Balloon Dilation for Obstructive Eustachian Tube Dysfunction in Children

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Objective: Determine the safety and efficacy of balloon dilation of the Eustachian tube (ET) in pediatric patients.
Study Design: Retrospective matched cohort study.
Setting: Tertiary medical center.
Patients: Pediatric patients (<18 yr) with persistent (>1.5 yr) chronic Eustachian tube dysfunction (ETD) with previous tympanostomy tube (TT) insertion versus matched controls.
Intervention(s): Balloon dilation of the cartilaginous ET (BDET) was performed using concomitant myringotomy with/without tube placement and adjunctive procedures if indicated versus controls (TT).
Main Outcome Measure(s): Otitis media with effusion (OME)/retraction with need for additional tube, tympanogram, audiogram, otomicroscopy, ET mucosal inflammation/opening score, and Valsalva maneuver.
Results: Forty six ETs (26 patients), ages 7 to 17 years (mean 12.5) underwent BDET. Mean follow-up was 2.3 years (standard deviation [SD], 1.1; range, 6 mo–5 yr). Significant improvements were observed for all measures. Tympanic membranes were healthy in 9% preoperatively, 38% at 6 months, 55% at 12 months, and 93% at 36 months postoperatively. Tympanograms improved to type A in 50% at 6 months, 59% at 12 months, and 85% at 36 months. Mean scores of mucosal inflammation declined from 3.2 (±0.6) preoperatively to 2.5 (±0.7) at 6 months and 1.7 (±0.6) at 36 months postoperatively. BDET had lower risk of failure versus TT insertion (adjusted hazard ratio [HR] 0.26; 95% confidence interval [CI]: 0.10, 0.70; $p = 0.007$). Probability of being failure free at 2 years was 87% (95% CI: 70, 94%) after BDET and 56% (95% CI: 40, 70%) after TT insertions.
Conclusions: BDET is a safe and possibly effective procedure in selected pediatric patients with chronic ETD.
Key Words: Balloon dilation—Children—Eustachian tube—Eustachian tube dysfunction.

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The Eustachian tube (ET) has multiple functions, including pressure equalization and ventilation, mucociliary clearance of secretions from the middle ear, and protection of the middle ear from pathogens, nasopharyngeal secretions, and sound (1). The cartilaginous portion of the ET serves as a valve where tubal dilation and ventilation of the middle ear takes place (2).

Eustachian tube dysfunction (ETD) is a spectrum of disorders that ranges from obstructive ETD (OETD) through patulous ETD. OETD at its worst involves complete blockage of the ET, resulting in otitis media with effusion (OME). Insufficient opening results in negative pressure and lesser degrees of obstruction may cause difficulty only when subjected to significant changes in ambient pressure (barochallenge). Loss of volume in the valve that results in a leak of air and sound causes the symptoms of patulous ET (1).

Almost 40% of all children develop OETD. When chronic, it is commonly associated with acute otitis media (AOM), persistent or recurrent OME, retraction of the tympanic membrane, hearing loss, speech and language delays, and the development of chronic otitis media (3). This in turn can lead to complications such as cholesteatoma (3).

Treatment of ET dysfunction was primarily limited to indirect treatments targeted at the tympanic membrane and adenoids. Early experience with removing inflammation from the lumen of the ET with laser cautery showed some modest efficacy, suggesting that methods to treat inflammation may have promise (4). Ockermann et al. (5) introduced transnasal endoscopic balloon dilation of the cartilaginous ET (BDET) in 2010 in a study of eight adult patients with severe dilatory dysfunction. The results showed improvement in all patients assessed by a

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non-validated ET score at 2 months clinical follow up. Longer term results were reported by Silvola et al. (6) who conducted a prospective cohort study on 37 patients (41 ETs) with a mean follow-up time of 2.5 years. They achieved 80% (33/41) success in patients' ability to perform a Valsalva maneuver as well as normalization of tympanograms in 56% of ETs. Furthermore, a systematic review on BDET efficacy demonstrated consistent improvements in the outcomes studied: otoscopy, tympanometry, ET assessment scores, and ability to perform a Valsalva. Limitations of the review included significant heterogeneity between studies, high risk of bias, and use of level 4 evidence (7). Recent randomized, controlled trials of BDET support the safety and efficacy seen in the earlier cohort trials (8–10).

Few studies with balloon dilation of the Eustachian tube in children have been reported. Maier et al. (11) published a retrospective analysis on 66 children undergoing BDET after failing conventional therapy (antibiotics, adenoidectomy, myringotomy, etc.) with improvement in clinical symptoms for 80% of patients. Jenckel et al. (12) reported on 33 children (56 ETs) who underwent uncomplicated BDET and achieved improvements in otorrhea, otalgia, and hearing loss. However, their success rate was lower and they questioned the efficacy of using tubomanometry in younger children as part of the ET score, finding it difficult to obtain consistent results in pediatric patients.

In all patients, children and adults, optimal conservative treatment of underlying diseases should be done before surgery is considered. Procedures such as adenoidectomy, myringotomy, and insertion of tympanostomy tubes are generally considered the gold standard in the treatment of chronic OETD in children and young adults.

The purpose of this study is to compare the efficacy of BDET, along with adjunctive procedures as indicated, with tympanostomy tube placement in children with OETD and to examine the effects of BDET in the pediatric age group.

PATIENTS AND METHODS

This retrospective matched cohort study was performed at a tertiary medical center and was approved by the institutional IRB. Twenty-seven patients underwent balloon dilation of the Eustachian tube between 2013 and 2017. One patient with Trisomy 21 syndrome was excluded leaving 26 patients (46 ears) for study.

Inclusion criteria included patients age 7 to 17 years, persistent (>18 mo) symptoms of unilateral/bilateral ETD according to documented visits to a physician or non-fixed tympanic membrane (TM) retraction who had failed to improve despite at least 6 weeks of optimal medical treatment. This included treatment of any identified underlying conditions such as allergy (with oral antihistamine, intranasal corticosteroid, and modified Valsalva maneuver) or reflux (with referral to gastroenterologist). Nine patients who had recurrent OME had had between two and six sets of tympanostomy tubes with different intervals for up to several years indicating a wide variability of symptoms. When their OME lasted for over 3 months they were treated with tympanostomy tubes as the guidelines suggest. Exclusion criteria included conditions with increased susceptibility for recurrent ear infections including Trisomy 21 and other syndromes, craniofacial anomalies, cleft palate, chronic inflammatory diseases, chronic ear disease (other than OME or AOM) or immunodeficiency.

Patients were coached in performing a modified Valsalva maneuver (nose and mouth closed, gently initiating nose blow to generate positive intranasal pressure, simultaneous swallow) and if unable, they were given instructions for a mechanical device that uses nasal inflation of a balloon to try to ventilate the ET and middle ear (Otovent, ABIGO Medical, Askim, Sweden).

Patients had a thorough work-up for Eustachian tube function including ability to perform a modified Valsalva maneuver, otomicroscopy, nasopharyngoscopy, and video endoscopy of the ET with a flexible pediatric endoscope as previously described (13). Briefly, our endoscopic ET examination includes a dynamic assessment of the ET during vocalization of ''kah-kah-kah,'' (to elevate the levator veli palatini muscle in isolation, rotate the torus medially and assess possible interference by the adenoid), swallowing (to assess the normal dilatory process), yawning, and vocalization of ''Ahhh'' (to assess maximal dilatory effort). The degree of mucosal inflammation and opening of the functional valve was scored using a validated instrument from 1 = normal, 2 mild inflammation, valve opening not compromised, 3 moderate inflammation, valve opening compromised, to 4 severe inflammation, valve never opens (13).

BDET was performed under general anesthesia using concomitant myringotomy with/without tube placement if indicated. Myringotomy was done to release non-fixed TM retraction to the incus or promontory to facilitate early middle ear aeration if there were a partial effusion. A tympanostomy tube was inserted when the middle ear was filled with effusion or when lysis of middle ear adhesions was performed. Adjunctive lateral adenoidectomy with light cautery of the tubal tonsil tissue was performed if anterior thrusting of the torus tubarius was seen to compromise the opening of the ET valve due to compression by the adenoid during swallows on office endoscopic examination. Additionally, turbinectomy and/or cartilage tympanoplasty were used adjunctively in selected cases. For suspected disease in the bony ET (CT findings of persistent opacification within the bony ET in the absence of middle ear effusion or absence of pathology within the cartilaginous ET on pre-op endoscopy), an illuminated guide-wire was used to probe and attempt to clear the lumen (off-label use of a sinuplasty wire). If guidewire probing of the ET was planned, high resolution computed tomography (CT) was performed in all cases, if not already obtained, to exclude dehiscence of the internal carotid artery (ICA) within the wall of the bony ET. CT was obtained for 17/26 patients (65%) and guidewire probing was performed on four of them. Dehiscence of the ICA in the bony ET was a contraindication for insertion of an illuminated guidewire into the bony portion of the ET.

The control group was collected from pediatric patients, aged 7 to 17, who had undergone tympanostomy tube placement at our hospital between 2010 and 2017 for unilateral/bilateral chronic/recurrent OME or non-fixed (TM) retraction. The BDET treatment cases and controls were matched by number of previous tympanostomy tubes, age, sex, and history of adenoidectomy as closely and consecutively as possible to minimize any risk of bias. The matched cohort (tympanostomy tube) was selected retrospectively, therefore, not all of the

outcome variables (otomicroscopy, tympanogram, audiogram, mucosal inflammation, and Valsalva) were collected in the patient records. Hence, the comparison of the complete set of outcome variables was presented only for the analysis of the BDET group, pre versus post op. Investigators were blinded to the number of tubes received by the control group in the follow-up period. Exclusion criteria were the same as for the treatment group.

Surgical Procedures

All procedures were performed by the senior author under general anesthesia. A 3.5×10, 3.5×12, 5×16, or 6×16 sinuplasty balloon (off-label use, Acclarent, Irvine, CA) was used for dilation of the cartilaginous ET commensurate with the size of the child. The 6×16 balloon was used for subjects of adult size. The AERA balloon (off-label use for pediatric patients, Acclarent, Irvine, CA) was used for six patients.

Balloon Dilation Technique

We performed BDET using our previously described technique (6,14). Using a 45 degrees, 3 mm nasal endoscope (Karl Storz, CA) for viewing, a 70-degree guide catheter loaded with the sinuplasty balloon catheter (or the 55 degrees guide catheter for the AERA balloon) was inserted along the floor of the nasal cavity and directed toward the ET. The insertion of the balloon catheter was done with great care to allow the flexible catheter to guide along the s-shaped curvature of the tubal lumen and to avoid any trauma to the mucosa with lacerations or mucosal tears. Entry into a false passage and inflation outside of the ET can potentially cause backpressure into the middle ear, bleeding, and—most seriously—carotid injury. The catheter was inserted gently until meeting resistance from the bony-cartilaginous isthmus to avoid entrance into the bony ET. A yellow marker 31 mm from the balloon distal end would usually at this point of insertion be at the level of the ET anterior pillar (never inside the orifice as the average length of the adult cartilaginous ET is 25 mm) (3). The yellow marker was variably farther outside of the ET in younger children. The balloon was inflated with saline up to 12 atm and maintained for 2 minutes in most cases or 1 to 1.5 minutes in subjects with milder inflammatory disease. In the younger children, the guide catheter was too acutely angulated or too long to direct the balloon catheter into the tubal orifice due to nasal anatomy. In those cases, a transoral approach was used, passing the balloon catheter through an olive tipped maxillary antral suction into the lumen of the ET while maintaining the endoscope in the nasal cavity. In total, with seven patients (13 ears) a transoral approach was used, three 7-year-olds, one 8-year-old, one 10-year-old, one 12-year-old, and one 13-year-old. One of the 7-year-olds ended up having re-dilation 21 months later at which point transnasal approach was feasible.

In general, an attempt to determine the duration of balloon inflation is made during the office visit, based on:

1) Burden of disease—Grade 2 and mild grade 3 are more likely to have a reduced duration.
2) Progression of disease—If slowly improving, reduced duration may be offered.
3) Any history of patulous ET—All patients are asked about whether they have ever had any symptoms of autophony and if so, they are felt to be at increased risk for developing persistent patulous symptoms. If there is any positive history of ever having patulous autophony, the duration may be reduced.
4) Evidence of mucosal atrophy within the functional valve of the cartilaginous ET. Patches of atrophy can place patients at risk for developing patulous ET, even though there may be robust inflammatory disease in the remainder of the lumen. This situation occurs particularly frequently with chronic allergic rhinitis, which is the most common condition associated with patulous ET (15).

Myringotomy was performed in all cases of middle ear effusion to facilitate early middle ear aeration. A tympanostomy tube was inserted when the middle ear was completely filled with fluid.

Postoperative Follow-up

Patients were advised not to from blow their nose or perform Valsalva maneuvers during the first week after BDET. They were then instructed to do a modified Valsalva maneuver hourly while awake for the subsequent 3 weeks and to continue their medical treatment for any associated allergy, reflux, or sinonasal disease as indicated. Postoperative visits were scheduled at a minimum for 1, 6, and 12 months. Outcome measures included ability to perform modified Valsalva, otomicroscopy, tympanometry, pure tone audiometry, and mucosal inflammation/opening rating score for ET. Criteria for clinical success after BDET were: 1) normal or mildly retracted TM by otomicroscopy and 2) type A tympanogram or type C tympanogram if hearing was normal. Criteria for failure were absence of the criteria for success, including: 1) OME, moderate, or severe TM retraction/atelectasis/retraction pockets by otomicroscopy or 2) type B tympanogram or type C with decreased hearing (e.g., patients with a cartilage graft tympanoplasty may have a type B tympanogram on the basis of the stiffness of the TM, yet have an aerated middle ear and absence of hearing loss or barochallenge. Such patients were considered a clinical success), or 3) necessity of tympanostomy tube.

Statistical Analysis

Longitudinal data analysis comparing data before and after surgery was conducted using generalized linear models. A three-level hierarchical model using a generalized estimating equations (GEE) approach was employed to account for the correlations between repeated measures over time and between each pair of ears. We evaluated any change in outcomes between the preoperative period (baseline) and postoperative period with months of follow-up time as a continuous variable. For otomicroscopic findings, tympanogram, and Valsalva, we used a logistic regression model using a GEE approach. For mucosal inflammation, we used a model with a gamma distribution and log link function. Kaplan–Meier survival plots were constructed to compare the failure-free survival probability during the first 2 years between patients who received BDET versus matched patients who received TT insertions. We used Cox proportional hazards model with frailty term to account for matched pairs of BDET and TT patients adjusted for age, sex, and number of previous tympanostomy tubes. The gamma distribution was specified for the frailty term. Hazard ratio (HR) and 95% confidence interval (CI) were estimated. Model diagnostics were performed to assess the fit of the model and the proportional hazards assumption. All analyses were conducted using SAS version 9.4 and R statistical software.

RESULTS

A total of 46 BDETs were performed in 26 pediatric patients (62% men, 38% women) with a mean age at surgery of 12.5 years (SD 3.3; range, 7–17). The mean

TABLE 1. *Characteristics of pediatric patients who underwent balloon dilation of the Eustachian tube*

Characteristics	N (%) or Mean (SD)
Patient characteristics (n = 26)	
Gender, female	10 (38%)
Age at surgery, years, mean (SD)	12.5 (± 3.3)
Symptom duration, years, mean (SD)	9.1 (± 3.9)
Number of prior tympanostomy tubes, mean (SD)	3.7 (± 1.4)
Prior adenoidectomy	22 (85%)
Allergy	7 (27%)
Allergic rhinitis	5 (19%)
Asthma	5 (19%)
Procedure (n = 46)	
Indication	
Chronic OME	24 (52%)
Recurrent OME	6 (13%)
Chronic or recurrent OME, retracted	10 (22%)
Chronic or recurrent OME, atelectasis	6 (13%)
Adjunctive procedure	46 (100%)
Preoperative CT	17 (65%)
Duration of follow up, years, mean (SD)	2.3 (± 1.1)

OME indicates otitis media with effusion.

TABLE 2. *Adjunctive procedures*

Adjunctive Procedure	N = ears (%)
Revision adenoidectomy	13 (28%)
Revision adenoidectomy, M and T	6 (13%)
Adenoidectomy, M and T	3 (7%)
M and T	3 (7%)
M, revision adenoidectomy	2 (4%)
Lysis of ME adhesions, M and T, revision adenoidectomy	2 (4%)
Lysis of ME adhesions, revision adenoidectomy	2 (4%)
Revision adenoidectomy, M and T, turbinate reduction	2 (4%)
Revision adenoidectomy, tympanoplasty	2 (4%)
M and T, turbinate reduction	1 (2%)
M, lysis of ME adhesions	1 (2%)
Revision adenoidectomy, tympanoplasty, cartilage graft, SA tube	1 (2%)
Adenoidectomy, M and T, lysis of ME adhesions	1 (2%)
Lysis of ME adhesions, M and T, revision adenoidectomy, turbinate reduction	1 (2%)
Revision adenoidectomy, patch TM	1 (2%)
Revision adenoidectomy, turbinate reduction	1 (2%)
Revision adenoidectomy, tympanoplasty, cartilage graft, SA tube	1 (2%)
Revision adenoidectomy, tympanoplasty, excision cholesteatoma, cartilage graft, SA tube	1 (2%)
Turbinate reduction	1 (2%)
Tympanoplasty, mastoidotomy, OCR, cartilage graft, SA tube, revision adenoidectomy	1 (2%)

OCR indicates ossicular chain reconstruction; SA, subannular; TM, tympanic membrane.

symptom duration was 9.2 years (SD 3.8). All patients had previously undergone tympanostomy tube insertion, with an average of 3.7 (SD 1.4) procedures (Table 1). Adjunctive procedures were performed in all patients (Table 2). The mean duration of follow up was 2.3 years (SD 1.1; range, 6 mo–5 yr).

Statistically significant improvement in middle ear function was observed following BDET (Table 3). The tympanic membrane was intact healthy or healthy graft in 38% of cases at 6 months, 55% at 12 months, and 93% at 36 months postoperatively. Tympanograms gradually improved to type A in 50% of cases at 6 months, 59% at 12 months, and 85% at 36 months. Air/bone (A/B) gap significantly decreased from 17.5 (±11.9) preoperatively to 10.8 (±10.8) at 6 months and 5.7 (±4.8) at 36 months postop. A/B gap closure was observed in 70% (32/46) of cases at the last follow up visit. The mean score of mucosal inflammation declined from 3.2 (±0.6) preoperatively to 2.5 (±0.7) at 6 months postop and 1.7 (±0.6) at 36 months postop. Ability to perform a modified Valsalva maneuver also significantly improved.

Adjunctive Procedures

All patients underwent adjunctive procedures at the time of BDET. Six of 46 ears underwent cartilage tympanoplasty. In addition, one of these six was noted to have an obstruction in the bony ET during the primary procedure and required a subannular tube at a later time.

Risk of Failure After BDET Versus TT Insertion

Patients who underwent BDET and matched cohorts of patients who underwent TT insertion had similar clinical characteristics (Table 4). A total of five ears failed in patients who underwent BDET. One patient (two ears) required redilation due to continuing ETD including TM retractions and mastoid opacification from inadequately treated significant allergic rhinitis. Preoperative mucosal score was 3. Cartilage graft tympanoplasty, ossicular chain reconstruction, and mastoidotomy were performed on one side. The patient had previously had two sets of tympanostomy tubes that lasted for up to a year each time. One patient (two ears) demonstrated recurrent effusion and had significant return of lymphoid hyperplasia on the Torus tubarius of the ETs after initial reduction following BDET. This was suspected to be due to return of allergic symptoms despite negative allergy testing. Mucosal score was four preoperatively, myringotomy and revision adenoidectomy were done adjunctively. Patient history included six sets of tympanostomy tubes lasting from 6 months to 2 years. One patient (one ear) failed because of a blocked bony ET which was recognized during guidewire probing during the BDET procedure. Preoperative mucosal score was three. Myringotomy and lysis of middle ear adhesions were also done. The patient had previously had four sets of tympanostomy tubes and a chronic perforation for 4 years. The patient developed recurrence of effusion during follow up and required tympanostomy tube placement.

For matched control patients who underwent TT insertion, 19 ears failed with documented type B tympanograms with effusion or recurrent AOM or TM retraction requiring additional tube placement during the 2-year follow up period. Patients who underwent BDET had a

TABLE 3. *Pre and postoperative outcomes after balloon dilation of the Eustachian tube*

	Pre-op (n = 46)	Post 1 m (n = 42)	Post 6 m (n = 39)	Post 12 m (n = 29)	Post 24 m (n = 17)	Post 36 m (n = 14)	*p*-Value
Otomicroscopy							
Intact healthy/healthy graft	4 (9%)	7 (17%)	15 (38%)	16 (55%)	13 (68%)	13 (93%)	<0.001
Perforated/tube	10 (22%)	26 (62%)	15 (38%)	7 (24%)	4 (21%)	0 (0%)	
Retracted	18 (39%)	7 (17%)	6 (15%)	5 (17%)	2 (11%)	1 (7%)	
Effusion	8 (17%)	2 (5%)	2 (5%)	0 (0%)	0 (0%)	0 (0%)	
Atelectasis/retracted, adherent	6 (13%)	0 (0%)	1 (3%)	1 (3%)	0 (0%)	0 (0%)	
Tympanogram							
A	9 (23%)	6 (24%)	15 (50%)	16 (59%)	9 (53%)	11 (85%)	<0.001
B (OME/negative pressure)	11 (27%)	2 (8%)	1 (3%)	2 (7%)	0 (0%)	0 (0%)	
B (normal pressure)	0 (0%)	0 (0%)	1 (3%)	2 (7%)	2 (12%)	2 (15%)	
Open	9 (23%)	16 (64%)	11 (37%)	5 (19%)	3 (18%)	0 (0%)	
C	11 (27%)	1 (4%)	2 (7%)	2 (7%)	3 (18%)	0 (0%)	
Audiogram							
PTA air-bone gap, mean (SD)	17.5 (±11.9)	8.5 (±9.5)	10.8 (± 10.8)	12.4 (± 9.2)	11.5 (± 7.7)	5.7 (± 4.8)	<0.001
PTA air, mean (SD)	21.9 (± 13.2)	14.3 (± 9.1)	19.5 (± 10.6)	17.6 (± 11.2)	14.8 (± 8.7)	12.4 (± 4.9)	
PTA bone, mean (SD)	4.4 (±5.3)	5.8 (±4.8)	8.7 (±6.8)	5.3 (±7.1)	3.3 (±4.7)	6.7 (±5.0)	
Mucosal inflammation/dilation							
Mean (SD)	3.2 (±0.6)	2.0 (±0.7)	2.5 (±0.7)	2.0 (±0.9)	1.2 (±0.4)	1.7 (±0.6)	<0.001
Valsalva							
Total	15	16	10	11	6	3	
Positive	4 (27%)	9 (56%)	5 (50%)	10 (91%)	6 (100%)	3 (100%)	<0.001
Negative	11 (73%)	7 (44%)	5 (50%)	1 (9%)	0 (0%)	0 (0%)	

p-Value based on any change in the outcome between pre-operative period and post-operative period (months of follow-up as a continuous variable). The generalized estimating equations approach was employed to account for within-individual correlations for the longitudinal data analysis. OME indicates otitis media with effusion.

lower risk of failure than patients who underwent TT insertion (adjusted HR: 0.26; 95% CI: 0.10, 0.70; $p = 0.007$; Table 5 and Fig. 1). The probability of being failure free at 2 years was 87% (95% CI: 70, 94%) in BDET and 56% (95% CI: 40, 70%) in TT insertions.

Subgroup Analysis

A subgroup of 21 patients (34 ears) who underwent BDET without tympanoplasty or turbinate reduction was also examined. Patients who underwent BDET without tympanoplasty or turbinate reduction had a lower risk of failure than matched patients who underwent TT (HR 0.30; 95% CI: 0.10, 0.92; $p = 0.04$; Supplementary Figure 1, http://links.lww.com/MAO/B148). Pre- and postoperative changes in otomicroscopic findings and tympanograms did not differ by patients who underwent BDET with or without tympanoplasty and/or turbinate reduction (p for interaction >0.10; Supplementary Table 1, http://links.lww.com/MAO/B149). We also found that improvements in the outcomes after BDET did not differ by transoral versus transnasal approach, the preoperative severity of mucosal inflammation/dilation, or sex (p for interaction >0.10; Supplementary Tables 2–4, http://links.lww.com/MAO/B149).

Adverse Events

There were no intraoperative or postoperative complications. Pain was limited to mild sore throat in the area of the larynx, usually for about 2 days. Two patients reported symptoms of patulous ET that resolved over months.

DISCUSSION

This is the first trial evaluating the efficacy of balloon dilation of the cartilaginous Eustachian tube in children by comparing a matched cohort of patients who

TABLE 4. *Characteristics of patients who underwent BDET and matched patients who underwent TT insertions*

	Balloon Dilation of Eustachian tube	Tympanostomy Tube Insertion
Total number of included patients, n	26	26
Total number of included procedures, n	46	46
Gender, male	16 (62%)	14 (54%)
Age at surgery, years, mean (SD)	12.5 (±3.3)	12.2 (±3.3)
Prior adenoidectomy	22 (85%)	25 (96%)
Number of prior tympanostomy tubes, mean (SD)	3.6 (±1.5)	3.3 (±1.4)

BDET indicates balloon dilation of the cartilaginous ET; TT, tympanostomy tube.

TABLE 5. *Two-year risk of failure requiring revision surgery in patients who underwent BDET and matched patients who underwent TT insertions*

	No. Failure/No. Procedure	2-Year Failure-Free Probability (95% CI)	Adjusted HR (95% CI)	*p*-Value
Balloon dilation of Eustachian tube	5/46	87% (70, 94%)	0.26 (0.10, 0.70)	0.007
Tympanostomy tube insertion	19/46	56% (40, 70%)	Reference	

Adjusted hazard ratio (HR) and 95% confidence interval (CI) were based on the Cox proportional hazards model with frailty term that accounts for matched pairs that matched on age, gender, and number of prior tympanostomy tubes. BDET indicates balloon dilation of the cartilaginous ET; TT, tympanostomy tube.

underwent TT insertion. The results suggest that BDET, in conjunction with adjunctive procedures as indicated, is effective in selected pediatric patients with chronic or recurrent OME who have failed to resolve the conditions with previous tympanostomy tube placement. In fact, significant improvements were seen in otomicroscopic findings, tympanograms, mucosal inflammation/opening score, audiometry, and the ability to perform modified Valsalva maneuver with mean 2.3 years follow up. When comparing the BDET group and matched controls who had only underwent TT placement, statistically significantly fewer patients needed further tympanostomy tubes in the balloon dilation group over the follow-up period.

Current treatment methods have been shown to have shortcomings when treating chronic inflammation with obstructive ETD. Empiric treatment of OME with effusion with nasal steroids failed to improve tympanometric findings or patient reported symptom scores in a randomized controlled trial (16). Furthermore, tympanostomy tube insertion does not address the inflammatory disease of the ET and may cause other complications (17). Balloon dilation addresses inflammatory pathology within the lumen of the ET by crushing inflamed mucosa and submucosal adenoid-like lymphoid hyperplasia within the cartilaginous ET lumen allowing for healing with a thin scar covered by healthy new mucosa, similar to adenoidectomy (18).

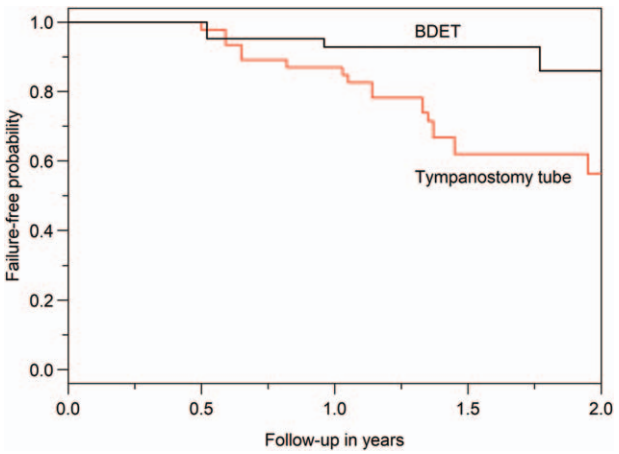

FIG. 1. Kaplan–Meier curve for failure-free probability comparing patients who received balloon dilation of ET versus matched patients who received tympanostomy tube insertion ($p = 0.007$). ET indicates Eustachian tube.

Leichtle et al. (19) reported on BDET in 52 children (97 ears) demonstrating an increase in type A tympanograms from 14% preoperatively to 50% postoperatively at both 6 and 12 months. Also, the ability to perform middle ear pressure equalization improved from 13 to 60%. Both of these results are comparable to what we observed in the current study and continued to improve with time as the follow-up continued to 2 and 3 years. In addition, Maier et al. (11) reported the results of BDET in 66 children with 6 months follow-up. They collected their results with a questionnaire and reported improvement in clinical symptoms in 80% of patients as assessed by patient questionnaires. The Leichtle and Maier studies described BDET as a single procedure or combined with paracentesis only, which is in contrast to our experience where our patients required adjunctive procedures to treat contributing conditions or complications of chronic ETD. On the other hand, in Jenckel et al's cohort (12) 42% of patients underwent tympanoplasty before balloon dilation. Ashry et al. (20) specifically studied the effect of adjunctive procedures combined with balloon dilation in adults and the results showed similar significant improvement in the groups undergoing BDET with or without adjunctive procedures. Expanding the indications for BDET to include greater burdens of ET inflammation and associated diseases did not decrease the success rate.

Importantly, there have been no reports of serious adverse effects of BDET in children to date, including our present study. These results support that the procedure can be safely performed in pediatric patients. Careful technique to confine balloon dilation to the cartilaginous portion of the ET and to avoid mucosal injury or false passage are key principles for optimizing safety.

Limitations of our study include the inclusion of adjunctive procedures in our study cohort creating the possibility that some of the benefit attributed to BDET may actually be from the other procedure. On the other hand, after cartilage tympanoplasty, patients have persistent type B tympanograms in spite of improved middle ear pressures and ET function, which may actually underestimate the efficacy of BDET. The number of subjects in the study is also limited and it was therefore not possible to perform significantly powered subgroup analysis of the effect of all the various adjunctive procedures separately. In addition, while we attempted to match cases and controls as closely as possible, there

were some patients who could not be matched perfectly, which may be an additional source of bias. Finally, at our center we have excluded all patients less than 7 years of age to date from this procedure and thus we cannot comment on the efficacy of this procedure in that age group. One of the strengths of the study was that the majority of patients had long follow-up of up to 5 years (mean duration of 2.3 yr). All patients had a long duration of preoperative symptoms (average, 9 yr).

CONCLUSION

The present study adds to the literature on pediatric balloon dilation of the cartilaginous portion of the Eustachian tube and supports it as a safe and possibly effective procedure, in conjunction with adjunctive procedures as indicated, in selected pediatric patients with chronic or recurrent OME who have failed to resolve the conditions with previous tympanostomy tube placement. It is important to stress that conservative treatment such as optimizing any underlying medical conditions (e.g., treatment of allergy, reflux, and chronic rhinosinusitis) should always be considered before more invasive surgical procedures. Procedures such as adenoidectomy and myringotomy and insertion of tympanostomy tubes remain the current gold standard in the initial surgical treatment of chronic ETD in children and young adults. Endoscopic BDET appears to be a safe and effective alternative treatment option, when conventional therapy of chronic ETD does not succeed in children.

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