.7	<.0001	

Note: Results are presented as mean ± SD.
Abbreviations: ETDQ-7, 7-item Eustachian Tube Dysfunction Questionnaire; MCID, minimal clinically important difference; TM, tympanic membrane.
[a]The ETDQ-7 responses can range from 1 (no symptoms) to 7 (severe symptoms). A change from baseline of ≥0.5 points is considered the MCID.
[b]*P* values are from signed rank tests for the change from baseline.
[c]*P* values are from Wilcoxon rank sum tests for comparison between groups for the distribution of change from baseline in ETDQ-7 scores.

TABLE 6 Work productivity and activity impairment questionnaire

Follow-up period	WPAI parameter[a]	*N*	Baseline	Follow-up	Change from baseline	*P* value[b]
6 weeks	Absenteeism	82	0.0 [0.0, 4.8]	0.0 [0.0, 0.0]	0.0 [−2.2, 0.0]	<.0001
	Presenteeism	81	39.5 [10.0, 56.9]	0.0 [0.0, 20.0]	−20.0 [−41.7, 0.0]	<.0001
	Productivity loss	82	30.0 [10.0, 50.0]	0.0 [0.0, 20.0]	−20.0 [−40.0, 0.0]	<.0001
	Activity impairment	162	30.0 [10.0, 60.0]	0.0 [0.0, 10.0]	−20.0 [−50.0, 0.0]	<.0001
6 months	Absenteeism	68	0.0 [0.0, 4.8]	0.0 [0.0, 0.0]	0.0 [−3.5, 0.0]	.012
	Presenteeism	67	37.8 [10.0, 50.0]	0.0 [0.0, 20.0]	−20.0 [−42.9, 0.0]	<.0001
	Productivity loss	68	30.0 [10.0, 50.0]	0.0 [0.0, 20.0]	−20.0 [−40.0, 0.0]	<.0001
	Activity impairment	150	30.0 [10.0, 60.0]	0.0 [0.0, 10.0]	−20.0 [−50.0, 0.0]	<.0001

Note: Results are presented as median [IQR] as a percentage of impairment (range 0–100).
[a]WPAI work-related questions are answered only by participants employed for pay. Productivity loss is calculated as the sum of absenteeism and the product of presenteeism and time worked. Participants who are not employed respond only to the question regarding activity impairment. Higher scores indicate worse outcomes and negative changes from baseline indicate improvement.
[b]*P* values are from signed rank tests for the change from baseline.

from 7 days to 208 days after the index study procedure. Two participants underwent multiple procedures. Tympanostomy with placement of ventilation tubes was the most common procedure. Only one participant underwent a repeat balloon dilation.

For participants who underwent BDET only, the SNOT-22 scores were reduced from a mean of 40.9 ± 26.8 at baseline to 25.4 ± 19.9 (mean change −15.5; $P < .0001$) at 6 weeks and 22.2 ± 22.4 (change −18.0; $P < .0001$) at 6 months. Participants undergoing concurrent procedures had greater SNOT-22 score reductions from a mean of 48.4 ± 22.6 at baseline to 19.2 ± 18.0 (mean change −29.2; $P < .0001$) at 6 weeks and 19.7 ± 18.9 (mean change −28.8; $P < .0001$). The differences between groups are statistically significant at 6 weeks ($P < .001$) and at 6 months ($P = .020$).

Table 6 presents the impact of BDET treatment on work productivity and activities (from the WPAI questionnaire). Statistically significant reductions were noted in presenteeism, productivity loss, and overall activity impairment at both 6 weeks and 6 months post BDET.

There were no SAEs reported. Four nonserious treatment-related AEs were reported in 4 participants. One participant developed acute otitis media 2 days post procedure that was treated with amoxicillin/clavulanate and resolved 8 days later. A second participant developed effusion in the left ear at 10 days post procedure that was treated with prednisone, amoxicillin/clavulanate, and tramadol, and resolved 14 days later. The third participant developed otalgia on the day of the procedure that resolved 31 days later without any intervention. The fourth participant experienced increased blood pressure during the procedure that was resolved by adjusting the anesthesia.

4 | DISCUSSION

BDET is a novel treatment that has gained interest in the field of otolaryngology over the last decade. The ideal indications and populations for the treatment are still being defined. The results from the current registry using a seeker-based device demonstrate that BDET is a safe and effective treatment option for patients with ETD symptoms. Although ETD is ubiquitous in otolaryngology practice, there are no universally accepted diagnostic criteria for all patients with ETD. The ETDQ-7, tympanograms, Valsalva, and physical examination provide potentially useful information but there remain gaps in the diagnostic criteria, specifically in patients with symptoms of ETD and a normal tympanogram. The present study highlights the results of real-world use of BDET in a spectrum of patients with varying degrees of ETD symptoms and physical findings. ETD symptoms, as documented by the ETDQ-7, were improved for the majority (85.1%, 131/154)) of participants, with or without baseline tympanic membrane abnormality.

Given the procedure's novelty, there is debate about the safety of seeker-based technology vs wire-based technology for BDET. Our current data set of BDET using seeker-based technology adds to the growing body of literature demonstrating its safety. There were no serious side effects in the 169 participants and only 3 participants with minor side-effects of otitis media (2) and otalgia (1). One participant had a reaction to anesthesia with high blood pressure that was not directly related to the technique. This 1.7% rate of minor complications is similar to the 2% rate that Huisman et al found in their systematic review of 1151 patients (1881 procedures).[16] In our current study, there were no SAEs such as hemotympanum or subcutaneous emphysema.

To demonstrate how BDET is used in everyday practice, inclusion criteria were purposely kept broad in this study, resulting in a cohort of participants with a high rate of concurrent procedures (77.5%, 131/169). Thirty-nine percent of the participants had BSD along with BDET. This rate is consistent with the finding by Marino et al, where 43.3% of patients with rhinosinusitis based on SNOT-22 scores had a significantly positive ETDQ-7 score.[17] However, the ETDQ-7 outcomes in the group with concurrent procedures were comparable to the group without concurrent procedures. Also, procedures were performed in the office (53.8%) more than they were performed in the operating room or ambulatory surgical center (46.2%). This real-world practice behavior illustrates that BDET is suitable for the office setting.

Despite the difference in study design and lack of strict inclusion criteria for participant selection, the improvement in ETD symptoms is consistent with those reported in the randomized control trials.[8-11] The baseline mean total ETDQ-7 reported by Meyer et al[8] was identical to the baseline for our cohort (4.6) and compared well with that reported by Poe et al (4.7).[10] In 51 participants who underwent balloon dilation, Meyer et al[8] reported a mean change from baseline of −2.5 at 6 months compared with our mean change from baseline of −2.0 in 154 participants. Similarly, Anand et al reported a mean total ETDQ-7 change from baseline of −2.4 in 124 participants at 12 months.[11]

Durability of the procedure was previously demonstrated by Cutler et al who found a significant long-term improvement in ETDQ-7 scores in 47 participants undergoing seeker-based BDET, with 93.6% of them improved by 1 point or more after 2 years.[9] Anand et al found enduring normalization of tympanograms (39.6%), improvement of tympanograms (46%), normalization of ETDQ-7 scores (46%), and improvement ETDQ-7 scores (79%) 1 year after BDET with a wire-based device.[11]

Our current data set demonstrates a normalization of ETDQ-7 scores in 50.6% of participants, with 85.1% exceeding the MCID at 6 months. A notable finding was that participants with baseline ETDQ-7 scores of 3 or greater had significantly more improvement in symptoms at the 6-month follow-up than those with baseline scores less than 3. This information may be used to improve patient selection for this procedure as well as counsel patients on expectations.

Tympanometry has been the standard diagnostic test used to evaluate patients with suspected obstructive ETD, where type B and C were considered positive for ETD. However, in the authors' experience (RTS, JBG, JLR, and EDM), there is a large subset of patients who have ETD symptoms with normal tympanograms. Once evaluations exclude other causes, such as temporomandibular joint dysfunction, nasopharyngeal/oropharyngeal lesions, or Eagle syndrome, ETD remains the most likely cause of symptoms, despite normal tympanograms. Such patients comprised the majority of our study participants, where 79.8% had type A baseline tympanograms. Even though these patients had

normal tympanograms and tympanic membrane positions at baseline, their symptoms based on the ETDQ-7 significantly improved following BDET (Table 5). This improvement is similar to results from other studies of BDET for participants with type A tympanograms,[8,18] and supports the supposition that tympanometry alone is not sufficient to determine candidates for BDET. In the future, the historic criterion of an abnormal tympanogram for diagnosis of ETD may be further refined to reflect the potential for varying degrees of obstructive ETD among patients with type A tympanograms.[19]

Statistically and clinically significant improvements were noted in the WPAI and SNOT-22 scores after BDET. The WPAI is a validated measure of work impairment,[15] and in our population, statistically significant improvements were seen in the presenteeism, productivity loss, and activity impairment components of the WPAI at both 6 weeks and 6 months after BDET. Much more modest improvements, though still statistically significant, were seen on absenteeism at 6 weeks and 6 months post procedure. The 77.5% of study participants who underwent concurrent nonotologic procedures collectively had worse baseline SNOT-22 scores and a statistically significant greater improvement in SNOT-22 scores after treatment compared with participants who underwent BDET alone. This is expected, since the most common concurrent procedures were inferior turbinate reduction and BSD, and the SNOT-22 is a validated quality of life metric for sinonasal symptoms. These improvements in the WPAI and SNOT-22 harmonize with the statistically significant improvements we found in the ETDQ-7 and underscore the efficacy of BDET when used as either a standalone procedure or as part of a comprehensive treatment for ETD and sinonasal disease in a single operation.

Conclusions from this study are inherently limited by the design as a single-arm series without a control group. Enrollment of only patients who were planning to have an intervention introduces the possibility of selection bias. The use of a patient-reported subjective assessment as the primary outcome measure carries potential difficulties, including issues related to patient health literacy, the influence of seasonal symptom patterns, and inattentive question responses. Nonetheless, in the real-world setting a patient-centered assessment is a relevant determinant of treatment success and patient satisfaction. Additionally, the latest follow-up assessment at 6 months after the procedure prevents an inference about the long-term effects of BDET. Among the strengths of this study are the multicenter design, which reflects a variety of practice types, geographic settings, and patient populations. The unsupervised inclusion of tympanogram types, variable symptom severity, and concurrent procedures permits an appreciation for the potential role of BDET outside of a controlled setting.

5 | CONCLUSION

This study provides real-world evidence that BDET with a seeker-based device is a safe and effective procedure, further establishing BDET as a viable treatment option for patients with persistent ETD symptoms. BDET is effective at reducing ETD symptoms for patients in the office and the operating room setting, in patients with either type A or type B/C tympanograms, and in patients undergoing concurrent procedures.

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AUTHOR CONTRIBUTIONS

Robert T. Standring: data acquisition, interpretation of data, drafting and revision of manuscript, final approval, accountable for all aspects; **Ellen M. O'Malley:** conception and design of work, interpretation of data, drafting and revision of manuscript, final approval, accountable for all aspects; **Joshua B. Greene:** data acquisition, interpretation of data, drafting and revision of manuscript, final approval; **Joseph L. Russell:** data acquisition, interpretation of data, drafting and revision of manuscript, final approval; **Edward D. McCoul:** conception and design of work, data acquisition, interpretation of data, drafting of manuscript, critical revision, final approval.

CONFLICT OF INTERESTS

Ellen M. O'Malley is an employee of Stryker ENT. Robert T. Standring, Joshua B. Greene, and Edward D. McCoul are consultants for Stryker. Joseph L. Russell has no conflicts to disclose.

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