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

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Review Article

Mr C Sevilla takes responsibility for the integrity of the content of the paper

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Abstract

Background. Ménière's disease often presents with aural fullness, for reasons that are currently not well understood. Transtympanic ventilation tube insertion has been historically used for the management of this symptom, though the nature and mechanism of effectiveness is unclear.

Objective. To give an overview of the data available on the effects of ventilation tube insertion on aural fullness in Ménière's disease.

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 ventilation tube insertion on aural fullness, while three others measured it as a placebo to assess another treatment. Considerable heterogeneity was found amongst the studies, including conflicting conclusions.

Conclusion. There is a paucity of evidence investigating the effect of grommet insertion on aural fullness in Ménière's disease. This work directs future research into this topic.

Introduction

Ménière's disease 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 Ménière's disease symptoms can be attributed to endolymphatic hydrops – a 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]

Compared to other symptoms, aural fullness is considered a lesser complaint of Ménière's disease, 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 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 had statistically significant results. This suggests a possible psychological element to the symptom.

Studies investigating aural fullness in Ménière's disease have been lacking, potentially because of the perceived mildness of this complaint compared to the other disease symptoms. During active Ménière's disease and even in remission, the symptom of aural fullness can be extremely troublesome in older patients. This complaint is not uncommon in the ENT clinic; it was the chief complaint in almost 1.5 per cent of patients seen in one clinic, of which 23 per cent had an inner-ear cause.[8]

In the treatment of Ménière's disease, the insertion of ventilation tubes, 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 per cent of responders chose to insert a ventilation tube 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 used to treat Ménière's disease. Historically, studies looking at treatments for Ménière's disease have included ventilation tube insertion.[11,12] Whether this is to treat the symptom of aural fullness or the disease itself is unclear. The use of ventilation tubes is attractive as it potentially carries far fewer risks than alternatives such as intratympanic gentamicin therapy and endolymphatic sac surgery.[13]

The reasons why ventilation tubes may help alleviate endolymphatic hydrops are not well understood.[14] Proposed mechanisms include: decreasing middle-ear pressure, which consequently reduces endolymphatic pressures; and the alleviation of hypoxic inner-ear environments that lead to hydrops by the 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 ventilation tube insertion, nor the symptom of aural fullness, on Ménière's disease.

Objectives

This review aimed to catalogue the data on the use of ventilation tubes on aural fullness in Ménière's disease. The primary objective of this paper is not to determine whether ventilation tube 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.

Materials and methods

This review follows the five-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 described how ventilation tube insertion affected the degree of perceived aural fullness in participants with Ménière's disease.

Exclusion criteria

The exclusion criteria were the following: (1) studies showing the effect of ventilation tubes exclusively on other Ménière's disease symptoms; (2) studies showing the effect of ventilation tube insertion on aural fullness exclusively on conditions other than Ménière's disease; (3) studies that only showed how aural fullness changed after the administration of a secondary therapy to ventilation tube insertion (e.g. pressure therapy, gentamicin treatment); (4) studies not specifying aural fullness specifically as the symptom being affected by ventilation tube insertion (e.g. only mentioning how ventilation tube insertion improved general patient functioning, without specifying aural fullness as the improved symptom); and (5) review articles synthesising existing data.

Electronic searches

The following databases were searched: PubMed, Embase, Medline, Scopus, Web of Science, Central, OpenGrey, DART-Europe (Digital Access to Research Theses), ProQuest and Google Scholar. The search terms used were: ('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'). The search was conducted on 14 January 2018. Search results were limited to include only English-language 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 regarding 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, were 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, and so on); (4) method of aural fullness assessment; (5) time elapsed after ventilation tube insertion until aural fullness was measured; (6) changes in aural fullness, both qualitative and quantitative; and (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 study removal, 559 results remained for scrutiny by 2 authors under the set criteria (Figure 1). Another study was found through searching the references of relevant papers.

Ten records remained after the exclusion of records based on title and abstract. Four studies meeting the criteria based on their full articles were found via the electronic search. These were studies by 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 the references of papers, also met the criteria and was included. Table 1 summarises the details of these studies.[19–23]

Study aims and characteristics

A detailed analysis of the quality of the studies included 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 ventilation tube insertion on aural fullness;[19,23] the other studies included ventilation tube insertion as a placebo to assess another therapy.[20–22]

For example, in the study by Odkvist *et al.*,[21] the effect of ventilation tube insertion on aural fullness could be inferred from the placebo treatment, as a ventilation tube was inserted, but the placebo device did not deliver any pressure pulses. Therefore, any changes in aural fullness could be attributed to ventilation tube 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 ventilation tube insertion on the symptoms of their patients with Ménière's disease. The case series by Dayal[19] directly observed the effects of ventilation tube insertion on the symptoms of patients with Ménière's disease. The studies by Odkvist *et al.*,[21] Densert *et al.*[20] and Postema *et al.*[22] were

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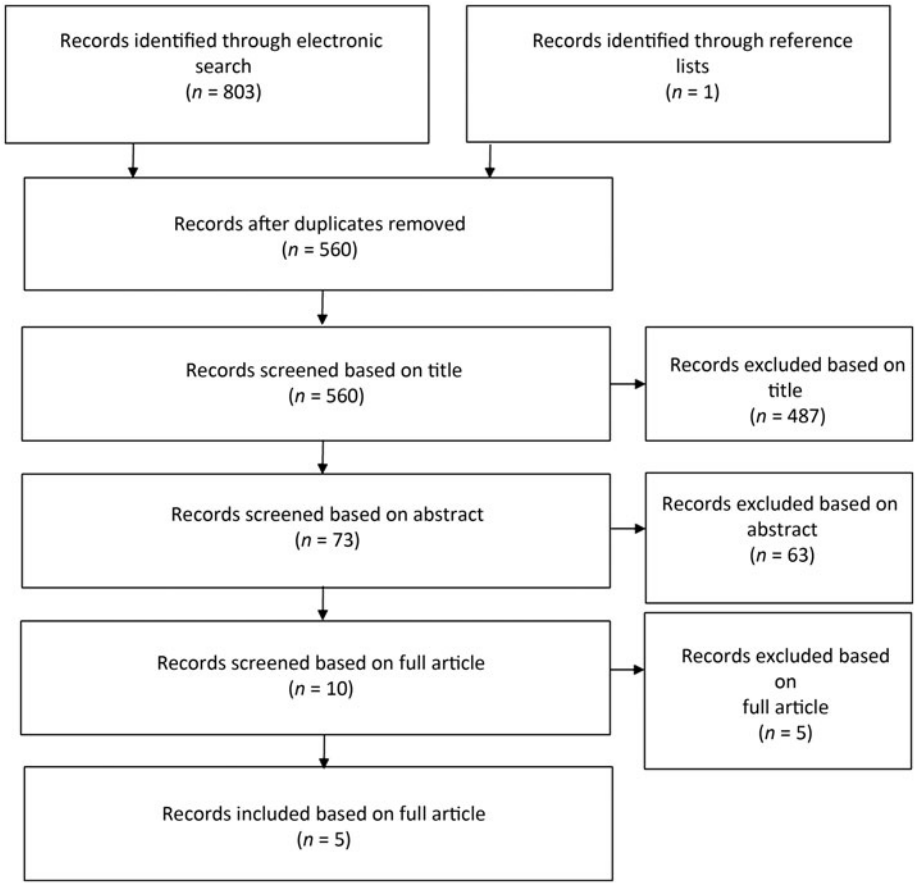

Fig. 1. Flowchart showing literature searching process for review.

randomised placebo-controlled trials, although none directly measured the effects of ventilation tube insertion on Ménière's disease 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; all seven patients in that study were male. Table 2 shows the number of participants in each study.[19–24]

Although Lall's[23] study had the highest 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 ones to measure aural fullness in all patients receiving ventilation tubes, although data were 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 to this and how severe the symptom was.

Ménière's disease diagnostic criteria

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 Ménière's disease based on the criteria set out by the 1995 American Academy of Otolaryngology – Head and Neck Surgery.[20,22] This is also likely the case for the study by Odkvist *et al.*,[21] as they described their patients as all having 'definite Ménière's disease'. Specific diagnostic criteria for patient recruitment are not stated in the other two papers. The patients in the studies by Densert *et al.*[20] and Postema *et al.*[22] all had unilateral Ménière's disease, while disease laterality was unspecified in the other three studies.

Aural fullness measurement

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 reflecting severe symptoms.

Lall[23] acquired data from several surgeons, using a questionnaire, on how aural fullness changed after ventilation tube insertion. Although the exact nature of this questionnaire is unknown, the changes in symptoms were categorised as either 'relieved', 'no change' or 'incomplete data'. Changes in the other Ménière's disease symptoms were also assessed in this paper, and options for these 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-treatment

Odkvist *et al.*[21] made a clinical and audiological assessment two weeks after ventilation tube insertion. At this point,

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Table 1. Summary of studies included in review[19–23]

Study (year)	Study aims	Study methods	Number of patients involved	Aural fullness assessment method	Time elapsed until aural fullness measurement after VT insertion	Changes in aural fullness
Dayal (1971)[19]	Observing effect of grommet insertion on unilateral MD patients' symptoms	Grommets were inserted in affected patients' ears. Changes in symptoms were recorded during follow up	7	Unspecified	Varied between 3 months & 1 year. Not specified for each patient	Relieved in 6 patients, unchanged in 1
Densert *et al.* (1997)[20]	Placebo-controlled randomised control study testing change in electrocochleographic measurements after VT insertion, & after exposure to middle-ear pressure generator or 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. Active treatment delivered positive pressure changes to ear via a generator; the placebo was a similar looking device that did not deliver any pressure pulses	39 patients overall. 18 were treated with placebo & hence VT alone	Visual scales were used to measure subjective symptom of aural fullness	Unspecified	No significant changes. Exact results not shown
Odkvist *et al.* (2000)[21]	Placebo-controlled study testing effects of middle-ear pressure therapy (via Meniett device) on clinical symptoms of MD patients	Patients had a VT inserted, & underwent clinical & audiological assessment prior to this & 2 weeks after insertion. Those who met criteria received 2 weeks of pressure or placebo treatment; clinical symptoms & hearing were then evaluated	56 patients overall. 25 were treated with placebo & hence VT alone	VAS questionnaires were used to measure frequency & intensity of aural fullness. Exact nature of VAS is unknown	4 weeks	No significant improvement. Specific results are unavailable
Postema *et al.* (2008)[22]	Double-blind, placebo-controlled, randomised control trial comparing effects of intratympanic gentamicin therapy with a placebo on vertigo in unilateral MD patients	A middle-ear VT was inserted in participants' affected ears. 4 weeks later, weekly gentamicin or placebo was delivered into middle ear through the VT weekly for 4 more weeks. Patients' symptoms & degree of hearing loss were measured at specified points	28 patients overall. 12 were treated with placebo & hence VT alone	Patients completed a form, rating aural fullness as 0 (none), 1 (mild), 2 (moderate) or 3 (severe), before & 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-week waiting period after VT insertion, & then at 6 weeks & 6 months	Perceived fullness did not change
Lall (1969)[23]	Survey conducted to understand therapeutic effects of grommet insertion on MD	Questionnaires were sent to surgeons who were British Association of Otolaryngologists members in 1966. Surgeons reported on results of grommet operations carried out up to end of 1967. Specific details about 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, with responses categorised as 'relieved', 'no change' or 'incomplete data'. It is unclear how each surgeon specifically evaluated patients' symptoms	Varied between 2 & 14 months. Not specified for each patient	66% relieved, 22% no change, 12% incomplete data

VT = ventilation tube; MD = Ménière's disease; VAS = visual analogue scales

Table 2. Details of patients in included studies

Study	Level of evidence[24]	Total patients (*n*)	Number of patients whose aural fullness was assessed	Patient age (years)	Patient gender	Disease type
Dayal (1971)[19]	Case series (level 4)	7	7	30–55	Male	All had unilateral MD, based on history, symptoms, pure tone audiogram, Fowler's recruitment test & caloric test
Densert *et al.* (1997)[20]	Randomised trial (level 2)	39	18 patients were treated with placebo & hence VT alone; it was not specified how many patients actually had aural fullness	20–65	Unspecified	All had MD, according to 1995 AAOHNS criteria, for duration of at least 1 year but no more than 6 years prior to test. Laterality of disease unspecified
Odkvist *et al.* (2000)[21]	Randomised trial (level 2)	56	25 patients received placebo treatment & hence VT alone; it was not specified how many patients actually had aural fullness	20–65	Unspecified	Patients all had definite MD, though laterality & diagnostic criteria were unspecified. All patients had 20–65 dB hearing impairment & active vestibular symptoms close to time of diagnosis
Postema *et al.* (2008)[22]	Randomised trial (level 2)	28	12 patients received placebo treatment & hence VT alone. Complete data could not be acquired for 2 of these patients	Median ages of 53 & 55 years for placebo (VT) & intervention (gentamicin) groups respectively	Unspecified	All had unilateral MD, according to 1995 AAOHNS criteria
Lall (1969)[23]	Case series (level 4)	147	129 (data were available for 88% of patients)	Unspecified	Unspecified	132 patients had MD of varying severity. Disease laterality was unspecified. The other 15 patients were classified as having 'Ménière's syndrome'

MD = Ménière's disease; VT = ventilation tube; AAOHNS = American Academy of Otolaryngology – Head and Neck Surgery

patients still fulfilling the entry criteria for having Ménière's disease continued in the study. It is unstated if aural fullness measurement was part of this clinical assessment. After a further two 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 four-week waiting period after ventilation tube insertion, and then administered gentamicin treatment or placebo weekly for four weeks. Aural fullness was measured at each visit, and then at six weeks, six months and one year post-treatment initiation. Aural fullness data are only available for one year after placebo therapy.

The ranges in follow-up periods for participants in Lall's[23] and Dayal's[19] studies were 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-treatment

Densert *et al.*[20] and Odkvist *et al.*[21] both stated that their placebo, and hence ventilation tube 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. 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 were only available for 10 patients at 12 months.

Dayal[19] stated that six out of seven patients experienced relief of aural fullness after ventilation tube insertion, while one 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 per cent showed relief of aural fullness after ventilation tube insertion and 22 per cent showed no change. Data were incomplete for the remaining 12 per cent. Again, the data reflecting 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 ventilation tube insertion compared to more destructive surgical interventions; however, this is not discussed in detail. Dayal[19] also highlighted the limitation that the patient must be careful not to allow water to enter the ear.

Lall[23] reported that 28 patients experienced relapse of symptoms following ventilation tube extrusion, though it is unclear what these symptoms were. Some of these patients underwent another procedure for re-insertion, although the safety implications of these were not discussed. In the same study, it is noted that 3 per cent, 3 per cent and 6 per cent 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.

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The other three studies did not comment on the safety of ventilation tube insertion. None of the studies commented on whether the ventilation tube was inserted under local or general anaesthetic.

Levels of evidence

The studies by Dayal[19] and Lall,[23] which directly addressed the effect of ventilation tube insertion on aural fullness, were case series (level 4 evidence). The other three studies, which used this treatment as a placebo,[20–22] were randomised controlled trials (level 2 evidence).[24] However, as these trials did not measure the effect of ventilation tube insertion on aural fullness as their primary outcome, this level of evidence cannot be correctly applied to these studies.[20–22] The case series are a lower form of evidence given the risk of bias by the author's opinions, as well as the lack of confounding factor control.[25]

Discussion

Importance of research question

This review has identified studies that attempted to determine the effects of ventilation tube insertion on aural fullness in Ménière's disease patients. However, despite a wide search strategy that encompassed all study types and all patient demographics, and that accepted ventilation tube insertion and measurement of aural fullness as secondary aspects to the investigation, only five studies met the criteria. From the outset, this indicates a gap in the literature.

Ventilation tube 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 as a result of ventilation tube insertion used 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 ventilation tube on aural fullness were published around fifty years ago. Although considered as part of the diagnostic criteria of Ménière's disease,[1] aural fullness may not be regarded 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 ventilation tube 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-reported, subjective, visual analogue scale, indicating that this is 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] Lall[23] employed a different approach, and simply asked patients whether the symptom was relieved or not; this does 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 regarding the optimal time to measure changes in aural fullness after ventilation tube insertion, with follow-up measurements ranging from 4 weeks to 14 months. Given the lack of understanding concerning the pathophysiology behind aural fullness development in Ménière's disease, it is unknown when best to measure the effects of ventilation tube insertion on the symptom. However, the minimum timeframe until measurement of symptoms was four weeks after ventilation tube insertion in the included studies; it is therefore unknown whether there were 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 Ménière's disease.

Efficacy of intervention

The studies included in this review have shown mixed results as to the effects of grommet insertion on aural fullness in Ménière's disease. While this review cannot determine the effectiveness of ventilation tube insertion in Ménière's disease aural fullness, it has shown that no randomised controlled 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 ventilation tube insertion in Ménière's disease 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 Ménière's disease.

Conclusion

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.[19] 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.

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Competing interests. None declared

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