

Effectiveness of Balloon Tuboplasty on the Eustachian tube function (A Systematic Review)

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Abstract: Background: Eustachian tube dysfunction is a disorder for which there are limited medical and surgical treatments. Recently, Eustachian tube balloon dilation has been proposed as a potential solution. **Aim of the Work:** The aim of our study was to look at the effectiveness of balloon dilation of the Eustachian tube through literature review and/or meta-analysis. **Method:** A systematic review was performed. Studies were selected according to inclusion and exclusion Criteria. Data was collected. Pooled data analysis and qualitative analysis were conducted. **Results:** Ten prospective case series and one RCT were included describing 1485 balloon dilations of the Eustachian tube procedures in 971 adult patients (aged 18–86 years). Follow-up duration ranged from 1.5 to 18 months. Type A tympanogram was included as a follow-up measure in 6 of 10 Studies (without RCT) and improved from 0.39% to 64.5% following Eustachian tube balloon dilation. Normal TM (by Otoscopy) was included as a follow-up measure in 5 of the 11 Studies and improved from 7.5% to 72.3% following Eustachian tube balloon dilation. Normal hearing (by PTA) was included as a follow-up measure in 1 of the 11 Studies and improved from 18% to 58% following Eustachian tube balloon dilation. Ability to perform Valsalva maneuver was included as a follow-up measure in 7 Studies (without RCT) and improved from 5.8% to 84% following Eustachian tube balloon dilation. ETS was included as a follow-up measure in 3 of the 11 Studies and improved from 1.67(mean) pre-dilation to 5.339(mean) following Eustachian tube balloon dilation. ETDQ-7 was included as a follow-up measure in 1 of 10 Studies (without RCT) and improved from 4.5(mean) pre-dilation to 2.8(mean) following Eustachian tube balloon dilation. ET mucosal inflammation Score was included as a follow-up measure in 2 of 10 Studies (without RCT) and improved from 2.855(mean) pre-dilation to 1.565(mean) following Eustachian tube balloon dilation. As regard RCT: There was a significant ($P < .0001$) Improvement in the investigational arm compared to the control arm as regard Tympanometry associated with significant ($P < .0001$) normalization of ETDQ-7 and ET mucosa beside the ability to perform valsalva maneuver. **Conclusion:** This up-to-date Systematic review can confirm the safety of Eustachian tube balloon dilation as a potential solution for chronic Eustachian tube dysfunction; further investigations are warranted to establish a higher level of evidence of efficacy.

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1. Introduction

The Eustachian tube (ET) is a conduit between the middle ear space and the nasopharynx, which opens in a physiologically complex and poorly understood manner to provide ventilation to the middle ear, and so equalize middle ear and ambient pressures (**Moore et al., 2013**).

Eustachian tube dysfunction (ETD) is a common medical issue, occurring in at least 1 % of the adult population. Patients suffering from ET dysfunction typically present with complaints of hearing loss or sensation of pressure or plugged ear, which can lead to impaired quality of life. Over time ETD can result in conductive hearing loss or cholesteatoma formation. Effective therapeutic options for ET dysfunction are few. Eustachian tube balloon dilation is a novel surgical technique being used to treat ETD (**Browning et al., 1992**).

Findings of ET dysfunction can include serous effusion, conductive hearing loss (on tuning fork or

audiometric testing), or negative middle ear pressure (on pneumatic otoscopy or tympanometry). Later, there may be findings of sequelae of this dysfunction, such as retraction pockets, perforations, chronic drainage or cholesteatoma. The underlying etiology and natural history of ET dysfunction is poorly understood. There is a lack of clear diagnostic criteria, which further impairs our ability to study the disease and potential therapies. Anti-reflux therapy or nasal steroid sprays are often used first line treatments, without much evidence to support their efficacy. A randomized, placebo controlled study examining the effect of nasal steroid spray on ET dysfunction found no significant difference between treatment and placebo. Similarly, a recent systematic review found no significant effect of any intervention including observation, nasal steroids, and various surgical techniques (**Gluth et al., 2011**).

The standard surgical treatment of ET dysfunction is myringotomy and tympanostomy tube

placement in the tympanic membrane (TM). This technique allows equalization of middle ear pressure and drainage of fluid via the TM, effectively bypassing the ET. This approach effectively relieves symptoms but does not treat the ET dysfunction. Tympanostomy tubes often need to be replaced multiple times if ET dysfunction persists. This places a burden on the health care system and adds to patient discomfort and inconvenience. Tympanostomy tubes also have some risk of perforations of the tympanic membrane, with associated conductive hearing loss. Other novel surgical therapies have emerged, which focus on the ET itself (Smith and Greinwald, 2011).

In select patients there is redundant mucosa in the area of the opening of the ET, impairing its dilation. Ablation of this tissue with laser or microdebrider has shown promise in small studies but these interventions are not appropriate for all patients. Other novel therapies have focused on the cartilaginous portion of the ET. Of particular note, a

recent, promising innovation is balloon dilation of this portion of the ET (Caffier et al., 2011).

Eustachian tuboplasty by balloon dilation involves the cannulation of the cartilaginous portion of the ET via the nasopharynx with a balloon catheter. This catheter is inflated to multiple atmospheres of pressure (typically 10–12 bar) for a short period of time and then removed. The surgical technique is also variable in the literature. Balloons used range between 3–7 mm in diameter, and are of variable lengths. They are typically inflated for 1–2 min. currently; no evidence exists regarding the optimal balloon diameter, pressure, or duration of inflation (Silvola et al., 2014).

Numerous studies have demonstrated the safety of this procedure. A systematic review preformed in 2014 showed no adverse outcomes in 103 patients who had undergone balloon dilation of the Eustachian tube (Llewellyn et al., 2014).

2. Patients and methods

Table 1: Inclusion and Exclusion Criteria for eligible studies

	Inclusion Criteria	Exclusion Criteria
Study design	Prospective clinical design of study	abstracts, publications without peer review, technical studies, Published conference, case reports, retrospective studies and not clinical studies
Study language	English language only	Any other language
Study date	Any date	
Sample size	Any sample size	
Participants	<ul style="list-style-type: none"> Adults eligible for balloon Eustachian tuboplasty with a clinical diagnosis of Eustachian tube dysfunction Patients with intact Tympanic membrane 	<ul style="list-style-type: none"> diagnosis of adenoid tissue, rhinopharyngeal tumors, patulous tube & cleft palate Patients with Tympanic membrane perforation, tympanostomy tube or TM graft
Intervention	Only Trans-nasal Balloon dilatation of the Eustachian tube	<ul style="list-style-type: none"> Trans-tympanic balloon dilatation of the Eustachian tube BET + another intervention
	Inclusion Criteria	Exclusion Criteria
Outcomes	Change in symptoms (severity or frequency), middle ear pathology, eardrum status, Eustachian tube function tests, Hearing assessment, adverse events, complications and health-related quality of life	Outcomes not assessed

The study has fulfilled the following steps:

- A. Identification and location of articles.
- B. Screening and evaluation of articles.
- C. Data collection.
- D. Data analysis.
- E. Discussion.

F. Conclusion.

A. Identification and location of articles:

PubMed and Medline databases were searched on 25 March, 2017, using the following keywords: ‘balloon’, ‘tuboplasty’, ‘Eustachian tube’ or ‘auditory tube’ and ‘dilation’ or ‘dilatation’ looking for

published relevant papers in English language. No restrictions were placed on study date, type or language due to the emerging nature of balloon dilatation of the Eustachian tube.

Google scholar, Trial registers, regulatory agencies' websites, and citations of relevant studies were also searched.

A total of 16100 records were identified from the searches of databases.

B. Screening and evaluation of articles:

Records yielded by the search engine were screened and evaluated. Only articles fulfill the following criteria included:

- 1) Study design: prospective clinical design of study.
- 2) Study date: any date.
- 3) Study language: English language only.
- 4) Sample size: any sample size.
- 5) Patient selection:
 - a) Age group: any age group.
 - b) Sex: Both sexes are included.
 - c) Persons with a clinical diagnosis of Eustachian tube dysfunction without underlying organic lesion affecting Eustachian tube (adenoid tissue, rhino-pharyngeal tumors, patulous tube & cleft palate).
 - d) Patients with intact Tympanic membrane.
 - e) Intervention (Exposure): trans-nasal balloon dilatation of the Eustachian tube.
 - f) Outcomes: one or more of the following outcomes:
 - a) Change in subjective symptoms of ETD (severity or frequency).
 - b) Eardrum status (Otoscopy findings).
 - c) Eustachian tube function tests.
 - d) Hearing assessment (PTA).
 - e) Complications.
 - f) Health-related quality of life.

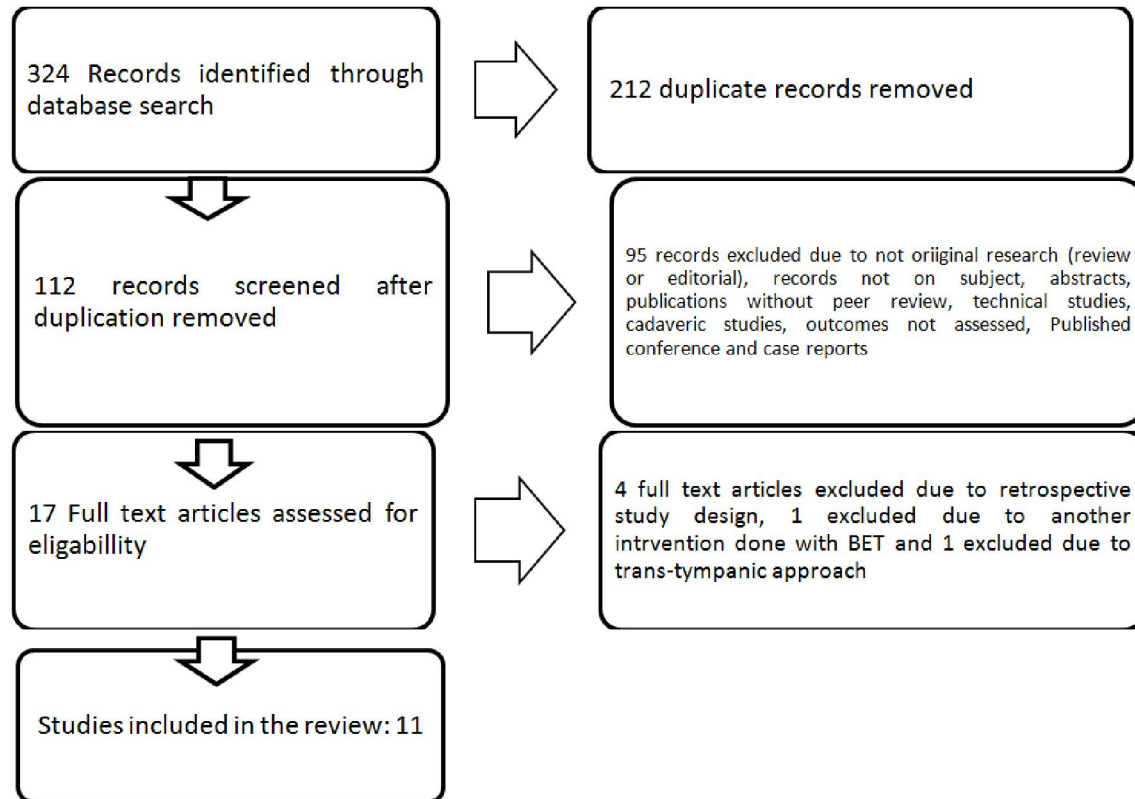


Figure 1: Flow chart of the study selection

As shown in figure1 (Flow chart of the study selection): 212 duplicate records removed.

96 records were excluded due to: records not original research (review or editorial), records not on subject, abstracts, publications without peer review, technical studies, cadaveric studies, outcomes not assessed, published conference and case reports.

4 full text articles were excluded due to retrospective study design and 1 excluded due to there is another intervention done in association with BET.

The 11 full text articles that were eligible for inclusion in this systematic review were assessed independently by the researcher and his supervisors

and any disagreements were resolved by discussion between them.

Table 2: The excluded 5 full text articles and reasons why they were excluded

Study Authors	Year	Exclusion reason
Bast F. et al.	2013	Retrospective study
Williams B. et al.	2016	Retrospective review
Jenckel F. et al.	2015	Retrospective study
Schröder S. et al.	2015	Retrospective cohort study
Abdelghany A.	2013	BET with Myringoplasty
Tarabichi M. & Najmi M.	2015	Trans-tympanic dilation of the Eustachian tube

3. Results

Table 3: Comparison between Studies' results (ETDQ-7, Normal TM, Type A Tympanogram)

	ETDQ-7 Mean (SD)		Normal TM by Otoscopy (%)		Type A Tympanogram (%)	
	pre-operative	post-operative	pre-operative	post-operative	pre-operative	post-operative
Okerman 2010	N/A	N/A	N/A	N/A	N/A	N/A
	ETDQ-7 Mean (SD)		Normal TM by Otoscopy (%)		Type A Tympanogram (%)	
	pre-operative	post-operative	pre-operative	post-operative	pre-operative	post-operative
Poe 2011	N/A	N/A	0%	50%	0%	50%
Catalano 2012	N/A	N/A	N/A	N/A	0%	89.2%
Mccoul 2012	4.5 (±1.2)	2.8 (±1.3)	5.7%	100%	0%	97.1%
Schroder 2013	N/A	N/A	N/A	N/A	N/A	N/A
Jurkiewicz 2013	N/A	N/A	0%	71.4%	0%	85.7%
Tiesh 2013	N/A	N/A	N/A	N/A	N/A	N/A
Silvola 2014	N/A	N/A	0%	90.2%	2.34%	56.1%
Wancher 2014	N/A	N/A	31.8%	50%	0%	27.3%
Dalchow 2016	N/A	N/A	N/A	N/A	N/A	N/A
Dennis Poe 2017	Investigation group: 4.7 (±1.1) Control group: 4.8 (±1.3)	Investigation group: 56% return to normal (<2.1) Control group: only 8.5% returned to normal	N/A	N/A	Investigation group: 0.4% Control group: 3.4%	Investigation group: 57.8% Control group: 13.9%

Table 4: Comparison between Studies' results (Normal PTA and Positive Valsalva test)

	Normal Hearing in PTA (%)		Positive Valsalva (%)	
	pre-operative	post-operative	pre-operative	post-operative
Okerman2010	N/A	N/A	0%	92.3%
Poe 2011	N/A	N/A	0%	100%
Catalano 2012	N/A	N/A	N/A	N/A
Mccoul 2012	N/A	N/A	N/A	N/A
Schroder 2013	N/A	N/A	11.85%	63.7%
Jurkiewicz 2013	N/A	N/A	14.28%	85.7%
Tiesh 2013	N/A	N/A	8%	90%
Silvola 2014	N/A	N/A	0%	80%
Wancher 2014	18%	58%	7%	77%
Dalchow 2016	N/A	N/A	N/A	N/A

Dennis Poe 2017	N/A	N/A	Investigation group: 45% Control group: 40%	Investigation group: 87% Control group: 47%
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Table 5: Comparison between Studies' results (ETS, SNOT-22, ET inflammation score)

	ETS Mean (SD)		SNOT-22 Mean (SD)		ET mucosal inflammation Score	
	pre-operative	post-operative	pre-operative	post-operative	pre-operative	post-operative
Okerman2010	1.077 (±0.605)	7.539 (±1.391)	N/A	N/A	N/A	N/A
	ETS Mean (SD)		SNOT-22 Mean (SD)		ET mucosal inflammation Score	
	pre-operative	post-operative	pre-operative	post-operative	pre-operative	post-operative
Poe 2011	N/A	N/A	N/A	N/A	2.91 (±0.83)	1.73 (±0.79)
Catalano 2012	N/A	N/A	N/A	N/A	N/A	N/A
Mccoul 2012	N/A	N/A	51.4 (±21.1)	30.0 (±23.9)	N/A	N/A
Schroder 2013	Group1: 1.25 (±1.83) Group2: 2.21 (±2.02)	Group1 after 12 months: 6.2 (±2.61) Group2 after 2 months: 5.4 (±2.53)	N/A	N/A	N/A	N/A
Jurkiewicz 2013	N/A	N/A	N/A	N/A	N/A	N/A
Tiesh 2013	N/A	N/A	N/A	N/A	N/A	N/A
Silvola 2014	N/A	N/A	N/A	N/A	2.8 (±1.2)	1.4 (±0.8)
Wancher 2014	N/A	N/A	N/A	N/A	N/A	N/A
Dalchow 2016	2.23 (±1.147)	After 1 year: 2.68 (±1.011)	N/A	N/A	N/A	N/A
Dennis Poe 2017	N/A	N/A	N/A	N/A	(no inflammation) Investigation group: 39.2% Control group: 47.4%	(no inflammation) Investigation group: 61.2% Control group: 52%

4. Discussion and Limitations

The Eustachian tube in adults is approximately 37.5 mm long, and consists of bony and cartilaginous portions, extending from the middle ear cleft to the nasopharynx (Perskey M. & Manolidis S., 2014).

It has several physiological functions, which include pressure equalization, drainage of the middle ear and protection from the nasopharyngeal environment (Perskey M. & Manolidis S., 2014).

Poor or inadequate Eustachian tube function causes Eustachian tube dysfunction, which is a physiological disorder that may be temporary and spontaneously resolving (Smith M. et al., 2016).

Chronic Eustachian tube dysfunction occurs when the dysfunction lasts for over three months; it is a poorly defined clinical entity, with variable

diagnostic criteria based on clinical history, otoscopy and tympanogram results (Norman G. et al., 2014).

It can be a difficult pathology to manage, with debilitating symptoms affecting quality of life; current conventional treatments may not be effective.

A recent health technology assessment found that there was minimal evidence of effectiveness for current medical and surgical interventions, including nasal decongestants, topical and systematic corticosteroids, antihistamines, mechanical devices, and nasal surgery (Norman G. et al., 2014).

It identified only one study with a low risk of bias, a randomized, controlled trial, which found no improvement in Eustachian tube dysfunction symptoms after six weeks of nasal steroids (Vila P. et al., 2017).

In cases of chronic Eustachian tube dysfunction refractory to conventional treatment, multiple insertions of ventilation tubes may be required. This can cause persistent perforation requiring dry ear precautions and/or myringoplasty.

As a potential solution for this, Eustachian tube balloon dilation (proposed as a treatment for chronic Eustachian tube dysfunction) aims to ventilate and drain the middle ear by improving the physiological function of the Eustachian tube (**Dean M. et al., 2016**).

The mechanisms by which Eustachian tube balloon dilation improves Eustachian tube function is an area of ongoing research, but appear to include both anatomical dilation of the cartilaginous Eustachian tube and the initiation of histopathological changes (**Dai S. et al., 2016**).

A recent study examining the histopathological changes associated with Eustachian tube balloon dilation found that the balloon had a crushing effect on inflammatory cells within the Eustachian tube mucosa while sparing the basal layer, rapidly replacing the inflamed mucosa with a fibrous scar (**Dai S. et al., 2016**).

The initial papers by (**Ockermann T. et al. in 2010**) and (**Poe D. & Hanna B. in 2011**) focused on establishing the safety of Eustachian tube balloon dilation by performing both cadaveric and clinical studies.

The cadaveric studies revealed no evidence of fractures to the cartilaginous or bony lumen, and no damage to the internal carotid artery. Only minor mucosal lacerations at the Eustachian tube orifice were noted (**Jufas N. et al., 2016**).

Since then, numerous prospective cohort studies have examined the role of Eustachian tube balloon dilation.

In 2011, National Institute for Health and Clinical Excellence reviewed the literature on balloon dilatation of the Eustachian tube and concluded that the procedure should remain limited to use in research (**Hwang S. et al., 2016**).

The literature at this time consisted of three case series, two of which were conference abstracts, detailing 73 balloon dilatations of the Eustachian tubes performed on 50 patients.

(**Miller B. & Elhassan H., 2013**) reviewed the literature on balloon dilatation of the Eustachian tube and concluded that Balloon dilatation of the Eustachian tube appears to be safe, effective and affordable. Like many newly introduced techniques, the evidence remains limited to non-controlled case series, with heterogeneous data collection methods and lacking long-term outcomes. However, short-term data provides promising, consistent results based on objective measures, and when used selectively in

patients refractive to maximal existing therapy, balloon dilatation presents a potentially significant advance.

The literature at this time consisted of 5 case series, detailing 375 balloon dilatations of the Eustachian tubes performed on 235 patients.

(**Randrup T. & Ovesen T., 2015**) systematically reviewed the literature on balloon dilatation of the Eustachian tube and concluded that 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.

The literature at this time consisted of 9 case series, one of which was retrospective study, detailing 642 balloon dilatations of the Eustachian tubes performed on 443 patients.

(**Hwang S. et al., 2016**) systematically reviewed the literature on balloon dilatation of the Eustachian tube and concluded that: Prospective case series can confirm the safety of Eustachian tube balloon dilation. As a potential solution for chronic Eustachian tube dysfunction, further investigations are warranted to establish a higher level of evidence of efficacy.

The literature at this time consisted of 9 case series, all of which were prospective studies, detailing 713 balloon dilatations of the Eustachian tubes performed on 474 patients.

Our up-to-date Systematic review provides significant additional material detailing 1485 balloon dilatations of the Eustachian tube procedures in 971 adults, and strengthens existing evidence that the procedure is safe and effective when carried out by adequately trained otolaryngologists.

It is consisted of 10 prospective case series plus it includes the only RCT which demonstrated superiority of balloon dilation of the Eustachian tube with balloon catheter in conjunction with medical management compared to medical management alone to treat Eustachian tube dilatory dysfunction in adults. (**Poe D. et al., 2017**)

Pooled data analysis in this review revealed that:

Type A tympanogram was included as a follow-up measure in 6 of 10 Studies (without RCT) and improved from 0.39% pre-dilatation to 64.5% following Eustachian tube balloon dilation.

Normal TM (by Otoscopy) was included as a follow-up measure in 5 of the 11 Studies and improved from 7.5% pre-dilatation to 72.3% following Eustachian tube balloon dilation.

Normal hearing (by PTA) was included as a follow-up measure in 1 of the 11 Studies and improved from 18% pre-dilatation to 58% following Eustachian tube balloon dilation.

Ability to perform a Valsalva maneuver was included as a follow-up measure in 7 Studies (without RCT) and improved from 5.8% pre-dilation to 84% following Eustachian tube balloon dilation.

ETS was included as a follow-up measure in 3 of the 11 Studies and improved from 1.67(mean) pre-dilation to 5.339(mean) following Eustachian tube balloon dilation.

ETDQ-7 was included as a follow-up measure in 1 of 10 Studies (without RCT) and improved from 4.5(mean) pre-dilation to 2.8(mean) following Eustachian tube balloon dilation.

ET mucosal inflammation Score was included as a follow-up measure in 2 of 10 Studies (without RCT) and improved from 2.855(mean) pre-dilation to 1.565(mean) following Eustachian tube balloon dilation.

SNOT-22 was included as a follow-up measure in 1 of the 11 Studies and improved from 51.4(mean) pre-dilation to 30(mean) following Eustachian tube balloon dilation.

As regard RCT: There was a significant ($P < .0001$) Improvement in the investigational arm compared to the control arm as regard Tympanometry (56.4% increase in type A in investigation group VS. 10.5% in control group) associated with significant ($P < .0001$) normalization of ETDQ-7 (56% returned to normal ETDQ-7 in investigation group VS. 8.5% in control group) and ET mucosa (22% increase in number of normal ET mucosa in investigation group VS. 3.6% in control group) beside the ability to perform valsalva maneuver (42% increase in number of patients with Positive valsalva in investigation group VS. 7% in control group).

Further statistical analysis is inappropriate because of the heterogeneity of the inclusion criteria, techniques and outcome measures in the 11 prospective studies included in this review.

Despite the aforementioned results of this review, (Bluestone C., 2014) suggested, in 2014, that the efficacy of Eustachian tube balloon dilation remains unverified. This is because the majority of studies have small numbers of patients, limited follow up, a weak definition of 'cure' and do not evaluate the direct effect of Eustachian tube balloon dilation on Eustachian tube function. This suggests that a more rigorous clinical trial is required.

Study limitations:

Our evaluation of the evidence for Eustachian tube balloon dilation is limited by the quality of the papers included, as the highest level of evidence available is 1 RCT and otherwise the remaining are prospective case series. Four papers had less than 20 patients, and only 2 papers had an average follow-up period longer than 12 months. Also, there were significant variations in terms of the assessment of

patients, indications for Eustachian tube balloon dilation and assessment of outcomes.

The diagnosis, investigations and indications for Eustachian tube balloon dilation were not standard across the papers. This standardization is in part limited by the subjective clinical nature by which chronic Eustachian tube dysfunction is diagnosed.

Although all studies reviewed used clinical history, otoscopy and tympanometry to diagnose chronic Eustachian tube dysfunction, the indications for Eustachian tube balloon dilation differed. In some papers, Eustachian tube dysfunction refractory to conventional treatment was required, while in others a diagnosis of chronic Eustachian tube dysfunction was sufficient. In future evaluations of Eustachian tube balloon dilation, diagnostic criteria that include objective measurements of tympanometry and the seven-item Eustachian Tube Dysfunction Questionnaire should be used.

In addition, the technique of Eustachian tube balloon dilation differed across the 11 papers, with the two main techniques being those described in the Results section. In both techniques, the target for balloon dilation is the 8–12 mm segment that acts as a valve within the cartilaginous Eustachian tube, as this is where the physiological deficiency in chronic Eustachian tube dysfunction is thought to originate (Poe D. et al., 2011). Hence, care is taken to not push the balloon catheter past the cartilaginous and bony isthmus, or to use a balloon size that is too large for the patient.

However, this has meant that a variety of balloon sizes and pressures have been employed, especially among those who use the Acclarent balloon catheters. No 'best' way to perform Eustachian tube balloon dilation has yet been established; at the current early stages of evaluating its efficacy, the heterogeneity of techniques confounds the ability to draw conclusions.

4. Conclusion

This is the first systematic review to describe the Effectiveness of Balloon Tuboplasty on The Eustachian tube function that included a RCT.

Our search was thorough and included no 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, only one RCT (case-control study) on BET was identified. The other included case series all suffer from high risk of bias and poor study design:

- No absolute indication for the procedure can be identified.

- 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.
- More RCTs or case-control studies using a strict definition of ETD are needed.

Overall, this review found that Eustachian tube balloon dilation is a procedure with a low rate of complications and may be considered as a potential solution for refractory chronic Eustachian tube dysfunction in adults. More rigorous studies with standardized indications, techniques and outcomes are required to provide a higher level of evidence before its mainstream use. Nevertheless, the current data suggest a potential benefit of this procedure for a condition that can be difficult to manage.

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