

Efficiency and safety of dilation methods in eustachian tube dysfunction: a systematic review

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ABSTRACT

Background: Eustachian tube dysfunction is a pathological condition that comes under Otolaryngology specialty. Eustachian tube dysfunction constitutes a public health problem that has to be recognized and treated in appropriate way.

Aim: This study aims to investigate the effectiveness and safety of dilation methods as treatment for Eustachian tube dysfunction. It is important to notice that in clinical praxis every case could be different, and the treatment as well varies. This paper aims to study the dilation methods of Eustachian tube, when these are decided as the treatment.

Materials and Methods: A research was conducted in PubMed database and Cochrane Database of Systematic Reviews (CDSR) using the keywords: 'Eustachian tube dysfunction', 'Balloon dilation', 'Eustachian tube treatment', 'review'.

Results: The search strategy produced 29 results totally . Only 6 studies were eligible for inclusion, with basic criterion to include only systematic reviews with or without a meta-analysis.

Conclusions: According to the reviews included, Eustachian tube dilation may have a benefit in treatment of the disease but the evidence needs to be supported with more studies, taking into account the adverse effects of the intervention.



Keywords: Eustachian tube dysfunction, balloon dilation, Eustachian tube dilation, review



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BACKGROUND

Description of the condition

Definition

Although a standard definition is lacking [1], a definition was proposed as a “failure of the functional valve of Eustachian tube to open and / or close properly” [2]. A strict definition could be “the failure to perform any of its functions” [2].

Study description

In this review 6 studies are included [3-8].

History

The auditory tube was described by Eustachius in 1563 and after by Valsava in 1717. Carus in 1818 and Rathke in 1825 published observations in amphibian embryos and pig embryos respectively [9]

Anatomy and physiology

The eustachian tube is composed of bony and cartilaginous parts. It is longer in adults than infants. Four muscles support the tube; these are the levator veli palatini, tensor veli palatini, tensor tympani and salpigopharygeus. [10]

The Eustachian tube, also known as pharyngotympanic tube, is a tube that connects the middle ear with nasopharynx. Its functions are the following [10]

1. Equalizes the atmospheric pressure in middle ear cavity.
2. Protects the middle ear from secretions and sound pressures.
3. Clears the mucus of middle ear to nasopharynx.

Eustachian tube dysfunction

The prevalence of the disease is about 0.9% on general population indicating a significant impact [3].

There are recognized three subtypes of dysfunction [2]:

1. Patulous Eustachian tube dysfunction
2. Baro-induced Eustachian tube dysfunction
3. Dilatory Eustachian tube dysfunction.

Symptoms of the disease that the patients may experience are muffle hearing, pain, tinnitus and feeling of fullness in the ear [11].

Description of the intervention

Patients suffering from Eustachian tube dysfunction, undergone dilation of Eustachian tube in order to improve symptoms or treat the disease.

How the intervention might work

In order to treat the disease, two of the most common procedures are balloon dilation and laser tuboplasty [6]. In case of balloon dilation, a balloon catheter is inserted into

Eustachian tube and inflated in order to dilate the canal [6].

Why it is important to do this overview

As stated already, Eustachian tube dysfunction constitutes a significant impact on general population. For this reason it was considered important to perform a research about the possible treatments of the disease, and summarize them in an overview. The aggregated results of reviews, gives the potential to extract conclusions on well based scientific evidence.

MATERIALS AND METHODS

Objectives

To investigate the efficiency and safety of Eustachian tube dilation methods as treatment modalities.

Inclusion criteria

1. Studies including patients with Eustachian tube dysfunction.
2. Studies in which balloon dilation was applied alone or in comparison with other treatment.
3. Only review studies with or without meta analysis.

Exclusion criteria

1. Studies that do not include patients with Eustachian tube dysfunction
2. Studies that do not apply balloon dilation as a treatment

3. Studies that are not reviews.

PICO

Population: Patients suffering from eustacian tube dysfunction.

Intervention: Balloon dilation, Eustachian tube tuboplasty.

Comparison: No treatment or other intervention (laser tuboplasty).

Outcomes: Improvement of symptoms of Eustachian tube dysfunction and safety of the procedures.

Search methods for identification of reviews

For the research the Pubmed database, Cochrane Database of Systematic Reviews and Google Scholar was used.

- PubMed Keywords were used like "Eustachian tube dysfunction", "balloon dilation", and "Eustachian tube treatment". Filter was applied for reviews only. The exact search strategy was the following:

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((("Eustachian tube"[MeSH Terms] OR
("Eustachian"[All Fields] AND "tube"[All
Fields]) OR "eustachian tube"[All Fields])
AND ("physiopathology"[Subheading] OR
"physiopathology"[All Fields] OR
"dysfunction"[All Fields])) AND ((balloon[All
Fields] AND ("dilatation"[MeSH Terms] OR
"dilatation"[All Fields] OR "dilation"[All
Fields])) OR (balloon[All Fields] AND
tuboplasty[All Fields])) AND
("review"[Publication Type] OR "review
literature as topic"[MeSH Terms] OR
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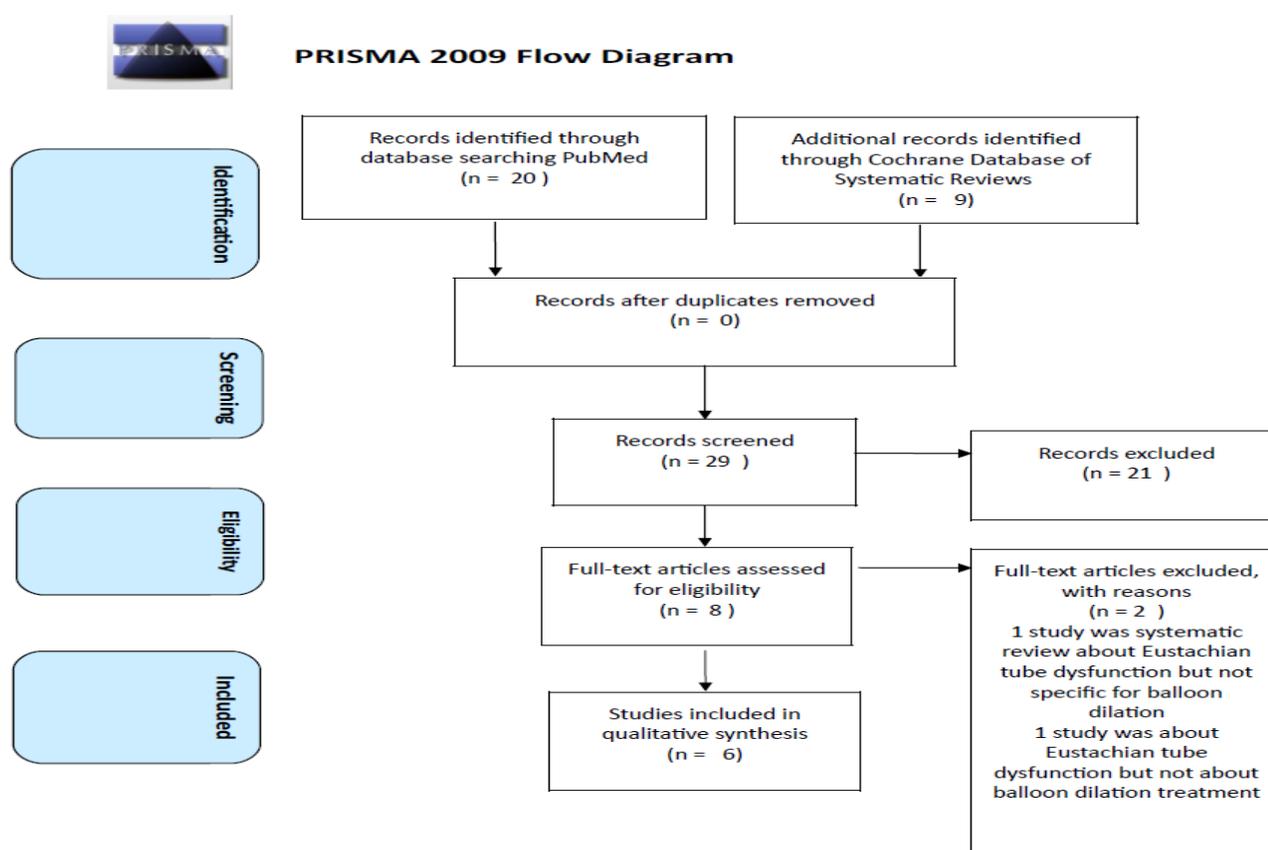
"review"[All Fields]), which yielded 20 results.

- Cochrane Database of Systematic Reviews Keywords "Balloon dilation", "Eustachian tube dysfunction", which produced 9 results. No chronological limit was applied.
- Google Scholar was used as an additional tool. Only 6 studies were eligible to be

included according to the criteria of this overview.

Flow diagram

For the description of the search strategy a prisma flow diagram [12] was used.



Selection of reviews

The studies identified through the search strategy, selected according to the selection criteria decided.

Data extraction and management

For the data extraction, a data collection form was used. Information collected was about review title or ID, type of study, type of intervention, participants, type of comparison, types of outcome measures, aim

of study, funding and possible conflict of interests.

Quality assessment of included reviews

For the quality assessment of included reviews, the AMSTAR 2 [13] appraisal tool was used. A full version of the tool is found here

https://amstar.ca/Amstar_Checklist.php.

According to the author's appraisal, the included reviews were low or critically low overall confidence.

RESULTS

Description of included reviews

In order to describe the included studies, five elements were selected. These are number of patients, intervention, comparison, outcomes and number of studies included in each review

- Huisman et al [3] conducted Systematic review with meta-analysis including 15 Case Series studies [14-28] comprising 1155 patients. The intervention was Eustachian Tube Balloon Dilation. The main outcomes were: 1. Otoscopy 2. Valsalva maneuver or Toynbee maneuver and 3. Eustachian tube score.
- Hwang et al [4] in their Systematic review included 9 Prospective studies (cohort or randomized) [15,19,21-23,25,26,29,30] comprising 474 patients. The intervention was Eustachian Tube Balloon Dilation and the outcomes were: 1. Valsalva or Toynbee maneuver, 2. Tympanometry, 3. Quality of life and 4. Complications.
- Jufas and Patel [5] conducted a Systematic review including 3 case series studies [31-

33] comprising 11 patients and 6 human cadavers. The intervention under study was Eustachian Tube Balloon Dilation (Trans - tympanic approach only). Outcomes were safety and efficiency.

- Wang et al [6] performed a Systematic Review with Meta-analysis. The intervention was Eustachian Tube Balloon Dilation versus Laser Eustachian Tuboplasty as a comparison. The study included 2 Balloon Retrospective studies [18,24], 6 Balloon prospective [17,19,21-23,25] and 5 Laser prospective [34-38] comprising 1063 patients (942 eustachian tube balloon dilation and 121 laser tuboplasty). The main outcomes of the study were: 1. Improvement of Eustachian Tube Score, 2. Tympanometry results, 3. Valsalva maneuver results.
- Luukkainen et al [7] conducted a systematic review including 6 prospective studies [17,21,23,25,39,40] and 4 retrospective studies [14,24,28,41] comprising 1160 patients. The intervention examined was Eustachian Tube Tuboplasty and outcomes were: 1. Symptoms and Disease-Specific Questionnaire ETDQ-7, 2. Valsalva and Toynbee Maneuvers. 3. Tympanometry and 4. Computed Tomography (CT) Scans.
- Randrup and Ovesen [8] performed a systematic review including 9 case series [14,15,19,21-23,25,29,30] comprising 443 patients. The intervention examined was Eustachian Tube Tuboplasty and outcomes reported were: 1. ETDQ-7 score, 2. Valsalva test, 3. Tympanometry and 4. Mucosal inflammation.

Effect of interventions

- Huisman et al [3] in meta-analysis conducted, found that Eustachian tube balloon dilation showed:

1. Reduction of abnormal tympanic membranes detected by otoscopy “(RR: 0.38, 95% CI 0.07–2.05, P = 0.26, I₂ = 99%)”.

2. After Eustachian tube balloon dilation a reduction in inability to perform Valsava manuver was observed “(RR: 0.13, 95% CI: 0.04–0.38, P = 0.0002, I₂ = 78%)”.

3. Decline in inability to dilute the Eustachian tubes “(RR: 0.47, 95% CI 0.32–0.70, P = 0.0002, I = 84%)”.

4. The Eustachian tube score showed improvement of “3.94 (95% CI: 2.60–5.27, P < 0.00001, I₂= 66%)”.

- Hwang et al [4] found that the ability to perform Valsava or Toynbee maneuver before and after Eustachian tube dilation showed improvement from 8 per cent to 72 percent, from total 245 ears subjected to the procedure. According to the study [4] tympanograms classifies as type A (5 per cent) before the procedure and (61 per cent) post operatively. For the quality of life outcome, a statistically significant improvement was detected. According to a study of the review [21] the “7-item Eustachian Tube Dysfunction

Questionnaire pre-operative mean score of 4.5 decreased to 2.8 at 6 months (p <0.001), and the SNOT-22 pre-operative mean score decreased from 51.4 to 30 at 6 months (p= 0.001).

- Jufas et al [5] reports 3 studies about Eustachian tube dilation via transnasal approach. A study [31] in the review was about Eustachian tube dilation in cadavers. In other study [32], the method was applied in live human patients. The study describes no

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operative complications. The other study [33] of the review was on live human patients. In this study transnasal and transtympanic approach was applied.

- Wang et al [6] performed meta analysis comparing of Balloon dilation vs Laser Eustachian tuboplasty. According to the study

1. Balloon Eustachian tuboplasty (BET) showed improvement in “Eustachian tube score, SMD 0.94; 95% confidence interval [CI], 0.23- 1.66; P = .009)”.

2. Balloon Eustachian tuboplasty showed improvement in tympanometry, “pooled event rate = 73% vs 13%; P = .001, in comparison to laser tuboplasty”.

3. Valsava maneuver showed no difference among the two methods.

- Lukkainen et al [7] reports that studies were heterogeneous in selecting patients and outcome measurement. According to Lukkainen et al [7], the “Valsava maneuver improved 80-98% , overall subjective symptoms improved in 73-98% , otoscopic findings 90% , tympanometry in 24-54% and tubanometry in 28-43% of the patients”. Furthermore the “aural fullness disappeared in 83% of the patients , feeling of pressure dissappeared in 26% , subjective hearing loss improved in 21% and otalgia in 6% of the patients”.

- Rundrup et al [8] reports a positive mean score in EDTQ-7, from 4.5 (SD, 1.2) to 2.8 (SD 1.3) p< 0.001 [21]. According to the studies of the review [8] tympanic membrane (TM) status tends to normal (50-97%) at follow up 6 months to 1.5 years. Furthermore high rate of

changes were observed from type B and C tympanograms to type A at follow up (6 months to 1.5 years). The authors report improvement on Valsava maneuver. The authors report a study [14] that found increased quality of life (QoL) in 30 patients “(88% response) by the Glasgow Benefit Inventory (GBI) questionnaire at a range of 6 to 18 months”.

DISCUSSION

Main results

This study closely adheres with PRISMA guidelines [12] and Cochrane guidelines of Overview of reviews [42] chapter 22. In this overview included 6 reviews, 2 of them included also a meta-analysis. Totally of them comprise 28 unique studies. Since the included reviews had one or more critical flaws with or without non critical weakness, the rating for overall confidence was low or critically low according to the author's appraisal interpretation.

The reviews included [3-8] had high heterogeneity in individual studies included as reported due to heterogeneous inclusion criteria, study outcomes, follow up times and methods applied as well as high risk of bias. Moreover the reviews agree that further research is needed about the efficiency and safety of balloon dilation for Eustachian tube dysfunction. Huisman et al [3] concluded that the Balloon dilation of the Eustachian tube can be a helpful. Hwang et al [4] concluded a “potential benefit” of balloon dilation although further research is needed. As far as transtympanic balloon dilation, Jufas et al [5]

concluded that there is limited evidence with “conflicting results” which should be interpreted with caution. Furthermore safety concerns arise about the procedure. According to Wang et al [6] both balloon eustachian tuboplasty and laser tuboplasty can improve symptoms of Eustachian tube dysfunction but due to limited evidence is unclear which procedure is most beneficial. Luukkainen et al [7] conclude that “the long-term outcome of BET is promising”. Randrup and Ovesen [8] report that no standard conclusion can be extracted about “patients who will benefit from the procedure” and “to predict surgical results” and “the results suggest a certain benefit of BET”.

Adverse events

Huisman et al [3] reported “diffuse crash injury” and “local bleeding of the mucosa at the site of the Eustachian tube”. Jufas et al [5] reported for transtympanic method “a risk of carotid artery injury”. Furthermore Randrup and Ovesen [8] reported “minor epistaxis” and “temporarily increased tinnitus”.

Strengths and limitations of the study

This overview consolidates the current literature about the research question, creating stronger evidence. A limitation of this study was the lack of sufficient number of existing studies to be assessed and included.

Future research

Further research is needed with studies of higher quality.

Overall completeness and applicability of evidence

This study focusing at review level evidence about the efficiency and safety of Eustachian tube dilation methods identified a lack of sufficient evidence in the literature.

Potential biases in the overview process

The research strategy was comprehensive and no bias detected in the overview.

CONCLUSION

According to the reviews included in this overview, there is a low level of evidence that Eustachian tube dilation may have a benefit to the patients with Eustachian tube dysfunction although to support the evidence more studies of higher quality are needed.

Furthermore, it is important to consider the adverse effects of the intervention.

Disclosures

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Αποτελεσματικότητα και ασφάλεια των μεθόδων διάνοιξης στη δυσλειτουργία της Ευσταχιανής Σάλπιγγας: συστηματική ανασκόπηση

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ΠΕΡΙΛΗΨΗ

Υπόβαθρο : Η δυσλειτουργία της Ευσταχιανής σάλπιγγας είναι μια παθολογική κατάσταση που εμπίπτει στην ειδικότητα της Ωτορινολαρυγγολογίας. Η δυσλειτουργία της Ευσταχιανής σάλπιγγας , αποτελεί πρόβλημα που άπτεται της δημόσιας υγείας , και για αυτόν τον λόγο χρειάζεται να αντιμετωπιστεί με τον κατάλληλο τρόπο.

Σκοπός: Αυτή η μελέτη στοχεύει στη διερεύνηση της αποτελεσματικότητας και της ασφάλειας των μεθόδων διαστολής ως θεραπεία στην δυσλειτουργία της Ευσταχιανής σάλπιγγας. Είναι σημαντικό να διευκρινιστεί ότι στην κλινική πράξη οι περιπτώσεις της πάθησης μπορούν να διαφέρουν και για αυτόν τον λόγο , η αντιμετώπιση τους ποικίλει. Η παρούσα έρευνα αποσκοπεί στο να ερευνήσει την διαστολή της Ευσταχιανής σάλπιγγας ως θεραπεία , όταν κριθεί απαραίτητη.

Υλικά - Μέθοδος: Διεξήχθη έρευνα στη βάση δεδομένων PubMed και στη βάση δεδομένων Cochrane Systematic Reviews (CDSR) χρησιμοποιώντας τις λέξεις-κλειδιά: 'δυσλειτουργία της Ευσταχιανής σάλπιγγας' , 'διαστολή με μπαλόνι', 'θεραπεία Ευσταχιανής σάλπιγγας', 'ανασκόπηση'.

Αποτελέσματα: Η στρατηγική αναζήτησης έδωσε συνολικά 29 αποτελέσματα. Μόνο 6 μελέτες συμπεριλήφθηκαν , με βασικό κριτήριο να είναι μόνο συστηματικές ανασκοπήσεις με ή χωρίς μετα - ανάλυση.

Συμπεράσματα: Σύμφωνα με τις ανασκοπήσεις που περιλαμβάνονται, η διαστολή της Ευσταχιανής σάλπιγγας μπορεί να έχει όφελος στην θεραπεία της πάθησης, αλλά τα στοιχεία πρέπει να υποστηριχθούν με περισσότερες μελέτες λαμβάνοντας υπ' όψιν και τις επιπλοκές της παρέμβασης.



Λέξεις ευρετηρίου: Δυσλειτουργία Ευσταχιανής σάλπιγγας, διαστολή με μπαλόνι, διαστολή Ευσταχιανής σάλπιγγας, ανασκόπηση



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