Aural fullness and transtympanic ventilation tubes in Ménière's disease: A scoping review.

Christian Sevilla, BMedSci
5th Year A100 Medicine Student, School of Medicine, University of Nottingham, Nottingham, United Kingdom

Jack Goody, BMedSci
5th Year A100 Medicine Student, School of Medicine, University of Nottingham, Nottingham, United Kingdom

David M. Baguley, PhD
Professor in Hearing Sciences
Hearing Sciences, Division of Clinical Neuroscience, School of Medicine, University of Nottingham, Nottingham, United Kingdom
NIHR Biomedical Research Centre, University of Nottingham, Nottingham, United Kingdom
Nottingham Audiology Services, Nottingham University Hospitals NHS Trust, Nottingham, United Kingdom

Anand V. Kasbekar, BMedSci, DOHNS, FRCS(ORL-HNS), DM
Consultant ENT Surgeon, Honorary Assistant Professor
Hearing Sciences, Division of Clinical Neuroscience, School of Medicine, University of Nottingham, Nottingham, United Kingdom
Department of Otorhinolaryngology, Head & Neck Surgery, Nottingham University Hospitals NHS Trust, Nottingham, United Kingdom

University of Nottingham

Running title: Aural fullness and transtympanic VTs in MD

Please contact **Christian Sevilla** for correspondence, reprint requests and to send proofs.

Address: 40 Castle Gardens, Nottingham, United Kingdom, NG7 1HH

E-mail: cksevilla1109@googlemail.com **Phone:** +447473633923

Abstract

Background. Ménière's Disease (MD) often presents with aural fullness, for reasons that are currently not well understood. Insertion of transtympanic ventilation tubes (VTs) has been historically used for the management of this symptom, though the nature and mechanism of effectiveness is unclear. *Objectives.* To give an overview of the data available on the effects of VT insertion on aural fullness in MD. *Methods.* The databases PubMed, EMBASE, Medline, SCOPUS, Web of Science, CENTRAL and Google Scholar were searched to identify relevant records. Records were subsequently analysed and data extracted. *Results*. Only two studies directly measured the effect of VT insertion on aural fullness, while three others measured it as a placebo to another treatment. Considerable heterogeneity was found among the studies, including conflicting conclusions. *Conclusions*. There is a paucity of evidence investigating the effect of grommet insertion on aural fullness in MD. This work directs future research into this topic.

Keywords:

Otolaryngology

Earache

Meniere Disease

Middle Ear Ventilation

Endolymphatic Hydrops

Introduction

Ménière's Disease (MD) is a condition characterised by attacks of vertigo which are accompanied by tinnitus, low-frequency hearing loss and the perception of aural fullness[1]. It is thought that symptoms of MD can be attributed to endolymphatic hydrops – pathological excess of endolymph in the scala media of the inner ear, resulting in distension of membranous structures such as Reissner's membrane and the semicircular canals[2, 3]. In comparison to other symptoms, aural fullness is considered a lesser complaint of MD as it is usually less debilitating than the vertigo, tinnitus and hearing loss[4]. Although the exact mechanism of how aural fullness occurs is unclear, it has been postulated that it could be due to associated degeneration in the trigeminal ganglion[5]. The recent identification of nociceptive fibres in the mammalian cochlea may indicate an alternative mechanism[6, 7]. Levo *et al.*[4] has shown that although several conservative methods such as salt restriction may be attempted to alleviate aural fullness, only relaxation showed statistically significant results. This suggests a possible psychological element to the symptom.

Studies investigating aural fullness in MD have been lacking, potentially due to the perceived mildness of this complaint compared to the other disease symptoms. During active MD and even in remission, the symptom of aural fullness can be extremely troublesome in the senior experience. This complaint is not uncommon in the ENT clinic and was the chief complaint in almost 1.5% of patients seen in one clinic of which 23% had an inner ear cause[8]. In the treatment of MD, insertion of ventilation tubes

(VT), or "grommets", has been a popular intervention amongst UK Otolaryngologists for decades. Smith *et al.*[9] reported a national survey of UK otolaryngologists and found that 8% of responders chose to insert a VT as initial surgical management. Harcourt *et al.*[10] also acknowledged the intervention's popularity in their review of Ménière's Disease in 2014. This practice is changing with the concept of evidence based medicine; however it is still seen in practice today to treat MD. Historically, studies looking at treatments for MD have included VT insertion[11, 12]. Whether this is to treat the symptom of aural fullness or the disease itself is unclear. The use of VTs is attractive as it potentially carries far fewer risks than alternatives such as intratympanic gentamicin and endolymphatic sac surgery[13]. The reasons why VTs may help alleviate endolymphatic hydrops are not well understood[14]. Proposed mechanisms include decreasing middle ear pressure which consequently reduces endolymphatic pressures and alleviation of hypoxic inner ear environments that lead to hydrops by introduction of oxygenated air from the external ear[15, 16]. In the presence of a functioning Eustachian tube, it is difficult to understand these hypotheses fully[17]. Despite being a relatively popular surgical treatment option for the condition[10], there are no existing systematic or scoping reviews targeting the effects of VT insertion, nor the symptom of aural fullness, on MD.

Objectives

This review aims to catalogue the data on the use of VTs on aural fullness in Ménière's disease. The primary objective of this paper is not to

determine whether VT insertion is effective in treating this symptom, but to give an overview of data available in this field, regardless of the quality of evidence, and to summarise key findings.

Methods

This review follows the 5-stage methodological framework outlined by Arksey and O'Malley for conducting a scoping review[18].

Inclusion criteria

Studies of all types published in English language journals and grey literature were included as long as they describe how ventilation tube insertion affects the degree of perceived aural fullness in participants with MD.

Exclusion criteria

Exclusion criteria were the following:

1) Studies showing the effect of VTs exclusively on other MD symptoms.
2) Studies showing the effect of VTs insertion on aural fullness exclusively on conditions other than MD.
3) Studies that only showed how aural fullness changed after administration of a secondary therapy to VT insertion e.g. pressure therapy, gentamicin.
4) Studies not specifying aural fullness specifically as the symptom being affected by VT insertion e.g. only mention how VT insertion

improved general patient functioning without specifying aural fullness as the improved symptom.

5) Review articles synthesising existing data.

Electronic searches

The following databases were searched: PubMed, EMBASE, Medline, SCOPUS, Web of Science, CENTRAL, OpenGrey, DART-Europe, Proquest and Google Scholar. Search terms used: ("menier* disease" OR "menier* syndrome" OR "endolymphatic hydrops") AND ("grommet" OR "ventilation tube" OR “transtympanic tube” OR “transtympanic ventilation tube”) AND ("fullness" OR "pressure" OR “otalgia”). Search date 14th January 2018. Search results were limited to only include English and human studies.

Searching other resources

The reference lists of identified studies were also screened for papers that were not found by the electronic search. Any additional studies meeting the criteria for this review were added to the results.

Selection process

Two authors independently scanned the search hits based on titles, keywords and available abstracts. The titles and abstracts of the search results were screened for relevant articles to be included in the review based on the inclusion and exclusion criteria. The full texts of the remaining articles were then acquired and screened. In cases where there was uncertainty on the relevance of a record based on its abstract, the full text was screened. Discrepancies about which articles to include were

discussed and subsequently resolved, by third party involvement if necessary.

Data Analysis

The following data, if available, was extracted from studies meeting the criteria for this review:

1) Aims and methods of the study.
2) Details of patients involved (e.g. age, gender, number).
3) The type of disease being treated i.e. whether Ménière's Disease or Syndrome, laterality etc.
4) Method of aural fullness assessment.
5) Time elapsed after VT insertion until aural fullness was measured.
6) Changes in aural fullness, both qualitative and quantitative.
7) Discussion on the safety of the intervention.

Results

Search results

A total of 803 search hits were acquired through the electronic search strategy previously described. After duplicate removal, 559 results remained for scrutiny by two authors under the set criteria (Figure 1). Another study was found through searching references of relevant papers. Ten records remained after exclusion of records based on title and abstract. Four studies meeting the criteria based on their full articles were found via the electronic search, which were Dayal[19], Densert *et al.*[20], Odkvist *et al.*[21] and Postema *et al.*[22]. An additional study by Lall[23], which

was identified from references of papers, also met the criteria and was included. Table 1 summarises the details of these studies.

Study aims and characteristics

A detailed analysis of the quality of the studies involved is beyond the scope of this review, as its aim is not to determine the efficacy of this treatment. However, it is notable that only two of the included studies directly measured the effect of VT insertion on aural fullness[19, 23] while the other studies included it based on their use of the VT as a placebo to another therapy[20-22]. For example, in the study by Odkvist *et al*.[21], the effect of VT insertion on aural fullness could be inferred from the placebo treatment as a VT was inserted but the placebo device did not deliver any pressure pulses. Therefore, any changes in aural fullness could be attributed to VT insertion alone. Lall[23] compiled data received from questionnaires sent to members of the British Association of Otolaryngologists at the time about the effect of VT insertion on the symptoms of their patients with MD. The case series by Dayal[19] directly observed the effects of VT insertion on the symptoms of patients with MD. The studies by Odkvist *et al.*[21], Densert *et al.*[20] and Postema *et al.*[22] were randomised placebo-controlled trials, although none directly measured the effects of VT insertion on MD symptoms.

Patient demographics

In studies where patient ages were specified, all were adults (20 – 65 years old)[19-22]. Only Dayal[19] specified the gender of participants and in

this case, all 7 patients in this study were male. Table 2 shows the number of participants in each study. Although Lall's[23] study had the most number of patients (147 patients), this was a conglomerate of results that the author acquired from a questionnaire sent out to multiple surgeons, and the specific age, gender and disease type of these patients are unknown. Dayal[19] and Postema *et al.*[22] were the only to measure aural fullness in all patients receiving VTs, although data was lost for two patients in the latter study. Additionally, it is only clear in Dayal's[19] study that all of his patients had aural fullness prior to intervention. In the others, it is unknown how many of the patients receiving intervention had complained of aural fullness prior, nor the symptom severity.

Diagnostic criteria for Ménière's Disease

The vast majority of patients were defined as having "Ménière's Disease", with only 15 patients in the study by Lall[23] being defined with "Ménière's Syndrome." Two studies diagnosed MD based on the criteria set out by the 1995 Academy of Otolaryngology-Head and Neck Surgery (AAOHNS) [20, 22]. This is also likely the case for the study by Odkvist *et al.*[21], as they described their patients all having "definite Ménière's Disease". Specific diagnostic criteria for patient recruitment are not stated in the other two papers. The patients in the study by Densert *et al.*[20] and Postema *et al.*[22] all had unilateral MD, while disease laterality was unspecified in the other three studies.

Measurement of aural fullness

Visual analogue scales were used in the studies by Densert *et al.*[20] and Odkvist *et al.*[21]. The exact nature of both scales is unknown, although Odkvist *et al.*[21] stated that their scale measured symptom frequency and intensity. Postema *et al.*[22] asked participants to use a 0-3 scale to rate their symptom severity, with 0 equating to no symptoms and 3 being severe. Lall[23] acquired data on how aural fullness changed after VT insertion from several surgeons using a questionnaire. Although the exact nature of this questionnaire is unknown, the changes in symptoms were presented as either "relieved", "no change" or "incomplete data." Changes in the other MD symptoms were also presented in this paper and options for these also included "worsened", "complete lasting relief", "slight lasting relief" and "temporary relief". It is unknown if these options were also present to describe the change in aural fullness. Additionally, it is not stated how any of the surgeons responding to the questionnaire measured aural fullness. Dayal[19] did not specify how aural fullness was assessed after the operation, although their results were presented in the paper.

Time elapsed until aural fullness measurement post-VT insertion

Odkvist *et al.*[21] made a clinical and audiological assessment 2 weeks after VT insertion. At this point, patients still fulfilling the entry criteria for having MD continued in the study. It is unstated if aural fullness measurement was part of this clinical assessment. After a further 2 weeks, aural fullness was measured in both the active pressure treatment

and placebo group, and it is the result of this placebo group that is considered by this review. Postema *et al*.[22] left a 4 week waiting period after VT insertion, and then afterwards administered gentamicin treatment or placebo weekly for 4 following weeks. Aural fullness was measured at each visit, and then afterwards at 6 weeks, 6 months and 1 year post-treatment initiation. Aural fullness data is only available for 1 year post-placebo therapy. Follow-up periods for participants in Lall's [23] and Dayal's[19] studies ranged between 2-14 months and 3-12 months respectively, although specific patient follow-up periods are unstated. Densert *et al.*[20] did not specify when they measured aural fullness.

Changes in aural fullness post-VT insertion

Densert *et al.*[20] and Odkvist *et al.*[21] both stated that their placebo, and hence VT only, groups showed no significant changes in aural fullness post-treatment. Specific quantitative results from their visual scales are not presented. Postema *et al.*[22] also showed that their placebo group's perceived aural fullness did not change. However, they presented their results as histograms showing the distribution of perceived aural fullness as stated by patients according to their numerical scale before and after therapy. However, it is unknown how the aural fullness of each individual patient changed, only that the overall distribution of symptom severity did not change. Two of these patients were lost to follow-up and so data was only available on 10 patients at 12 months. Dayal[19] stated that 6 out of 7 patients experienced relief of aural fullness post-VT insertion, while 1 patient experienced no change in symptoms. However, the degree of

relief or initial symptom severity was not stated. Finally, Lall's[23] survey showed that, of all the patients treated by the responding surgeons, 66% showed relief of aural fullness after VT insertion and 22% showed no change. Data was incomplete for the remaining 12%. Again, the degree of relief and change from initial symptoms were not available for individual patients. Additionally, it is not stated how many of these patients experiencing symptomatic relief were classified as having either "Ménière's Disease" or "Ménière's Syndrome".

Safety of intervention

Dayal[19] and Lall[23] both commented on the general ease and safety of VT insertion compared to more destructive surgical interventions, however this is not discussed in detail. Dayal[19] also stated the limitation that the patient must be careful to not allow water to enter the ear. Lall[23] stated that twenty-eight cases experienced relapse of symptoms following VT extrusion, though it is unclear what these symptoms are. Some of these cases underwent another procedure for re-insertion, although the safety implications of these were not discussed. In the same study, it is noted that 3%, 3% and 6% of patients experienced worsened symptoms of vertigo, deafness and tinnitus respectively, although it is not stated whether these could be attributed at all to the intervention. The other three studies did not comment on the safety of VT insertion. None of the studies commented on whether the VT was inserted under local or general anaesthetic.

Levels of evidence

The two studies by Dayal[19] and Lall[23] which directly address the effect of VT insertion on aural fullness were case series (Level 4 evidence), whereas the other three studies which used it as a placebo[20-22] were RCTs (Level 2 Evidence)[24]. However, as the RCTs do not measure the effect of VT insertion on aural fullness as their primary outcome, these levels of evidence cannot be correctly applied to these studies[20-22]. The case series are a lower form of evidence due to the risk of bias by the author's opinions, as well as lack of confounding factor control[25].

Discussion

Importance of the research question

This review has identified records that have attempted to determine the effects of VT insertion on aural fullness in MD patients. However, despite a wide search strategy that encompasses all study types, all patient demographics, and that accepts VT insertion and measurement of aural fullness as secondary aspects to the study, only five studies met the criteria. From the outset, this indicates a gap in the literature. VT insertion is a safe, simple procedure and it would be beneficial to the patient if their symptoms could be controlled with this approach, prior to more destructive interventions[17, 23]. It is notable that only two studies measured the changes in aural fullness due to VT insertion as the primary intervention and in neither of those studies was that symptom the primary outcome[19, 23]. It is also noteworthy that the two studies directly measuring the effects of VT on aural fullness were published 50 years

ago. Although considered as part of the diagnostic criteria of MD[1], aural fullness may not be considered as a main feature of the condition by some clinicians, being overshadowed by the classic triad of vertigo, hearing loss and tinnitus[26, 27]. However, aural fullness is still an important feature of the condition as severe manifestations can significantly impact a patient's quality of life, leading to social isolation[4]. The lack of recent studies directly measuring the effect of VT insertion on aural fullness shows scope for an update to research on this topic.

Measuring aural fullness

Three out of the five studies measured aural fullness using a patient subjective visual analogue scale, showing that this was the preferred way of assessing changes in the symptom[20-22]. However, as two of these studies did not specify what was included in their questionnaires, it cannot be ascertained what should be included in such a scale to best measure aural fullness[20, 21]. While Lall[23] employed a different approach by simply asking whether the symptom was relieved or not, this would not allow measurement of the degree of symptom change. No objective measure of aural fullness was mentioned in any of the studies, most likely because the mechanism of development of this symptom is not understood. Additionally, no consensus exists as to when best to measure changes in aural fullness post-VT insertion, with follow-up measurements ranging from 4 weeks to 14 months. Due to lack of understanding the pathophysiology behind aural fullness development in MD, it is unknown when best to measure the effects of VT insertion on the symptom.

However, the minimum timeframe until measurement of symptoms is 4 weeks post-VT insertion in the included studies; therefore it is unknown whether there are any changes in aural fullness prior to this. Knowing how quickly aural fullness is relieved, if at all, may help direct understanding of why this symptom occurs in MD.

Efficacy of intervention

The studies included in this review have shown mixed results as to the effects of grommet insertion on aural fullness in MD. While this review cannot determine the effectiveness of VT insertion in MD aural fullness, it has shown that no randomised control trial exists to answer this question. Finally, the possibility of a placebo effect being the cause of symptomatic improvement after grommet insertion must be considered. A placebo-controlled trial would be needed to distinguish the true effect of VT insertion in MD aural fullness from placebo effects[28], a practice supported by the Royal College of Surgeons[29]. We recognise that this may not be feasible or required given the lack of evidence to support this treatment in MD.

Conclusions

Although the quality of evidence was not formally appraised, this scoping review reveals a severe lack of literature detailing the effects of grommet insertion on aural fullness in patients with Ménière's Disease, with the latest direct evaluation published in 1971. Although there is a theoretical need for future research to fill this gap in knowledge, in order to

definitively confirm or disprove the efficacy of this intervention on this often debilitating symptom, the evidence presented does not lend much weight to its efficacy.

Acknowledgements

This report is independent research. We would like to thank Dr Derek Hoare for his advice when writing this review.

Funding

David Baguley's involvement was funded by the National Institute of Health Service Research (NIHR). The opinions expressed herein are his own, not those of the NIHR nor the UK Department of Health and Social Care. The involvement of the other authors was not funded by any institution or third party. We have no conflicts of interest to declare.

References

1. Goebel JA. 2015 Equilibrium Committee Amendment to the 1995 AAO-HNS Guidelines for the Definition of Meniere's Disease. Otolaryngol Head Neck Surg 2016;154:403-4

2. Naganawa S, Nakashima T. Visualization of endolymphatic hydrops with MR imaging in patients with Meniere's disease and related pathologies: current status of its methods and clinical significance. Jpn J Radiol 2014;32:191-204

3. Salt AN, Plontke SK. Endolymphatic hydrops: pathophysiology and experimental models. Otolaryngol Clin North Am 2010;43:971-83.

4. Levo H, Kentala E, Rasku J, Pyykko I. Aural fullness in Meniere's disease. Audiol Neurootol 2014;19:395-9

5. Vass Z, Shore SE, Nuttall AL, Miller JM. Endolymphatic hydrops reduces retrograde labeling of trigeminal innervation to the cochlea. Exp Neurol 1998;151:241-8

6. Flores EN, Duggan A, Madathany T, Hogan AK, Marquez FG, Kumar G, et al. A non-canonical pathway from cochlea to brain signals tissue-damaging noise. Curr Biol 2015;25:606-12

7. Liu C, Glowatzki E, Fuchs PA. Unmyelinated type II afferent neurons report cochlear damage. Proc Natl Acad Sci U S A 2015;112:14723-7

8. Smith WK, Sankar V, Pfleiderer AG. A national survey amongst UK otolaryngologists regarding the treatment of Meniere's disease. J Laryngol Otol 2005;119:102-5

9. Harcourt J, Barraclough K, Bronstein AM. Meniere's disease. BMJ 2014;349:g6544

10. Thomsen J, Bonding P, Becker B, Stage J, Tos M. The Non-specific Effect of Endolymphatic Sac Surgery in Treatment of Meniere's Disease: A Prospective, Randomized Controlled Study Comparing "Classic" Endolymphatic Sac Surgery with the Insertion of a Ventilating Tube in the Tympanic Membrane. Acta Otolaryngol 1998;118:769-73

11. Montandon P, Guillemin P, Hausler R. Prevention of vertigo in Meniere's syndrome by means of transtympanic ventilation tubes. ORL J Otorhinolaryngol Relat Spec 1988;50:377-81

12. Ogawa Y, Otsuka K, Hagiwara A, Inagaki A, Shimizu S, Nagai N, et al. Clinical study of tympanostomy tube placement for patients with intractable Meniere's disease. J Laryngol Otol 2015;129:120-5

13. Park J, Chen Y, Westhofen M. Meniere's disease and middle ear pressure–vestibular function after transtympanic tube placement. Acta Otolaryngol 2009;129:1408-13

14. Sugawara K, Kitamura K, Ishida T, Sejima T. Insertion of tympanic ventilation tubes as a treating modality for patients with Meniere's disease: a short- and long-term follow-up study in seven cases. Auris Nasus Larynx 2003;30:25-8

15. Kimura RS, Hutta J. Inhibition of experimentally induced endolymphatic hydrops by middle ear ventilation. Eur Arch Otorhinolaryngol 1997;254:213-8

16. Syed I, Aldren C. Meniere's disease: an evidence based approach to assessment and management. Int J Clin Pract 2012;66:166-70

17. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. Int J Soc Res Methodol 2005;8:19-32

18. Dayal P. Observations on the use of grommets in meniere's disease. Indian J Otolaryngol 1971;23:119-23

19. Densert B, Densert O, Arlinger S, Sass K, Ödkvist L. Immediate effects of middle ear pressure changes on the electrocochleographic recordings in patients with Meniere's disease: A clinical placebo-controlled study. Am J Otol 1997;18:726-33

20. Odkvist LM, Arlinger S, Billermark E, Densert B, Lindholm S, Wallqvist J. Effects of middle ear pressure changes on clinical symptoms in patients with Meniere's disease - A clinical multicentre placebo-controlled study. Acta Otolarngol Suppl 2000:99-101

21. Postema R, Kingma C, Wit H, Albers F, Van Der Laan B. Intratympanic gentamicin therapy for control of vertigo in unilateral Meniere's disease: a prospective, double-blind, randomized, placebo-controlled trial. Acta Otolaryngol 2008;128:876-80

22. Lall M. Meniere's disease and the grommet (a survey of its therapeutic effects). J Laryngol Otol 1969;83:787-91

23. Oxford Levels of Evidence Working Group. The Oxford Levels of Evidence 2: Oxford Centre for Evidence-Based Medicine. In: https://www.cebm.net/index.aspx?o=5653 [13 January 2019]

24. Burns PB, Rohrich RJ, Chung KC. The levels of evidence and their role in evidence-based medicine. Plast Reconstr Surg 2011;128:305-10

25. Yardley L, Dibb B, Osborne G. Factors associated with quality of life in Meniere's disease. Clin Otolaryngol Allied Sci 2003;28:436-41

26. Belinchon A, Perez-Garrigues H, Tenias JM, Lopez A. Hearing assessment in Meniere's disease. Laryngoscope 2011;121:622-6

27. Probst P, Grummich K, Harnoss JC, Hüttner FJ, Jensen K, Braun S, et al. Placebo-Controlled Trials in Surgery: A Systematic Review and Meta-Analysis. Medicine (Baltimore) 2016;95

28. RCS Policy Unit. Position Statement: Use of placebo surgery in surgical research. Bulletin of the Royal College of Surgeons of England 2016;98:80-1

Tables and Figures

Table I

Summary of studies included in this review.[19-23]

Study	Aims of study	Methods of study	Number of patients involved	Method of aural fullness assessment	Time elapsed until aural fullness measurement after VT insertion	Changes in aural fullness
Dayal (1971) *Observations on the use of grommets in Meniere's disease.* (19)	Observing the effect of grommet insertion on the symptoms of patients with unilateral MD.	Grommets were inserted in the ears of affected patients. Change in symptoms was then recorded during follow-up.	7	Unspecified	Varied between 3 months to 1 year. Not specified for each patient.	Relieved in 6 patients, unchanged in 1.
Densert *et al.* (1997) *Immediate effects of middle ear pressure changes on the electrocochleographic recordings in patients with Meniere's disease: A clinical placebo-controlled study.* (20)	Placebo-controlled randomised control study testing the change in electrocochleographic measurements after VT insertion and then after exposure to a middle ear pressure generator/placebo.	Patients meeting study criteria had a VT inserted into their tympanic membrane. In most cases, patients were exposed to active or placebo treatment a week later. The active treatment delivered positive pressure changes to the ear via a generator, while the placebo was a similar looking device that did not deliver any pressure pulses.	39 patients overall. 18 were treated with placebo and hence the VT alone.	Visual scales were used to measure the subjective symptom of aural fullness.	Unspecified	No significant changes. Exact results not shown.
Odkvist *et al.* (2000) *Effects of middle ear pressure changes on clinical symptoms in patients with Meniere's disease - A clinical multicentre placebo-controlled study.* (21)	Placebo-controlled study testing the effects of middle ear pressure therapy (via a Meniett device) on the clinical symptoms of patients with Meniere's disease.	Patients had a VT inserted and had a clinical and audiological assessment prior to this and 2 weeks after insertion. Those who met criteria received two weeks of pressure/placebo treatment, at which point the clinical symptoms and hearing were evaluated.	56 patients overall. 25 were treated with placebo and hence the VT alone.	Visual analogue scales (VAS) questionnaires were used to measure the frequency and intensity of aural fullness. The exact nature of this VAS is unknown.	4 weeks	No significant improvement. Specific results are unavailable.
Postema *et al.* (2008) *Intratympanic gentamicin therapy for control of vertigo in unilateral Meniere's disease: a prospective, double-blind, randomized, placebo-controlled trial.* (22)	Double blind placebo-controlled randomised control trial comparing the effects of intratympanic gentamicin therapy to a placebo on vertigo in patients with unilateral MD.	A middle ear VT was inserted in participants' affected ears. Four weeks after this, weekly gentamicin or placebo was delivered into the middle ear through the ventilation tube weekly for 4 more weeks. Patient's symptoms and degree of hearing loss was measured at specified points.	28 patients overall. 12 were treated with placebo and hence the VT alone.	Patients completed a form rating their aural fullness as 0 (none), 1 (mild), 2 (moderate) and 3 (severe). This was done before and at every follow-up appointment during therapy.	Results are for 1 year follow-up. Measurements were also taken weekly for 4 weeks following an initial 4 weeks post-VT insertion, 6 weeks and 6 months.	Perceived fullness did not change.
Lall (1969) *Meniere's disease and the grommet (a survey of its therapeutic effects)* (23)	A survey conducted to understand the therapeutic effects of grommet insertion on Meniere's disease.	Questionnaires were sent to surgeons who were members of the British Association of Otolaryngologists in 1966. Surgeons replied on the results of grommet operations carried out up to the end of 1967. Specific details about the individual operations of participating surgeons were not available.	147 patients, treated by 36 surgeons.	Survey sent to surgeons asked about how aural fullness changed post-operation. The study publishes this as "relieved", "no change" or "incomplete data." It is unclear how each surgeon specifically evaluated patients' symptoms in this case.	Varied between 2 and 14 months. Not specified for each patient.	66% relieved, 22% no change, 12% incomplete data.

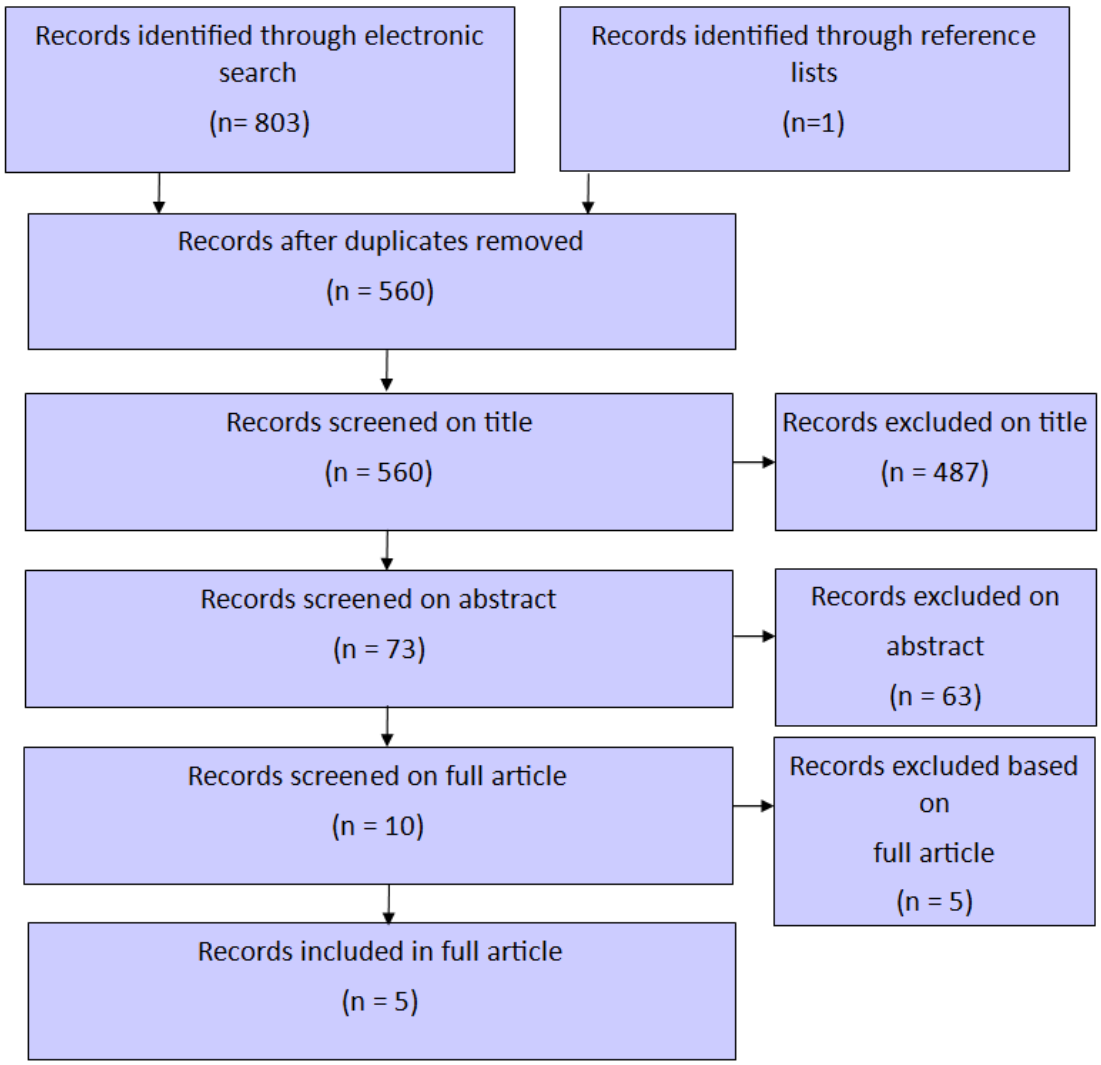
Table II

Details of patients in included studies.[19-24]

Study	**Level of evidence** (24)	**Total no. of patients in study**	**No. of patients whose aural fullness was assessed**	**Age of patients**	**Gender of patients involved**	**Type of disease**
Dayal (1971) *Observations on the use of grommets in Meniere's disease.* (19)	Case Series (Level 4)	7	7	30-55	Male	All unilateral MD based on history, symptoms, pure tone audiogram, Fowler's Recruitment test and the Caloric test.
Densert *et al.* (1997) *Immediate effects of middle ear pressure changes on the electrocochleographic recordings in patients with Meniere's disease: A clinical placebo-controlled study.* (20)	Randomised trial (Level 2)	39	18 patients were treated with placebo and hence the VT alone, although it is unspecified how many of these patients actually had aural fullness.	20-65	Unspecified	MD according to 1995 AAOHNS criteria for duration of at least 1 year but no more than 6 years prior to the test. Laterality of disease unspecified.
Odkvist *et al.* (2000) *Effects of middle ear pressure changes on clinical symptoms in patients with Meniere's disease - A clinical multicentre placebo-controlled study.* (21)	Randomised trial (Level 2)	56	25 patients received placebo treatment and hence VT alone, although it is unspecified how many of these patients actually had aural fullness.	20-65	Unspecified	Patients all had definite MD, though laterality and diagnostic criteria are unspecified. All patients had a 20-65 dB hearing impairment and active vestibular symptoms close to the test.
Postema *et al.* (2008) *Intratympanic gentamicin therapy for control of vertigo in unilateral Meniere's disease: a prospective, double-blind, randomized, placebo-controlled trial.* (22)	Randomised trial (Level 2)	28	12 patients received the placebo treatment and hence VT alone. Complete data could not be acquired for 2 of these patients.	Median ages of 53 and 55 for the placebo (VT) and intervention (gentamicin) groups respectively.	Unspecified	All unilateral MD according to 1995 AAOHNS criteria.
Lall (1969) *Meniere's disease and the grommet (a survey of its therapeutic effects)* (23)	Case series (Level 4)	147	129 (Data was available on 88% of the patients)	Unspecified	Unspecified	132 patients had MD of varying severity. Disease laterality was unspecified. The other 15 patients were classified as having "Meniere syndrome."

Figure I

Flowchart showing literature searching process for review.



Summary

- Ménière’s disease can present with aural fullness, the mechanisms of which is not currently understood.
- There is no current consensus on the ideal way of treating aural fullness in Ménière’s Disease.
- Despite a thorough literature search, only five studies could be found measuring the effects of transtympanic ventilation tube insertion on aural fullness in Ménière’s Disease, only two of which directly measured the effect of the intervention on aural fullness.
- In light of the paucity of evidence, heterogeneity and mixed findings of available studies, it is our recommendation that future clinical trials be conducted to determine the place of ventilation tube insertion in the management of the symptom of aural fullness in Ménière’s Disease.
- The current evidence does not allow the recommendation of ventilation tube insertion to treat aural fullness in Ménière’s Disease.