Positive pressure therapy for Ménière's disease

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Abstract

Introduction

Ménière's disease is a disorder of the inner ear characterized by episodes of spontaneous vertigo, fluctuating hearing loss and tinnitus. Positive pressure therapy has been used to reduce the intensity and frequency of episodes, but it is not clear whether it is actually effective.

Methods

We searched in Epistemonikos, the largest database of systematic reviews in health, which is maintained by screening multiple information sources, including MEDLINE, EMBASE, Cochrane, among others. We extracted data from the systematic reviews, reanalyzed data of primary studies, conducted a meta-analysis and generated a summary of findings table using the GRADE approach.

Results and conclusions

We identified five systematic reviews including 22 studies overall, of which five were randomized trials. We concluded positive pressure therapy probably leads to slightly worse hearing and makes little or no difference in the intensity of vertigo. In addition, we are uncertain whether positive pressure therapy improves functionality or decreases vertigo attacks as the certainty of the evidence has been assessed as very low.

Problem

Ménière's disease is characterized by episodes of spontaneous vertigo, tinnitus and fluctuating hearing loss. The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) guidelines has defined the diagnostic criteria as two episodes of vertigo lasting more than 20 minutes, sensorineural hearing loss confirmed by audiometry and tinnitus or aural fullness [1]. The proposed mechanism of Ménière's disease would be an increase in endolymphatic pressure in the inner ear, whose cause is idiopathic. This would increase the frequency of episodes that, even though may transiently remit, can last several months, with the consequent deterioration in the quality of life [2].

The treatment aims to reduce the number and severity of vertigo episodes, to revert hearing loss and tinnitus, to relieve chronic symptoms and to prevent the progression of the disease. However, there are no treatment alternatives that can achieve these objectives, so positive pressure therapy has been proposed as a minimally invasive intervention.

This therapy uses a device (Meniett) that is inserted into the external auditory canal and produces low intensity pressure pulses. It is believed that these pulses are transmitted to the inner ear, exerting pressure. Before using this device, it is necessary to install a ventilation tube (collar) in the tympanic membrane to allow the passage of waves. This treatment is considered second line and there is still controversy regarding its efficacy in Ménière's disease.

Key messages

- Positive pressure therapy probably leads to slightly worse hearing and makes little or no difference in the intensity of vertigo in Ménière's disease.
- We are uncertain whether positive pressure therapy improves functionality or decreases the frequency of vertigo attacks as the certainty of the evidence has been assessed as very low

About the body of evidence for this question

What is the evidence. See evidence matrix in Epistemonikos later	We found five systematic reviews[3-7] including 22 primary studies[8-29] of which five corresponded to randomized trials[14,18,20,23,27]. This table and the summary in general are based on the latter, since the observational studies did not increase the certainty of the existing evidence nor provide additional relevant information.
What types of patients were included*	The diagnostic criteria used in four of the trials[14,18,20,27] were those of the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) of 1995 for definitive diagnosis of Ménière's disease, specifying certain special characteristics for each of them, while in one trial [23] the criteria were not specified.
What types of interventions were included*	All trials used the Meniett device or some similar device as intervention, which produced pressure to the middle and inner ear. All trials used a placebo device that was identical to the functioning device, but did not produce pressure. In four trials, the ventilation tube was installed two weeks to two months prior to the beginning of treatment[18,20,23,27]. In one trial it was not reported[14]. All trials compared against placebo[14,18,20,23,27].
What types of outcomes were measured	The trials evaluated multiple outcomes, which were grouped by the systematic reviews as follows: • Control of vertigo • Loss or improvement of hearing • Severity of tinnitus • Perception of aural fullness • Functional disability • Complications and adverse effects • Proportion of days with active disease • Electrocochleography

Methods

We searched in Epistemonikos, the largest database of systematic reviews in health, which is maintained by screening multiple information sources, including MEDLINE, EMBASE, Cochrane, among others, to identify systematic reviews and their included primary studies. We extracted data from the identified reviews and reanalyzed data from primary studies included in those reviews. With this information, we generated a structured summary denominated FRISBEE (Friendly Summary of Body of Evidence using Epistemonikos) using a pre-established format, which includes key messages, a summary of the body of evidence (presented as an evidence matrix in Epistemonikos), meta-analysis of the total of studies when it is possible, a summary of findings table following the GRADE approach and a table of other considerations for decision-making.

	The average follow-up of the trials was 10.5 weeks, with a range between 2 and 16 weeks.

* The information about primary studies is extracted from the systematic reviews identified, unless otherwise specified.

Summary of Findings

The information on the effects of positive pressure therapy in Ménière's disease is based on three randomized trials[18,20,27] that included 163 patients in total. The other two trials did not provide sufficient data to be incorporated into a meta-analysis. Two trials[18,20] reported change in hearing (123 patients),one trial[27] evaluated functionality and frequency of vertigo episodes (40 patients) and one trial reported[20] the intensity of vertigo (68 patients).

The summary of findings is as follows:

- Positive pressure therapy probably leads to slightly worse hearing at four months after starting treatment (moderate certainty evidence).
- We are uncertain whether positive pressure therapy improves functionality as the certainty of the evidence has been assessed as very low.
- We are uncertain whether positive pressure therapy decreases the frequency of vertigo attacks as the certainty of the evidence has been assessed as very low.
- Positive pressure therapy probably makes little or no difference in the intensity of vertigo (moderate certainty evidence).

Positive pressure therapy for Ménière's disease

Patients Ménière's disease
Intervention Positive pressure therapy
Comparison Placebo

Outcome	Absolute effect*		Certainty of evidence (GRADE)
	WITHOUT positive pressure	WITH positive pressure	
Hearing threshold (dB)**	44.4 dB	51.78 dB	⨁⨁⨁◯[1] Moderate
	MD: 7.38 worse (Margin of error: 2.51 to 12.7 worse)		
Level of functionality ***	3.5 points	2.4 points	⨁◯◯◯[2,3] Very low
	MD: 1.1 better (Margin of error: 0.39 to 1.81 better)		
Frequency of vertigo attacks****	4 attacks/ period	1.9 attacks/ period	⨁◯◯◯[2,3] Very low
	MD: 2.1 better (Margin of error: 1.05 worse to 5.25 better)		
Intensity of vertigo*****	19.23 points	15.55 points	⨁⨁⨁◯[3] Moderate
	MD: 3.68 better (Margin of error: 6.88 worse to 14.24 better)		

Margin of error: 95% confidence interval (CI).
MD: Mean difference.
GRADE: Evidence grades of the GRADE Working Group (see later).

*The risk WITHOUT positive pressure is based on the risk in the control group of the trials. The risk WITH positive pressure (and its margin of error) is calculated from absolute effect (and its margin of error).

** Hearing threshold measured in decibels (average frequencies 0.25, 0.5 and 1 MHz) between the start and after 4 months of treatment. The higher the threshold in decibels, the worse the hearing.
*** Functionality level measured with the AAO-HNS scale, which ranges from 1 (best) to 6 (worst). Comparison between 8 weeks before the start of treatment and the last 4 weeks of treatment (total duration was 8 weeks).
**** Frequency of vertigo attacks were measured between 8 weeks before the start of treatment and the last 4 weeks of treatment (whose total duration was 8 weeks).
***** Intensity of vertigo was measured with a scale that goes from 0 (without vertigo) to 4 (worse). Daily vertigo intensity is the difference between the month before the start of treatment and the fourth month of treatment.
[1] The certainty of the evidence was downgraded in one level for risk of bias, since the attrition bias was not clear. Additionally, the trial with greater weight applied a pressure of 2 cm H2O to the placebo group, whose therapeutic effect cannot be discarded.
[2] The certainty of the evidence was downgraded in two levels for risk of bias, since the trial had a high risk of selective reporting bias and the generation and concealment of the randomization sequence, and the information on excluded patients/losses was not clearly stated.
[3] The certainty of the evidence was downgraded in one level for imprecision, since each end of the confidence interval would lead to different decisions.

Follow the link to access the interactive version of this table (Interactive Summary of Findings – iSoF)

About the certainty of the evidence (GRADE)*

⊕⊕⊕⊕
High: This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different† is low.

⊕⊕⊕◯
Moderate: This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different† is moderate.

⊕⊕◯◯
Low: This research provides some indication of the likely effect. However, the likelihood that it will be substantially different† is high.

⊕◯◯◯
Very low: This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different† is very high.

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* This concept is also called 'quality of the evidence' or 'confidence in effect estimates'.

† Substantially different = a large enough difference that it might affect a decision

Other considerations for decision-making

To whom this evidence does and does not apply

To whom this evidence does and does not apply This evidence applies to patients diagnosed with definitive active Ménière's disease.

It does not apply to patients with Ménière's disease who have received previous surgical treatment.

About the outcomes included in this summary

The outcomes included in the summary of findings table are those considered critical for decision-making, according to the opinion of the authors of this summary, and in general coincide with the systematic reviews identified.

Adverse effects were not reported in the systematic reviews identified.

Balance between benefits and risks, and certainty of the evidence

It is not possible to make an adequate balance between risks and benefits of positive pressure therapy in Ménière's disease due to the uncertainty of the existing evidence.

No adverse effects associated with the use of the positive pressure device were reported. However, in one study[20] otitis media related to the ventilation tube was reported.

Although adverse effects were not reported, it is necessary to consider them and the complications associated with the installation of the ventilation tube as tympanic perforation, among others.

Resource considerations

The cost associated with the positive pressure device is high, considering the device and the procedure for installation of the ventilation tube.

It is not possible to make an adequate balance between benefits and costs due to the associated uncertainty, although the null effect on hearing threshold and intensity of vertigo increase the likelihood of a less favorable balance.

What would patients and their doctors think about this intervention

Faced with the evidence presented in this summary, most patients and clinicians should lean against its use.

However, it is expected that in the absence of better therapeutic alternatives in the management of Ménière's disease, some clinicians and patients might opt for an alternative whose benefit is not proven.

Differences between this summary and other sources

This summary reaches similar conclusions to those presented by two of the five systematic reviews included[5,6], which consider that the evidence is not sufficient to justify the use of this therapy and they differ with those of the remaining three[3,4,7], which favor its use.

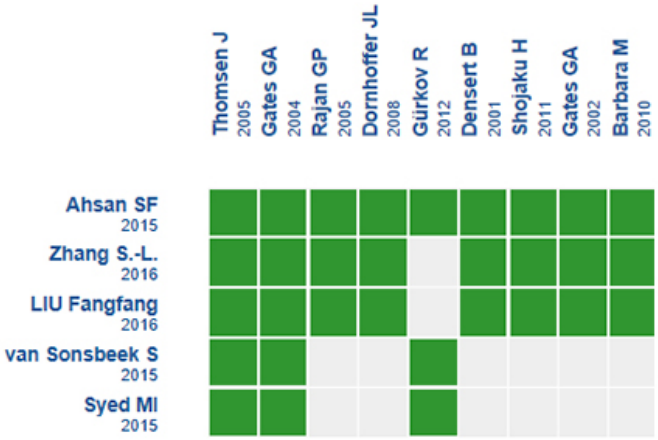
In the clinical practice guideline on Ménière's disease of Spain[30], positive pressure therapy is mentioned but it is not considered within the treatment algorithm. The clinical guidelines of Mexico[31] and France[32] do not mention it within the therapeutic alternatives. The American AAO-NHS guidelines are ongoing.

Could this evidence change in the future?

It The probability that the evidence provided in this summary changes with future evidence is high due to the uncertainty of the existing evidence.

There are at least two trials that are not included in the systematic reviews identified, which could shed light on this subject[33,34].

A search on the World Health Organization's clinical trials platform and the PROSPERO database identified one ongoing trial[35] and one ongoing systematic review[36].



An evidence matrix is a table that compares systematic reviews that answer the same question.
Rows represent systematic reviews, and columns show primary studies.
The boxes in green correspond to studies included in the respective revisions.
The system automatically detects new systematic reviews including any of the primary studies in the matrix, which will be added if they actually answer the same question.

Follow the link to access the **interactive version:** Positive pressure therapy for Ménière's disease.

Notes

The upper portion of the matrix of evidence will display a warning of "new evidence" if new systematic reviews are published after the publication of this summary. Even though the project considers the periodical update of these summaries, users are invited to comment in *Medwave* or to contact the authors through email if they find new evidence and the summary should be updated earlier.

After creating an account in Epistemonikos, users will be able to save the matrixes and to receive automated notifications any time new evidence potentially relevant for the question appears.

This article is part of the Epistemonikos Evidence Synthesis project. It is elaborated with a pre-established methodology, following rigorous methodological standards and internal peer review process. Each of these articles corresponds to a summary, denominated FRISBEE (Friendly Summary of Body of Evidence using Epistemonikos), whose main objective is to synthesize the body of evidence for a specific question, with a friendly format to clinical professionals. Its main resources are based on the evidence matrix of Epistemonikos and analysis of results using GRADE methodology. Further details of the methods for developing this FRISBEE are described here (http://dx.doi.org/10.5867/medwave.2014.06.5997)

Epistemonikos foundation is a non-for-profit organization aiming to bring information closer to health decision-makers with technology. Its main development is Epistemonikos database

www.epistemonikos.org.

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