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Balloon Eustachian Tuboplasty: A Systematic Review

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Abstract

Objective. A systematic review and meta-analysis of the evidence on balloon Eustachian tuboplasty (BET) as a treatment modality for Eustachian tube dysfunction (ETD). We followed the PRISMA guideline and registered with PROSPERO No. CRD42014009461.

Data Sources. We searched 12 databases including PubMed and Embase from January 1, 2010, to April 7, 2014, for studies of BET. Endpoints: change in symptoms, middle ear pathology, eardrum status, Eustachian tube function tests, hearing, adverse events, complications, and health-related quality of life.

Review Methods. Study quality was assessed using the modified Delphi technique quality appraisal tool for case series studies. Risk of bias was assessed using the Cochrane Collaboration's tool for assessing risk of bias.

Results. Nine case series studies with 443 patients (642 tubes) were included. Population size n = 4 (7 tubes) to n = 210 (320 tubes). All studies were of poor quality and featured a high risk of bias. We found reduction of patient symptoms in ETD questionnaire ($P < .001$), postoperative normalization of the tympanic membrane, conversion of type B or type C into type A tympanograms, reduced mucosal inflammation, increased number of positive Valsalva test and Swallowing tests, improvement in Eustachian tube score, reduction in Sino-Nasal Outcome Test (SNOT)-22 score ($P = .001$), and increased quality of life ($P = .001$). No serious adverse events were found.

Conclusion. The evidence of BET is poor and biased. No firm conclusions can be made to identify patients who will benefit from the procedure or to accurately predict surgical results. Randomized controlled trials or case-control trials are needed.

Keywords

Eustachian tube, Eustachian tube dysfunction, balloon Eustachian tuboplasty, otology, surgery, systematic review

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Introduction

Eustachian tube dysfunction (ETD) is a frequent diagnosis in otology practice even if common diagnostic criteria are lacking. The symptoms associated with ETD are muffled hearing, fullness of the ear, otalgia, inability to equilibrate middle ear (ME) pressure, tinnitus, and vertigo. An abnormal tympanogram or eardrum appearance may be present. Symptoms fluctuate over time, and none are pathognomic for ETD. The symptoms can progress to more severe and chronic conditions of otitis media with effusion (OME), atelectasis of the ME, adhesive otitis, perforation of the eardrum, and possibly the development of cholesteatoma.[1]

Only 1 study on the prevalence of ETD is available, reporting a prevalence of ETD of 0.9% in a random sample of 48,313 adults in a British population. The diagnosis was based on otoscopy (normal/intact-abnormal), a ME pressure below −100 mmH2O, and an air-bone-gap (ABG) of 15 dB or more.[2]

The etiology of ETD is attributed to structural as well as functional entities and includes viral upper respiratory tract infection, chronic sinusitis, allergic rhinitis, adenoid hypertrophy, tobacco smoke, reflux, cleft palate, radiation therapy, reduced mastoid air cell system, and exposure to nitrous oxide.[1]

Many approaches to the treatment of ETD have been attempted. Only 1 randomized controlled trial (RCT) is available, and it shows no effect of nasal steroids on ETD symptoms.[3] Other treatments include auto pressure equalization technique, treatment with decongestants, antihistamines, and surgical procedures including ventilation tubes, laser tuboplasty, or microdebrader tuboplasty. No RTCs for these treatments are available, and no firm conclusions can be drawn as to the effectiveness of these procedures due to the variability in the diagnostic criteria used and the limited evidence for each of these procedures.[4-7]

The use of balloon dilatation Eustachian tuboplasty (BET) in a group of patients with ETD was first described

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Table 1. Inclusion and Exclusion Criteria.

Participants	Persons eligible for balloon Eustachian tuboplasty with a clinical diagnosis of Eustachian tube dysfunction Exclusion: diagnosis of adenoid tissue, rhinopharyngeal tumors, patoulous tube, cleft palate
Intervention	Balloon dilation Eustachian tuboplasty
Comparators	Any or none
Outcomes	Change in symptoms (severity or frequency), middle ear pathology, eardrum status, Eustachian tube function tests, hearing, adverse events, complications, health-related quality of life
Study design	Any Exclusion: abstracts, publications without peer review

by Ockermann et al[8] in 2010. At least 2 other groups had been working on feasibility studies simultaneously,[9,10] and they have since published case series as well as long-term results of BET. BET has been available to physicians and patients for 5 years, and interest in BET is growing; however, no systematic review of the evidence of BET has so far been published.

We here present a systematic review of the evidence for treating ETD by BET. Where the included studies fall short in providing high-level evidence, we recognize the authors for pioneering a new field of surgery with all the risks involved. The purpose of this review is to establish the current level of evidence available for the intervention.

Methods

We performed a systematic review according to the PRISMA 2009 guideline.[11] The review protocol was registered with the PROSPERO database for systematic reviews,[12] registration No. CRD42014009461. The protocol can be accessed online.

The inclusion criteria for eligible studies are listed in **Table 1**. The present evidence on BET was very limited, and no RCTs or case-control studies were available. Thus, we placed no restriction on study design or sample size.

We searched 12 databases on April 7, 2014, using the following search string: Eustachian (tube OR dysfunction) (dilation OR dilatation OR balloon OR tuboplasty) without restrictions on language. The search was limited to results after January 1, 2010, due to the novelty of BET. The search was expanded using the MESH terms for each item. Trial registers, regulatory agencies' websites, and citations of relevant studies were also searched. A complete list of searched resources is included in **Table 2**.

Data extraction was performed by the main author and checked by the senior author. We extracted data for preoperative diagnostics, inclusion/exclusion criteria, methods, results, adverse events, and complications. We identified the following outcomes for results: patients' reports of symptom reduction, Eustachian tube dysfunction questionnaire (ETDQ-7),[13] tympanic membrane status, tympanometry, mucosal inflammation, Eustachian tube score (ETS), the Swallowing test and the Valsalva test, the 22-item Sino-Nasal Outcome Test (SNOT-22),[14] and the Glasgow Benefit Inventory (GBI).[15] When available, mean differences with standard deviation and 95% confidence intervals or *P* values were extracted. The data could not be numerically synthesized due to the high variability in the criteria for inclusion and the lack of consensus on outcome measures between the studies. As a consequence, no attempt was made to pool the data for a meta-analysis.

Table 2. Resources Searched.

	No. Hits
PubMed	36
Embase	36
Web of Science (Science Citation Index Expanded & Conference Proceedings Citation Index-Science)	41
Scopus	40
Cochrane Database of Systematic Reviews (SDSR)	1
Cochrane Database of Abstracts of Reviews of Effects (DARE)	0
Cochrane Central Register of Controlled Trials (CENTRAL)	0
Cochrane Methodology Register	0
Health Technology Database	0
NHS Economic Evaluation Database	0
Latin America and Caribbean Health Sciences (LILACS)	0
Others:	
Clinicatrials.gov	0
Controlled-trials.com	1
Clinicaltrialsregister.eu	0
MHRA.gov.uk	0
Fda.gov	0
Who.int/ictrp/en	0

Since only case series studies were identified, we chose to evaluate the quality of the included studies using the modified Delphi technique quality appraisal tool for case series studies.[16] The authors separately appraised the quality of each study after agreeing on the importance of each item in the tool. A shared decision was made to exclude 2 criterions rewarding multicenter studies and blinding and to include an additional criterion rewarding prospective study design. The authors compared the results of the analysis, and a consensus on each item was stated.

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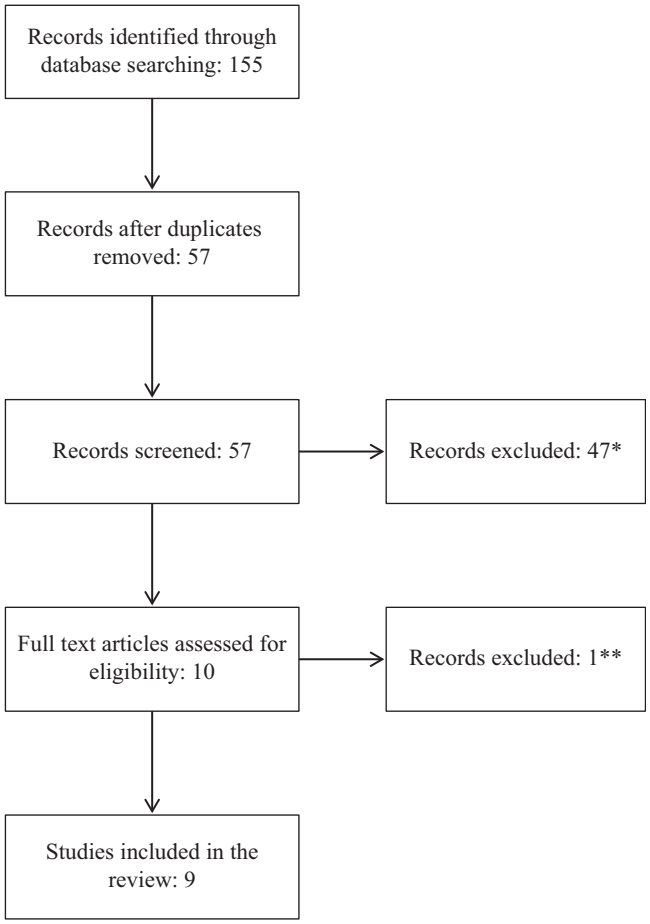

Figure 1. Flow chart of the study selection.
*Reasons for exclusion: records not on subject, conference abstracts.
**Reason for exclusion: no isolated balloon Eustachian tuboplasty results could be extracted.

The risk of bias in the included studies was evaluated by use of the Cochrane Collaboration's tool for assessing the risk of bias.[17] We disregarded the domain of random sequence generation, as it does not apply in nonrandomized studies.

We adopted a systematic approach to the final data analysis, which was performed as a narrative synthesis of the data categories recorded.

Results

The search identified 155 records. A flow chart of the study selection process is depicted in **Figure 1**. The search identified 1 ongoing RCT testing ventilation tubes versus BET in adult ETD patients.[18]

Nine case series studies with a total of 443 patients (642 Eustachian tubes) were included.[8,19-26] The population sizes range from n = 4 (7 Eustachian tubes) to n = 210 (320 Eustachian tubes). All patients are adults. The characteristics of the studies are shown in **Tables 3** through **6**.

All included studies have a high risk of bias in the domains of selection bias, performance bias, detection bias, and reporting bias. One study has a low risk of bias owing to a conflict of interest or sources of support,[19] 2 have a medium risk of bias due to impartial information disclosure,[20,21] and the remaining studies have a high risk of bias. Overall, the risk of bias in all of the included studies is high.

Diagnostics, Inclusion, and Exclusion Criteria

The criteria for inclusion differ widely across the studies; only 2 of the smaller studies[21,23] present an overview of the patients' status. No attempt was made to include the patients at a similar point in the disease in any of the studies.

In most studies, information on preoperative medication was insufficient, and no information about continued use of decongestants or nasal steroids after surgery is available.

Methods of Surgery

All procedures were performed under general anesthesia, except in 1 study where 47 patients were operated under local anesthesia. The approach of local anesthesia gave rise to problems with patients' compliance and poorer outcome in regards to durability and symptom relief.[20]

Three different instruments are in use: the Bielefeld Balloon System (Spiggle & Theiss, Overath, Germany) (length 20 mm, diameter 3.28 mm), the Reliva Solo Sinus Balloon Dilation System (length 16 mm, diameter 7 mm), and the Reliva Vortex Sinus Irrigation Catheter (length 16 mm diameter 5 mm) (Acclarent, Inc, Menlo Park, California, USA).

The following summarizes the main steps of the procedure as described for the Bielefeld Balloon System. The use of the Reliva Solo Sinus Balloon Dilation System and the Reliva Vortex Sinus Irrigation Cathetersystems are off-label. The surgery begins with visualization of the Eustachian orifice by optics inserted through the contralateral nostril, which is followed by visually guided insertion of a catheter via the Eustachian orifice into the cartilaginous part of the ET. The balloon is then inflated with a saline solution to 10 bar for 2 minutes. After deflation, the catheter is extracted. Variations in the individual studies are noted in **Table 5**.

Outcomes and Follow-Up

Patients' subjective outcome is described in 2 studies. Tisch et al[26] utilized an ad hoc scale and reported a beneficial effect. Catalano et al[20] mentioned increased patient satisfaction but presented no data.

McCoul and Anand[22] found a significant, positive change in the mean score of ETDQ-7 from 4.5 (SD, 1.2) to 2.8 (SD, 1.3) at 6 months ($P < .001$). A large proportion of the included patients had adjunctive surgery. No significant difference in ETDQ-7 scores could be found between this group and the group who had only BET ($P = .34$).

All reports of TM status favor normalization (50%-97%) at all follow-up times (range, 6 weeks-1.5 years).[21-23,25] The results defy a more detailed interpretation due to variability at inclusion.

The results of tympanometry show a high rate of conversion of type B or type C into type A tympanogram at follow-up (range, 6 weeks-1.5 years).[20-23,25]

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Table 3. Overview of Studies.

Study	Design	n	Diagnostics
Ockermann (2010)	Case series	8 (13 tubes)	Rhinopharyngeal endoscopy, otomicroscopy, tubomanometry, Valsalva, Swallowing test, HR-CT of the temporal bone
Poe (2011)	Case series	11 (11 tubes)	Rhinopharyngeal endoscopy, otomicroscopy, tympanometry, HR-CT of the temporal bone, Valsalva
McCoul (2012)	Case series	22 (35 tubes)	ENT exam, pneumatic otoscopy, tympanometry, pure-tone audiometry, CT of the temporal bone
Schröder (2012)	Case series	1 group of 66 (115 tubes)	ENT exam, audiometry, tympanometry, tubomanometry, Valsalva, Swallowing test, CT of the temporal bone
		1 group of 12 (20 tubes)	
Catalano (2012)	Case series	70 (100 tubes)	Tympanometry
Jurkiewicz (2012)	Case series	4 (7 tubes)	ENT exam, rhinopharyngeal endoscopy, tympanometry, pure-tone audiometry, pressure-swallow test, Valsalva, CT angiography of the carotid artery
Tisch (2013)	Case series	210 (320 tubes)	Valsalva, Toynbee test, subjective evaluation, tympanometry, otomicroscopy
Bast (2014)	Retrospective quality of life questionnaire	30	ENT exam, audiometry, tympanometry, CT of the petrosal bone
Silvola (2014)	Prospective series Some of the patients are follow-up from a pilot study (Poe 2011)	37 (41 tubes)	Rhinopharyngeal endoscopy with systematic mucosal inflammation score, otomicroscopy, tympanometry, HR-CT of the temporal bone, Valsalva

Abbreviation: HR-CT, high-resolution computed tomography.

Mucosal inflammation at the tubal orifice was described in 2 studies by the same research group with an overlap of study populations.[23,25] The results show a significant reduction in inflammation at 6 months and 1.5 years.

Valsalva's test shows a positive effect at all available endpoints (range, 6 weeks-1.5 years) in 5 studies.[8,21,23,25,26] The Swallowing test is available in 1 study,[8] and the results correlate with those of the Valsalva test. The groups working with Sudhoff[8,24] are using the ETS. Both studies show a significant improvement at all follow-ups (range, 8 weeks-12 months).

McCoul and Anand[22] found a significant reduction in the 22-item sino-nasal outcome test from a mean of 51.4 (SD, 21.1) to 30.0 (SD, 23.9) at 6 months ($P = .001$).[22] Bast et al[19] found increased quality of life (QoL) in 30 patients (88% response) by the GBI questionnaire at a range of 6 to 18 months. Bast et al[19] reported an increase in the median value of the total GBI score ($P = .001$) and in the subgroups general health ($P = .001$) and physical health ($P = .039$). The numeric value of the scores was not provided. An increase in the GBI of +17 to a median of the total score was estimated from the box-plot provided; at least 25% of the patients reported no change.

Complications and Adverse Events

There are no reports of severe morbidity or mortality due to adverse events or complications directly attributed to BET. Two cases of emphysema were found.[24,26] Reports of minor epistaxis and temporarily increased tinnitus are noted.

Quality of the Included Studies

The assessment of quality guided by the modified Delphi technique quality appraisal tool for case series studies is listed in **Table 7**.

The overall quality of all the included studies is poor.

Discussion

BET is a promising treatment modality for ETD owing to its noninvasive nature. The underlying mechanism has not yet been identified, but it is hypothesized that submucosal micro-hemorrhages from the applied pressure cause fibrosis and expansion of the internal ET diameter during healing.[22]

Comparison of results across the studies included in the present review cannot be made due to the heterogeneity of their inclusion criteria. However, the present lack of diagnostic consensus does not prevent subgroups of ETD

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Table 4. Overview of Studies, Inclusions and Exclusions.

Study	Inclusion	Exclusion
Ockermann (2010)	Symptoms of chronic obstructive ETD or recent tympanoplasties caused by acute relapsing OM or chronic OME as a consequence of ETD	N/a
Poe (2011)	Unilateral or bilateral OME for ≥5 consecutive years, broken only by grommet insertion or TM perforation	N/a
McCoul (2012)	Age >18 years, abnormal tympanogram (non-A-curve with admittance <0.2 mmho or resting pressure <−100 daPa, abnormal otosopic examination, symptoms of unilateral or bilateral ETD, failure to improve symptoms by medical therapy over 2 months	Any head and neck surgery within 3 months, history of RT to the head and neck, sinonasal malignancy, acute upper respiratory infections, nasal polyposis, cleft palate, craniofacial syndrome, cystic fibrosis or other immunodeficiency
Schröder (2012)	Tuba score ≤5, anamnestic and clinical signs of ETD	Age < 18 years, tumor of the rhinopharynx, dehiscent bony canal of the carotid artery, severe septal deviation, severe hypertrophy of the nasal turbinates
Catalano (2012)	Adults with a history of chronic ETD symptoms	Temperomandibular joint disease, early hydrops
Jurkiewicz (2012)	Lasting or periodic uni- or bilateral partial hearing loss, feeling of obstruction, clicking noises	N/a
Tisch (2013)	Adult patients with symptoms of ETD and prior failed attempts to treat with medicine or surgery	N/a
Bast (2014)	Chronic ETD	Age <18 years, unidentifiable opening of the ET in the nasopharynx, dehiscence of the bony canal of the carotid artery, septal deviation, hyperplastic turbinates
Silvola (2014)	Unilateral or bilateral persistent OME or significant nonadherent TM ≥5 years and follow-up ≥1, 5 years	Dehiscence of the bony canal of the carotid artery

Abbreviations: ET, Eustachian tube; ETD, Eustachian tube dysfunction; OM, otitis media; OME, otitis media with effusion; RT, radiotherapy; TM, tympanic membrane.

populations from being described in detail, and future research should be based on strict criteria for inclusion to make the study populations homogenous. Most authors left out information on confounding factors such as untreated allergy, smoking status, comorbidity, recent head and neck surgery, or earlier radiotherapy to the rhinopharynx, adding further to the heterogeneity of the study populations. Strict criteria for exclusion are equally important.

Diagnostics included preoperative computed tomography (CT) of the temporal bone in 8 of the 9 studies. Studies in cadaver models with intentional dilation of the bony part of the ET showed no detectable micro-fractures of the bone on CT scans post intervention.[10,27] This does not rule out the possibility of a fracture along a dehiscent bony canal with possible penetrating trauma to the internal carotid artery (ICA). At present, 2 studies have addressed the need for a preoperative CT scan.[28,29] Tisch et al[28] examined 1000 CT scans and found no sign of any dehiscence, aneurysm, or vascular malformation. Abdel-Aziz et al[29] examined the CT scans of 284 patients with 510 ETs eligible for BET and found 18 cases of dehiscence of the carotid canal. No clear connection can be made between ETD and dehiscence of the bony canal, but patients with petrous carotid aneurysms have been known to present with otologic symptoms of hearing loss and tinnitus.[30,31] In light of the current evidence, we therefore support the continued use of preoperative CT scan of the temporal bone and the exclusion of patients with a bony dehiscence or petrous aneurysms.

Hearing loss in ETD is mentioned in all studies, yet not a single study has reported pre- and postsurgery results of pure-tone or speech audiometry. We recommend the inclusion of hearing tests and reporting, as a minimum, of air-bone-gaps at 500, 1000, and 2000 Hz.

The use of ad hoc scales for patients' reports of symptom relief should be abandoned in favor of systematic, psychometrically consistent, and validated questionnaires. The ETDQ-7 was developed as a disease-specific symptom score but has not yet been used extensively. McCoul et al[13]

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Table 5. Overview of Studies, Methods and Follow-up.

Study	Methods	Follow-up
Ockermann (2010)	Bielefeld balloon system. The catheter was introduced into the cartilaginous and the bony canal of the ET. Inflation to 20 mm length and 3 mm width at 10 bar for 2 minutes	1, 2, and 8 weeks
Poe (2011)	Reliva Solo Sinus Balloon Dilation System, catheter introduced into the cartilaginous part of the ET. Inflation to 12 atm for 1 minute in 7 cases and 8-10 atm for 1 minute in 5 cases 5 patients had adjunctive procedures (2 grommet insertions, 3 grommet removals)	1 and 6 months
McCoul (2012)	Reliva Solo Sinus Balloon Dilation System, catheter (5×24 mm^2 [n = 17] or 7×24mm^2 [n = 18]) introduced into the cartilaginous part of the ET. Adjunctive surgery: all patients had partial inferior turbinectomy; 15 submucosal resection of the nasal septum, 12 sphenoethmoidectomy with maxillary sinostomy, 2 revision ethmoidectomy, 1 grommet inserted, 1 myringoplasty	3, 6, 12 weeks and 6 months
Schröder (2012)	Bielefeld Balloon System, dilation of the cartilaginous part of the ET; 6 patients had adjunctive surgery of paranasal sinuses, nasal septum, or turbinates	2 months, 12 months (group 2)
Catalano (2012)	Relieva Vortex Sinus Irrigation Catheter introduced into the cartilaginous part of the ET 44 patients had BET under GA (no specified pressure or time of dilation) 5 had adjunctive otologic surgery, 39 sinonasal surgery 26 patients had BET under LA in office setting. n = 5 tolerated only 6 atm dilation, n = 20 8 atm for 10 seconds, n = 22 8 atm for 30 seconds	30 weeks
Jurkiewicz (2012)	Bielefeld Balloon System, dilation of the cartilaginous part of the ET	6 weeks
Tisch (2013)	Bielefeld Balloon System, dilation of the cartilaginous part of the ET	N/a
Bast (2014)	Bielefeld Balloon System, dilation of the cartilaginous part of the ET	6-18 months
Silvola (2014)	Reliva Solo Sinus Balloon Dilation System, catheter introduced into the cartilaginous part of the ET, 12 atm for 1 minute (15 patients from the pilot) 12 atm for 1 minute, then deflation and redilation 12 atm 1 minute (26 patients) All patients instructed to do Valsalva $\geq$2 times a day for 1 week after surgery	1,5 years

Abbreviations: BET, balloon Eustachian tuboplasty; ET, Eustachian tube; GA, general anaesthesia; LA, local anesthesia.

identified the sensitivity (100%) and specificity (100%) of the EDTQ-7 test to identify ETD at a mean score of 2.1 or above. We recommend that future research on BET include pre- and postinterventional ETDQ-7 scores.

The precise relation between TM retraction, TM compliance, and ETD is not clearly described. However, to achieve more homogenous populations in future studies, we recommend to focus on accurate description of the TM and pooling of patients into groups of retraction, OME, atelectasis, and adhesive otitis, which will allow better data analysis and extrapolation of treatment recommendations. Tympanometry should be included to support the otoscopic data, and patients with pre-BET type A tympanograms should be excluded.

A systematic approach for rating mucosal inflammation is proposed by Poe et al[32] but has not yet been established as a common outcome in ETD research. The relation between mucosal inflammation of the Eustachian orifice and ETD is unclear, and no information on the specificity and sensitivity of mucosal inflammation to ETD is available.

The best estimates of the sensitivity and the specificity of Valsalva's test (55%/85%) and the Swallowing tests (52%/51%) for ETD are reported by Doyle et al.[33] The results

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Table 6. Overview of Studies, Results and Complications.

Study	Results	Complications
Ockermann (2010)	Significant improvement in ETS at all follow-up examinations Pre-BET mean ETS = 1.077, week 1 = 4.154, week 2 = 5.846, week 8 = 7.539 Pre-BET swallowing test = 12 never, 1 infrequent; week 8 = 1 never, 6 infrequent, 5 always Pre-BET Valsalva = 9 never, 2 infrequent, 1 always; week 8 = 1 never, 6 infrequent, 5 always	None
Poe (2011)	TM status recovered to normal in 2/4 with preoperative intact TM, the 2 remaining had grommets inserted when seen at follow-up. Tympanometry measured, but results are inconclusive due to perforations and grommets. Mucosal inflammation was reduced from a mean of 2.91 (0.83) to 1.73 (no SD available) no *P* value reported. Preoperative Valsalva = 11 never; 6 month = 11 always	Mucosal tear n = 5, C6-7 contralateral radiculopathy due to neck extension in 1 patient
McCoul (2012)	Pre-BET TM status: 33 TM showed retraction (4 with OME, 1 with early attic cholesteatoma), 1 had a grommet, and 1 had a stable TM perforation Post-BET TM status: 35 free of retraction, 1 ear had a resolving perforation from grommet insertion Pre-BET tympanometry: type C = 20, type B = 5, type A = 10. Post-BET tympanometry: type A = 34, type B = 1 (perforated) Mean ETDQ-7 scores improved significantly at all follow-up visits. Mean SNOT-22 scores improved significantly at all follow-up visits.	n = 1 bleeding from the turbinectomy site on day 3 resulting in bilateral haematotympanon, myringotomy was required
Schröder (2012)	Significant improvement after 2 months in tuba score by $\geq$2 points in 60%, 1-2 points in 19%, and no change in 21% from a subgroup of 66 patients (115 tubes) The first 20 patients were followed 12 months; 12 were available for follow-up; in this subgroup the tubas core was improved by $\geq$2 points in 10 patients and 1-2 points in 2 patients	2 reports of self-limiting enhancement of known tinnitus, 1 self-limiting epistaxis
Catalano (2012)	Pre-BET tympanometry: abnormal (type B or C) in 28 ears, post-BET improvement (type A) in 25 of the 28 Overall 71% patients showed notable improvement or reduction in symptoms (no information of specific endpoints included),	1 preauricular emphysema, resolved spontaneously
Jurkiewicz (2012)	Pre-BET tympanometry: abnormal (type B or C) in 7 ears, post-BET improvement (type A) in 6 of the 7 Pre-BET Valsalva positive in 1/7 ears, post-BET Valsalva positive in 6/7 ears Pre-BET PST negative in 7/7 ears, post-BET PST positive in 7/7 ears Otoscopic examination pre-BET 7/7 TM retraction, post-BET otoscopic examination 5/7 TM normal, 2/7 no change	None
Tisch (2013)	Post-BET patient report of symptoms: 150 a lot better or completely resolved, 35 better, 25 no change Valsalva pre-BET was negative in 92%, post-BET in 10%	10 cases of minor epistaxis, 1 case of emphysema in the face, neck and mediastinum
Bast (2014)	Significant improvement in total score ($P = .001$) and subscores general health ($P = .001$) and physical health ($P = .039$) in GBI	N/a
Silvola (2014)	TM status: pre-BET 41/41 abnormal, post-BET 37/41 normal OME: pre-BET 38/41, post-BET 1 Retraction/atelectasis: pre-BET 3/41, post-BET 3/41 Tubal inflammation was reduced from 2.8 to 1.4 ($P < .001$) Tympanometry: pre-BET type A = 1, type B or C = 16 perforation or grommet 24; post-BET: type A = 23, type B = 0, type C = 6 perforation or grommet 12 Valsalva pre-BET was negative in 100%, post-BET in 20%	None

Abbreviations: BET, balloon Eustachian tuboplasty; ETDQ-7, Eustachian tube dysfunction questionnaire; ETS, Eustachian tube score; GBI, Glasgow Benefit Inventory; OME, otitis media with effusion; SNOT-22, Sino-Nasal Outcome Test; TM, tympanic membrane.

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Table 7. Study Quality.

	Ockermann	Poe	McCoul	Schröder	Catalano	Jurkiewicz	Tisch	Bast	Silviola
Hypothesis stated?	Yes	Yes	Yes	Unclear	Yes	Unclear	Yes	Yes	Yes
Participants described?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Inclusion and exclusion criteria?	Partial	Partial	Yes	Yes	Yes	Partial	Partial	Yes	Yes
Consecutive recruitment?	No	Unclear	Yes	Unclear	Unclear	Unclear	Unclear	Yes	Yes
Inclusion at similar point in the disease?	No	No	Unclear	No	Unclear	No	No	No	Yes
Procedure described?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Co-interventions reported?	No	Unclear	Unclear	No	Unclear	No	No	No	Unclear
Outcomes clearly defined?	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Outcomes appropriately measured?	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes
Outcomes measured before and after?	Yes	Yes	Yes	Yes	No	Yes	Yes	Not relevant	Yes
Appropriate statistical tests?	Not relevant	Yes	Yes	Yes	Unclear	Not relevant	No	Yes	Yes
Follow-up reported?	Yes	Yes	Yes	Yes	Yes	Yes	Not relevant	Yes	Yes
Loss to follow-up reported?	Not relevant	Not relevant	Yes	Yes	Yes	Not relevant	Not relevant	Yes	Yes
Variability in outcomes reported?	Yes	Yes	Yes	Yes	No	Not relevant	No	Yes	Yes
Adverse events reported?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No
Conclusion supported by results?	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No
Conflict of interest reported?	Yes	Yes	Partial	Yes	Partial	Partial	Unclear	Yes	Yes
Prospective study?	Yes	Unclear	Yes	Unclear	Unclear	Unclear	Unclear	No	Yes

were obtained in a case-control study with a sample size of 23 ears with ventilation tubes for ETD. The subjects in the control group of 15 ears had a high frequency of allergic rhinitis, sinusitis, and gastroesophageal reflux disease. Conclusions should not be drawn from Valsalva's test and Swallowing tests without support of otoscopic findings and tympanometry data. We recommend continued use of Valsalva's test in future BET research.

Tubomanometry (TMM), introduced by Estéve[34] and modified by Sudhoff et al,[35] measures the dynamic capacity of the ET. We were unable to identify peer-reviewed data on the specificity and sensitivity of the TMM for ETD. The ETS combines the results of the Valsalva test, the Swallowing test, and the TMM for a score of 0 to 10. More research on the TMM and its ability to identify ETD is needed.

SNOT-22 is a disease-specific QoL measurement tool for patients with rhinosinuitis. Despite a certain overlap of symptoms between rhinosinusitis and ETD, the tool is not applicable to ETD, and its use cannot be advised in future BET research.

QoL remains an important outcome in surgery. The GBI has been used extensively in clinical ear-nose-throat literature. We do not consider the results this far to show a significant increase to patient's quality of life.

The science of ETD and BET is in its infancy, and the lack of consistent effect measures challenges those performing the procedure to provide high-level evidence. The included studies fall short on scientific quality but have exposed the current gap between our knowledge of ET function and dysfunction. As such, the studies provide a pioneering insight into a common clinical problem using the best available tools and outcomes and thereby unveil the urgent need for future consensus on diagnostics and uniform reporting of outcomes.

Conclusion

This is the first systematic review to describe the evidence for BET in the published literature. Our search was thorough and included no language, study design, or sample size restrictions. We followed international recommendations for methods and used established tools for assessment of the quality and bias in the included studies. Readers are advised that the validity of our conclusions is limited by the quality of the data available.

Despite an extensive search, no RTCs or case-control studies on BET were identified. The included case series all suffer from high risk of bias and poor study design:

- No absolute indication for the procedure can be identified.

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Table 8. Reporting Outcomes Recommended in BET.

	Measures
Audiometry	ABG of 500, 1000, 2000, and 4000 Hz
Otoscopy	Normal eardrum, retracted eardrum, atelectasis, OME, perforation
Tympanometry	A, B, C1, C2, perforated
Valsalva	Pass/no pass
ETDQ-7	Score 1-7

Abbreviation: ABG, air-bone-gap; BET, balloon Eustachian tuboplasty; ETDQ-7, Eustachian tube dysfunction questionnaire; OME, otitis media with effusion.

- The evidence offers no support for accurate prediction of results.
- The evidence provides some measure of supports for the feasibility and safety of BET.
- The results suggest a certain benefit of BET.
- RCTs or case-control studies using a strict definition of ETD are needed.

Recommendations for Research

The main priority in the research of ETD is to establish consensus of diagnostic criteria. Until then, we recommend against further publishing of studies intervening on ETD. With common diagnostic criteria, homogenous groups of patients could be included in randomized clinical trials.

The science of BET need not be halted by the lack of consensus on the ETD diagnosis. Case-control studies of uniform groups of patients with chronic OME, chronic retractions of the eardrum, adhesive otitis, or atelectasis of the middle ear could be designed and provide a useful insight into the effectiveness and durability of the procedure.

There is likely a substantial placebo effect related to BET, and a blinded randomized placebo study of the intervention in a uniform group of patients would provide valuable knowledge. In this case, a group of patients with bilateral symptoms could act as their own control group.

Randomized controlled trials of BET versus established treatments such as ventilation tubes in uniform groups of patients would also be valuable.

BET might improve long-term results of myringoplasty or cholesteatoma recurrence rates if performed as co-intervention to established treatments; long-term results from randomized trials are warranted.

Regardless of study design, we recommend at least 1 year follow-up.

A proposal for uniform reporting of outcomes in reporting of BET is listed in **Table 8**.

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Thomas Skov Randrup, design, acquisition of data, data analysis, drafting, final approval, responsibility for content of manuscript; **Therese Ovesen**, data analysis, critical revision, final approval, responsibility of content of manuscript.

Disclosures

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Bibliography

1. Seibert JW, Danner CJ. Eustachian tube function and the middle ear. *Otolaryngol Clin North Am*. 2006;39:1221-1235.
2. Browning GG, Gatehouse S. The prevalence of middle ear disease in the adult British population. *Clin Otolaryngol*. 1992; 17:317-321.
3. Gluth MB, McDonald DR, Weaver AL, Bauch CD, Beatty CW, Orvidas LJ. Management of eustachian tube dysfunction with nasal steroid spray: a prospective, randomized, placebo-controlled trial. *Arch Otolaryngol Head Neck Surg*. 2011;137: 449-455.
4. McCoul ED, Lucente FE, Anand VK. Evolution of eustachian tube surgery. *Laryngoscope*. 2011;121:661-666.
5. Norman G, Llewellyn a, Harden M, et al. Systematic review of the limited evidence base for treatments of eustachian tube dysfunction: a health technology assessment. *Clin Otolaryngol*. 2014;39:6-21.
6. Adil E, Poe D. What is the full range of medical and surgical treatments available for patients with eustachian tube dysfunction? *Curr Opin Otolaryngol Head Neck Surg*. 2014;22:8-15.
7. Sudhoff H, Schroder S, Reineke U, Lehmann M, Korbmacher D, Ebmeyer J. Therapy of chronic obstructive eustachian tube dysfunction: evolution of applied therapies. *HNO*. 2013;61(6):477-482.
8. Ockermann T, Reineke U, Upile T, Ebmeyer J, Sudhoff HH. Balloon dilatation eustachian tuboplasty: a clinical study. *Laryngoscope*. 2010;120:1411-1416.
9. McCoul ED, Singh A, Anand VK, Tabaee A. Balloon dilation of the eustachian tube in a cadaver model: technical considerations, learning curve, and potential barriers. *Laryngoscope*. 2012;122:718-723.
10. Poe DS, Hanna BMN. Balloon dilation of the cartilaginous portion of the eustachian tube: initial safety and feasibility analysis in a cadaver model. *Am J Otolaryngol*. 2011;32:115-123.
11. PRISMA. Home page. http://www.prisma-statement.org/. Accessed April 30, 2014.
12. PROSPERO—international prospective register of systematic reviews. Home page. http://www.crd.york.ac.uk/PROSPERO/prospero.asp. Accessed April 30, 2014.
13. McCoul ED, Anand VK, Christos PJ. Validating the clinical assessment of eustachian tube dysfunction: the Eustachian tube dysfunction questionnaire (ETDQ-7). *Laryngoscope*. 2012;122: 1137-1141.
14. Piccirillo JF, Merritt MG Jr, Richards ML. Psychometric and clinimetric validity of the 20-item sino-nasal outcome test (SNOT-20). *Otolaryngol Head Neck Surg*. 2002;126:41-47.

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15. Robinson K, Gatehouse S, Browning GG. Measuring patient benefit from otorhinolaryngological surgery and therapy. *Ann Otol Rhinol Laryngol*. 1996;105:415-422.
16. Development of a quality appraisal tool for case series studies using a modified delphi technique. http://www.ihe.ca/documents/Case%20series%20studies%20using%20a%20modified%20Delphi%20technique.pdf. Accessed April 30, 2014.
17. Cochrane handbook for systematic reviews of interventions. http://www.cochrane.org/handbook. Accessed April 30, 2014.
18. Oluwasanmi A. Balloon eustachian tuboplast (BET). http://www.controlled-trials.com. Accessed April 30, 2014.
19. Bast F, Frank A, Schrom T. Balloon dilatation of the eustachian tube: postoperative validation of patient satisfaction. *ORL J Otorhinolaryngol Relat Spec*. 2013;75:361-365.
20. Catalano PJ, Jonnalagadda S, Yu VM. Balloon catheter dilatation of eustachian tube: a preliminary study. *Otol Neurotol*. 2012;33:1549-1552.
21. Jurkiewicz D, Bien D, Szczygielski K, Kantor I. Clinical evaluation of balloon dilation eustachian tuboplasty in the eustachian tube dysfunction. *Eur Arch Otorhinolaryngol*. 2013;270:1157-1160.
22. McCoul ED, Anand VK. Eustachian tube balloon dilation surgery. *Int Forum Allergy Rhinol*. 2012;2:191-198.
23. Poe DS, Silvola J, Pyykko I. Balloon dilation of the cartilaginous eustachian tube. *Otolaryngol Head Neck Surg*. 2011;144:563-569.
24. Schroder S, Reineke U, Lehmann M, Ebmeyer J, Sudhoff H. Chronic obstructive eustachian tube dysfunction in adults: long-term results of balloon eustachian tuboplasty. *HNO*. 2013;61:142-151.
25. Silvola J, Kivekas I, Poe DS. Balloon dilation of the cartilaginous portion of the eustachian tube. *Otolaryngol Head Neck Surg*. 2014;151:125-130.
26. Tisch M, Maier S, Maier H. Eustachian tube dilation using the bielefeld balloon catheter: clinical experience with 320 interventions. *HNO*. 2013;61:483-487.
27. Ockermann T, Reineke U, Upile T, Ebmeyer J, Sudhoff HH. Balloon dilation eustachian tuboplasty: a feasibility study. *Otol Neurotol*. 2010;31:1100-1103.
28. Tisch M, Storrle P, Danz B, Maier H. Role of imaging before eustachian tube dilation using the bielefeld balloon catheter. *HNO*. 2013;61:488-491.
29. Abdel-Aziz T, Schroder S, Lehmann M, Gehl H, Ebmeyer J, Sudhoff H. Computed tomography before balloon eustachian tuboplasty-a true necessity? *Otol Neurotol*. 2014;35:635-638.
30. Moonis G, Hwang CJ, Ahmed T, Weigele JB, Hurst RW. Otologic manifestations of petrous carotid aneurysms. *AJNR Am J Neuroradiol*. 2005;26:1324-1327.
31. Cooper L, Ford K, Talwar R, Wareing M. An unusual cause of chronic otitis media with effusion. *J Laryngol Otol*. 2014;128:179-181.
32. Poe DS, Metson RB, Kujawski O. Laser eustachian tuboplasty: a preliminary report. *Laryngoscope*. 2003;113:583-591.
33. Doyle WJ, Swarts JD, Banks J, Casselbrant ML, Mandel EM, Alper CM. Sensitivity and specificity of eustachian tube function tests in adults. *JAMA Otolaryngol Head Neck Surg*. 2013;139:719-727.
34. Ars B. *Fibro-Cartilaginous Eustachian Tube-Middle Ear Cleft*. The Hague, the Netherlands: Kugler Publications; 2003.
35. Sudhoff H, Ockermann T, Mikolajczyk R, et al. Clinical and experimental considerations for evaluation of eustachian tube physiology. *HNO*. 2009;57:428-435.

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