Original Article

Outcomes after balloon dilation of the eustachian tube in children: a systematic review and meta-analysis

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Background: Balloon dilation of the eustachian tube (BDET) is a new treatment modality for eustachian tube (ET) dysfunction. There is currently hesitancy in performing BDET in children due to their shorter and more horizontal ET. This systematic review and meta-analysis aims to summarise objective and subjective outcomes for BDET in children.

Methods: A literature search was conducted in six databases (CINAHL, Cochrane, Embase, Medline, PubMed, and Scopus) for articles published up to and including 24 October 2023. Articles were selected if they provided primary data for the efficacy of BDET in children. Risk of bias was evaluated using the Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool. Objective outcomes included complications, otomicroscopy, tympanometry, pure tone audiometry (PTA), pressure equalisation through Valsalva manoeuvre (VM) and tubomanometry. Subjective outcomes included patient symptoms, satisfaction, and quality of life (QOL). For the meta-analyses, mean differences were used for continuous outcomes and odds ratios for binary outcomes.

Results: Eleven articles were identified, of which eight were retrospective case series and three were historic cohort studies. A total of 589 patients were included in the review for an aggregate of 945 procedures. No serious complications were found, with the estimated rate of minor complications being 3.6% [95% confidence interval (CI): 2.0% to 6.2%; P<0.001], the majority of which were self-limiting hemotympanum and epistaxis. Post-operative improvements were seen in otomicroscopy [odds ratio for otitis media (OM), 0.0033; 95% CI: 0.0010 to 0.0115; P<0.001; and retraction, 0.0073; 95% CI: 0.0007 to 0.0735; P<0.001], tympanometry, air conduction (AC; mean difference, −8.95 dB; 95% CI: −11.06 to −6.84; P<0.001), air-bone gap (ABG; mean difference, −14.23 dB; 95% CI: −22.83 to −5.63; P<0.001), pressure equalisation (odds ratio, 0.041; 95% CI: 0.019 to 0.086; P<0.001), and questionnaires relating to symptoms, satisfaction, and QOL. Meta-analyses were unable to be performed for some outcomes, and so were evaluated qualitatively. The findings for tubomanometry were less convincing with only one of two studies observing a positive trend in tube opening.

Conclusions: BDET is a safe and potentially effective procedure for the treatment of obstructive eustachian tube dysfunction (OETD). As the current body of evidence is largely based on retrospective case series, further research in the form of prospective cohort studies and randomised control trials (RCTs) are needed before BDET can be recommended as evidence-based management.

Keywords: Paediatric; balloon dilation; otitis media (OM); eustachian tube dysfunction (ETD); otolaryngology

Received: 26 August 2023; Accepted: 26 December 2023; Published online: 15 March 2024.

doi: 10.21037/ajo-23-38

View this article at: https://dx.doi.org/10.21037/ajo-23-38

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Introduction

The eustachian tube (ET) is a canal that extends anteriorly, medially and inferiorly from the middle ear to the nasopharynx (1). The anteromedial two-thirds are cartilaginous, while the posterolateral one-third is bony (2). A <10 mm segment of opposing mucosal tissue within the midportion of the cartilaginous ET acts as a valve (3). The valve is closed in its resting position and opens primarily through contraction of the tensor veli palatini (4).

The ET has three primary physiological functions pertaining to the middle ear: (I) pressure equalisation and ventilation; (II) mucociliary clearance of secretions; and (III) protection from nasopharyngeal pathogens, secretions and sounds (5). ET dysfunction (ETD) is defined as failure to perform any of these three functions (2). It is classified as either obstructive (dilatory) or patulous, with further categorisation into acute or chronic depending on whether signs and symptoms last longer than 3 months (5).

Obstructive ETD (OETD) refers to inadequate opening of the tubal lumen, and can be further divided into (I) functional obstruction, (II) dynamic obstruction, and (III) anatomical obstruction. Functional obstruction refers to mucosal changes in the lumen and is often caused by inflammation from an upper respiratory tract infection (URTI) or allergic rhinitis (5). Dynamic obstruction refers to muscular failure; and anatomical obstruction refers to extraluminal growths, for example adenoidal hypertrophy or tumours of the post nasal space (6). Otitis media (OM), middle ear effusion, tympanic membrane (TM) retraction, cholesteatoma and TM perforation are features of OETD. OETD causes a constellation of symptoms such as aural fullness, altered hearing, tinnitus, and a constant need to perform jaw-thrust or Valsalva manoeuvres (VMs) to equalise pressure (5). Comparatively, patulous ETD results from inadequate closure of the tubal lumen. It is much less common than OETD, with the majority of cases being idiopathic. Patients present with aural fullness and autophony (4,5).

Treatment of ETD can be divided into medical and surgical management. Medical management can include intranasal corticosteroids, intranasal decongestants, oral antihistamines and oral antibiotics, aiming to improve mucosal inflammation within the nasal cavity and ET (7). For adults, this is typically in conjunction with medical therapy for concomitant comorbidities, for example antacids or proton pump inhibitors for laryngoesophageal reflux (8). Comparatively, first-line surgical treatment includes any combination of adenoidectomy, myringotomy/paracentesis, and ventilation tube (VT) insertion. Recently, balloon dilation of the ET (BDET) is being used when dysfunction is refractory to first-line medical and surgical management (9).

BDET involves dilation of the ET by passing a balloon catheter under transnasal endoscopic visualisation. The procedure was first reported in 2009 (10), and has since grown in popularity worldwide (8). The literature is dominated by retrospective case series without any control group on this topic, however, three randomised control trials (RCTs) have been identified that demonstrated a statistically significant improvement in symptoms and tympanometry up to 12 months post-dilation in adults (11-13). The long-term effect is less conclusive as few studies report outcomes beyond 12 months (8). In any case, the literature primarily focusses on the adult population, with few studies assessing the procedure's safety and efficacy in children (14).

By way of their anatomical make up, children have a greater tendency to develop ETD than adults, yet there is hesitancy in performing BDET in children due to the ET being shorter and lying closer to the horizontal plane. While the majority of anatomical maturation of the ET occurs by 5 years, adult morphology is only reached in early adolescence. This is an important factor when considering the approaching angle and length of the balloon catheter, as well as the angle of the endoscope (1).

This review aims to build on the works of Saniasiaya *et al.* (14) and Aboueisha *et al.* (15). Saniasiaya *et al.* (14) performed a systematic review of seven studies published up to December 2020, focussing on the indications for BDET and associated complications, while touching briefly on outcomes. Comparatively, Aboueisha *et al.* (15) performed a meta-analysis of seven studies, collating data on complications, tympanometry, and pure tone audiometry (PTA). This is the first study to comprehensively synthesise data across a large number of objective and subjective outcomes. Objective parameters include: (I) complications; (II) otomicroscopy; (III) tympanometry; (IV) PTA; (V) pressure equalisation through VM; and (VI) tubomanometry. The first five parameters are frequently measured. Tubomanometry, however, is a less common technique that measures the latency (R) of a pressure change transmitted to the TM when pressure is applied to the nasopharynx: R =0 indicates no opening, 0< R <1 indicates immediate opening, R =1 indicates accurate opening, and R >1 indicates delayed opening (15). In contrast, subjective parameters include

patient symptoms, satisfaction, and quality of life (QOL). We present this article in accordance with the PRISMA reporting checklist (available at https://www.theajo.com/article/view/10.21037/ajo-23-38/rc).

Methods

A systematic review was performed to evaluate the literature regarding BDET in the paediatric population. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) (ID: CRD42023430248). Because of the retrospective nature of the research, the requirement for informed consent was waived.

Literature search

Articles published up to and including 24 October 2023 were identified through CINAHL, Cochrane, Embase, Medline, PubMed, and Scopus using search strategies described in the Cochrane Handbook for Systematic Reviews of Interventions (16). All searches were completed on 24 October 2023, and search terms included "balloon", "tuboplasty", "endonasal", "dilation", "eustachian", "auditory", "pharyngotympanic", "tube", "child", "preschool", "school age", "paediatric", and "adolescent". The full search strategies are listed in Table S1.

Selection

Two reviewers screened titles and abstracts against the inclusion and exclusion criteria. Studies were included if they investigated BDET, involved patients aged 18 years old and under, and were published up to and including 24 October 2023. Studies were excluded if the safety and/or efficacy of BDET was not assessed, if segregated data was not available for patients under 18 years old, and if the full text could not be accessed. Review articles and case reports were excluded, and non-English papers were translated to English through Google Translate.

Validity assessment

The included studies were appraised by two reviewers using the Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool as described in the Cochrane Handbook. This tool evaluates the risk of bias related to (I) confounding, (II) selection of participants, (III) classification of interventions, (IV) deviations from intended interventions, (V) missing data, (VI) measurement of outcomes, and (VII) selective reporting. Each domain was evaluated as low, moderate, serious, critical or no information. Discrepancies were resolved with discussion.

Data extraction

Data was extracted using a standardised collection form by one reviewer and verified by another. Extracted data included citation, aim, study population, summary statistics, sample size, region, department, setting, study design, intervention (anaesthesia, preparation, access, dilation, removal), outcomes and key findings. The outcomes evaluated were complications, otomicroscopy, tympanometry, PTA, pressure equalisation through VM, tubomanometry, ear-related symptoms, satisfaction, and QOL.

Statistical analysis

For this meta-analysis, two different summary estimates (effect sizes) were calculated: mean differences for the continuous outcomes (PTA) and odds ratios for the binary outcomes (otomicroscopy, tympanometry, and VM). For the binary outcomes, the normal outcome was set as the negative outcome and the others as positive outcomes. If studies reported outcomes across multiple follow-up periods, the measure at 12 months or less was taken to ensure a sufficient sample size.

For all outcomes, separate random-effects models were fitted using a conditional generalized linear mixed-effects model (GLMM). This framework accounts for the repeated nature of the data (pre/post paired cohorts), while also incorporating an additional random component that accurately estimates the associated variance components. The likelihood ratio test was carried out for testing residual heterogeneity. Heterogeneity was examined using the Higgins I^2 statistic, where low, moderate, and high heterogeneity were indicated by I^2 values in the ranges of 0–25%, >25–75%, and >75–100%, respectively. Forest plots (main text) and funnel plots (Figures S1-S6) were produced for visualization of summary effect sizes and publication bias, respectively. If heterogeneity was not significant, summary estimates were presented with 95% confidence intervals (CIs). The metafor package (version 4.0-0) in R was used to conduct the meta-analyses.

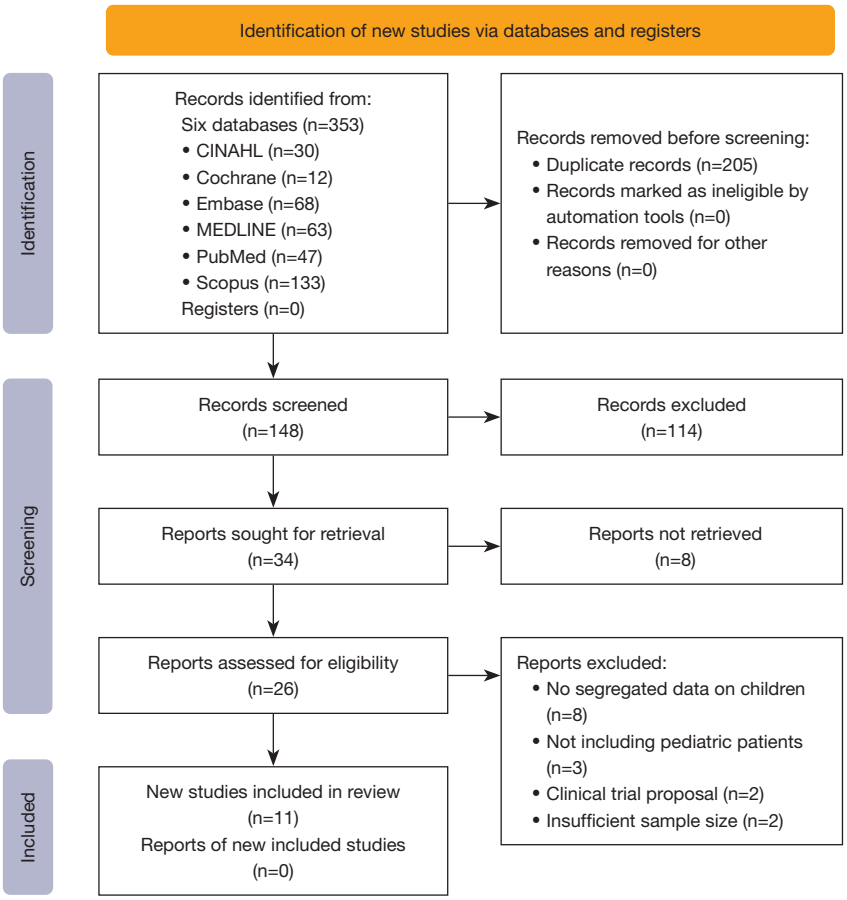

Figure 1 PRISMA flow diagram illustrating selection process.

Results

Results of search

The primary search yielded 353 titles and abstracts, of which 319 were excluded after screening. Major reasons for exclusion were duplicate publications (n=205), no relevance to BDET in children (n=88), and review-type studies (n=26). Of the remaining 34 articles, eight studies were excluded for being inaccessible, eight did not present segregated data for children, three did not include paediatric patients, two were clinical trial proposals, and two were case reports. Eleven records met eligibility criteria (*Figure 1*).

Study characteristics

Characteristics of each study are summarised in *Table 1*. Eight of the eleven included studies were retrospective case series, while the remaining three were historic cohort studies. The majority of studies originated in Germany (n=5), with other contributions from Turkey (n=2), United States (n=2), China (n=1), and Finland (n=1).

Patients

A total of 589 patients were included in the review for an aggregate of 945 procedures. All studies included patients under the age of 18 years old. The youngest patient was 28 months (20), and the oldest patient was 18 years old (26). Chronic OETD was a diagnostic indication for BDET in all studies, but the precise eligibility criteria varied. Some studies defined otomicroscopic and tympanometry findings in their criteria, while others were more generic. Eight of the 11 studies (17,20-26) included resistance to first-line medical therapy (anti-inflammatory, decongestant, antibiotics, corticosteroids) and/or surgical management (adenoidectomy, tympanic drainage, paracentesis, VT insertion) as an eligibility criterion, but the precise therapies were again subject to variance. *Table 1* provides a summary

Table 1 Characteristics of included studies

Study	Country	Study design	Patients	Procedures	Age range	Indication for procedure	Follow-up
Maier *et al.* (17), 2015	Germany	RCS	66	121	4–14 years old	Chronic OETD AND refractory to medical/surgical therapy	Mean, 96 days
Jenckel *et al.* (18), 2015	Germany	RCS	33	56	5–14 years old	Recurrent OM OR chronic adhesions with poorly mobile TM	1, 3, 6, 9, 12, and 15 months
Leichtle *et al.* (19), 2017	Germany	RCS	52	97	3–15 years old	Recurrent OM OR chronic adhesions with poorly mobile TM OR persistent TM perforation OR cholesteatoma	0.5, 2, 6, and 12 months
Tisch *et al.* (20), 2017	Germany	RCS	94	90	28 months–13 years old	Chronic ETD AND refractory to medical/surgical therapy	Mean, 13 months
Chen *et al.* (21), 2020	China	HCS	25 [49]	46 [92]	4–14 years old	Chronic ETD refractory to either tympanocentesis or tympanostomy tube insertion	6, 12, and 18 months
Demir & Batman (22), 2020	Turkey	HCS	30 [62]	55 [105]	3–12 years old	Chronic ETD refractory to medical therapy	Mean (range), 14.4 months (13–16 months)
Demir & Batman (23), 2020	Turkey	HCS	30 [62]	55 [105]	3–12 years old	Chronic ETD refractory to medical therapy	1.5 and 12 months
Tisch *et al.* (24), 2020	Germany	RCS	167	299	4–12 years old	COME for >3 months OR more than three episodes of AOM in last year OR CSOM OR cholesteatoma OR mesotympanic retraction pockets, AND refractory to medical/surgical therapy	Mean (95% CI), 2.6 months (0.3–16.1)
Toivonen *et al.* (25), 2021	United States	RCS	26	46	7–17 years old	Chronic ETD with previous tympanostomy tube insertion OR non-fixed TM retraction, AND failing medical therapy	1, 6, 12, 24, and 36 months
Howard *et al.* (26), 2021	United States	RCS	43	80	6.6–17.7 years old	ETD OR chronic serous OM OR recurrent OM, AND refractory to medical/surgical therapy	NR
Oehlandt *et al.* (27), 2022	Finland	RCS	23	NR	<16 years old	Chronic ETD	Mean ± SD, 33±12 months

"Patients" refers to the number of patients who underwent either unilateral or bilateral BDET, while "procedures" refers to the number of BDET procedures. For historic cohort studies, the total number of patients and procedures performed among the BDET and control groups is given in square brackets. RCS, retrospective case series; OETD, obstructive eustachian tube dysfunction; OM, otitis media; TM, tympanic membrane; ETD, eustachian tube dysfunction; HCS, historic (retrospective) cohort study; COME, chronic otitis media with effusion; AOM, acute otitis media; CSOM, chronic suppurative otitis media; CI, confidence interval; NR, not reported; BDET, balloon dilation of the eustachian tube.

Table 2 Summary of the BDET procedure for included studies

Study	Preparation	Endoscope	Applicator system	Dilation	Post-operative care
Maier *et al.* (17), 2015	NR	NR	Bielefeld; 3.28 mm × 20 mm†; 45° or 70°†	10 bars for 2 min	Xylometazoline spray and panthenol oil for 3 days, followed by tube ventilation through Valsalva/Otovent
Jenckel *et al.* (18), 2015	Xylometazoline	3 mm; 45°	Spiggle and Theis; 3.28 mm × 20 mm†; 30°, 45°, or 70°	10 bars for 2 min	NR
Leichtle *et al.* (19), 2017	Xylometazoline	3 mm; 0° or 45°	Spiggle and Theis; 3.28 mm × 20 mm†; 30°, 45°, or 70°	8 bars for 2 min	NR
Tisch *et al.* (20), 2017	Xylometazoline	Diameter NR; 30°	NR	10 bars for 2 min	NR
Chen *et al.* (21), 2020	NR	NR	Spiggle and Theis; 3.28 mm × 20 mm; angle NR	10 bars for 2 min	NR
Demir & Batman (22), 2020	Xylometazoline	2.5 mm; 0° or 45°	Spiggle and Theis; 3.28 mm × 20 mm†; 30°, 45°, or 70°	10 bars for 2 min, repeated after 2 min	Nasal saline irrigation and xylometazoline for 5 days
Demir & Batman (23), 2020	Xylometazoline	2.5 mm; 0° or 45°	Spiggle and Theis; 3.28 mm × 20 mm†; 30°, 45° or 70°	10 bars for 2 min, repeated after 2 min	Nasal saline irrigation and xylometazoline for 5 days
Tisch *et al.* (24), 2020	Xylometazoline	3.28 mm; angle NR	Spiggle and Theis; 3.28 mm × 20 mm†; angle NR	10 bars for 2 min	Xylometazoline in recovery room
Toivonen *et al.* (25), 2021	Xylometazoline	3 mm; 45°	Karl Storz/70°; diameter NR; AERA/55°; 6 mm × 16 mm†	12 bars for 2 min	VMs and continued medical therapy
Howard *et al.* (26), 2021	Oxymetazoline	3 mm; 0° or 30°	AERA; 6 mm × 16 mm†; angle NR	10–12 bars for 2 min, repeated	Nasal corticosteroid for 30 days, ear drops for 5 days, and VMs
Oehlandt *et al.* (27), 2022	Cotton-soaked epinephrine	Diameter NR; 0° to 70°	Spiggle and Theis; 3.3 mm × 20 mm; 45° or 70°	10 bars for 2 min	NR

†, information sourced from product catalogue as not provided within paper. BDET, balloon dilation of the eustachian tube; NR, not reported; VM, Valsalva manoeuvre.

of the patient eligibility criteria for each study.

Procedure

The BDET procedure can be divided into five stages: (I) preparation; (II) access; (III) dilation; (IV) removal; and (V) post-operative care. The use of a decongestant was consistent across all studies that reported the preparation stage, with xylometazoline being the most common.

In terms of access, seven studies (18,19,21-24,27) used the Spiggle and Theis applicator system, Maier *et al.* (17) used Bielefeld catheters, Howard *et al.* (26) used AERA catheters, and Toivonen *et al.* (25) used a combination of AERA and Karl Storz catheters. Only Jenckel *et al.* (18) customised the applicator system for their paediatric patients, amending the insertion parts to be thinner. The angle of the endoscope and applicator system varied across publications and are summarised in *Table 2*. While many studies had the option of different angles, the frequency of each was not reported. Most studies dilated the balloon at 10 bars for 2 min, with three studies (22,23,26) repeating the procedure before removing the catheter. Toivonen *et al.* (25) found the guide catheter to be too acutely angulated to perform transnasal BDET in seven (13 ears) of their 26 patients (46 ears). A transoral approach was used instead for these patients. The authors also decided to vary the duration of balloon inflation based on the burden and progression of disease.

Table 3 Parameters measured in the included studies

Study	Objective						Subjective		
	Compl.	Otomic.	Tymp.	PTA	TMM	VM	Sx	Sat.	QOL
Maier *et al.* (17), 2015	√	√	√	√		√		√	
Jenckel *et al.* (18), 2015	√				√		√		
Leichtle *et al.* (19), 2017	√		√		√	√	√	√	√
Tisch *et al.* (20), 2017	√					√	√	√	
Chen *et al.* (21), 2020	√			√			√		
Demir & Batman (22), 2020	√						√	√	√
Demir & Batman (23), 2020	√	√	√	√					
Tisch *et al.* (24), 2020	√	√	√	√		√			
Toivonen *et al.* (25), 2021	√	√	√	√		√			
Howard *et al.* (26), 2021	√								
Oehlandt *et al.* (27), 2022		√				√	√		

Compl., complications; Otomic., otomicroscopy; Tymp., tympanometry; PTA, pure tone audiometry; TMM, tubomanometry; VM, Valsalva manoeuvre; Sx, symptoms; Sat., satisfaction; QOL, quality of life.

Table 4 No serious complications were reported after BDET in the included studies, but a summary of self-limiting adverse events is provided

Study	Events	N	Event rate (%)	Description
Maier *et al.* (17), 2015	0	66	0.0	–
Jenckel *et al.* (18), 2015	0	33	0.0	–
Leichtle *et al.* (19), 2017	4	52	7.7	Hemotympanum (n=1), epistaxis (n=3)
Tisch *et al.* (20), 2017	2	94	2.1	Hemotympanum (n=1), post-operative otalgia (n=1)
Chen *et al.* (21), 2020	3	25	12.0	Epistaxis (n=3)
Demir & Batman (22,23), 2020	2	30	6.7	Hemotympanum (n=2)
Tisch *et al.* (24), 2020	4	167	2.4	Epistaxis (n=4)
Toivonen *et al.* (25), 2021	2	26	7.7	Patulous ET (n=2)
Howard *et al.* (26), 2021	2	43	4.8	Epistaxis (n=1), vestibular migraine (n=1)

BDET, balloon dilation of the eustachian tube; ET, eustachian tube.

Removal after balloon deflation was consistent across all studies, and post-operative care was only reported in six studies. Four of these studies used a decongestant (17,22-24), two used nasal saline irrigation (22,23) and three used VMs (17,25,26). The timeframe for post-operative care varied among studies and is summarised in *Table 2*.

Parameters

Table 3 provides a summary of which parameters each study investigated, categorised into objective and subjective parameters. A systemic review was performed on all included studies, and meta-analyses were performed where possible.

Complications

No serious complications were reported in any of the studies (*Table 4*). The most common minor complications were self-limiting hemotympanum and epistaxis, with post-

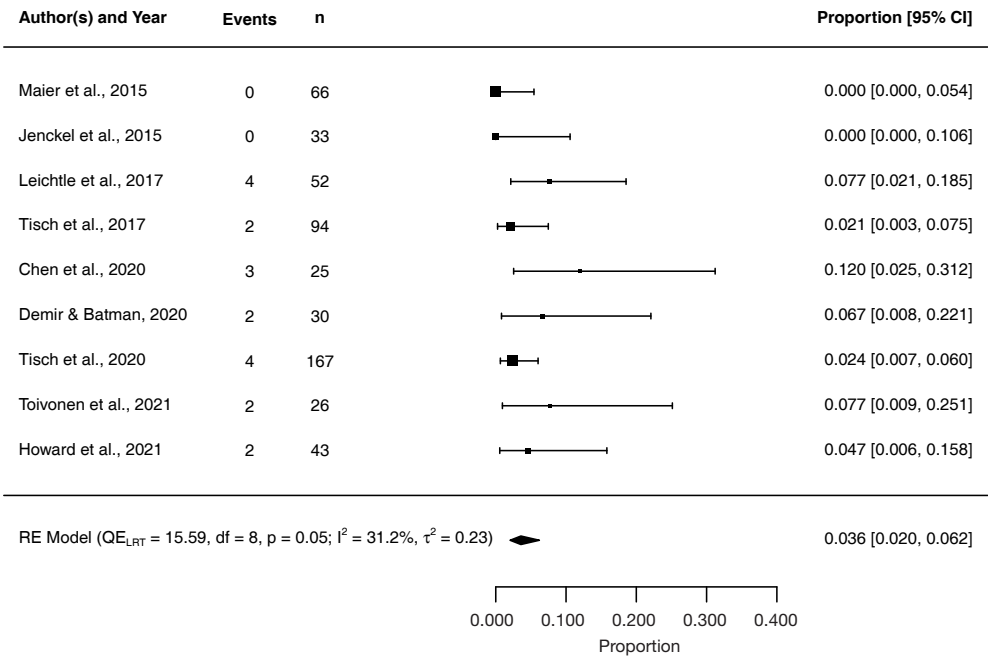

Figure 2 Forest plot for the estimated complication rate with BDET. The estimated rate was 3.6% (95% CI: 2.0% to 6.2%; P<0.001). CI, confidence interval; RE, random-effects; QE, Q-test for homogeneous effect sizes; LRT, likelihood ratio test; df, degree of freedom; BDET, balloon dilation of the eustachian tube.

operative otalgia, patulous ET and vestibular migraine being uncommon. The pooled estimate of the rate of complication was 3.6% (95% CI: 2.0% to 6.2%; P<0.001), as shown in *Figure 2*. The highest event rates were seen in studies with small sample sizes (19,21,24).

Otomicroscopy

Four studies (17,24,25,27) assessed otomicroscopic findings pre- and post-operatively, while Demir and Batman (23) compared post-operative otomicroscopy between BDET and VT groups (*Table 5*). The incidence of normal otomicroscopy was seen to improve post-BDET in three studies (17,24,25), but was not reported by Oehlandt *et al.* (27). The latter study only reported a lack of significant difference in the incidence of TM retraction after BDET. All other studies reported the incidence of OM, retraction, adhesions, effusions, atrophy, perforation and cholesteatoma to decrease after BDET. This estimated average odds ratio of OM and retraction before and after BDET were 0.0033 (95% CI: 0.0010 to 0.0115; P<0.001) and 0.0073 (95% CI: 0.0007 to 0.0735; P<0.001), respectively (*Figures 3,4*). This indicates that the prevalence of OM and retraction are estimated to be 99.7% and 99.3% lower after undertaking BDET, respectively. Unfortunately, meta-analyses could not be performed for the otomicroscopic findings of effusion, perforation and atelectasis as the model was unable to be fit.

The varying post-operative follow-up periods between studies suggest that improvement can be seen as early as 3 to 36 months post-procedure (*Table 5*). The mean post-operative follow-up period for Maier *et al.* (17) and Tisch *et al.* (24) was 96 days and 2.6 months respectively. Improvement in otomicroscopy findings was more pronounced in both these studies when compared to the 1-month post-operative results of Toivonen *et al.* (25). While the incidence of normal otomicroscopy for Toivonen *et al.* (25) increased at 1 month, the incidence of perforated TMs more than doubled. It was only at the 6-month mark that perforations reduced. Despite a high attrition rate (70.0%), the improvement in otomicroscopic findings appears to continue to 36 months (25).

Furthermore, the results of Demir and Batman (23) suggest that normal otomicroscopy was more prevalent after BDET (93%, n=30) than VT insertion (28%, n=32) at the 12-month follow-up (*Table 5*). The pre-operative breakdown of otomicroscopic findings was not provided for comparison.

Table 5 Summary of results for objective parameters from the included studies

Study	Parameters	Result	P
Maier *et al.* (17), 2015	Otomicroscopy	Increase in the incidence of normal TM (0% to 80%), with a correlating decrease in OM (14% to 0%), retraction/adhesions (37% to 6%), and tympanic effusions (49% to 14%), pre-operative n=84, post-operative n=66	NP
	Tympanometry	Increase in the incidence of type A (16% to 59%), with a correlating decrease in type B (65% to 27%) and type C (19% to 14%), pre-operative n=132, post-operative n=132	NP
	PTA	AC at 1 kHz decreased from 18.39±12.29 to 10.54±11.13 dB, pre-operative n=65, post-operative n=22	NP
	VM	Incidence of positive VM increased from 4% to 39%, n=39	NP
Jenckel *et al.* (18), 2015	TMM	No trend towards improvement of tube opening, n=33	NP
Leichtle *et al.* (19), 2017	Tympanometry	Increase in the incidence of type A (14% to 50%), with a correlating decrease in type B (56% to 26%) and type C (15% to 13%), pre-operative n=52, post-operative n=14	NP
	TMM	Improvement in tube opening from 19% pre-operative (n=52) to 58% at 2 months (n=38) and 46% at 12 months (n=14)	NP
	VM	Incidence of positive VM increased from 13% (n=52) to 60% at 6 months (n=27) and 12 months (n=14)	NP
Tisch *et al.* (20), 2017	VM	Incidence of positive VM increased from 9% to 82%, pre-operative n=60, post-operative n=60	NP
Chen *et al.* (21), 2020	PTA	Decrease in ABG was more significant at 18 months in BDET (30.33±7.51 to 11.30±7.41 dB, n=25) *vs.* VT (32.26±7.14 to 15.87±7.10 dB, n=24) group. There was no significant difference at 6 or 12 months	0.003
Demir & Batman (23), 2020	Otomicroscopy	Higher incidence of normal TM in BDET (93%) *vs.* VT (28%) group, with a correlating lower incidence of OM (7% *vs.* 34%), atrophy (0% *vs.* 16%), myringosclerosis (0% *vs.* 13%) and perforation (0% *vs.* 9%), BDET n=30, VT n=32	NP
	Tympanometry	Higher incidence of type A in the BDET (93%) *vs.* VT (65%) group, with a correlating lower incidence of type B (3% *vs.* 22%) and type C (3% *vs.* 13%), BDET n=30, VT n=32	NP
	PTA	Greater decrease in ABG in BDET (27.6±7.6 to 9.6±3.6 dB) *vs.* VT (25.6±6.1 to 17.6±8.4 dB) group, BDET n=30, VT n=32	0.043
Tisch *et al.* (24), 2020	Otomicroscopy	Increase in the incidence of normal TM (1% to 72%), with a correlating decrease in OM (11% to 3%), effusion (47% to 12%), and retraction (41% to 14%), pre-operative n=285, post-operative n=274	<0.001
	Tympanometry	Increase in the incidence of type A (13% to 56%), with a correlating decrease in type B (60% to 29%) and type C (27% to 15%), pre-operative n=258, post-operative n=209	<0.001
	PTA	AC at 1 kHz decreased from 20±9 to 10±7 dB, pre-operative n=285, post-operative n=196	<0.001
	VM	Incidence of positive VM increased from 13% to 60%, pre-operative n=132, post-operative n=126	NP

Table 5 *(continued)*

Table 5 *(continued)*

Study	Parameters	Result	P
Toivonen *et al.* (25), 2021	Otomicroscopy	Increase in the incidence of normal TM at 1 month (17%, n=42), 6 months (38%, n=39), 12 months (55%, n=29), 24 months (68%, n=19), and 36 months (93%, n=14) compared to pre-operative (9%, n=46), with a correlating decrease in perforation, retraction, effusion and atelectasis	<0.001
	Tympanometry	Increase in the incidence of type A at 6 months (50%, n=30), 12 months (59%, n=27), 24 months (53%, n=17), and 36 months (85%, n=13) compared to pre-operative (23%, n=40), with a correlating decrease in type B and C. There was no change at 1 month (24%, n=25)	<0.001
	PTA	Decrease in ABG from pre-op (17.5±11.9 dB, n=46) to 1 month (8.5±9.5 dB, n=42), 6 months (10.8±10.8 dB, n=39), 12 months (12.4±9.2 dB, n=29), 24 months (11.5±7.7 dB, n=17), and 36 months (5.7±4.8 dB, n=14). Decrease in AC from pre-operative (21.9±13.2 dB) to 1 month (14.3±9.1 dB), 6 months (19.5±10.6 dB), 12 months (17.6±11.2 dB), 24 months (14.8±8.7 dB), and 36 months (12.4±4.9 dB) in the same groups of patients	<0.001
	VM	Incidence of positive VM increased from pre-operative (27%, n=15) to 1 month (56%, n=16), 6 months (50%, n=10), 12 months (91%, n=11), 24 months (100%, n=6), and 36 months (100%, n=3)	<0.001
Oehlandt *et al.* (27), 2022	Otomicroscopy	No significant difference in the incidence of TM retraction, effusion or perforation after BDET, n=23	>0.05
	VM	No significant difference in the incidence of a positive VM after BDET, n=9	>0.05

TM, tympanic membrane; OM, otitis media; NP, not performed; PTA, pure tone audiometry; AC, air conduction; VM, Valsalva manoeuvre; TMM, tubomanometry; ABG, air-bone gap; BDET, balloon dilation of the eustachian tube; VT, ventilation tube insertion.

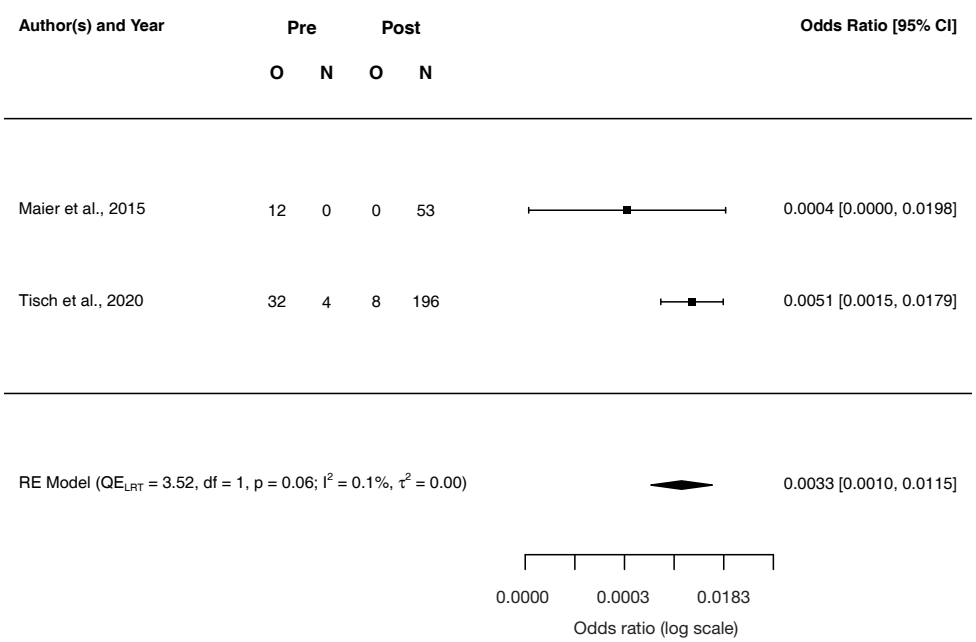

Figure 3 Forest plot for the estimated odds ratio for the prevalence of otitis media before and after BDET. The estimated average odds ratio was 0.0033 (95% CI: 0.0010 to 0.0115; P<0.001). O, otitis media; N, normal; CI, confidence interval; RE, random-effects; QE, Q-test for homogeneous effect sizes; LRT, likelihood ratio test; df, degree of freedom; BDET, balloon dilation of the eustachian tube.

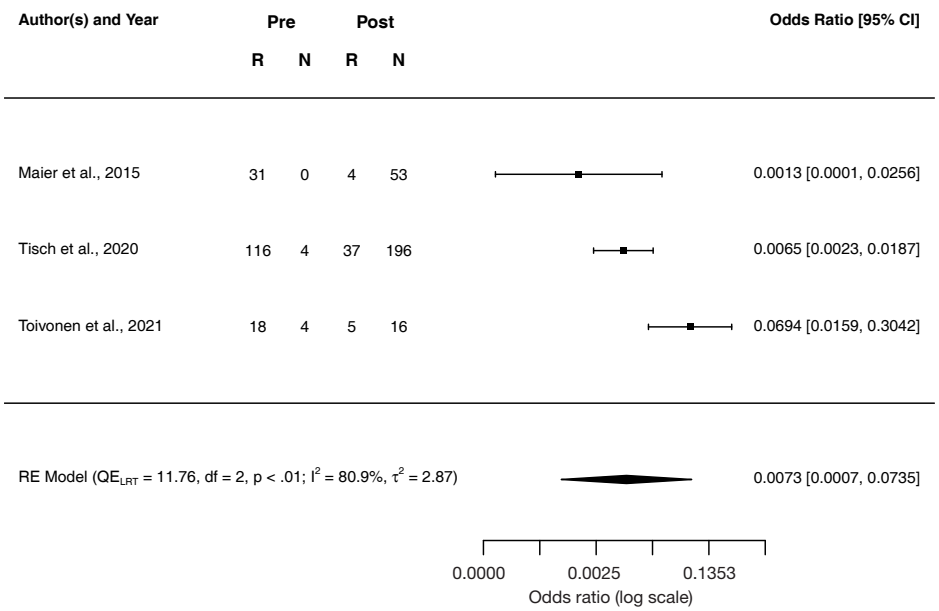

Figure 4 Forest plot for the estimated odds ratio for the prevalence of retraction before and after BDET. The estimated average odds ratio was 0.0073 (95% CI: 0.0007 to 0.0735; P<0.001). R, retraction; N, normal; CI, confidence interval; RE, random-effects; QE, Q-test for homogeneous effect sizes; LRT, likelihood ratio test; df, degree of freedom; BDET, balloon dilation of the eustachian tube.

Tympanometry

Five studies assessed tympanometry (17,19,23-25), with Toivonen *et al.* (25) providing the most detailed post-operative analysis (*Table 5*). While models could not be fit to perform a meta-analysis, all studies found an increase in the incidence of type A tympanograms post-BDET, with a corresponding decrease in type B and C tympanograms. Toivonen *et al.*'s (25) study suggests that type C tympanograms convert to type B as early as 1-month post-operative, but it takes up to 6 months to see a conversion to type A tympanograms. Furthermore, Demir and Batman (23) found that type A tympanograms were more common after BDET (93%, n=30) than VT insertion (66%, n=32) at 12 months. However, pre-operative tympanogram findings were not available for comparison.

PTA

Five studies assessed PTA, where two studies measured air conduction (AC) (17,24), two studies measured air-bone gap (ABG) (21,23), and one study measured both (25) (*Table 5*). The frequency (1 kHz) was specified for only two studies (17,24). BDET was observed to reduce AC by a mean of 8.95 dB (95% CI: −6.84 to 11.06; P<0.001), and ABG by a mean of 14.23 dB (95% CI: 5.63 to 22.83; P<0.001) (*Figures 5,6*). Toivonen *et al.* (25) found the decrease to arise from as early as 1-month and continue until at least 36-month post-operative (P<0.001). Demir and Batman (23) compared BDET with VT insertion, where both BDET and VT insertion groups had statistically significant decreases in ABG at 12 months (P<0.05); the decrease was considerably more efficacious in the BDET group (P<0.05).

Tubomanometry

Two studies assessed tubomanometry over time. Jenckel *et al.* (18) found no consistent trend in results, while Leichtle *et al.* (19) found a reduction in obstructed ETs and an increase in tube opening (*Table 5*). Trends were mild at 2-week post-operative, but become significant at 2 months.

Valsalva

Five of six studies (17,19,20,24,25) found the incidence of a positive VM to improve after BDET, with Oehlandt *et al.* (27) the only study to find no difference with a small sample size of n=9 (*Table 5*). The estimated average odds ratio for the prevalence of an abnormal VM before and

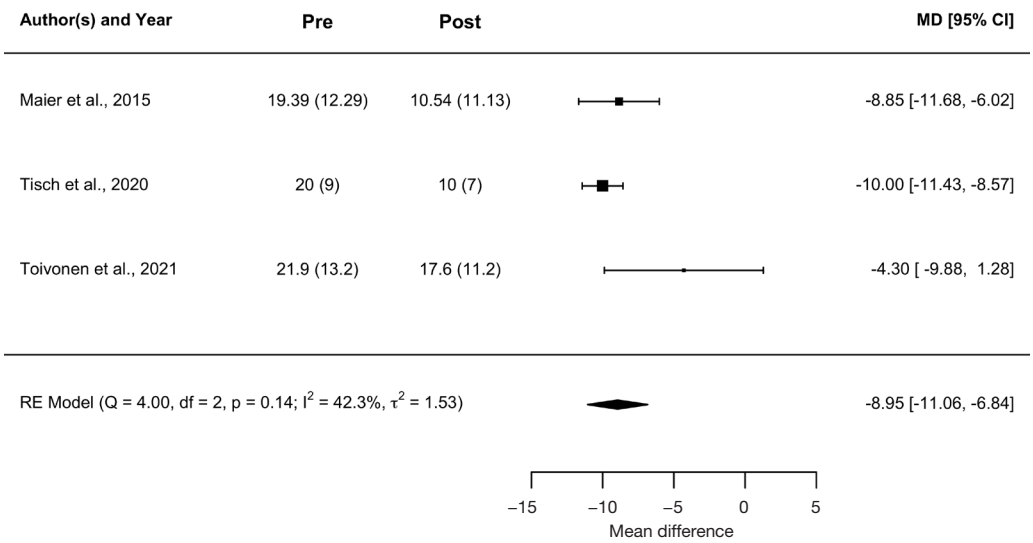

Figure 5 Forest plot for the estimated mean difference in AC before and after BDET. The estimated difference was −8.95 dB (95% CI: −11.06 to −6.84; P<0.001). Pre, pre-operative; post, post-operative; MD, mean difference; CI, confidence interval; RE, random-effects; Q, Q-test for homogeneous effect sizes; df, degree of freedom; AC, air conduction; BDET, balloon dilation of the eustachian tube.

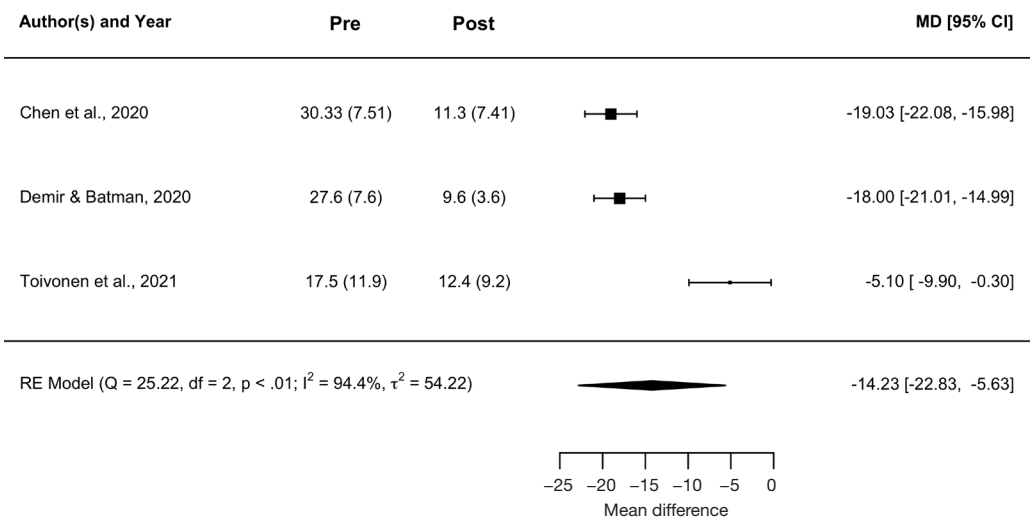

Figure 6 Forest plot for the estimated mean difference in ABG before and after BDET. The estimated difference was −14.23 dB (95% CI: −22.83 to −5.63; P<0.001). Pre, pre-operative; post, post-operative; MD, mean difference; CI, confidence interval; RE, random-effects; Q, Q-test for homogeneous effect sizes; df, degree of freedom; ABG, air-bone gap; BDET, balloon dilation of the eustachian tube.

after BDET was 0.041 (95% CI: 0.019 to 0.086, P<0.001), suggesting the procedure improves pressure equalisation by an average of 95.9% (*Figure 7*). The improvement was seen as early as 2 weeks post-operative by Leichtle *et al.* (19), and continued for as long as 36 months post-operative with Toivonen *et al.*'s (25) study (*Table 5*).

Symptoms, satisfaction, and QOL

Five studies (18-21,26) assessed the prevalence of ear-related symptoms prior to and after BDET. Although none of the studies used validated questionnaires, an improvement was seen in the frequency of hearing loss, otalgia, ear pressure, and otalgia from as early as 2 weeks post-operative (*Table 6*).

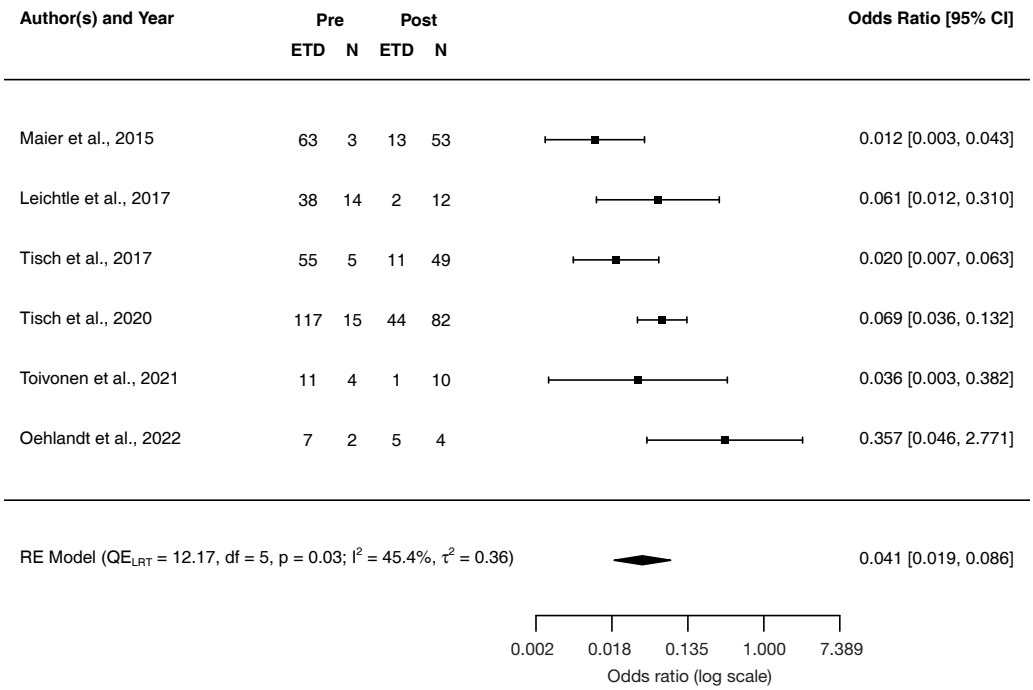

Figure 7 Forest plot for the estimated average odds ratio for the prevalence of an abnormal VM before and after BDET. The estimated average odds ratio was 0.041 (95% CI: 0.019 to 0.086; P<0.001). Pre, pre-operative; post, post-operative; ETD, eustachian tube dysfunction (abnormal VM); N, normal VM; VM, Valsalva manoeuvre; CI, confidence interval; RE, random-effects; QE, Q-test for homogeneous effect sizes; LRT, likelihood ratio test; df, degree of freedom; BDET, balloon dilation of the eustachian tube.

This improvement continued until 15 months (18), after which no data was available. Oehlandt *et al.* (27) obtained mixed results, finding recurrences of acute OM to cease in 12 of 14 children, but the incidence of aural fullness, otalgia, and hearing loss to be unchanged after BDET.

Three studies (17,19,20) assessed the satisfaction of patients after the procedure, all finding >70% of patients to be either satisfied or very satisfied post-BDET (*Table 6*). Leichtle *et al.* (19) was the only study to assess the satisfaction and limitation in activities of daily living (LADLs) over time, finding satisfaction to remain >70% from 2 weeks post-operative and LADLs to decrease from 2 months post-operative. Lastly, Demir and Batman (22) used OM-6, a validated questionnaire about symptoms, satisfaction, and QOL, where a lower score represents a better outcome. BDET was observed to outperform VT (P<0.05) insertion at 6 months (15±6 *vs.* 18±7), but was equivalent at 12 months (8±2 *vs.* 8±2).

Validity assessment

An overview of the validity assessment is provided in *Table 7*. The overall risk of bias was evaluated to be low across all the included studies. However, several studies had moderate risk in one or more domains. Firstly, attrition over the follow-up period was moderate in three studies (19,20,25). This could not be assessed for Jenckel *et al.* [2015] and Oehlandt *et al.* (27) as sample sizes were not reported over the follow-up period. Additionally, the risk of selective reporting was moderate for two studies. Oehlandt *et al.*'s (27) study included adults and children, but only some of the outcomes were segregated for children. Toivonen *et al.* (25), on the other hand, had a control group where they assessed the number of failed procedures and the 2-year failure-free probability, but no other objective or subjective outcomes were reported from this control group. No explanations were provided for the omission in either paper.

Discussion

ETD constitutes a large number of visits to healthcare practitioners for both adults and children. The exact pathophysiology is yet to be elucidated, but microbial overload, anatomical obstruction and negative pressure

Table 6 Summary of results for subjective parameters from the included studies

Study	Parameters	Result	P
Maier *et al.* (17), 2015	Satisfaction	Patients rated their satisfaction as very satisfied (65%), satisfied (21%), neutral (14%), and unsatisfied (0%), n=66	NP
Jenckel *et al.* (18), 2015	Sx	Incidence of hearing loss reduced from pre-operative (21/25) to 1 month (6/15) and 15 months (4/11). Otalgia (5/19 to 2/9 to 1/13) and otorrhea (7/20 to 1/10 to 2/13) also reduced at the same timeframes	NP
Leichtle *et al.* (19), 2017	Sx	Incidence of hearing loss reduced from pre-operative (37%) to 2 weeks (32%), 2 months (10%), 6 months (9%), and 12 months (8%). Ear pressure (84%, 44%, 16%, 9%, 12%) and otalgia (21%, 7%, 5%, 8%, 10%) also reduced at the same timeframes	NP
	Satisfaction	Patient satisfaction increased from pre-operative (0%, n=52) to 2 weeks (72%), 2 months (76%), 6 months (68%), and 12 months (72%)	NP
	QOL	LADLs decreased from pre-operative (60%) to 54%, 14%, 16% and 18% at the same timeframes and sample sizes as the satisfaction data	NP
Tisch *et al.* (20), 2017	Sx	Hearing loss improved in 76% of patients, n=34	NP
	Satisfaction	Patients rated their satisfaction as very satisfied (56%), satisfied (26%), neutral (15%), and unsatisfied (3%), n=34	NP
Chen *et al.* (21), 2020	Sx	Incidence of complete symptom resolution was 35% in the BDET group and 28% in the VT group	0.116
Demir & Batman (22), 2020	Sx/satisfaction/ QOL	OM-6 questionnaire scores were significantly reduced from pre-operative (BDET 31±5 *vs.* VT 29±4) to 6 months (BDET 15±6 *vs.* VT 18±7) and 12 months (BDET 8±2 *vs.* VT 8±2) (P<0.001). The reduction was greater in the BDET group at 6 months (P=0.018) but not 12 months (P=0.510)	0.018
Oehlandt *et al.* (27), 2022	Sx	Incidence of aural fullness, otalgia and hearing loss was unchanged after BDET. However, recurrences of acute OM reportedly ceased in 12/14 children	0.001

NP, not performed; Sx, symptom; QOL, quality of life; LADLs, limitation in activities of daily living; OM, otitis media; BDET, balloon dilation of the eustachian tube; VT, ventilation tube insertion.

appear to play key roles (28). These are emphasised in children, who contribute 1.3 healthcare visits to every one adult visit (29). Children have shorter and more horizontal tubes, allowing pathogens and nasopharyngeal secretions to ascend easily into the middle ear. This is combined with a "floppy" cartilaginous tube that has reduced elastin and therefore restricted tube opening. Larger adenoids close to the tubal ostium can also limit the drainage of secretions (30). Although negative pressure was thought to be a by-product of hypertrophic adenoids, this does not explain the incidence of retracted TMs in patients who have undergone adenoidectomies and VT insertions. It has been postulated that chronic inflammation of the tensor tympani may be an additional factor that causes negative pressure through retraction of the malleus (28). This aetiology in children appears to be driven by developmental factors, whereas adult ETD is more commonly linked to allergic rhinitis and laryngoesophageal reflux (30,31).

BDET is becoming an increasingly popular therapy in adults who have failed standard medical and surgical therapy. However, anatomical differences in the ET of children have limited its use in this population. This review provides quantitative and qualitative evidence to support the use of BDET in children, building on the works of Saniasiaya *et al.* (14) and Aboueisha *et al.* (15). Saniasiaya *et al.* (14) performed a systematic review of seven studies published up to December 2020, focussing on the indications for BDET and associated complications, while touching briefly on outcomes. Comparatively, Aboueisha *et al.* (15) performed a meta-analysis of seven studies, collating data on complications, tympanometry and PTA. This is the first study to comprehensively synthesise data across a large number of objective and subjective outcomes.

The mechanism by which BDET works is relatively

Table 7 Validity assessment based on the ROBINS-I tool

Study	ROBINS-I							
	I	II	III	IV	V	VI	VII	Overall
Maier *et al.* (17), 2015	Low	Low	Low	Low	Low	Low	Low	Low
Jenckel *et al.* (18), 2015	Low	Low	Low	Low	NI	Low	Moderate	Low
Leichtle *et al.* (19), 2017	Low	Low	Low	Low	Moderate	Low	Low	Low
Tisch *et al.* (20), 2017	Low	Low	Low	Low	Moderate	Low	Low	Low
Chen *et al.* (21), 2020	Low	Low	Low	Low	Low	Low	Low	Low
Demir & Batman (22), 2020	Low	Low	Low	Low	Low	Low	Low	Low
Demir & Batman (23), 2020	Low	Low	Low	Low	Low	Low	Low	Low
Tisch *et al.* (24), 2020	Low	Low	Low	Low	Low	Low	Low	Low
Toivonen *et al.* (25), 2021	Low	Low	Low	Low	Moderate	Low	Moderate	Low
Howard *et al.* (26), 2021	Low	Low	Low	Low	Low	Low	Low	Low
Oehlandt *et al.* (27), 2022	Low	Low	Low	Low	Low	Low	Moderate	Low

ROBINS-I tool evaluates the risk of bias related to (I) confounding, (II) selection of participants, (III) classification of interventions, (IV) deviations from intended interventions, (V) missing data, (VI) measurement of outcomes, and (VII) selective reporting. Overall bias is also included in the final column. Each domain is evaluated as low, moderate, serious, critical or no information. ROBINS-I, Risk Of Bias In Non-randomized Studies of Interventions.

unknown, but is thought to be due to elastic deformation of the ET. In the short term, dilation of the ET causes mucosal tears and cracks in the cartilage (32). As low compliance is a feature of OETD, the subsequent increase in compliance post-procedure improves the functional obstruction and tube opening (33). In the long term, damage to the mucosa and submucosa induces regeneration of healthy ciliated pseudo-columnar epithelium. The damage appears to extend to the inflamed cell lining that comprises macrophages, lymphocytes, and lymphoid follicles, reducing the inflammatory burden (32). This correlates with reduced mucosal inflammation observed after BDET (25,34).

The predominance of research uses BDET in patients who have OETD refractory to standard medical and surgical treatment, a trend also seen in publications in this review. Demir and Batman (23) was the only study to assess BDET as a first-line surgical procedure in children, demonstrating better outcomes to VT insertion in otomicroscopy, tympanometry and PTA. A subjective assessment of ear-related symptoms, satisfaction and QOL through the OM-6 questionnaire was also more improved at 6-month, but became equivalent at 12 months. One study, however, is not sufficient to guide evidence-based management, and neither is data from uncontrolled studies. Extrapolating from adult RCTs, Siow and Tan (35) recommend BDET in patients who have aural fullness >12 weeks, a type B or C tympanogram, a score ≥2 on the Eustachian Tube Dysfunction Questionnaire (ETDQ-7), no improvement with VMs, and failure of either nasal steroids for 4 weeks or oral steroids for 1 week. Being refractory to surgical management is not a component of this indication criteria, but the recommendation was only based on two RCTs and would need further assessment in children.

In terms of the BDET procedure, the balloon catheter was dilated with 10 bars of pressure for two minutes in most studies. Demir and Batman (23) and Howard *et al.* (26) were the only studies that repeated dilation before catheter removal. However, Demir and Batman (23) compared BDET with VT insertion rather than pre-operative measures, and Howard *et al.* (26) only assessed the frequency of complications. As comparative data is not available in adult studies either, further research would be required to elucidate whether two dilations within a single procedure improves outcomes.

Interestingly, most studies used adult balloon catheters to perform BDET in children. The most common applicator system in the included studies was from Spiggle & Theis (18,19,21-24,27), which contrasts to the Stryker system being the most common in Australia. Other companies include AERA (25,26), Bielefeld (17), and Karl Storz (25).

Jenckel *et al.* (18) was the only study to use customised insertion parts that were thinner, but the angles and length of the catheter were the same. No complications were observed in their study, but Maier *et al.* (17) and Toivonen *et al.* (25) also reported no complications with entirely adult equipment. Moreover, the complications described in other studies were minor and self-limiting. Overall, this would suggest that adult catheters are safe and effective in children.

The use of adult catheters in children conforms with Magro *et al.*'s (1) computed tomography (CT) study that found the 95% CI for cartilaginous ET length to be 19–21 mm in children ≤4 years old and 24–25 mm in children 5–7 years old. Despite the Spiggle and Theis balloon being 20 mm in length, it was used on children as young as 2 years old without any serious complications. Nevertheless, the AREA catheter would be more appropriate for children ≤4 years old as its balloon length is 16 mm. No lengths could be obtained for Bielefeld and Karl Storz catheters. Furthermore, the horizontal angle of the ET only increases by an average of 7° from patients ≤4 years old (17°) to >18 years old (24°) (1). As most companies offer a range of catheter angles, there would be no requirement to customise this for children. In the case that the catheter is too acutely angled, a transoral approach can be used as described by Toivonen *et al.* (25).

Overall, BDET was found to be effective in both objective and subjective parameters. Firstly, no serious complications were reported in any of the studies. The estimated event rate for minor complications (3.6%; 95% CI: 2.0% to 6.2%; P<0.001) was comparable to Aboueisha *et al.*'s (15) meta-analysis (5.1%; 95% CI: 3.2% to 8.1%; P<0.001), representing self-limiting epistaxis, hemotympanum and otalgia. Substantial improvements were noted in otomicroscopy, tympanometry, PTA and VMs when comparing pre-operative and post-operative results. These findings also aligned with Aboueisha *et al.* [2022], which found a 48.1% reduction in type B tympanograms (64.2% pre-operative *vs.* 16.1% post-operative) and a 59.7% reduction in ABG (25.3 dB pre-operative *vs.* 10.2 dB post-operative) on PTA. In contrast, tubomanometry was only seen to improve in Leichtle *et al.*'s (19) study, with Jenckel *et al.* (18) observing no trend. The utility of tubomanometry has been promising in adults, including patients with OM (36). Yet, Jenckel *et al.* (18) and Leichtle *et al.* (19) are the only studies to assess this technique in children. Jenckel *et al.* (18) claims that low compliance, narrow anatomy and excess mucous may cause inaccuracies in children. However, clear trends in Leichtle *et al.*'s (19) research suggests that this may not be the case. Further evaluation of tubomanometry in children is needed before evaluating its utility.

Improvements were also noted in ear-related symptoms and QOL, with the majority of patients (or their parents) reporting satisfaction with the procedure. These trends were only observed through non-validated questionnaires, with Demir and Batman (23) being the only study to use a validated questionnaire (OM-6). While the latter found a statistically significant reduction in OM-6 score post-operatively, they did not segregate data into the parameters described above. The OM-6 questionnaire is currently the only validated ETD questionnaire for children (37). While the ETDQ-7 is commonly used, it has only been validated in adults (38,39).

Furthermore, Demir and Batman (23) was the only study to assess BDET as first-line surgical management. Comparing its efficacy to VT insertion, BDET was found to be superior in otomicroscopy, tympanometry, and PTA. The OM-6 score was also found to be lower at 6 months, but became equivocal at 12 months. The results suggest that BDET may be an effective first-line surgical procedure for children refractory to medical therapy. However, as with most findings in this review, further research with prospective trials would be needed to validate this indication.

Strengths & limitations

As mentioned previously, this systematic review and meta-analysis is more comprehensive than previous publications, encompassing a larger number of objective and subjective parameters across a greater number of studies to strongly support the safety of BDET in children. This review provides a strong platform to setup prospective studies and randomised Controlled trial of BDET in children.

In spite of this, several key limitations hinder its ability to draw robust conclusions. Firstly, the reliance on a small sample size of only 11 studies raises concerns about the generalizability of findings, limiting the strength of any conclusions. Moreover, most of the included studies are retrospective case series without control groups or historic cohort studies, which are inherently susceptible to bias and confounding variables. Additionally, the variations in follow-up periods across these studies create challenges when trying to assess the effect size at different time points, making it difficult to draw a clear temporal relationship between interventions and outcomes. Heterogeneity among

objective outcome measures also poses a challenge. Due to small number of studies, moderator analyses could not be performed for otomicroscopic retraction and ABG, both showing heterogeneity >50%. Lastly, the lack of a validated questionnaire to assess ETD-related symptoms and QOL in children underscores the reliability of the subjective outcomes. These limitations highlight the need for more rigorous and standardized research in this area to draw more robust conclusions regarding the effectiveness of BDET in children.

Conclusions

BDET is a safe and potentially effective procedure for the treatment of OETD. No serious complications have been reported in the literature, with most adverse events being self-limiting epistaxis and hemotympanum. Post-operative improvements were seen in otomicroscopy, tympanometry, PTA, pressure equalisation through VMs, and questionnaires relating to symptoms, satisfaction, and QOL. The findings for tubomanometry were less convincing with only one of two studies observing a positive trend in tube opening. As the current body of evidence is based on retrospective case series and historic cohort studies, further research in the form of prospective cohort studies and RCTs would be needed before BDET can be recommended as evidence-based management. Future research should also assess the utility of tubomanometry as an objective parameter, investigate BDET as first-line surgical management, and use validated questionnaires for subjective evaluation.

Acknowledgments

Our sincere thanks to Joshua Knowles and Dr. Farah Zahir from the Queensland Cyber Infrastructure Foundation Facility for Advanced Bioinformatics for conducting statistical analyses for the meta-analysis.

Footnote

Reporting Checklist: The authors have completed the PRISMA reporting checklist. Available at https://www.theajo.com/article/view/10.21037/ajo-23-38/rc

Peer Review File: Available at https://www.theajo.com/article/view/10.21037/ajo-23-38/prf

Funding: None.

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://www.theajo.com/article/view/10.21037/ajo-23-38/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) (ID: CRD42023430248). Because of the retrospective nature of the research, the requirement for informed consent was waived.

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doi: 10.21037/ajo-23-38
Cite this article as: Ramagiri B, Lynch A, Lloyd G, Chang A. Outcomes after balloon dilation of the eustachian tube in children: a systematic review and meta-analysis. Aust J Otolaryngol 2024;7:10.

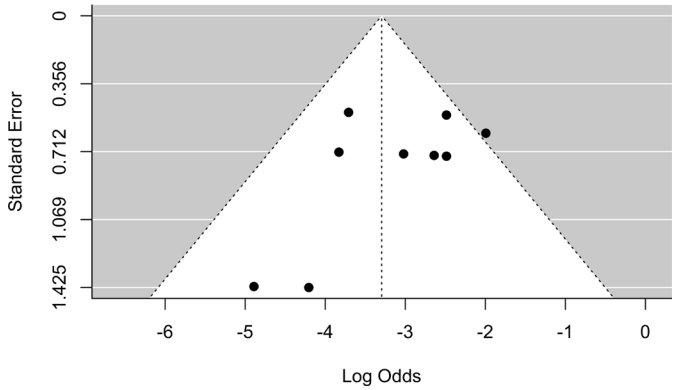

Figure S1 Funnel plot for the estimated complication rate with BDET. The I^2 value (31.2%) and test for heterogeneity suggested moderate significant heterogeneity among the studies (Q=15.59; df =8; P=0.05). BDET, balloon dilation of the eustachian tube; df, degree of freedom.

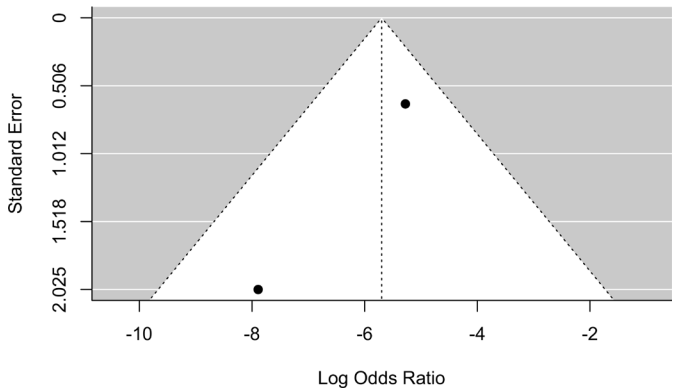

Figure S2 Funnel plot for the estimated odds ratio for the prevalence of OM before and after BDET. The I^2 value (0.1%) and test for heterogeneity suggested low non-significant heterogeneity among the studies (Q=3.52; df =1; P=0.06). OM, otitis media; BDET, balloon dilation of the eustachian tube; df, degree of freedom.

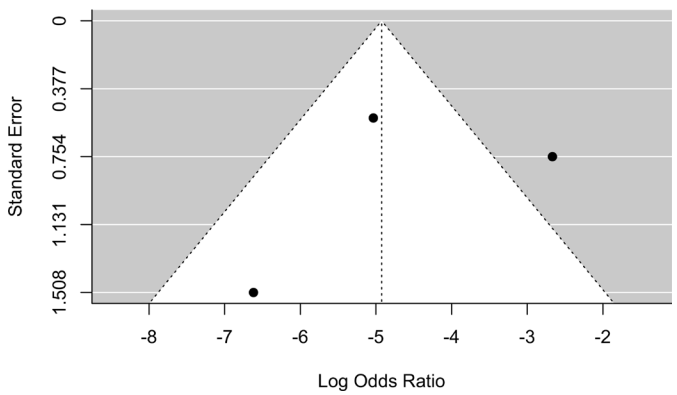

Figure S3 Funnel plot for the estimated odds ratio for the prevalence of retraction before and after BDET. The I^2 value (80.9%) and test for heterogeneity suggested high significant heterogeneity among the studies (Q=11.76; df =2; P<0.01). BDET, balloon dilation of the eustachian tube; df, degree of freedom.

https://dx.doi.org/10.21037/ajo-23-38

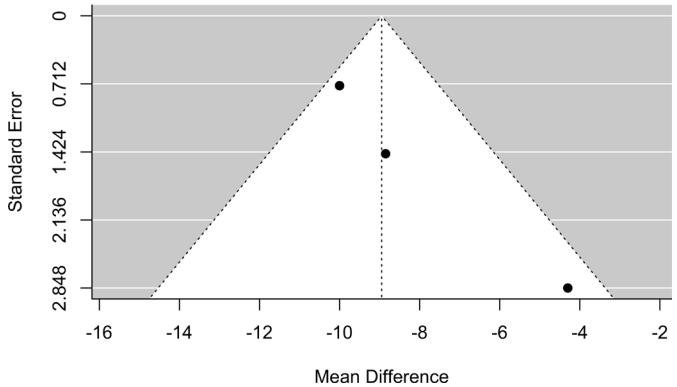

Figure S4 Funnel plot for the estimated mean difference in AC before and after BDET. The I^2 value (42.3%) and test for heterogeneity suggested moderate non-significant heterogeneity among the studies (Q=4.00; df =2; P=0.14). AC, air conduction; BDET, balloon dilation of the eustachian tube; df, degree of freedom.

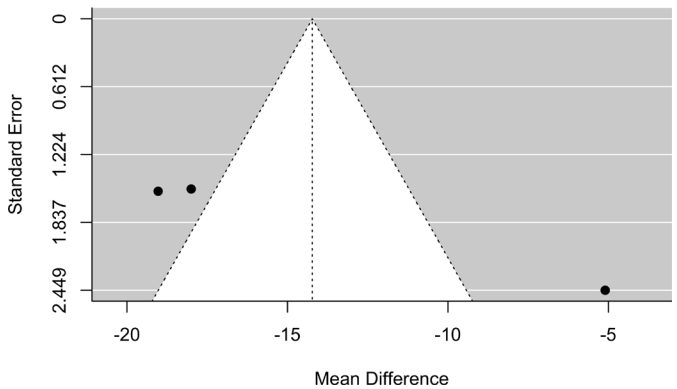

Figure S5 Funnel plot for the estimated mean difference in ABG before and after BDET. The I^2 value (94.4%) and test for heterogeneity suggested high significant heterogeneity among the studies (Q=25.22; df =2; P<0.01). ABG, air-bone gap; BDET, balloon dilation of the eustachian tube; df, degree of freedom.

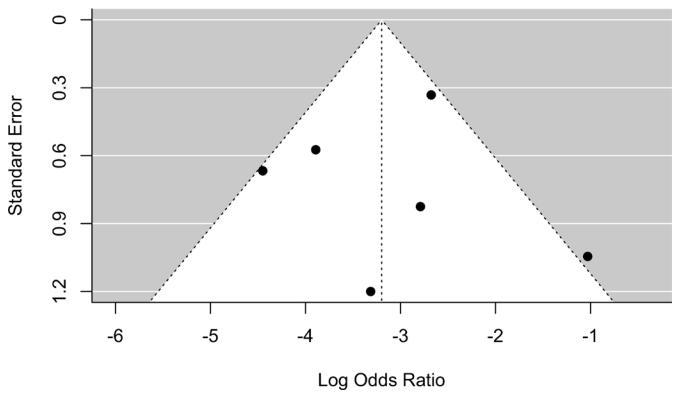

Figure S6 Funnel plot for the estimated average odds ratio for the prevalence of an abnormal VM before and after BDET. The I^2 value (45.4%) and test for heterogeneity suggested moderate significant heterogeneity among the studies (Q=12.17; df =5; P=0.03). VM, Valsalva manoeuvre; BDET, balloon dilation of the eustachian tube; df, degree of freedom.

https://dx.doi.org/10.21037/ajo-23-38

Table S1 Search strategy

Database	Search strategy	Number of results
CINAHL	1. TI (balloon OR balloons OR tuboplasty OR tuboplasties OR endonasal) OR AB (balloon OR balloons OR tuboplasty OR tuboplasties OR endonasal)	30
	2. MH “dilatation” OR TI dilat* OR AB dilat*	
	3. MH “eustachian tube” OR TI (“auditory tube” OR “eustachian tube” OR “pharyngotympanic tube”) OR AB (“auditory tube” OR “eustachian tube” OR “pharyngotympanic tube”)	
	4. MH “child” OR MH “preschool child” OR MH “adolescent” OR MH “pediatric” OR TX (child* OR paediatric* OR pediatric* OR “school age*”)	
Cochrane	1. (balloon OR balloons OR tuboplasty OR tuboplasties OR endonasal):ti,ab,kw	12
	2. MeSH descriptor: [Dilatation] explode all trees	
	3. (dilat*):ti,ab,kw	
	4. #2 OR #3	
	5. MeSH descriptor: [Eustachian Tube] explode all trees	
	6. (auditory tube* OR eustachian tube* OR pharyngotympanic tube*):ti,ab,kw	
	7. #5 OR #6	
	8. MeSH descriptor: [Child] explode all trees	
	9. MeSH descriptor: [Child, Preschool] explode all trees	
	10. MeSH descriptor: [Adolescent] explode all trees	
	11. MeSH descriptor: [Pediatrics] explode all trees	
	12. (child* OR pediatric* OR paediatric* OR school age*)	
	13. #8 OR #9 OR #10 OR #11 OR #12	
	14. #1 AND #4 AND #7 AND #13	
Embase	1. balloon:ab,ti OR balloons:ab,ti OR tuboplasty:ab,ti OR tuboplasties:ab,ti OR endonasal:ab,ti	68
	2. ‘dilatation’/exp OR dilat*:ab,ti	
	3. ‘eustachian tube’/exp OR ‘auditory tube’:ab,ti OR ‘eustachian tube’:ab,ti OR ‘pharyngotympanic tube’:ab,ti	
	4. ‘child’/exp OR ‘preschool child’exp OR ‘adolescent’/exp OR ‘pediatric’/exp OR child* OR paediatric* OR pediatric* OR ‘school age*’	
MEDLINE	1. TI (balloon OR balloons OR tuboplasty OR tuboplasties OR endonasal) OR AB (balloon OR balloons OR tuboplasty OR tuboplasties OR endonasal)	63
	2. MH “dilatation” OR TI dilat* OR AB dilat*	
	3. MH “eustachian tube” OR TI (“auditory tube” OR “eustachian tube” OR “pharyngotympanic tube”) OR AB (“auditory tube” OR “eustachian tube” OR “pharyngotympanic tube”)	
	4. MH “child” OR MH “preschool child” OR MH “adolescent” OR MH “pediatric” OR TX (child* OR paediatric* OR pediatric* OR “school age*”)	
PubMed	1. Balloon[tiab] OR balloons[tiab] OR tuboplasty[tiab] OR tuboplasties[tiab] OR endonasal[tiab]	47
	2. Dilatation[MeSH] OR dilat*[tiab]	
	3. Eustachian tube[MeSH] OR auditory tube*[tiab] OR eustachian tube*[tiab] OR pharyngotympanic tube*[tiab]	
	4. Child[MeSH] OR child, preschool[MeSH] OR adolescent[MeSH] OR pediatric[MeSH] OR child*[text] OR pediatric*[text] OR paediatric*[text] OR school age*[text]	
Scopus	1. TITLE-ABS-KEY (balloon OR balloons OR tuboplasty OR tuboplasties OR endonasal)	133
	2. INDEXTERMS (dilatation) OR TITLE-ABS-KEY (dilat*)	
	3. INDEXTERMS (“eustachian tube”) OR TITLE-ABS-KEY (“auditory tube” OR “eustachian tube” OR “pharyngotympanic tube”)	
	4. INDEXTERMS (“child”) OR INDEXTERMS (“preschool child”) OR INDEXTERMS (“adolescent”) OR INDEXTERMS (“pediatric”) OR (child* OR paediatric* OR pediatric* OR “school age*”)	

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