

Systematic Review

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Surgical treatment of patulous Eustachian tube – a systematic review

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ABSTRACT

INTRODUCTION: Patulous Eustachian tube (PET) seems to be caused by a defect in the mucosal valve of the Eustachian tube. It causes troublesome autophony occasionally leading to an impaired quality of life. In the present study, we aimed to evaluate the effect of surgical treatment of PET through a systematic review of published studies.

METHODS: A systematic review was performed according to the Preferred Reporting Items for Systematic reviews and Meta-Analysis statement. Medline, Embase and Cochrane were searched systematically for publications about PET.

METHODS: Fourteen publications counting a total of 510 ears from 390 patients who had been treated surgically for PET were included. Complete relief of symptoms ranged from 7% to 77%, improvement from 7% to 86% and 0% to 41% had no response. No studies reported aggravation of symptoms.

CONCLUSIONS: A number of suggested treatments appear to be promising for PET, but it is difficult to propose a specific surgical treatment due to low numbers of patients, lack of clinical trials and cohort studies without control groups.

KEY POINTS

- Patulous Eustachian tube (PET) is an underdiagnosed condition with insufficient data on appropriate treatment.
- Conservative treatment is not always sufficient for PET.
- Various surgical treatment options for PET have been proposed; some have shown promising results.
- This review attempts to identify weaknesses and suggests methods to improve the quality of future studies for surgical treatment of PET.

The Eustachian tube is involved in the normal physiology of the (middle) ear by serving as an opening that drains the middle ear from secretions and facilitates ventilation. Two centuries ago, it was generally believed that the Eustachian tube was always open. However, in 1853, Toynbee proposed that the tube is passively closed and opens only briefly by contraction of two muscles named the tensor and levator veli palatini [1]. It was discovered that the purpose of this contraction is to prevent sound transmission from the pharynx to the ears when talking or breathing and to stop reflux of secretions from the nasopharynx to the middle ear. In a healthy ear, the tube opens briefly by action of the two muscles during activities such as swallowing or yawning. The tube may also open as a result of applied pressure, for instance when performing the Valsalva manoeuvre or during sneezing [2, 3]. In patulous Eustachian tube (PET), the tube is chronically open.

The most reported risk factor for PET is weight loss [4, 5]. The risk also increases during pregnancy. A Danish study from 1979 examined 270 pregnant women among whom a total of 19 women were found to have PET. This number was significantly higher than in a control group [6].

The primary symptom in PET is voice and breath autophony, where nasal voice and nasal respiration, in particular, constitute the most bothersome symptoms. Another major symptom is aural fullness (sensation of blockage in the ear). Patients may also suffer from tinnitus or vertigo [7]. It was reported that exercise and use of nasal decongestant aggravate the symptoms [8], while lying down or sniffing reduces the symptoms [9].

In 1988, Bluestone & Doyle suggested that reflux of nasopharyngeal contents due to a chronically open Eustachian tube could cause otitis media [2]. In another study by Oshima et al from 2011, it was demonstrated that cholesteatoma was more common in patients with PET due to habitual sniffing which relieves PET symptoms but causes retraction of the tympanic membrane. The authors compared two cohorts: one consisting of 97 patients with “sniff-positive PET” and another cohort consisting of 39 patients with “sniff-negative PET”. Cholesteatoma (or signs of previous cholesteatoma) was noticed in five of the “sniff-positive patients”, whereas in the “sniff-negative PET” group, there were no signs of present or previous cholesteatoma [10]. In addition, a similar study from 2009 suggested that the incidence of PET in patients with cholesteatoma was significantly higher than in patients with other ear conditions such as chronic otitis media or otosclerosis [11]. Another study from 2013 also demonstrated an increased incidence of cholesteatoma in patients with habitual sniffing [12].

In 2018, Japan’s Otological Society proposed a set of diagnostic criteria for PET [13]. According to these criteria, the diagnosis should be based on three criteria; symptoms, symptom relief and objective findings. The first criterion is mandatory for the diagnosis. If a patient meets all three criteria, the diagnosis may be considered confirmed. If a patient meets only two criteria (symptoms and symptom relief or objective findings), the diagnosis is not confirmed but possible, and further examinations are required. In asymptomatic patients, symptoms should be provoked before examination, e.g., by instructing the patients to take a brisk walk, taking heavy nasal

breaths, swallowing or performing the Valsalva manoeuvre [8]. In 2007, D.S. Poe suggested a simple five-grade table to evaluate the outcome after treatment; worsening, unchanged, improved and satisfied, improved but dissatisfied or complete remission of symptoms. These are known as Poe's criteria [8].

PET is an uncommon condition. It can be refractive to conservative treatment (such as weight gain and information about the condition) [14]. Moreover, weight gain might be ill-advised in case of comorbidity. Therefore, there seems to be an indication for surgical treatment in the more affected patients. The intention of surgical treatment is to narrow the tube (tubaplasty) or make the ear drum less compliant to vibration (myringoplasty or myringotomy).

The aim of this study was to perform a systematic review focusing on treatments of PET according to the Preferred Reporting Items for Systematic reviews and Meta-Analysis (PRISMA) statement.

METHODS

We conducted a systematic review following the PRISMA guidelines [15]. The review was registered in the PROSPERO International Prospective Register of Systematic Reviews. The registration number is CRD42018095791.

Systematic literature search

A modified Population, Intervention, Outcome, and Study design (PICOS – PIOS) strategy was employed for the search. The target population consisted of patients with PET and the intervention was surgical treatment. The outcome measures were subjective patient evaluation of autophony and aural fullness changes after surgical treatment. The study design was without restrictions, provided original data were used.

We searched for studies from the electronic bibliographic databases Medline, Embase and Cochrane. The search was conducted on 30 April 2019 and was without restriction on publication date. The search strategy was based on a combination of all available free text terms for PET. The electronic search was performed by the first author (ZM).

Study selection

Duplicates in the literature search were removed manually. The eligibility process was conducted in two steps. First, two authors (ZM and TR) screened the titles and abstracts independently using predefined criteria for inclusion and exclusion. Subsequently, the same two authors independently evaluated the full-text version of any publications that had passed through the first steps. At each step, discrepancies were resolved by discussion or, if needed, CF served as an arbitrator. In case of doubt, the study passed to the next level. We included all studies written in English, Swedish, Norwegian or Danish and providing original data for a minimum of five patients surgically treated for PET. Case reports ($n < 5$ patients), conference abstracts and publications without relevant data were excluded.

Data items and collection process

ZM performed the data extraction. For each study, we extracted the number of ears and/or patients, gender distribution, follow-up time, complications and outcomes. We inserted outcomes in one of three groups – “complete remission”, “improved” or “no response”. Moreover, data were extracted for symptoms and diagnostic methods.

Risk of bias assessment

Risk of bias in the included studies was assessed using the SIGN Checklist for Cohort Studies [16]. The quality of each study was evaluated according to three domains; selection of subjects, study design and statistics.

Data synthesis

A descriptive synthesis was conducted, summarising diagnostic methods, surgical approach, follow-up, complications and subjective patient-reported outcome of surgical treatment.

RESULTS

Study selection and characteristics

The systematic literature search produced 412 publications (n = 233 after removal of duplicates). The study selection process is shown in **Figure 1**. A total of 48 publications were analysed as full text; 14 of these studies were included in the quantitative synthesis. Study characteristics are summarised in **Table 1**.

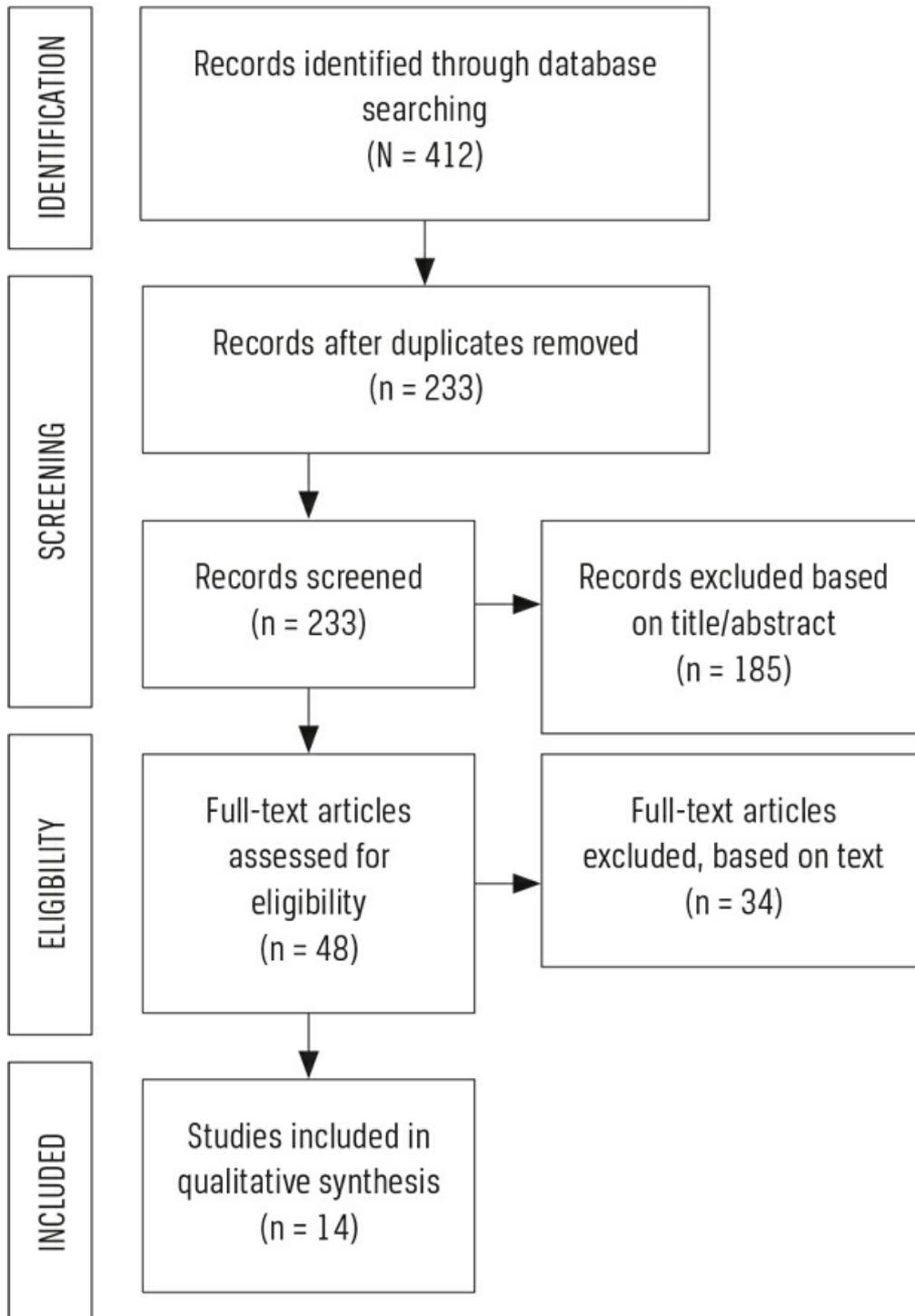
FIGURE 1 / Study selection flow chart.

TABLE 1 / Data extracted from included studies.

Reference	Patients (♂/♀), n Ears, n	Symptoms	Diagnostic methods	Procedure type and short description	F/U, average mo.s Range: Mean: 24	Outcome: n Ears CR: 5 I: 6 NR: 5	Complications: n
Virtanen & Palva, 1982 [21]	13 (8/5) 16	A	Otoscopy Sonotubometry	Tensor veli palatini transposition (n = 8) or transection (n = 8)	Range: 2-60 Mean: 24	Ears CR: 5 I: 6 NR: 5	-
Poe, 2007 [8]	11 (5/6) 14	A	Otoscopy Endoscopy	TN approach with ET reconstruction	Range: 3-30 Mean: 15,8	Ears CR: 1 I: 12 NR: 1	OM: 1
Yanez et al, 2011 [20]	11 (9/2) 14	A	Otoscopy Endoscopy Tymanometry	TN approach with laser-assisted curvature inversion of the ET	24	Ears CR: 8 I: 1 NR: 2	None
Busato & Agrawal, 2013 [22]	11 (3/8) 14	A	Otoscopy Endoscopy	TN approach with ligation of the ET	6	Ears CR: 9 I: 4 NR: 1	Epistaxis: 1
Vaezeafshar et al, 2014 [23]	14 (4/10) 22	A AF	Otoscopy Endoscopy	TN approach with injection of hydroxyapatite of the ET	Range: 9-36 Mean: 17,5	Ears ^a CR: 6 I: 7 NR: 9	None
Oh et al, 2015 [18]	29 (16/13) 35	A AF	Otoscopy	TT catheter insertion	Range: 6-37 Mean: 19,3	Ears CR: 22 I: 13 NR: 0	OM: 5 Mastoiditis: 1 Tube displacement: 3
Schroder et al, 2015 [17]	20 (8/12) 26	A AF T HL	Otoscopy Sonotubometry Tymanometry	TN approach with injection of soft-tissue bulking agent	12	Patients ^b CR: 10 I: 5 NR: 3 -: 2	Epistaxis ^c
Mackeith & Bottrill, 2016 [24]	11 (5/6) 19	A AF	Otoscopy Prone test	TN-TO approach with injection of polymethylsilaxone elastomer	Range: 3-44 Mean: 18,3	Patients CR: 2 I: 7 NR: 2	ME effusion: 1
Oh et al, 2016 [25]	25 (19/6) 33	A AF	Otoscopy	TN-TO approach with injection of autologous tragus cartilage	Range: 12-40 Mean: 25,2	Ears CR: 9 I: 20 NR: 4	OM: 1
Kikuchi et al, 2017 [19]	191 (84/107) 252	A AF	Otoscopy Prone test Obstruction test TTAG	TT plug insertion with plug.	Range: 3-168 Mean: 25,2	Ears CR: 163 I: 66 NR: 19 -: 4	OM: 37 TM perforation: 50 Tube displacement: 26
Jeong et al, 2018 [26]	11 (2/9) 14	A V	Questionnaire	TT tragus cartilage injection	Mean: 16,4	Ears CR: 4 I: 9 NR: 1	None
Alli et al, 2019 [27]	8 (3/5) 12	A AF	Questionnaire	CT-guided TC injection of silicone elastomer suspension implant into ET	Range: 6-62 Mean: 29	Ears CR: 7 I: 4 NR: 1	ME effusion: 1
Kim et al, 2019 [28]	23 (7/16) 26	A AF T	Otoscopy	Paper patching of TM using cigarette paper	1	Patients CR: 15 I: 6 NR: 2	None
Si et al, 2016 [29]	12 (4/8) 13	A AF	Otoscopy	Myringoplasty using tragus cartilage	6	Ears ^a CR: 10 I: 3 NR: 0	None

A = autophony (breath and/or voice); AF = aural fullness; CR = complete remission; ET = Eustachian tube; F/U = follow-up; HL = hearing loss; I = improved; ME = middle ear; NR = no responders; OM = otitis media; T = tinnitus; TC = transcutaneous; TM = tympanic membrane; TN = transnasal; TO = transoral; TT = transtympanic; TTAG = tubo-tympano-aerodynamic graphy; V = vibration sound.

a) Outcome presented for voice autophony only.

b) CR in this study is defined as "significant improvement".

c) Number not given.

Risk of bias assessment

According to the SIGN recommendations, three domains were assessed for each included study yielding a total of 42 assessments. The overall assessment was acceptable for all studies.

Synthesis of results

A total of 510 ears (390 patients) were treated surgically. The outcome was presented for each treated ear (or patient) based on a subjective report of post-operative symptoms. The outcome for patients or ears was as follows; complete relief of symptoms ranged from 7% to 77%, improvement from 7% to 86% and no response ranged from 0% to 41%. None of the studies presented patients with aggravation of symptoms. The average follow-up time ranged from one to 29 months. Data are presented in Table 1. Out of 510 treated ears, a minimum of 127 complications were observed. Complications were observed in nine of the 14 trials. Four trials reported no complications and one trial did not specify whether there were complications or not. One of the nine studies reporting complications did not specify how many [17]. Complications for each trial are presented in Table 1. We also divided the 14 trials by type of treatment. Twelve focused on tuboplasties [8, 17-27] and two on myringoplasties [28, 29]. In the tuboplasty trials, accounting for a total of 471 ears, 127 complications occurred, which corresponds to a 27% risk. In the two myringoplasty trials, comprising 39 ears, no complications were observed.

DISCUSSION

In the present study, we aimed to estimate the effect of surgical treatment for PET. We conducted a systematic literature search and found that a majority of patients benefited from surgical treatment. In total, we identified 14 studies with promising results and few serious complications. In many cases, the outcome was excellent, but the studies had a low evidence level. More and larger studies are needed.

The studies included in this review contained very few ears (a total of 510 ears, of which 252 were from one study alone) and only one study had a control group [28]. This study compared paper patching of the Eustachian tube with standard treatment at their department; saline irrigation. The authors showed that after three months, 65% of the patients treated with paper patching reported to be free of PET symptoms and 26% reported an improvement in symptoms. In the group receiving nasal saline irrigation, only 25% reported symptom relief, and 13% reported improvement after three months [28].

In most studies, complications resolved spontaneously and required only simple or no treatment. The complications are listed in Table 1. A few possibly serious complications were observed. There was a case of mastoiditis in a study by Oh et al. The authors treated 35 ears with transtympanic catheter insertion into the Eustachian tube. Five patients suffered from otitis media after the procedure, three resolved spontaneously and two were treated with ventilation tube for one year. One of the patients treated with a ventilation tube subsequently suffered from

mastoiditis, and the decision was made to remove the catheter completely. Furthermore, in three cases, the tube was missing during follow-up; it had probably displaced into the nasopharynx [18]. In 2016, a large study was published comprising 252 ears treated using a transtympanic catheter. A total of 113 complications were reported; 26 of these were catheter displacements into the nasopharynx [19]. In the two studies on transtympanic catheter insertions, a total of 29 catheters in 287 ears were displaced into the nasopharynx.

In a case series published in 2011 involving curvature inversion tuboplasty, complete remission was observed in 45.4% at six-month follow-up (satisfaction was reported by 73% of the patients). After 24 months, complete remission was reported by 73% (satisfaction was reported by 82% of the patients) [20]. In contrast, a study from 2019, which involved paper patching of the tympanic membrane, 83% reported complete remission at the one-month follow-up, but only 65% after three months [28]. This stresses the importance of a sufficiently long follow-up.

The previously mentioned study from 2019 that involved paper patching of the tympanic membrane [28] is the only study included in this review that had a control group. It consisted of patients treated with nasal saline irrigation. In this trial, sterilised cigarette paper was placed in the most mobile quadrant of the tympanic membrane when observed during nasal respiration. The procedure did not lead to any complications. Furthermore, it is non invasive, does not require general anaesthesia and can be performed in an outpatient setting. However, the study included only 23 patients.

CONCLUSIONS

A number of suggested treatments appear to be promising for treatment of PET, but a specific surgical treatment is difficult to propose due to low numbers of patients, lack of clinical trials and cohort studies without control groups. Based on this literature review, we suggest that the follow-up time should be at least one year in future studies. Future studies should be properly conducted, preferably duly controlled clinical trials with sufficient sample sizes. There is no generally accepted treatment for the condition. We suggest ventilation tube insertion or paper patching of the tympanic membrane [28] due to the low risk of complications, low cost and ease of application.

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