



Review Article

# Laser vs microdebrider eustachian tuboplasty for the treatment of chronic adult eustachian tube dysfunction: A systematic review

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## KEYWORDS

Eustachian tuboplasty;  
Eustachian tube;  
Treatment of Eustachian tube dysfunction

**Abstract** *Objectives:* Multiple treatments are described in the literature for the treatment of chronic Eustachian tube dysfunction but high-level quality evidence seems missing to support these treatments. This systematic review aimed to determine and compare the safety and efficacy of Laser Eustachian tuboplasty and Microdebrider Eustachian tuboplasty as a treatment for long-term Eustachian tube dysfunction.

*Data sources:* A total of 12 electronic databases were searched up to April 2018 for published and unpublished literature in the English language. References of included studies were checked.

*Methods:* A systematic review was undertaken. Outcomes assessed were: primary outcomes-subjective improvement in symptoms (ETDQ-7), audiometric improvement of hearing, improvement of negative middle ear pressure noticed in tympanometry, objective improvement of tympanic membrane retraction. Secondary outcomes were-the ability to auto-insufflate Eustachian tube i.e. Valsalva manoeuvre, improved quality of life, passive tubal opening, tubomanometry, swallowing test, reduction in mucosal inflammation of Eustachian tube orifice in the nose, complications from the procedure, the need for further procedures. Results are reported in a narrative synthesis as a meta-analysis was not possible due to heterogeneous data.

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**Results:** Three studies were included. All included studies were small-scale case series (13–38 participants). Studies were conducted outside the UK. Subjective and objective improvement of Eustachian tube function was reported in all studies. But all included studies were at high risk of bias and subject to multiple limitations. No major complications were reported in either study.

**Conclusions:** Based on current evidence, it is not possible to recommend the clinical use of either of these two interventions i.e. Laser or Microdebrider Eustachian tuboplasty. Lack of controlled studies was identified as a gap in the evidence. Future research should be directed toward designing randomised controlled trials. These trials should use strict standard methodology and reporting criteria. Future trials should make use of consensus statement document about Eustachian tube dysfunction definition, diagnostic methods, and outcome assessment criteria to design clinical trials.

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## Introduction

Eustachian tube dysfunction is a common problem, the reported incidence is about 0.9%–5%.<sup>1–4</sup> Various treatments are available but high-level evidence is missing supporting the efficacy and safety of these treatments.<sup>4,5</sup>

### The rationale for this study

The current focus of literature seems to be on Eustachian tuboplasty techniques as a potential solution for long term Eustachian tube dysfunction; as several recent studies are published about it.<sup>6–12</sup> There are 3 techniques described in the literature for Eustachian tuboplasty i.e. Balloon tuboplasty, Laser tuboplasty and Microdebrider tuboplasty. There is more high-level evidence available about balloon tuboplasty as compared to the other two techniques.<sup>6–9</sup> During our literature search, we did not find a systematic review comparing Laser and Microdebrider Eustachian tuboplasty as an intervention, hence we decided to analyse and compare available evidence about these two interventions.

### Objectives of the study

This study aims to systematically evaluate efficacy and safety profile of Laser Eustachian tuboplasty and Microdebrider Eustachian tuboplasty in the adult population. The objective is to compare these two interventions with one another to assess if one intervention is better than the other in providing long term relief from symptoms of Eustachian tube dysfunction and also to compare cost aspects of both interventions.

## Methods

### Project registration

This project was registered with the Faculty of Health & Social Care Edge Hill University, UK.

## Eligibility criteria

### Population

Focus of this review was on adult population i.e. 18 years or old with Eustachian tube dysfunction.

### Interventions

Laser Eustachian tuboplasty or Microdebrider Eustachian tuboplasty.

### Comparator

Any comparator i.e. placebo, no intervention, Microdebrider Eustachian tuboplasty, Laser Eustachian tuboplasty.

### Outcomes

The primary outcome measures were:

1. Subjective symptomatic improvement i.e. ideally reported by using a valid and reliable patient reporting scoring system ETDQ-7.
2. Improved hearing thresholds based on Pure Tone Audiometry.
3. Reduction of negative middle ear pressure measured by tympanometry i.e. conversion of Type B or C tympanogram to Type A or clearance of middle ear effusion.
4. Objective improvement in the eardrum appearance i.e. reduction of the eardrum retraction or normalisation of a retracted eardrum.

The secondary outcome measures were considered as improved compliance noticed on pneumatic otoscopy, improved Valsalva manouevre, improved quality of life, clearance of middle ear effusion, passive tubal opening, tubomanometry, improved toynbee manouevre, reduction in mucosal inflammation of Eustachian tube orifice in nose, procedural complications and the need for the future procedure.

### Study design

Any study design except commentary articles and individual case reports.

**Table 1** Overview of included studies in this systematic review.

Study	N	Country	Study design	Setting	Population	Intervention	Outcome measures
Metson et al. <sup>13</sup>	20	USA	Case series	The academic medical centre Single centre study	Adults (Age range 23–66) 40% Males 60% Females	Microdebrider Eustachian tuboplasty	1. Symptomatic improvement 2. Hearing 3. Clearance of middle ear effusion 4. Tympanometry 5. Complications
Poe et al. <sup>14</sup>	13	USA	Case series	Tertiary medical centre Single centre study	Adults (Age range 29–64) 92% Males 8% Females	Laser Eustachian tuboplasty	1. Hearing 2. Clearance of middle ear effusion 3. Tympanometry 4. Otoscopy 5. Further procedure 6. Complications
Sedlmaier et al. <sup>15</sup>	38	Germany	Case series	Not Recorded	Adults (Age range 21–76) 42% Males 58% Females	Laser Eustachian tuboplasty	1. Tympanometry 2. Valsalva manoeuvre 3. Passive tubal opening 4. Complications

N = number of patients.

## Literature search

A literature search was performed using following databases: Medline, CINAHL, Cochrane library, EMBASE, Academic research premier, Web of science core collection, BIOSIS citation index and data citation index, Home | Grey Literature Database, Clinical trial Gov and Conference papers & proceedings - Dissertation and thesis database were searched. References of the included articles were checked to look for any additional relevant articles (See [Appendix 1](#) and [Table 1](#)).

## Study selection

The title, abstracts and in some cases, the full text of identified articles were examined. Studies were included as long as they fulfil the inclusion criteria in terms of design, quality, setting, population and outcome.

## Quality assessment

The revised and validated version of MINORS (Methodological items for non-randomised studies) tool was used for quality assessment of included studies.

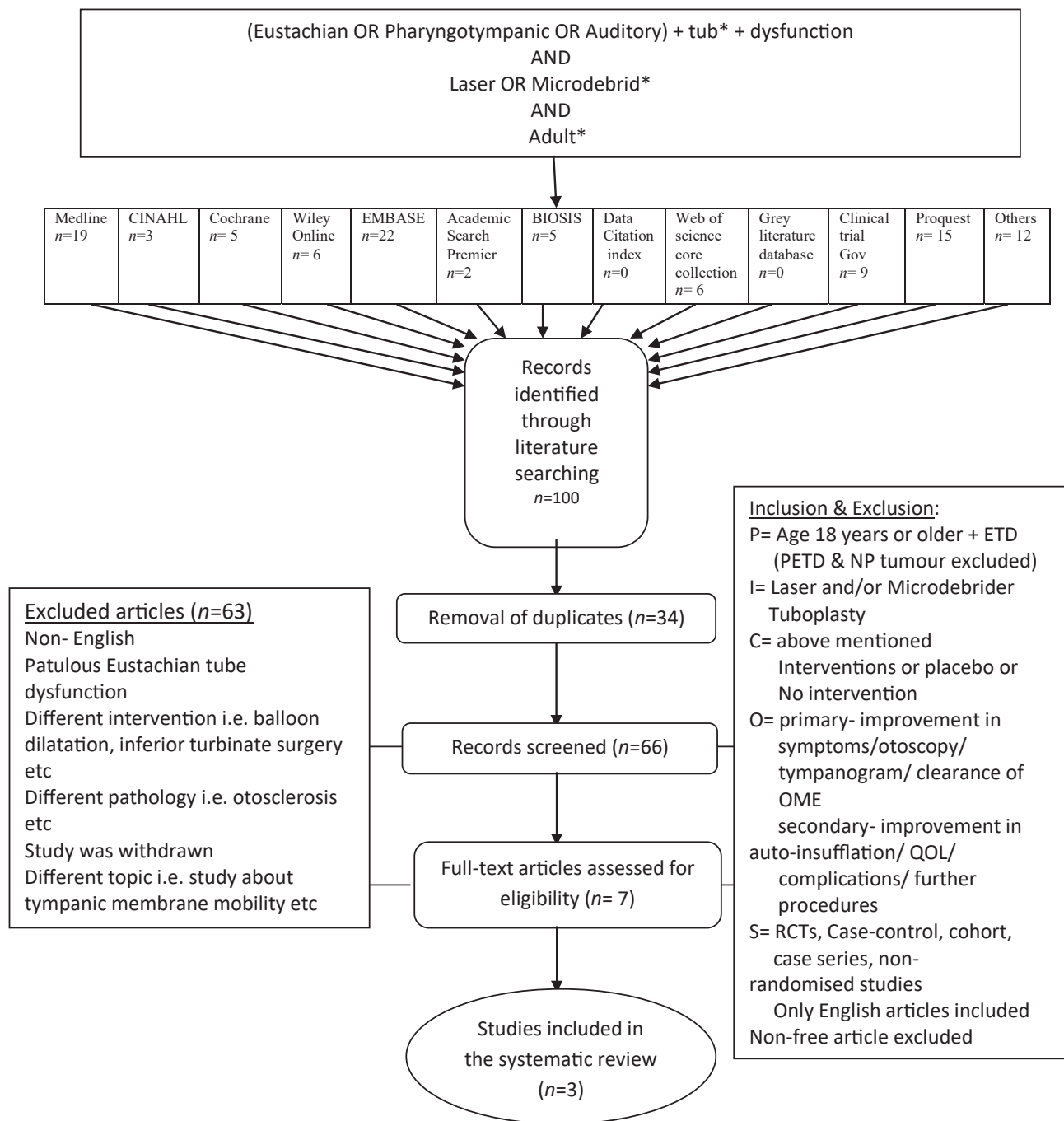
## Data extraction

Data were collected about study design, study setting, study place, number of participants, age, sex, ethnicity, body mass index, inclusion/exclusion criteria, study definition of Eustachian tube dysfunction, any associated condition, diagnostic method, scoring system, primary intervention, type of anaesthesia, any concomitant treatment, primary and secondary outcomes, cost analysis, ethical approval, funding and loss to follow up. Where possible, calculations were made based on intention to treat analysis. Relative risks were calculated for dichotomous outcomes (risk of negative event or risk of no improvement, with values < 1 favouring the intervention) and mean differences (between-group difference in change from baseline) were calculated for continuous outcomes; 95% confidence intervals (CIs) were calculated.

## Data analysis and synthesis

The significance level of  $P < 0.05$  and a confidence interval of 95% CI was accepted. Calculations were made on intention to treat basis. Statistical tests used were Fisher's exact test, paired *t*-test, McNemar test, and chi-squared test.

Due to significant heterogeneity among studies in terms of inclusion/exclusion criteria, diagnostic methods, outcome assessed, missing outcome and length of follow up; it was not possible to do quantitative synthesis. Hence results are reported in a narrative synthesis.



**Figure 1** Flow diagram of the study selection. P= Population, ETD = Eustachian tube dysfunction, PETD= Patulous Eustachian tube dysfunction, NP= Nasopharyngeal tumour, I= Intervention, C= Comparator, O= Outcome, S= Study design, OME= Otitis media with effusion, QOL = Quality of life, RCT = Randomised controlled trial.

## Ethics

Formal ethical approval from the National Research and Ethics Service was not required as there was no direct patient contact.

## Results

### Study selection

Eighty-eight articles were identified through the electronic search of databases. Additional 12 articles were identified from the reference search, making a total of 100. Thirty-four duplicates were removed. Sixty-six articles were screened, which resulted in the final 7 relevant studies. Out of these 7 studies, only 3 met inclusion criteria of our systematic review (See study selection flow diagram Fig. 1). All included studies were case series.

### Characteristics of the included studies

There was a wide range of heterogeneity among included studies in terms of inclusion criteria, diagnostic methods, outcome assessed and assessment tools (See Table 1).

### Quality of the included studies

Modified MINORS criteria were used for quality assessment of included studies. Some weaknesses were identified

during the quality assessment process i.e. 2 studies did not report consecutive recruitment of patients,<sup>13</sup> loss to follow up was not reported in one study (See Table 2).<sup>15</sup>

### Intervention and comparators

Nearly all participants in the included three studies had previous treatments or some form of medical or surgical treatments. In one study, all patients received topical nasal steroids and eligible patients received proton pump inhibitors and/or antihistamines, the previous set of grommets inserted.<sup>14</sup> Tympanoplasty and sinus surgery was performed as concomitant treatment in Sedlmaier et al,<sup>15</sup> and Metson et al,<sup>13</sup> respectively. Patients were treated in past with one or more of these treatments i.e. topical steroid nasal spray, antihistamine, proton pump inhibitor, myringotomy and grommet in Metson et al.<sup>13</sup>

### Outcome

Certain clinically relevant outcomes were not reported in some of the included studies i.e. improvement in symptoms was not reported in Poe et al<sup>14</sup> and Sedlmaier et al,<sup>15</sup> hearing improvement was not reported in Sedlmaier et al,<sup>15</sup> eardrum appearance was not reported in Metson et al<sup>13</sup> and Sedlmaier et al.<sup>15</sup>

### Primary outcomes

Symptomatic improvement was assessed in only one study,<sup>13</sup> reporting improvement in 70% (14/20) of the patients. The hearing outcome was assessed in 2 studies.<sup>13,14</sup> Clearance of middle ear effusion was assessed in only one study, reporting improvement in 85% cases.<sup>14</sup> Measurement of middle ear pressure in the form of tympanometry was reported in all three studies. However, the criteria for assessing tympanometric improvement was not uniform among studies i.e. one study differentiated between a less flattened curve (tympanogram) and a flat curve, but this differentiation was not made in the other studies.<sup>15</sup> One study reported an overall improvement in the tympanogram noticed on 2 years follow up.<sup>14</sup> Another study reported 31.5% (6/19) improvement but this was noticed only 8 weeks postoperatively, without describing the long-term tympanometry results.<sup>15</sup> One study reported ear drum appearance i.e. retracted or normal as an outcome and some improvement was noticed.<sup>14</sup>

### Secondary outcomes

Improved Valsalva manoeuvre was reported in one study.<sup>15</sup> No study reported quality of life as an outcome measure. Two studies reported that there was no short term or long term complications.<sup>13,15</sup> One study reported minor short-term complications postoperatively, which either resolved spontaneously or with the topical steroid nasal spray.<sup>14</sup> Need for a further procedure was discussed in only one study, reporting grommet insertion in 2/6 patients on two years follow-up.<sup>14</sup> No study reported cost analysis, tubomanometry, mucosal inflammation, pneumatic otoscopy, swallowing test (See Table 3).

**Table 2** Quality assessment of included studies using modified MINORS criteria.

	Poe et al. <sup>14</sup>	Sedlmaier et al. <sup>15</sup>	Metson et al. <sup>13</sup>
Clearly stated aim	2	2	2
The inclusion of consecutive patients	0	0	2
Prospective data collection	2	2	2
Endpoints appropriate to the study aim	2	1	2
Unbiased assessment of the study endpoints	1	1	0
Follow up period appropriate to the study aim	1	1	1
<5% loss to follow up	0	0	0
Prospective calculation of study size	2	2	2
Total score	12	9	11

**Table 3** Summary of outcome findings.

Item	Poe et al. <sup>14</sup>	Sedlmaier et al. <sup>15</sup>	Metson et al. <sup>13</sup>
Length of follow up	2 years	2 months	13 months
Symptomatic improvement	Not reported	Not reported	6/20 (30%) patients still symptomatic 14/20 (70%) patients asymptomatic
Hearing	Mean post-treatment PTA 2 year post-procedure 20.8 DB Statistical significance $P = 0.028$	Not reported	Mean PTA decrease by 6 DB ( $P = 0.013$ )
Tympanometry	2/4 (50%) Type A (Normal) 1/4 (25%) Type B (Abnormal) 1/4 (25%) Type C (Abnormal)	Intact ear drum group: Tympanogram improved in 6/19 (31.5%) patients.	11/17 (65%) patients showed improved tympanogram 6/17 (35%) patients did not show any improvement
Tympanic membrane appearance (Otoscopy)	0/6 Atelectasis 3/6 (50%) Retraction 1/6 (17%) Perforation	Not reported	Not reported
Clearance of middle ear effusion	2/13 (15%) patients had Otitis media with effusion	Not reported	Not reported
Further procedure	2 patient required grommet insertion	Not reported	Not reported
Quality of life	Not reported	Not reported	Not reported
Valsalva manoeuvre	Not reported	Perforated eardrum group: 14/19 (73%) patients had positive Valsalva manoeuvre Intact ear drum group: 14/19 (73%) patients had positive Valsalva manoeuvre	Not reported
Passive tubal opening	Not reported	Post operative passive tubal opening noticed in 9 patients (31%).	Not reported
Pneumatic otoscopy	Not reported	Not reported	Not reported
Tubomanometry	Not reported	Not reported	Not reported
Swallowing test	Not reported	Not reported	Not reported
Reduced mucosal inflammation	Not reported	Not reported	Not reported
Complications	4 patients had minor complications	No complications	No complications

## Study design and setting

All studies were uncontrolled case series conducted outside the UK.

## Discussion

Due to the presence of vast differences among included studies, a meta-analysis was not possible; hence results are reported in a narrative synthesis. The key finding of this review was a lack of reliable evidence. Only uncontrolled studies were identified. Limited quantity and poor quality evidence were found. Consequently, this systematic review failed to prove the clinical effectiveness of Laser Eustachian tuboplasty or Microdebrider Eustachian tuboplasty as a possible treatment for long-term Eustachian tube dysfunction. But this systematic review systematically analysed current evidence identified a gap in the literature and gave directions for future research.

## Key findings

### Factors affecting internal validity

All 3 studies were uncontrolled case series, found to be at high risk of bias. Due to the lack of a control group, there is no comparison to know if the findings are better or worse, with or without treatment, which raises the risk of bias.<sup>16</sup> Poe et al<sup>14</sup> and Sedlmaier et al<sup>15</sup> did not report consecutive recruitment of patients. Non-consecutive recruitment of patients can be indicative of preferential inclusion of patients with likely better outcome, leading to selection bias.<sup>16,17</sup> All studies were small-scale dealing with 13, 38 and 20 patients; resulting in low statistical power, which can potentially give rise to random chance findings.<sup>18–21</sup> A significant loss to follow up was noticed around 16% and 25% in Poe et al<sup>14</sup> and Sedlmaier et al<sup>15</sup> respectively. The loss to follow up leads to incomplete outcome data resulting in attrition bias.<sup>22</sup>

### Factors affecting external validity

Significant clinical heterogeneity was noticed among the included studies. Variations were seen among the studies in

**Table 4** Summary of outcome findings.

	Poe et al 2007	Sedlmaier et al 2009	Metson et al 2007
Length of follow up	2 years	2 months	13 months
Symptomatic improvement	Not reported	Not reported	6/20 (30%) patients still symptomatic 14/20 (70%) patients asymptomatic
Hearing	Mean post-treatment PTA 2 year post-procedure 20.8 DB Statistical significance $P = 0.028$	Not reported	Mean PTA decrease by 6 DB ( $P = 0.013$ )
Tympanometry	2/4 (50%) Type A (Normal) 1/4 (25%) Type B (Abnormal) 1/4 (25%) Type C (Abnormal)	Intact ear drum group: Tympanogram improved in 6/19 (31.5%) patients.	11/17 (65%) patients showed improved tympanogram 6/17 (35%) patients did not show any improvement
Tympanic membrane appearance (Otoscopy)	0/6 Atelectasis 3/6 (50%) Retraction 1/6 (17%) Perforation	Not reported	Not reported
Clearance of middle ear effusion	2/13 (15%) patients had Otitis media with effusion	Not reported	Not reported
Further procedure	2 patient required grommet insertion	Not reported	Not reported
Quality of life	Not reported	Not reported	Not reported
Valsalva manoeuvre	Not reported	Perforated eardrum group: 14/19 (73%) patients had positive Valsalva manoeuvre Intact ear drum group: 14/19 (73%) patients had positive Valsalva manoeuvre	Not reported
Passive tubal opening	Not reported	Post operative passive tubal opening noticed in 9 patients (31%)	Not reported
Pneumatic otoscopy	Not reported	Not reported	Not reported
Tubomanometry	Not reported	Not reported	Not reported
Swallowing test	Not reported	Not reported	Not reported
Reduced mucosal inflammation	Not reported	Not reported	Not reported
Complications	4 patients had minor complications	No complications	No complications

the inclusion/exclusion criteria, diagnostic criteria, duration of the follow-up and outcome assessment. Overall, all three included studies had limited generalisability.<sup>23</sup> In all included studies, several confounding factors were present i.e. presence of associated conditions (acid reflux, allergic rhinitis, rhinosinusitis), pre-treatment (proton pump inhibitors, antihistamines), concomitant treatments (sinus surgery, eardrum repair surgery). Confounding factor distorts the association between exposure and outcome.<sup>24</sup>

#### Factors affecting outcome assessment data

All 3 studies mostly reported positive outcome data findings (see Table 4). Certain clinically relevant outcomes were not reported in some of the included studies i.e. improvement in symptoms, hearing improvement, eardrum appearance.<sup>13–15</sup> Missing important outcome data and reporting positive findings only raise the risk of selective reporting resulting in outcome reporting bias.<sup>20–22</sup> No serious adverse event was reported in these studies. 2 studies reported no

complications from the procedure and in Poe et al,<sup>14</sup> only minor complications were reported about Laser Eustachian tuboplasty i.e. adhesion, small granuloma. Based on this complication rate data, both Laser and Microdebrider Eustachian tuboplasty appears as relatively safe procedures. But large-scale standard clinical randomised trials are still required to further prove safety and efficacy profile.

#### Comparison of the findings of this review with the previously published literature

Findings of this systematic review are in line with some of the previously published literature, demonstrating little evidence about Laser Eustachian tuboplasty or Microdebrider Eustachian tuboplasty as a treatment for adult Eustachian tube dysfunction.<sup>4,5</sup> On the contrary, the findings of all studies reporting Laser and Microdebrider Eustachian tuboplasty as an effective treatment are in

actuality based on low-level evidence. A recent systematic review and meta-analysis compared Balloon dilatation and Laser Eustachian tuboplasty.<sup>6</sup> This recent review analysed 13 uncontrolled studies dealing with 1063 patients.<sup>6</sup> This review concluded improvement in the symptoms of Eustachian tube dysfunction with the use of Balloon dilatation and Laser Eustachian tuboplasty.<sup>6</sup> But this conclusion was based on low-level evidence.<sup>6</sup> Similar recommendations were made by another recent case series review about Laser Eustachian tuboplasty based on poor quality evidence.<sup>25</sup> Very limited literature is available about Microdebrider Eustachian tuboplasty. The only study found was a case series of 20 patients.<sup>13</sup>

### Limitations of this systematic review

Only English language articles were included. Only one non-English language study was identified during literature search, which was not relevant i.e. dealing with otosclerosis.<sup>26–28</sup> Only, free full-text available articles were included in this systematic review. An effort was made to access articles which needed to be purchased, using Edge Hill University UK account resources and NHS Athens account from University Hospital North Staffordshire UK. Total 6 articles were identified during the literature search which needed to be purchased.<sup>29–34</sup> Abstract review of 2 articles i.e. Jumah and Sedlmaier<sup>34</sup> identified that the study was dealing with divers, so the results may not apply to the general population thus, limiting the external validity of these two studies. In Jumah et al<sup>33</sup> the only outcome assessed was Eustachian tube pressure measurement in a pressure chamber device instead of using clinically relevant outcomes, so no useful additional outcome data would have been obtained from this study. The remaining 4 articles were all either small case–control or uncontrolled studies, which may have fulfilled final selection criteria, but it's very unlikely that these would have influenced the conclusions of this systematic review.<sup>29–32</sup>

Adult population was the main focus of this study. Hence, the search term “adult” was used in the final literature search. A pilot literature search was performed on Medline via ESBO HOST with and without search term “adult”. The number of hits increased from 19 to 33 when the search term “adult” was removed from the search strategy. None of the additional articles was found to be relevant. Hence, the chances of missing any relevant articles by the use of search term “adult” were small, and no evidence was found for this problem during pilot literature search (See full search strategy in the methods section of this systematic review and [Appendix 1](#)).

Involvement of two or more reviewers is standard way and recommended by PRISMA guidelines. Multiple reviewers are involved in the process of study selection, quality assessment and data extraction. This systematic review was my Masters (MCh) research dissertation project, so it was not practically possible to involve other reviewers in this project. With the use of clear study selection criteria, inclusion/exclusion criteria, standard quality assessment tool, and standard data extraction tables' effort was made to reduce the risks associated with selection disagreement, data extraction and quality assessment.

### Gaps in the evidence

No controlled study was found dealing with either Microdebrider or Laser Eustachian tuboplasty. Only one study was identified about Microdebrider Eustachian tuboplasty during the literature search of this systematic review.

### Clinical implications

Due to the presence of above-mentioned limitations and risk of bias, it is not possible to draw clinical conclusions. It is not possible to recommend the clinical use of either of the named interventions i.e. Laser Eustachian tuboplasty or Microdebrider Eustachian tuboplasty. It is also difficult to prove the superiority of one intervention over the other in terms of clinical efficacy.

### Research implications

Variable definition of Eustachian tube dysfunction was used in included studies, which resulted in variability in inclusion and exclusion criteria among included studies and also resulted in differences in intended population characteristics. Future research trials should use a standard inclusion and exclusion criteria based on a standard definition of Eustachian tube dysfunction and clear diagnostic criteria. Future trials should use a consensus statement on a standard definition, clinical presentation and diagnostic criteria for Eustachian tube dysfunction (see introduction section for full details).<sup>35</sup>

Future research should focus on randomised controlled trials.<sup>36,37</sup> Controlled trials using standard methodology and reporting criteria should be designed in future to assess Laser and/or Microdebrider Eustachian tuboplasty as an intervention.

### Conclusions

Overall evidence available about the Laser Eustachian tuboplasty and the Microdebrider Eustachian tuboplasty is limited in quantity and of poor quality. All the included studies in this systematic review were at high risk of bias. Mainly, case series were published identifying the lack of controlled trials. Several confounding factors were present in all included studies. Variability in inclusion and exclusion criteria was noticed among studies. Limited internal and external validity was noticed in all included studies. None of the studies discussed cost aspects associated with the procedures.

### Funding

None.

### Declaration of Competing Interest

None.



## Appendix 1. Search strategy

EBSCO HOST- MEDLINE		
Search	Search terms	Number of hits
S12	S10 AND S11	19
S11	adult*	5,285,363
S10	S6 AND S9	33
S9	S7 OR S8	269,740
S8	microdebrid*	367
S7	Laser	269,441
S6	S4 AND S5	951
S5	Dysfunction	381,150
S4	S1 OR S2 OR S3	6,469
S3	pharyngotympanic tub*	22
S2	auditory tub*	2,360
S1	eustachian tub*	4,517

\* Truncation; Search date: 24 March 2018.

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