Indian J Otolaryngol Head Neck Surg
(July–Sept 2019) 71(3):406–412; https://doi.org/10.1007/s12070-019-01637-7

OTHER ARTICLES

A Systematic Literature Review of the Safety and Efficacy of Eustachian Balloon Tuboplasty in Patients with Chronic Eustachian Tube Dysfunction

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Received: 24 January 2019 / Accepted: 26 March 2019 / Published online: 9 April 2019

Abstract Eustachian tube dysfunction (ETD) is a common condition afflicting 1% of the adult population and is said to be higher in the pediatric population. Currently, it is primarily managed with medical therapy. However, newer management techniques like balloon tuboplasty have been introduced. To systematically review the available evidence on eustachian tube balloon dilation for treating chronic ETD covering indications, efficacy, safety, short term, and long term outcomes, a literature search was conducted on Google Scholar and Pubmed. 21 publications met the inclusion criteria. Based on the literature review the procedure was found to be effective in alleviating symptoms in adult and pediatric patients immediately postoperatively and long term, up to 5 years. The adverse event rate was 3% and these were mostly minor self-resolving complications. The perioperative protocol varies from center to center. Balloon tuboplasty was found to be safe and efficacious in the short and long term post operatively in select patients with chronic ETD.

Keywords Eustachian tube · Eustachian tube dysfunction · Balloon tuboplasty

Introduction

The eustachian tube (ET) in adults is approximately 37.5 mm long, and consists of bony and cartilaginous portions, extending from the middle-ear cleft to the nasopharynx. It has several physiological functions, which include pressure equalization, drainage of the middle ear and protection from the nasopharyngeal environment. Poor or inadequate eustachian tube function persisting over 3 months leads to chronic eustachian tube dysfunction (ETD) [1, 2]. ETD results in aural fullness, hearing impairment, pain, and tinnitus. In addition, complications such as serous otitis media, tympanic membrane retraction, and cholesteatoma can occur [1]. It can be a difficult pathology to manage, with debilitating symptoms affecting the quality of life; current conventional treatments may not be effective [1].

Although India specific data doesn't exist, global data suggests that the eustachian tube dysfunction affects around 1% of adults [2, 3]. In India that would amount to over 13,400,000 patients, as of 2018, suffering from eustachian tube dysfunction based on Census data and using the population growth rate [4]. ETD is higher among children with at least 80% of all preschool children are affected at least temporarily (acute) by this condition [5].

Current treatment modalities for eustachian tube dysfunction in India like pharmacological agents, mechanical devices and nasal surgery, can be ineffective in 25–35% of patients [1, 2]. A recent health technology assessment found that there was minimal evidence of effectiveness for current medical and surgical interventions, including nasal decongestants, topical and systemic corticosteroids, antihistamines, mechanical devices, and nasal surgery [2, 3].

Eustachian tube balloon dilation or balloon eustachian tuboplasty (BET) is a modern treatment for chronic ETD. It aims to improve tube compliance and middle-ear ventilation. Its proposed mechanisms include mechanical dilation of the cartilaginous eustachian tube and initiation of histopathological changes to the mucosa that can alter the inflammatory process [6]. However, eustachian tube

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balloon dilation is a relatively new procedure, and the operative technique needs further studies to confirm its efficacy and complications. This paper systematically reviews the available evidence on eustachian tube balloon dilation for treating chronic eustachian tube dysfunction. It covers indications, efficacy, safety, short term, and long term outcomes.

Methodology

We conducted a systemic online search on Google Scholar and Pubmed using the terms "Eustachian Tube" and "tuboplasty," excluding patents and citations. Inclusion criteria were: papers published in the last 10 years (i.e., 2008 and onwards); a cohort size of equal to or greater than 30; systematic review-type papers and meta-analyses papers. Excluded from our analysis were case reports, non-English papers, studies involving laser tuboplasty and duplicate publications of a study. No age limit set in inclusion or exclusion criteria.

To analyze the literature we collected data on cohort size, the age range of cohort, approach to the diagnosis of chronic ETD, indication for eustachian tuboplasty, peri-operative protocol, the technique used in the procedure, post-operative follow up protocol and efficacy of the procedure. Typically Efficacy was assessed in each study based on the various parameters. The parameters included the ETS-5 and ETS-7 severity scale, ETD classification, the ability of the patient to perform the Valsalva maneuver and Toynbee test, Tympanogram and/or Otomicroscopy and/or Tympanometry and/or Audiometry studies. Some self-reported data on hearing improvement, change in symptoms and procedure tolerance was also gathered. Data on adverse events and patient satisfaction, where present, was also collected.

Results

Summary of Literature

Based on the search terms, our Google Scholar Search using "Eustachian Tube" and "tuboplasty" using the filters from 2008 onwards, English only and excluding patents and citations yielded 275 results. Of the 275, 21 publications met our inclusion criteria and were selected. These included 14 clinical trials, 6 Systematic reviews, 1 meta-analysis.

Based on the search terms, our Pubmed Search using "Eustachian Tube" and "tuboplasty" using the filters 2008 onwards, English only and excluding patents and citations yielded 43 results. All 43 excluded, as 26 were not relevant to our review, 16 were repeats that we included in our Google Scholar search, and 1 was a non-English manuscript.

Each Study in Brief

Schroder et al. [7]: Retrospective 5-year results of BET in 622 patients and 1076 ears with chronic eustachian tube dysfunction. Significant improvements in the ETS were seen at 1 year as compared to pre-operatively (pre-operative: 3.13 (± 2.47 SD) to 5.75 (± 2.76 SD) at 1 year) with a statistically significant change in ETS in 73% of ears. At 2 years the average ETS improved from 2.65 (± 2.89 SD) to 6.26 (± 3.07 SD). ETS significantly improved in 82% of patients at 5 years. The subjective satisfaction of the patients was approximately 80%. Authors concluded that BET is safe and feasible treatment for chronic obstructive eustachian tube dysfunction with a success rate of more than 70%.

Weil et al. [8]: Retrospective analysis of 495 patients undergoing BET. Subgroups included patients before tympanoplastic revision, patients with adhesive process, cholesteatoma, middle ear effusion, chronic mesotympanal otitis and patients with normal eardrum. ETS-5 shows a statistically significant improvement with at least 2.2 points 1 year after BET.

Dalchow et al. [9]: Prospective study in 217 patients with symptoms of chronic eustachian tube dysfunction who underwent uni- or bilateral BET. The mean tube score showed a statistically significant improvement 1 year post procedure. Preoperative tube score: 2.23 (± 1.147) and 1 year post BET score was 2.68 (± 1.011).

Tisch et al. [5]: Conducted a retrospective analysis of the records of 60 children with a mean age of 6.3 years and a range from 28 months to 12 years who underwent balloon dilation of the eustachian tube Clinical symptoms improvement seen in over 80% of patients with reported deterioration of symptoms. A questionnaire based assessment of parents reported that 81.3% were very satisfied or satisfied with the outcome of BET.

Silvola et al. [10]: Prospective study of 41 BET procedures. Post procedure, 80% of participants could perform a Valsalva maneuver and reported symptomatic relief.

Catalano et al. [11]: Prospective study in 70 adults and BET of 100 eustachian tubes. Of the 100 ETs, ear fullness and pressure were improved in 71% of patients studied for 26.3 weeks. Among the patients followed up for a minimum of 34 months, 87% reported persistent improvement.

Meyer et al. [12]: Prospective, multicenter, randomized controlled trial. Sixty participants were randomized (31 balloon dilation, 29 control) to balloon dilation or control (continued medical management). The primary efficacy endpoint was the comparison between mean change from

baseline in the 7-item eustachian tube dysfunction questionnaire (ETS-7) score of the treatment arm and the control arm. Mean change in overall ETS-7 score at 6 weeks was − 2.9 for balloon dilation group compared to − 0.6 for the control group. Statistically significant improvements seen in the tympanogram type and the tympanic membrane position in balloon dilation compared to control. ETS-7 scores were maintained through 12 months after procedure. Balloon dilation superior to medical management.

Luukkainen et al. [13]: Conducted a retrospective questionnaire study based on ETS-7 among 46 patients who underwent BET. Symptom improvements reported in 75% of the ears included pain in the ears, feeling of pressure in the ears, and feeling that ears are clogged had reduced. 77% felt that their overall ear symptoms were reduced. 82% of all the patients reported willingness to undergo BET again if their ear symptoms returned.

Satmis and van der Torn [14]: Retrospective cohort study in 42 consecutive patients (66 ears). The ETS-7 score improved significantly from 4.28 to 3.09 one month post BET and from 4.10 to 2.96 at 3 months. Bone conduction thresholds did not differ significantly postoperatively but a significant improvement of air–bone gap was found postoperatively. The tympanic membrane and middle ear condition showed improvement in 62%. Subjective satisfaction 1 and 3 months postoperatively was 43 and 48%.

Xiong et al. [15]: Prospective study in 40 patients who underwent BET. A significant improvement reported in impedance audiometry, R-value in TMM, ETS and the ability to perform Valsalva at 1 week, 3 months and 12 month post surgery. The overall success rate was 98%.

Schmitt et al. [16]: Single-center retrospective study of 38 patients who underwent eustachian tube balloon dilation. Improvement in clinical symptoms was reported as 88%, 80% and 80% at respectively 2 months, 6 months, and 1 year. Improvements in function on tubomanometry reported in 81% of cases.

Wanscher and Svane-Knudsen [17]: Prospective, preliminary study in 34 patients who underwent 50 BET procedures. A significant improvement was reported in audiometry, tympanometry, Toynbee's test, classification of eustachian tube dysfunction and VAS questionnaires.

Jenkel et al. [3]: Retrospective study by analysing data of 33 children who underwent BET. Tubomanometry did not show improved tube function or favorable postoperative changes in the R-data. Most patients reported relief from ear-related symptoms.

Bast et al. [18]: Retrospective study in of 30 patients who underwent BET. Patient satisfaction based on Glasgow Benefit Inventory (GBI) was gauged. GBI analysis revealed significant improvements in the total score as well as in general and physical health in patients post BET.

Discussion

Diagnostic and Inclusion Criteria

The diagnostic and inclusion criteria varied significantly between studies. Inclusion criteria included: eustachian tube score (ETS) ≤ 5, ETS-7 ≤ 7, presence of at least one of the following clinical symptoms of chronic obstructive ET dysfunction; an obvious adhesive process; a flat line in the tympanogram (type B); or early recurrence of retraction after tympanoplasty (repair of the tympanic membrane), pure tone audiometry; refractory to medical alone; refractory to medical as well as surgical treatment. Most studies ruled out patients under the age of 18. That being said, the ages ranged from 12 months to over 80 years [20, 21]. The ET is said to reach human length by the age of seven but the five studies which included pediatric patients (under the age of 18) mention the importance of tactile resistance in these patients to ensure that only the cartilaginous portion is dilated [3, 5, 7, 9, 10]. It is important to note that the exact break up by age group was not mentioned in studies which included both adult and pediatric populations and hence could not be interpreted further (Tables 1, 2).

Table 1 Summary of study demographics of included clinical studies

Publication	Study design	Cohort size	Population
Schröder et al. [7]	Retrospective	622	Adult + pediatric
Weil et al. [8]	Retrospective analysis	495	Adult
Dalchow et al. [9]	Prospective	217	Adult + pediatric
Tisch et al. [5]	Retrospective	126	Pediatric
Silvola et al. [10]	Prospective	80	Adult + pediatric
Catalano et al. [11]	Prospective	70	Adult
Meyer et al. [12]	Prospective multicentre Randomized control trial	55	Adult
Luukkainen et al. [13]	Retrospective	46	Adult
Satmis and van der Torn [14]	Retrospective	42	Adult
Xiong et al. [15]	Prospective study	40	Adult
Schmitt et al. [16]	Retrospective	38	Adult
Wanscher and Svane-Knudsen [17]	Prospective	34	Adult
Jenckel et al. [3]	Retrospective	33	Pediatric
Bast et al. [18]	Retrospective	30	Adult

Table 2 Summary of clinical studies based on peri-procedural protocol

	Publication	Pre-operative	BET Procedure	LA/GA	Post operative
1	Schröder et al. [7]	CT scan	10 bars 2 min	GA	Nasal steroid spray 6 weeks
2	Weil et al. [8]	None mentioned	10 bars 2 min	GA	None mentioned
3	Dalchow et al. [9]	Digital volume tomography	10 bars 2 min	GA	Cefuroxime 2 × 500 mg prophylactically for 5 days and on the first postoperative day a single shot of 250 mg prednisolone
4	Tisch et al. [5]	28 underwent CT scan	10 bars 2 min	GA	Xylometazoline nasal drops and panthenol ointment for 3 days Some patients also received antihistamines or topical corticosteroids
5	Silvola et al. [10]	Pre-operative intranasal steroid spray for 1 month	12 atm 1 min	GA	None mentioned
6	Catalano et al. [11]	None mentioned	6-8 atm for 10–30 s	LA (except in hybrid procedures)	None mentioned
7	Meyer et al. [12]	None mentioned	12 atm for 2 min	Both LA and GA	None mentioned
8	Luukkainen et al. [13]	None mentioned	10–12 atm for 2 min	GA	None mentioned
9	Satmis and van der Torn [14]	None mentioned	10 bars 2 min	GA	None mentioned
10	Xiong et al. [15]	HRCT	10 bars 2 min	GA	None mentioned
11	Schmitt et al. [16]	CT scan	10 bar 2 min at the proximal part of the ET and 10 bar 2 min around the orifice	GA	None mentioned
12	Wanscher and Svane-Knudsen [17]	None mentioned	10 bars 2 min	GA + LA in 3 cases	Decongestant nasal spray (10 days) and corticosteroid spray (14 days)
13	Jenckel et al. [3]	None mentioned	10 bar 2 min	GA	None mentioned
14	Bast et al. [18]	CT scan	Not mentioned	GA	None mentioned

Surgical Procedure

Perioperative procedure varied from study to study with some studies not mentioning their protocol in detail. In some studies preoperative steroid sprays were advised. CT scan of the temporal and petrosal bone for carotid artery dehiscence seemed to be more common and more worrisome in pediatric patients but in some studies all participants underwent a CT scan to rule out anatomical aberrations. General anesthesia was used in most studies but local anesthesia too was used in some with the study by Catalano et al. mentioning a problem with tolerance. Intraoperatively the eustachian tube device used was either Spiggle and Theis or Acclarent. The same device was used regardless to the age of the patient. Here too protocols varied. Spiggle and Theis users tended to dilate the ET with the balloon set to 10 bars for 2 min and those who used Acclarent tended to maintain the balloon at 12 atm for 2 min. Post operatively some studies mentioned the use of antihistamines, decongestants and steroidal nasal sprays. They are said to reduce restenosis and scarring but data to back this claim is lacking [1].

Outcome Parameters

All types of evaluation of ETD showed an improvement in short-term follow-up. In general, treatment provided symptom relief, which either remained stable over time or improved even further. Follow up ranged from immediately post-op to up to 5 years [7].

Table 3 Adverse events summary

Total number of patients in all 14 studies	1928
Major complications reported[a]	5: Failure of BET
Minor complications reported[a]	Total: 22
	4: Surgical emphysema due to mucosal tear
	2: Unilateral soft tissue emphysema
	1: Hypoglossal nerve paresis
	2: Epistaxis
	7: Otitis media
	2: Tenderness
	1: Blood clot
	1: granulation tissue build up
	1: Patulous ET
	1: Transient dysesthesia of the tongue

[a]As mentioned in the respective manuscripts

Safety

Most complications reported were classified as relatively low and self-limiting. There were 6 major complications reported specifically in the included studies (0.3%) and all were failed BET procedures. On analysis, revisions had to be performed in a total of 132 out of the 1938 procedures (9%). However, the details of the procedures has not been included in the studies to assess the efficacy of revisions. No other major complications were reported. Minor complications were reported in 33 patients out of 1928 (1.7%). Surgical emphysema due to mucosal tears was reported to be the most common and was self-resolving in all cases included in this review (Refer Table 3).

Limitations

Overall the risk of bias of the included studies was high because all studies were case series, without a control group or blinding, and susceptible to selection bias. Only the randomised control trial by Meyer et al. which compared BET to continued medical therapy limits this bias. Moreover, data needed for adequate comparison between studies and patient populations were not alike in all studies. In addition, patient groups were not homogenous: some patients were pre operatively treated with decongestive nasal spray; others received a ventilation tube; and some patients received other therapy (nasal steroids, decongestants, antibiotics, and tympanoplasty) during or after BET [12].

Conclusion

Chronic eustachian tube dysfunction that does not respond to medication affects a large number of people each year. Balloon Eustachian Tuboplasty seems to be gaining acceptance as a safe

Table 4 Summary of systematic reviews and meta-analyses included in this review

	Publication	Study design	Summary
1	Wang et al. [19]	Meta-analysis	Patients with ETD treated with balloon dilatation or laser Tuboplasty in 2 retrospective and 11 prospective studies were included. Concluded that both procedures can improve symptoms of ETD but because of the limited numbers of studies reporting data of the outcomes of interest, it remains unclear which procedure provides greater benefits
2	Randrup and Ovesen [20]	Systematic review	Nine case series studies with 443 patients (642 tubes) were included. 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
3	Hwang et al. [21]	Systematic review	9 prospective studies, describing 713 eustachian tube balloon dilations in 474 patients (aged 18–86 years). Follow-up duration ranged from 1.5 to 18 months. BET is a safe and effective procedure
4	Norman et al. [22]	Systematic review	The observed benefits for tuboplasty and balloon dilatation could not be reliably attributed to the interventions assessed There was variability in definitions of the condition. Due to the limited evidence, it is difficult to make conclusions on the effectiveness the intervention. Consensus on diagnostic criteria for eustachian tube dysfunction is required to inform inclusion criteria of future trials
5	Huisman et al. [23]	Systematic review	15 studies with a total of 1155 patients were treated with balloon dilation. BET is safe and useful in ETD
6	Mahrous et al. [24]	Systematic review	10 prospective case series and 1 RCT were included describing 1485 balloon dilatations of the eustachian tube procedures in 971 adult patients. BET was concluded to be a safe and effective solution for chronic ETD
7	Luukkainen et al. [25]	Systematic review	5 articles fulfilled the inclusion criteria (follow-up $\geq$ 12 months). 5 additional articles (follow-up, 6–11 months) were analyzed to obtain supportive information. The proposed indications for BET include chronic bothersome symptoms referring to ETD, ETD-related symptoms when pressure changes rapidly, or recurring serous otitis media. Authors recommend treating only adults with BET

and effective procedure in adult and certain pediatric populations. There has been a lack of consensus both in the diagnostic criteria for ETD and the indications for Balloon Tuboplasty [19]. Based on this literature review, we believe that patients who would benefit from this procedure would include adhesive otitis media, barotrauma cases (example scuba divers, pilots, airhostesses), ETD patients before grommet insertion or myringotomy, tympanoplasty patients to improve post-operative outcomes and patients with chronic rhinosinusitis and concomitant ETD to improve Functional Endoscopic Sinus Surgery (FESS) outcomes especially those with persistent ETD symptoms. Although chronic ETD is more prevalent in the pediatric population, the research around BET in this population was significantly less than that in the adult population. Among the studies with pediatric patients, BET was found to be effective especially in patients over 13 years of age (Table 4).

This paper is a review and makes no claims beyond those of the papers reviewed. For future research on evaluating this promising therapy, three points need to be addressed. The relationship between symptoms underlying pathology and the extent of measurable tubal dysfunction is not always clear. This makes objective measurements and causal determination challenging. The second is the need for consensus on the exact indications for BET. Lastly, the perioperative protocol varies from center to center and there is an overall lack of recommendations. Overall, every published case study concluded that BET is safe and efficacious in the management of ETD, although further long term, homogenous, controlled studies are warranted.

Compliance with Ethical Standards

Conflict of interest Dr. Rohan D'Souza and Pooja Kadambi are employees of InnAccel Technologies Private Limited, Bangalore, which is currently developing a Balloon Tuboplasty Device, EustaCare.

Ethical Approval This article does not contain any studies with human participants performed by any of the authors.

Appendix

ETS-7

The eustachian tube score-7 facilitating quantification and interindividual comparison of eustachian tube function (Adapted from Schröder et al. [26])

Symptom/Finding	2 points	1 point	0 points
Clicking sound when swallowing	Always	Occasionally	Never
Positive subjective Valsalva	Always	Occasionally	Never
Objective Valsalva	Immediate	Weak and slow	Negative
Tympanometry			
TMM[a] 30 mbar	$R \leq 1$	$R > 1$	No R
TMM[a] 40 mbar	$R \leq 1$	$R > 1$	No R
TMM[a] 50 mbar	$R \leq 1$	$R > 1$	No R

Eustachian tube score-7 ranging from 0 to 14 points

[a]*TMM* tubomanometry

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