Cochrane Library

Cochrane Database of Systematic Reviews

Surgery for Ménière's disease (Review)

Pullens B, Verschuur HP, van Benthem PP

Pullens B, Verschuur HP, van Benthem PP.
Surgery for Ménière's disease.
Cochrane Database of Systematic Reviews 2013, Issue 2. Art. No.: CD005395.
DOI: 10.1002/14651858.CD005395.pub3.

www.cochranelibrary.com

WILEY

TABLE OF CONTENTS

[Intervention Review]

Surgery for Ménière's disease

Bas Pullens[1], Hendrik P Verschuur[2], Peter Paul van Benthem[3]

[1]ENT Surgery, University Medical Centre Utrecht, Utrecht, Netherlands. [2]Department of Otolaryngology, Medical Center Haaglanden, The Hague, Netherlands. [3]ENT Surgery, Gelre Ziekenhuizen, Apeldoorn, Netherlands

Contact address: Peter Paul van Benthem, ENT Surgery, Gelre Ziekenhuizen, Albert Schweitzerlaan 31, Apeldoorn, 7334 DZ, Netherlands. pvanbenthem@wxs.nl.

Editorial group: Cochrane ENT Group.
Publication status and date: New search for studies and content updated (no change to conclusions), published in Issue 2, 2013.

Citation: Pullens B, Verschuur HP, van Benthem PP. Surgery for Ménière's disease. *Cochrane Database of Systematic Reviews* 2013, Issue 2. Art. No.: CD005395. DOI: 10.1002/14651858.CD005395.pub3.

ABSTRACT

Background

This is an update of a Cochrane review first published in *The Cochrane Library* in Issue 1, 2010.

Ménière's disease is characterised by three major symptoms: vertigo, deafness, and tinnitus or aural fullness, all of which are discontinuous and variable in intensity. A number of surgical modalities, of varying levels of invasiveness, have been developed to reduce the symptoms of Ménière's disease, but it is not clear whether or not these are effective.

Objectives

To assess the effectiveness of surgical options for the treatment of Ménière's disease. All surgical interventions used in the treatment of Ménière's disease, either to alter the natural history of the disease or to abolish vestibular function, were considered for this review.

Search methods

We searched the Cochrane Ear, Nose and Throat Disorders Group Trials Register; the Cochrane Central Register of Controlled Trials (CENTRAL); PubMed; EMBASE; CINAHL; Web of Science; BIOSIS Previews; Cambridge Scientific Abstracts; ICTRP and additional sources for published and unpublished trials. The date of the most recent search was 7 November 2012.

Selection criteria

Randomised or quasi-randomised controlled studies of a surgical modality versus a placebo therapy in Ménière's disease.

Data collection and analysis

Two authors independently assessed trial quality and extracted data. We contacted study authors for further information.

Main results

The only surgical intervention which has been evaluated in randomised controlled trials and met the inclusion criteria was endolymphatic sac surgery. We identified two randomised trials, involving a total of 59 patients; one comparing endolymphatic sac surgery with ventilation tubes and one with simple mastoidectomy. Neither study reported any beneficial effect of surgery either in comparison to placebo surgery or grommet insertion.

Authors' conclusions

The two trials included in this review provide insufficient evidence of the beneficial effect of endolymphatic sac surgery in Ménière's disease.

PLAIN LANGUAGE SUMMARY

Surgery for Ménière's disease

Ménière's disease is characterised by recurrent attacks of three major symptoms: vertigo (rotational dizziness), deafness and tinnitus (ringing of the ears), and/or aural fullness, all of which are discontinuous and variable in intensity. The symptoms of Ménière's disease are thought to be caused by excess pressure in the fluids of the inner ear which leads to sudden attacks of vertigo and hearing loss. A number of surgical procedures, of varying levels of invasiveness, have been developed to reduce the symptoms of Ménière's disease, but it is not clear whether or not these are effective. The surgical interventions can be categorised as two types: one type of surgical intervention aims to affect the natural history of the disease, with conservation of vestibular function. The other type aims to relieve symptoms by abolishing vestibular function. Both types of surgical intervention are considered in this review. Despite an extensive search the review authors only found two randomised controlled trials studying surgical interventions for Ménière's disease. Both of these trials, involving a total of 59 patients, studied endolymphatic sac surgery; one comparing it to placebo surgery and the other to a different type of surgery. Neither trial detected a significant difference between the treatment and control group.

BACKGROUND

Description of the condition

This is an update of a Cochrane review first published in *The Cochrane Library* in Issue 1, 2010.

Ménière's disease is an incapacitating disease in which recurrent attacks of vertigo are accompanied by hearing loss, tinnitus and/or aural fullness. The attacks of vertigo may follow each other with intervals of days, weeks or even months. Usually, these become less severe and disappear after two to eight years in 60% to 80% of sufferers (Portmann 1980; Silverstein 1989), with profound lasting hearing loss and tinnitus, however there is great variability in the presentation and natural course of the disease. When no known cause of the disease is identified, the term Ménière's *disease* is applicable. When the symptoms are secondary to a known disease (e.g. meningitis), the term Ménière's *syndrome* is used.

Few articles have been published on the epidemiology of Ménière's disease. Great variation exists in the published reports of the incidence and prevalence of Ménière's disease, ranging from 17 cases per 100,000 population in Japan (Nakae 1984) to 46 cases per 100,000 population in Sweden (Stahle 1978). There seems to be a slight female preponderance, with up to 1.3 times more women affected than men. The disease is more common in adults in their fourth and fifth decade of life (Kotimaki 1999; Sajjadi 2008). The frequency of bilateral disease is unclear. Published reports vary greatly between 2% and 78% (Balkany 1980). In a large population study by Kitahara in Japan, bilaterality of disease was noted in 9.1% of patients in their first year of experiencing symptoms. This increased steadily to 41.5% after 20 years of disease (Kitahara 1991).

In 1861 Prosper Ménière first recognised that this disorder originated from the inner ear (the membranous labyrinth), but wrongly attributed the cause to haemorrhage (Meniere 1861). In 1938 Hallpike and Yamakawa independently described a hydrops (i.e. accumulation of fluid) of the endolymphatic system in patients with Ménière's disease (Hallpike 1938; Yamakawa 1938). In 1965 Kimura introduced an experimental model in which an endolymphatic hydrops was produced in guinea pigs after surgical obliteration of the endolymphatic sac and duct (Kimura 1967). Endolymphatic hydrops caused by an abnormality in the absorption of endolymph at the endolymphatic sac remains the most promising theory to explain the symptoms of Ménière's disease. Other explanations for the cause of an endolymphatic hydrops, such as a hypoplasia of the vestibular aqueduct (Egami 1978; Yamamoto 1992), a genetic predisposition (Morrison 1995) or a viral aetiology (Vrabec 2003), have been suggested.

Currently no 'gold standard' diagnostic test for Ménière's disease exists. Diagnostic criteria vary among practitioners, who mostly diagnose Ménière's disease based upon the patient's history, neurotologic evaluation and clinical response to medical treatment. In 1972 the American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) produced diagnostic guidelines (Alford 1972) which were revised in 1985 (Pearson 1985) and 1995 (Monsell 1995b). According to these guidelines Ménière's disease is 'definite' when the last two spontaneous episodes of vertigo occur for at least 20 minutes, hearing loss of at least 20 decibels (dB) is objectified and tinnitus or aural fullness in the affected ear is experienced. Further investigation has to be performed to exclude any other disorder (Monsell 1995b). When patients match the AAO-HNS criteria, but symptoms are secondary to a known cause, they are classified as having Ménière's syndrome.

Description of the intervention

There still is no unequivocal treatment for Ménière's disease, mainly because the precise aetiology is unknown. The disorder has been associated with a significant placebo effect and its relapsing, remitting nature has made evaluation of various treatments difficult. Primary treatment options include the use of diuretics, a low salt diet (to decrease fluid retention) and betahistine hydrochloride (Serc®). Betahistine and diuretics have been evaluated in Cochrane reviews (Burgess 2006; James 2001). A variety of other drugs may be used including antihistamines, benzodiazepines and corticosteroids. With medical management about 60% to 87% of patients with Ménière's disease are able to maintain their normal daily activities (Claes 2000; Santos 1993). For patients who still have incapacitating, disabling attacks after three to six months of conservative therapy and unilateral involvement, surgical intervention can be considered (Konrad 1986; Monsell 1988). If the patient's hearing is socially adequate (arbitrarily set at 50 dB and 80% speech discrimination) a non-destructive surgical procedure is advised. If the patient's hearing is socially inadequate a destructive operation can be considered (Wiet 1981).

Surgery

There are two types of surgery: destructive surgery which aims to control individual symptoms by abolishing vestibular function, and non-destructive surgery which aims to alter the natural course of the disease.

Destructive surgery

In Ménière's disease the vestibular end organ (labyrinth) is responsible for the attacks of vertigo and the hearing end organ (cochlea) is responsible for the hearing loss. The rationale for destructive surgery to the vestibule is to rid the patient of episodic vertigo by abolishing the vestibular end organ. The brain will eventually compensate for the loss of one labyrinth, provided that the other vestibular organ is working properly. Destructive procedures of the vestibular organ have a high risk of destroying the cochlea as well. These procedures are irreversible and should be avoided in patients with bilateral involvement and in patients with adequate hearing. Destructive procedures comprise:

1. selective vestibular nerve section, which aims to decrease vertigo by sectioning the vestibular nerve so the input of the diseased vestibular end organ cannot reach the brain, but at the same time leaves the patient with unilateral (and therefore sub-optimal) vestibular function via the opposite (non-operated ear);
2. cochleovestibular nerve section, which has the same effect as the above but in addition leads to total loss of hearing in the operated ear;
3. labyrinthectomy, which aims to decrease vertigo by total destruction of the labyrinth but in addition leads to total loss of hearing in the operated ear;
4. insertion of aminoglycosides or other medicine into the middle ear to perform a chemical labyrinthectomy, which aims to decrease vertigo but may result in loss of hearing.

Non-destructive surgery

Non-destructive procedures aim to change the natural history of the disease by reducing the frequency and severity of the symptoms. These procedures are less invasive and do not preclude use of conservative treatment modalities (Wiet 1981). Non-destructive procedures comprise:

1. endolymphatic sac decompression and/or shunt, which aims to increase endolymph drainage;
2. insertion of ventilation tubes which diminish middle ear pressure changes, on the assumption that symptoms are caused by pressure disturbances of the middle ear;
3. lateral semicircular canal plugging which aims to ablate endolymphatic movement in the occluded canal (Charpiot 2010).

Since Ménière's disease is a difficult disease to diagnose, with great variability in presentation, and has a fluctuating natural course, evaluation of any intervention is difficult and requires careful long-term follow-up, as advised by the American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) (Monsell 1995a).

Why it is important to do this review

In the current literature there is much controversy about the effectiveness of surgical procedures used to treat patients with Ménière's disease, most of which are more or less harmful to the inner ear. This review aims to assess the effectiveness and safety of these different procedures.

OBJECTIVES

To assess the effectiveness of the several surgical options, either destructive or non-destructive, in the treatment of Ménière's disease. We have assessed the effect of surgical treatment on the severity and frequency of acute attacks of vertigo, on symptoms such as tinnitus and aural fullness, and on sensory hearing loss. The safety and side effects of the procedures have also been evaluated.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised or quasi-randomised controlled trials.

Types of participants

Any patient suffering from Ménière's disease not otherwise controlled with conservative therapy. We graded studies which had used the AAO-HNS criteria to diagnose these patients 'I' and considered them superior to studies that did not use the AAO-HNS criteria, which we graded 'II'.

The study population had to be defined to enable identification of the operative intervention, ideally with relevant subgroups given if more than one.

Types of interventions

The study had to test some method of surgical intervention aimed at treating patients suffering from Ménière's disease and compare it with a placebo or alternative, ideally equally severely affected, intervention group. All surgical interventions described above were considered.

We excluded intratympanic installation of medicines, such as gentamicin or dexamethasone, and pressure therapy after placement of ventilation tubes as these are the subject of separate reviews (Pullens 2010a; Pullens 2011).

Types of outcome measures

1. Number and severity of acute attacks of vertigo
2. Loss or gain of hearing
3. Severity of tinnitus
4. Perception of aural fullness
5. Duration of symptoms correlated to the improvement of symptoms
6. Complications and side effects

Due to the natural history of Ménière's disease it is hard to say when a patient is cured. According to the Committee of Hearing and Equilibrium (Monsell 1995a) it is possible to define improvement subjectively. The patient counts their vertigo spells for six months before the intervention, then again for a further period of six months and at 18 to 24 months after the intervention. The quotient of the mean vertigo spells per month classifies the improvement of vertigo. When this quotient is zero, complete control of the vertigo has been achieved. As it is not clear whether this relief of vertigo is permanent, authors are encouraged to report results up to four years after the treatment.

Search methods for identification of studies

We conducted systematic searches for randomised controlled trials. There were no language, publication year or publication status restrictions. The date of the last search was 7 November 2012, following previous searches in 2012, 2009 and 2005.

Electronic searches

We searched the following databases from their inception: the Cochrane Ear, Nose and Throat Disorders Group Trials Register; the Cochrane Central Register of Controlled Trials (CENTRAL, *The Cochrane Library* 2012, Issue 10); PubMed; EMBASE; CINAHL; LILACS; KoreaMed; IndMed; PakMediNet; CAB Abstracts; Web of Science; BIOSIS Previews; ISRCTN; Clinicaltrials.gov; ICTRP; Google Scholar and Google.

We modelled subject strategies for databases on the search strategy designed for CENTRAL. Where appropriate, we combined subject strategies with adaptations of the highly sensitive search strategy designed by the Cochrane Collaboration for identifying randomised controlled trials and controlled clinical trials (as described in the *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0, Box 6.4.b. (Handbook 2011)). Search strategies for major databases including CENTRAL are provided in Appendix 1.

Searching other resources

We scanned the reference lists of identified studies for further trials. We searched PubMed, TRIPdatabase and *The Cochrane Library* to retrieve existing systematic reviews possibly relevant to this systematic review, in order to search their reference lists for additional trials. We sought abstracts from conference proceedings

via the Cochrane Ear, Nose and Throat Disorders Group Trials Register.

Data collection and analysis

Selection of studies

Two authors independently used titles, keywords and (where available) abstracts of the identified citations to exclude trials which clearly did not meet the inclusion criteria of the review. Authors and journal names were blinded at this stage. If one of the authors concluded that the trial might possibly meet the criteria, we obtained the full paper for further study. We then assessed hard copies of the articles passing this initial screening to determine whether they met the inclusion criteria. From this stage on, blinding of authors and journal names was no longer feasible. We compared the results of the two independent selections. Disagreements were resolved by discussion.

Data extraction and management

The two authors jointly extracted data. Disagreements were resolved by discussion.

We planned to extract following data, if available, for subgroup analysis.

1. Type of surgical intervention
2. Range of patients' ages
3. Duration of complaints
4. Ménière's disease versus Ménière's syndrome

Assessment of risk of bias in included studies

We assessed the quality of the selected studies using the Cochrane Collaboration's tool for assessing risk of bias. The domains of sequence generation, allocation concealment, selective outcome reporting, blinding, incomplete outcome data and other sources of bias are each addressed in the tool by a single entry for each study. The two authors judged these domains according to table 8.5.a of the *Cochrane Handbook for Systematic Reviews of Interventions* (Handbook 2011): low, high and unclear risk of bias. We incorporated these results into a 'Risk of bias' table in RevMan 5 (RevMan 2011) (see Characteristics of included studies). We have also assessed the length of follow-up, with 'low risk of bias' indicating complete follow-up (two years or more) and 'high risk of bias' meaning follow-up of less than two years.

We have also judged three extra domains: the certainty of diagnosis of Ménière's (see Types of participants), the quality of the outcome assessment (see Types of outcome measures) and the description of the protocol used. This is a modification following an earlier Cochrane review by James and colleagues (James 2001).

Assessment of heterogeneity

A test of heterogeneity and an appraisal of individual study odds ratio was to be reviewed within each comparison of the effectiveness of the surgical intervention to determine whether similar results were obtained from each study. Where significant heterogeneity existed, we planned to examine the trials for specific potential clinical differences.

Assessment of reporting biases

We planned to assess the potential effects of publication bias on the results of the meta-analysis from a funnel plot (graph of the sample size plotted against the odds ratio).

Data synthesis

We planned the following methods:

For each surgical procedure, we planned to produce tables of comparison (if possible). Tables of comparison were to include the following outcomes:

1. reduction in spells of vertigo to a clinically irrelevant level;
2. loss or gain of hearing (more than 15 dB on Fletcher index);
3. complications from intervention.

We would determine summary odds ratios (OR) with 95% confidence intervals (CI) using both a fixed-effect model (Mantel Haenszel) and a random-effects model (Der Simonian and Laird).

Subgroup analysis and investigation of heterogeneity

We planned subgroup analyses for:

1. each surgical procedure;
2. range of patients' ages;
3. duration of complaint;
4. Ménière's disease versus Ménière's syndrome.

In addition, we intended to calculate multivariate regression models. If subgroup analysis and multivariate analysis required further information, we would have contacted authors of studies.

We performed no subgroup analyses in this review, because meta-analysis was not possible.

Sensitivity analysis

A planned sensitivity analysis to compare the effect of inclusion and exclusion of studies of different qualities was not conducted because meta-analysis was not possible.

These methods may be utilised in future updates of this review if sufficient data are available.

RESULTS

Description of studies

Results of the search

The search identified 85 references, of which 10 were retrieved in full text. We identified three randomised controlled trials of surgery for Ménière's disease. Two trials studied endolymphatic shunt therapy versus placebo therapy. One study discussed ventilation tube placement solely and in combination with transtympanic dexamethasone placement. No placebo-controlled studies were found which studied vestibular or cochleovestibular nerve section and labyrinthectomy. Transtympanic aminoglycoside application therapy is studied in a separate review (Pullens 2011), as is ventilation tube placement in combination with pressure therapy (Pullens 2010a).

We updated the full searches in November 2012 and retrieved a total of 178 references. Following appraisal none met the criteria for inclusion in the review.

Included studies

Two randomised controlled trials of endolymphatic sac surgery were included (Bretlau 1989; Thomsen 1998). The Bretlau 1989 study is a nine-year follow-up report of an original study from 1981. They also published a three-year follow-up report of this study, but the nine-year follow-up was considered for this review (Thomsen 1981; Thomsen 1983). Dr Bretlau co-authored Thomsen 1981 and Thomsen 1983, and Dr Thomsen was a co-author of Bretlau 1989.

Participants

The two trials studied patients with a diagnosis of Ménière's disease only. None of the trials discussed Ménière's syndrome. The two trials recruited a total of 59 patients but seven patients withdrew. The smallest trial studied 29 patients (Thomsen 1998) and the largest 30 (Bretlau 1989). Although neither study explicitly stated that the AAO-HNS classification for certainty of diagnosis was used, Thomsen used the functional level scale according to the guidelines of the AAO-HNS and stated that all patients had typical symptoms of Ménière's disease (Thomsen 1998). The guidelines of the AAO-HNS are not mentioned in the study by Bretlau, but the inclusion criteria are identical to the aforementioned guidelines (Bretlau 1989). Both studies included patients who had received conservative therapy previously, but excluded patients who had received surgical therapy.

Intervention

Bretlau et al compared endolymphatic sac shunts to a placebo procedure, whereby a simple mastoidectomy is used as placebo surgery (Bretlau 1989). Thomsen et al compared endolymphatic sac shunts to the placement of a grommet, which is also considered a surgical intervention (Thomsen 1998).

Allocation

Both studies were randomised. Thomsen 1998 used sealed envelopes which were opened just before the operation. Bretlau 1989 stated that the patients were randomly allocated to each treatment group.

Trial design

The trial by Bretlau et al was double-blind. The trial by Thomsen et al was double-blind until just before the intervention; after this moment it was clear to the surgeon and the patient what surgery had been done because one group had a retroauricular surgical wound and the other group did not. Data from Bretlau 1989 were published with a follow-up period of nine years: on a monthly basis for 12 months and then three and nine years postoperatively. Thomsen 1998 had a follow-up period of 12 months and data were collected six and 12 months postoperatively.

Bretlau 1989 analysed the total scores of all five parameters using the Mann-Whitney U test, the Friedmann test and the Kolmogorov-Smirnoff two-sample test to identify significant differences. Thomsen 1998 used the Mann-Whitney and the Pratt's test to show significant differences for all the separate parameters.

Outcome measures

1. Vertigo

In Thomsen 1998 the frequency and severity of symptoms were recorded on a daily basis by the patients six months before and 12 months after the operation and the authors carried out a monthly interview about the subjective symptoms. The results were registered according to the functional level scale of the AAO-HNS guidelines of 1995. Bretlau 1989 used dizziness rating questionnaires and recorded the occurrence of nausea and vomiting. Bretlau 1989 also used a simple four-point rating system for the occurrence of nausea, vomiting/vertigo, tinnitus/fullness and hearing (none = 0, weak = +1, strong = +2, severe = +3).

2. Hearing

Pure-tone audiograms were recorded by Thomsen 1998 every month, based on a four-tone average (500 to 4000 Hz), and Bretlau 1989 monthly for the first 12 months and at three and nine years postoperatively based on three-tone average (250, 500, 1000 Hz).

3. and 4. Tinnitus and aural fullness

Bretlau 1989 used a simple four-point rating system (see 'Vertigo'). Thomsen 1998 recorded the subjective symptoms by interview.

5. Duration of symptoms correlated to the improvement of symptoms

Neither of the studies described the correlation between the duration and relief of symptoms.

6. Complications and side effects

Thomsen 1998 reported one patient with anacusis and one patient with severe sensory hearing loss as a complication of surgery. Bretlau 1989 did not report any complications or side effects.

Excluded studies

We excluded eight studies from the review (see Characteristics of excluded studies). Four studies were not randomised controlled trials, three studied intratympanic administration of dexamethasone or latanoprost, and one compared low-level laser therapy with betahistine. Low-level laser therapy was not considered to be a surgical intervention.

Risk of bias in included studies

See the 'Risk of bias' tables in the 'Characteristics of included studies' section.

Sequence generation

In Bretlau 1989 the method used to generate the allocation sequence was not described. The paper states that "...the patients were randomly assigned to each treatment group."

In Thomsen 1998 the method of randomisation was not described. The paper states that patients were randomised before the trial started. The demographic composition of the groups is shown in Table 1 in the paper, although without P values. Strangely, the female:male ratio was a lot larger in the ventilation tube group (3.67:1) than in the sac shunt group (0.67:1)

Allocation concealment

In Bretlau 1989 the method used to conceal the allocation sequence was not described. The paper states that participants and

postoperative investigators were unaware of the intervention used. The allocation was not of course concealed from the surgeon.

In Thomsen 1998 the randomisation results were kept in sealed envelopes. These were opened just before start of the surgery.

Blinding of participants, personnel and outcome assessors

In Bretlau 1989 the patients underwent control examinations after surgery in a university other than the university in which they were operated. In this way, the participants and the investigators were both blinded to the intervention used. As stated above, the patients were not told that they would possibly undergo a placebo operation and were blind to the type of intervention. A standardised operation description was written in the patient's chart to keep the nursing staff of the hospital unaware of the character of the operation.

In Thomsen 1998 the patients underwent control examinations after surgery in a university other than the one in which they were operated. However, neither the patients, the surgeons, nor the investigators were blind to the intervention used, as they could recognise the presence of a retro-auricular incision in the endolymphatic shunt group.

Incomplete outcome data

In the Bretlau 1989 study, of the original 30 patients in 1981, seven were not included in the nine-year follow-up analysis, of which three were in the active group and four in the placebo group. The analysis was carried out on the remaining 21 patients. There are data, however, from a 12-month and a 36-month follow-up interval.

In Thomsen 1998 there were no losses to follow-up. For the outcomes of pure-tone average and speech discrimination, full data were given with median values and confidence intervals. For the outcomes functional level scale and treatment effect, the results were depicted in diagrams. No numerical values were given.

Selective outcome reporting

The investigator who reported outcomes in Bretlau 1989 was blinded to the intervention used.

In Thomsen 1998 the investigators and patients were not blinded to the intervention used. There is a risk of selective outcome reporting.

Follow-up

Bretlau 1989 had a nine-year follow-up.

Follow-up was for one year in Thomsen 1998.

Certainty of diagnosis

In Bretlau 1989 inclusion criteria were the presence of typical attacks of fluctuating hearing loss, tinnitus and vertigo, with pressure in the ear, at least one attack every two weeks, for at least six months. Other causes of vertigo were excluded. There is no mention of the AAO-HNS criteria, but the inclusion criteria are identical.

The AAO-HNS criteria were used in Thomsen 1998.

Effects of interventions

1) Vertigo

In Bretlau 1989 both groups improved significantly ($P < 0.01$), but a significant difference could not be found between the two groups. Subgroups were analysed for nausea and vomiting and dizziness and vertigo. Both groups scored significantly lower postoperatively ($P < 0.01$), however no difference between the two groups was found.

In Thomsen 1998 a significant improvement following treatment was found using the Pratt's test ($P < 0.05$) comparing pre- and postoperative symptoms for both groups. No statistical difference could be found between the groups ($P > 0.05$, Mann-Whitney), but at 12 months the saccus group was slightly poorer. In both groups 33% of patients were completely free of vertiginous attacks, and 20% of the saccus and 29% of the ventilation group had only minor complaints. Two patients in the saccus group and one in the ventilation group were failures (class E and F).

2) Hearing

In Bretlau 1989 the placebo group did not score better postoperatively, but the active group did. The difference was "slightly" significant ($P < 0.05$). There was a non-significant tendency towards greater improvement in the actively treated group in which a greater number of patients showed hearing stabilisation.

Thomsen 1998 did not find a difference between the two groups regarding pure-tone average (PTA) and speech discrimination score (SDS) pre- and postoperatively ($P > 0.05$, Mann-Whitney).

3) Tinnitus

In Bretlau 1989 the active group improved more than the placebo group but not significantly. No significant difference could be found between the two groups.

In Thomsen 1998 the patients' tinnitus was unaffected by treatment ($P > 0.05$, Mann-Whitney) though some non-significant improvement could be observed in the ventilation group.

4) Aural fullness

In Bretlau 1989 both groups had a significant reduction in scores for pressure in the ear ($P < 0.01$). No significant difference could be found between the two groups.

Thomsen 1998 did not report this outcome measure in the results.

5) Correlation between duration and symptoms of Ménière's disease

None of the trials correlated the duration of Ménière's disease and its symptoms.

6) Complications and side effects

Bretlau 1989 did not mention any complications or side effects, but the percentage of bilateral Ménière's disease had increased to 35% after nine years follow-up versus 16% preoperatively.

In Thomsen 1998 one patient exhibited anacusis and another severe sensorineural loss with poor discrimination ability (values, however, were not decisive because median values were used).

Two other persons reported worsening of symptoms and no improvement was experienced by four patients in the saccus group. In the ventilation group one patient reported worsening of symptoms and one reported no change of symptoms.

7) Other measures used in the trials

According to the patients' subjective impressions in Thomsen 1998, 86% in the ventilation and 60% in the saccus group were improved, but no difference between groups was detected (P > 0.05, Mann-Whitney).

DISCUSSION

Summary of main results

Vertigo

Bretlau 1989 and Thomsen 1998 did not find a significant difference in the total score between the treatment and placebo group after nine years and 12 months respectively.

Hearing

Bretlau 1989 and Thomsen 1998 did not find a significant difference between the two groups.

Tinnitus

Bretlau 1989 reported improvement in both groups. Thomsen 1998 reported that tinnitus was not affected by treatment.

Complications and side effects were not mentioned by Bretlau 1989. Thomsen 1998 reported severe hearing loss in two patients and worsening of symptoms in two other patients in the intervention group, but this did not greatly affect the results because of the use of median values.

Overall completeness and applicability of evidence

Both studies adequately address the question posed by this review: namely, does a surgical intervention alleviate patients with Ménière's disease of their symptoms (vertigo/tinnitus/aural fullness/hearing loss). Both studies adequately report the effect of a surgical intervention on vertigo, hearing loss and tinnitus.

Quality of the evidence

Two studies have been included: Bretlau 1989 and Thomsen 1998. A total of 52 patients were reported on in these studies. Both studies used endolymphatic shunt surgery as intervention. Bretlau 1989 used a mastoidectomy as the placebo intervention and Thomsen 1998 used a ventilation tube placement as placebo. Although both studies used different placebo interventions, they both conclude that about 70% of participants in both the placebo and treatment group had alleviation of symptoms and there was no significant difference between the placebo and the treatment group. The study by Bretlau et al has been subject to debate (see Agreements and disagreements with other studies or reviews), while the study of Thomsen et al is of lower quality due to blinding issues.

Potential biases in the review process

Ultimately only two studies could be included in this review. One of these (Thomsen 1998) had poor blinding, while the other (Bretlau 1989) did not specify which statistical test was used for which parameter. It also remains unclear which statistical test was used to compare the two groups, and this has led to criticism by a number of authors (Welling 2000).

Agreements and disagreements with other studies or reviews

Since the initial publication of the Bretlau/Thomsen study in 1981 (Thomsen 1981), there has been great controversy concerning its contents and conclusions. In a letter to the editor, Dr. Arendberg stated that the conclusions of the authors are not supported by the data presented in the study (Arendberg 1981). He states that the methods used by the authors to determine therapeutic success are wrong and not in accordance with the American Academy of Ophthalmology and Otolaryngology criteria. In another letter to the editors, Dr. Vaisrub criticised the study on statistical grounds, stating that "...the reported findings by Thomsen et al. and the interpretations drawn from them suffer a number of shortcomings that raise numerous questions..." (Vaisrub 1981).

These and other comments have moved Welling et al (Welling 2000) to re-evaluate the original 1981 data, represented by Thomsen et al (Thomsen 1981). No numerical data ware represented by Thomsen et al, therefore three different observers extracted the data concerning vertigo complaints from the graphs, given by Thomsen and Bretlau in 1981. The averages of their estimates were used to re-analyse the data. For other variables, individual values were estimated by a single observer. After statistical analysis Welling et al found five areas (vertigo, nausea and vomiting, tinnitus and combined score) that differed from the analysis by Thomsen and Bretlau, favouring active group over placebo.

The Thomsen 1998 study had a lower methodological quality; because of the different surgical modalities the study could not be blinded.

Due to of the different ways the outcome measures were obtained, and because not all the required data were reported, we could not perform a meta-analysis in this review.

AUTHORS' CONCLUSIONS

Implications for practice

Only two randomised controlled trials of surgery for Ménière's disease were included, both studying endolymphatic sac surgery. In both of these trials, a statistically significant effect could not be established for the intervention versus placebo or grommet insertion, although the study by Bretlau 1989 has been the subject of great criticism. It is remarkable, however, that 70% of participants in both the endolymphatic sac surgery groups and the comparator experienced some relief of complaints. This either implicates a beneficial effect of any surgical intervention, or a beneficial effect of any intervention, surgical or non-surgical. This constitutes one of the biggest challenges investigators face when evaluating treatment for Ménière's disease. The two trials included in this review provide insufficient evidence for the beneficial effect of endolymphatic sac surgery in Ménière's disease.

Implications for research

Only two randomised controlled trials studying endolymphatic sac surgery were found. Both of these studies have their limitations, however, and are subject to debate. An additional randomised controlled trial would help to determine the effectiveness of this

therapy. However, a fully double-blinded trial with concealment of allocation is very difficult to undertake in the modern age due to ethical objections.

None of the other surgical treatment options for Ménière's disease have been evaluated in a randomised controlled trial. This implies a great need for the evaluation of surgical options for Ménière's disease in a randomised or controlled clinical trial setting. However, for ethical restrictions, a true double-blind set-up for any surgical intervention will not be possible. Studies which can be considered are those comparing surgical interventions to other interventions (e.g. grommet insertion, intratympanic gentamicin or medication), in which the outcome assessor is blinded.

ACKNOWLEDGEMENTS

We would like to thank the members of the UK Cochrane Centre and the Cochrane Ear, Nose & Throat Disorders Group.

REFERENCES

References to studies included in this review

Bretlau 1989 *{published data only}*

Bretlau P, Thomsen J, Tos M, Johnsen NJ. Placebo effect in surgery for Menière's disease: nine-year follow-up. *American Journal of Otology* 1989;**10**(4):259-61.

Thomsen 1998 *{published data only}*

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 Oto-laryngologica* 1998;**118**(6):769-73.

References to studies excluded from this review

Brinson 2007 *{published data only}*

Brinson GM, Chen DA, Arriaga MA. Endolymphatic mastoid shunt versus endolymphatic sac decompression for Ménière's disease. *Otolaryngology - Head and Neck surgery* 2007;**136**(3):415-21.

De La Cruz 2007 *{published data only}*

De La Cruz A, Borne Teufert K, Berliner KI. Transmastoid labyrinthectomy versus translabyrinthine vestibular nerve section: does cutting the vestibular nerve make a difference in outcome?. *Otology & Neurotology* 2007;**28**(6):801-8. [PUBMED: 17704714]

Durland 2005 *{published data only}*

Durland WF Jr, Pyle GM, Connor NP. Endolymphatic sac decompression as a treatment for Meniere's disease. *Laryngoscope* 2005;**115**(8):1454-7.

Garduno-Anaya 2005 *{published data only}*

Garduño-Anaya MA, Couthino De Toledo H, Hinojosa-González R, Pane-Pianese C, Ríos-Castañeda LC. Dexamethasone inner ear perfusion by intratympanic injection in unilateral Ménière's disease: a two-year prospective, placebo-controlled, double-blind, randomized trial. *Otolaryngology - Head and Neck Surgery* 2005;**133**(2):285-94.

Heatley 1990 *{published data only}*

Heatley DG, Brandenburg JH. A comparison of the long-term hearing outcome in surgically versus nonsurgically treated patients with Meniere's disease. Inner ear surgery: proceedings of the Third International Symposium and Workshops on Surgery of the Inner Ear Jul 29 - Aug 04 1990, Snowmass-Aspen, Colorado, USA. Amsterdam; New York: Kugler Publications, 1991:203-8.

Rask-Andersen 2005 *{published data only}*

Rask-Andersen H, Friberg U, Johansson M, Stjernschantz J. Effects of intratympanic injection of latanoprost in Meniere's disease: a randomized, placebo-controlled, double-blind, pilot study. *Otolaryngology - Head and Neck Surgery* 2005;**133**(3):441-3.

Silverstein 1998 *{published data only}*

Silverstein H, Isaacson JE, Olds MJ, Rowan PT, Rosenberg S. Dexamethasone inner ear perfusion for the treatment of Meniere's disease: a prospective, randomized, double-blind, crossover trial. *American Journal of Otology* 1998;**19**(2):196-201.

Teggi 2008 *{published data only}*

Teggi R, Bellini C, Fabiano B, Bussi M. Efficacy of low-level laser therapy in Meniere's disease: a pilot study of 10 patients. *Photomedicine and Laser Surgery* 2008;**26**(4):349-53.

Additional references

Alford 1972

Alford BR. Menière's disease: criteria for diagnosis and evaluation of therapy for reporting. Report of subcommittee on equilibrium and its measurement. *Transactions of the American Academy of Ophthalmology and Otolaryngology* 1972;**76**:1462-4.

Arendberg 1981

Arendberg IK. Placebo effect for Meniere's disease sac shunt surgery disputed [letter]. *Archives of Otolaryngology* 1981;**107**:773-4.

Balkany 1980

Balkany TJ, Sires B, Arenberg IK. Bilateral aspects of Meniere's disease: an underestimated clinical entity. *Otolaryngologic Clinics of North America* 1980;**13**(4):603-9.

Burgess 2006

Burgess A, Kundu S. Diuretics for Ménière's disease or syndrome. *Cochrane Database of Systematic Reviews* 2006, Issue 3. [DOI: 10.1002/14651858.CD003599.pub2]

Charpiot 2010

Charpiot A, Rohmer D, Gentine A. Lateral semicircular canal plugging in severe Meniere's disease: a clinical prospective study about 28 patients. *Otology & Neurotology* 2010;**31**(2):237-40. [PUBMED: 20101162]

Claes 2000

Claes J, Van de Heyning PH. A review of medical treatment for Meniere's disease. *Acta Oto-Laryngologica. Supplement* 2000;**544**:34-9.

Egami 1978

Egami T, Sando I, Black FO. Hypoplasia of the vestibular aqueduct and endolymphatic sac in endolymphatic hydrops. *Otolaryngology* 1978;**86**(2):327-39.

Hallpike 1938

Hallpike CS, Cairns H. Observations on the pathology of Menière's syndrome. *Proceedings of the Royal Society of Medicine* 1938;**31**:1317-31.

Handbook 2011

Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated

March]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

James 2001

James AL, Burton MJ. Betahistine for Ménière's disease or syndrome. *Cochrane Database of Systematic Reviews* 2001, Issue 1. [DOI: 10.1002/14651858.CD001873]

Kimura 1967

Kimura RS. Experimental blockage of the endolymphatic duct and sac and its effect on the inner ear of the guinea pig. A study on endolymphatic hydrops. *Annals of Otology, Rhinology and Laryngology* 1967;**76**(3):664-87.

Kitahara 1991

Kitahara M. Bilateral aspects of Meniere's disease. Meniere's disease with bilateral fluctuant hearing loss. *Acta Oto-Laryngologica. Supplement* 1991;**485**:74-7.

Konrad 1986

Konrad HR. Intractable vertigo - when not to operate. *Otolaryngology - Head and Neck Surgery* 1986;**95**(4):482-4.

Kotimaki 1999

Kotimaki J, Sorri M, Aantaa E, Nuutinen J. Prevalence of Meniere disease in Finland. *Laryngoscope* 1999;**109**(5):748-53.

Meniere 1861

Ménière P. Memoire sur les lesions de l'oreille interne donnant lieu à des symptômes de congestion cerebrale apoplectiforme. *Gazette Medicale de Paris* 1861;**16**:597-601.

Monsell 1988

Monsell EM, Brackmann DE, Linthicum FH Jr. Why do vestibular destructive procedures sometimes fail?. *Otolaryngology - Head and Neck Surgery* 1988;**99**(5):472-9.

Monsell 1995a

Committee on Hearing and Equilibrium. Committee on Hearing and Equilibrium guidelines for the diagnosis and evaluation of therapy in Meniere's disease. American Academy of Otolaryngology - Head and Neck Foundation, Inc. *Otolaryngology - Head and Neck Surgery* 1995;**113**(3):181-5.

Monsell 1995b

Monsell EM. New and revised reporting guidelines from the Committee on Hearing and Equilibrium. American Academy of Otolaryngology - Head and Neck Surgery Foundation, Inc. *Otolaryngology - Head and Neck Surgery* 1995;**113**(3):176-8.

Morrison 1995

Morrison AW. Anticipation in Meniere's disease. *Journal of Laryngology and Otology* 1995;**109**(6):499-502.

Nakae 1984

Nakae K, Komatuzaki K. Epidemiological study of Meniere's disease. *Pract Otol (Kyoto)* 1984;**69**:1783-8.

Pearson 1985

Pearson BW, Brackmann DE. Committee on Hearing and Equilibrium guidelines for reporting treatment results in Meniere's disease. *Otolaryngology - Head and Neck Surgery* 1985;**93**(5):579-81.

Phillips 2011

Phillips JS, Westerberg B. Intratympanic steroids for Ménière's disease or syndrome. *Cochrane Database of Systematic Reviews* 2011, Issue 7. [DOI: 10.1002/14651858.CD008514.pub2]

Portmann 1980

Portmann G. The old and new in Meniere's disease - over 60 years in retrospect and a look to the future. *Otolaryngologic Clinics of North America* 1980;**13**(4):567-75.

Pullens 2010a

Pullens B, van Benthem PP. Positive pressure therapy for Ménière's disease or syndrome. *Cochrane Database of Systematic Reviews* 2010, Issue 3. [DOI: 10.1002/14651858.CD008419]

Pullens 2011

Pullens B, van Benthem PP. Intratympanic gentamicin for Ménière's disease or syndrome. *Cochrane Database of Systematic Reviews* 2011, Issue 3. [DOI: 10.1002/14651858.CD008234.pub2]

RevMan 2011 [Computer program]

The Nordic Cochrane Centre, The Cochrane Collaboration. Review Manager (RevMan). Version 5.1. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2011.

Sajjadi 2008

Sajjadi H, Paparella MM. Meniere's disease. *Lancet* 2008;**372**(9636):406-14.

Santos 1993

Santos PM, Hall RA, Snyder JM, Hughes LF, Dobie RA. Diuretic and diet effect on Meniere's disease evaluated by the 1985 Committee on Hearing and Equilibrium guidelines. *Otolaryngology - Head and Neck Surgery* 1993;**109**(4):680-9.

Silverstein 1989

Silverstein H, Smouha E, Jones R. Natural history vs. surgery for Meniere's disease. *Otolaryngology - Head and Neck Surgery* 1989;**100**(1):6-16.

Stahle 1978

Stahle J, Stahle C, Arenberg IK. Incidence of Meniere's disease. *Archives of Otolaryngology* 1978;**104**(2):99-102.

Thomsen 1981

Thomsen J, Bretlau P, Tos M, Johnsen NJ. Placebo effect in surgery for Meniere's disease. A double-blind, placebo-controlled study on endolymphatic sac shunt surgery. *Archives of Otolaryngology* 1981;**107**(5):271-7.

Thomsen 1983

Thomsen J, Bretlau P, Tos M, Johnsen NJ. Placebo effect in surgery for Meniere's disease: three-year follow-up. *Otolaryngology - Head and Neck Surgery* 1983;**91**(2):183-6.

Vaisrub 1981

Vaisrub N. Placebo effect for Meniere's disease sac shunt surgery disputed [letter]. *Archives of Otolaryngology* 1981;**107**:773-4.

Vrabec 2003

Vrabec JT. Herpes simplex virus and Meniere's disease. *Laryngoscope* 2003;**113**(9):1431-8.

Welling 2000

Welling DB, Nagaraja HN. Endolymphatic mastoid shunt: a reevaluation of efficacy. *Otolaryngology - Head and Neck Surgery* 2000;**122**(3):340-5.

Wiet 1981

Wiet RJ, Kazan R, Shambaugh GE Jr. An holistic approach to Meniere's disease. Medical and surgical management. *Laryngoscope* 1981;**91**(10):1647-56.

Yamakawa 1938

Yamakawa K. Uber die pathologische Veranderung bei einem Menière-Kranken. *Proceedings of the 42nd Annual Meeting of the Oto-Rhino-Laryngological Society of Japan* 1938;**44**:2310-2.

Yamamoto 1992

Yamamoto E, Mizukami C, Ohmura M. Investigation of the external aperture of the vestibular aqueduct in Meniere's disease by three-dimensional image analysis. *Acta Otolaryngologica* 1992;**112**(1):31-5.

References to other published versions of this review

Pullens 2010b

Pullens B, Giard JL, Verschuur HP, van Benthem PP. Surgery for Ménière's disease. *Cochrane Database of Systematic Reviews* 2010, Issue 1. [DOI: 10.1002/14651858.CD005395.pub2]

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Bretlau 1989

Methods	Randomised, double-blind trial
Participants	Patients with Ménière's disease
Interventions	Regular mastoidectomy versus endolymphatic sac shunting
Outcomes	Vertigo Hearing Tinnitus/aural fullness
Notes	9 years follow-up

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The method used to generate the allocation sequence was not described
Allocation concealment (selection bias)	Unclear risk	The method used to conceal the allocation sequence was not described
Blinding (performance bias and detection bias) All outcomes	Low risk	The patients underwent control examinations after surgery in another university than the university in which they were operated
Incomplete outcome data (attrition bias) All outcomes	High risk	No intention-to-treat analysis
Selective reporting (reporting bias)	Low risk	The investigator who reported outcomes was blinded to the intervention used
Follow-up	Low risk	Bretlau 1989 has a 9-year follow-up

Bretlau 1989 *(Continued)*

Certainty of diagnosis	Low risk	There is no mention of the AAO-HNS criteria, but the inclusion criteria are identical

Thomsen 1998

Methods	Randomised, double-blind (until surgery)
Participants	Patients with Ménière's disease
Interventions	Ventilation tubes versus endolymphatic sac shunting
Outcomes	Vertigo Hearing Tinnitus/aural fullness
Notes	1-year follow-up

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The method of randomisation was not described
Allocation concealment (selection bias)	Low risk	The randomisation results were kept in sealed envelopes; these were opened just before start of the surgery
Blinding (performance bias and detection bias) All outcomes	High risk	Neither the patients, nor the surgeons, nor the investigators were blind to the intervention used
Incomplete outcome data (attrition bias) All outcomes	Low risk	There were no losses to follow-up
Selective reporting (reporting bias)	High risk	The investigators and patients were not blinded to the intervention used
Follow-up	High risk	Follow-up was 1 year
Certainty of diagnosis	Low risk	The AAO-HNS criteria were used

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Brinson 2007	ALLOCATION: No concealment of allocation
De La Cruz 2007	ALLOCATION: No concealment of allocation, no blinding, no randomisation

Study	Reason for exclusion
Durland 2005	ALLOCATION: No control group, therefore no concealment of allocation
Garduno-Anaya 2005	ALLOCATION: Patients were randomised into 2 groups. The sequence generation and concealment of allocation were not described. PARTICIPANTS: AAO-HNS criteria were used to diagnose Ménière's disease INTERVENTION: Intratympanic application of dexamethasone for the treatment of Ménière's disease, which is studied in a separate Cochrane review (Phillips 2011)
Heatley 1990	ALLOCATION: Non-randomised study
Rask-Andersen 2005	ALLOCATION: The sequence generation and allocation concealment were not described PARTICIPANTS: Patients with unilateral Ménière's disease. The AAO-HNS criteria were not used. INTERVENTION: Intratympanic application of latanoprost for the treatment of Ménière's disease will be studied in a separate Cochrane review
Silverstein 1998	ALLOCATION: Randomised PARTICIPANTS: Included patients with Ménière's disease and possible Ménière's disease INTERVENTIONS: Patients received 3 consecutive daily administrations of intratympanic dexamethasone or placebo. Intratympanic application of dexamethasone for the treatment of Ménière's disease is studied in a separate Cochrane review (Phillips 2011).
Teggi 2008	ALLOCATION: Randomised PARTICIPANTS: Patients with Ménière's disease according to the AAO-HNS criteria INTERVENTION: Low-level laser therapy (LLLT) versus betahistine. LLLT is not considered to be a surgical intervention

APPENDICES

Appendix 1. Search strategies

CENTRAL	PubMed	EMBASE (Ovid)

(Continued)

#1 MeSH descriptor Surgical Procedures, Operative explode all trees
#2 MeSH descriptor Ear explode all trees with qualifier: SU
#3 MeSH descriptor Mastoid explode all trees with qualifier: SU
#4 MeSH descriptor Endolymphatic Sac explode all trees with qualifier: SU
#5 MeSH descriptor Vestibular Nerve explode all trees with qualifier: SU
#6 (MASTOIDECTOMY or MASTOIDOTOMY or SURG* or OPERAT* or LABYRINTHECTOM* or LABYRINTHOTOM* or COCHLEAECTOM* or COCHLEOSACCULOT* or GROMMET* or EDSS* or TUBULATION)
#7 ((endolymphatic or sac) and shunt)
#8 (endolymphatic and (SURG* or DECOMPRES* or drainage))
#9 (ventilat* and tub*)
#10 (VESTIBULAR and (SURG* or SECTION or RESECT* or NEURECTOM* or NEUROTOM* or EXCISION or EXERESIS or RADICULECTOMY))
#11 (saccus and surg*)
#12 (MIDDLE and EAR and (VENTILATION or TUBE*))
#13 (TYMPAN* and TUBE*)
#14 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13)
#15 MeSH descriptor Meniere Disease explode all trees
#16 meniere*
#17 ((endolymphatic or labyrinth*) and (HYDROPS or SYNDROME))
#18 ((AURAL or LABYRINTH*) and VERTIGO)
#19 (COCHLEA* and HYDROPS)
#20 (#15 OR #16 OR #17 OR #18 OR #19)
#21 (#14 AND #20)
#22 MeSH descriptor Meniere Disease explode all trees with qualifier: SU
#23 (#21 OR #22)

#1 "Surgical Procedures, Operative"[Mesh]
#2 "Ear/surgery"[Mesh]
#3 "Mastoid/surgery"[Mesh]
#4 "Endolymphatic Sac/surgery"[Mesh]
#5 "Vestibular Nerve/surgery"[Mesh]
#6 (MASTOIDECTOMY [tiab] OR MASTOIDOTOMY [tiab] OR SURG* [tiab] OR OPERAT* [tiab] OR LABYRINTHECTOM* [tiab] OR LABYRINTHOTOM* [tiab] OR COCHLEAECTOM* [tiab] OR COCHLEOSACCULOT* [tiab] OR GROMMET* [tiab] OR EDSS* [tiab] OR TUBULATION [tiab])
#7 ((endolymphatic [tiab] OR sac [tiab]) AND shunt [tiab])
#8 (endolymphatic [tiab] AND (SURG* [tiab] OR DECOMPRES* [tiab] OR drainage [tiab]))
#9 (ventilat* [tiab] AND tub* [tiab])
#10 (VESTIBULAR [tiab] AND (SURG* [tiab] OR SECTION [tiab] OR RESECT* [tiab] OR NEURECTOM* [tiab] OR NEUROTOM* [tiab] OR EXCISION [tiab] OR EXERESIS [tiab] OR RADICULECTOMY [tiab]))
#11 (saccus [tiab] AND surg* [tiab])
#12 (MIDDLE [tiab] AND EAR [tiab] AND (VENTILATION [tiab] OR TUBE* [tiab]))
#13 (TYMPAN* [tiab] AND TUBE* [tiab])
#14 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13
#15 "Endolymphatic Hydrops"[Mesh]
#16 MENIERE* [tiab]
#17 ((endolymphatic [tiab] OR labyrinth* [tiab]) AND (HYDROPS [tiab] OR SYNDROME [tiab]))
#18 ((AURAL [tiab] OR LABYRINTH* [tiab]) AND VERTIGO [tiab])
#19 (COCHLEA* [tiab] AND HYDROPS [tiab])
#20 #15 OR #16 OR #17 OR #18 OR #19
#21 #14 AND #20
#22 "Endolymphatic Hydrops/surgery"[Mesh]
#23 #21 OR #22

1 exp Surgery/
2 (MASTOIDECTOMY or MASTOIDOTOMY or SURG* or OPERAT* or LABYRINTHECTOM* or LABYRINTHOTOM* or COCHLEAECTOM* or COCHLEOSACCULOT* or GROMMET* or EDSS* or TUBULATION).tw.
3 ((endolymphatic or sac) and shunt).tw.
4 (endolymphatic and (SURG* or DECOMPRES* or drainage)).tw.
5 (ventilat* and tub*).tw.
6 (VESTIBULAR and (SURG* or SECTION or RESECT* or NEURECTOM* or NEUROTOM* or EXCISION or EXERESIS or RADICULECTOMY)).tw.
7 (saccus and surg*).tw.
8 (MIDDLE and EAR and (VENTILATION or TUBE*)).tw.
9 (TYMPAN* and TUBE*).tw.
10 6 or 3 or 7 or 9 or 2 or 8 or 1 or 4 or 5
11 exp vestibular system/
12 (ENDOLYMPHATIC and SAC).tw.
13 (VESTIBULAR or SACCUS).tw.
14 11 or 13 or 12
15 neurectomy/
16 (NEURECTOMY or NEURONECTOMY or NEUROTOMY or EXCISION or EXERESIS or RADICULECTOMY or SURG* or OPERAT* or DECOMPRESS* or SECTION or DRAINAGE).tw.
17 16 or 15
18 17 and 14
19 Meniere Disease/
20 meniere*.tw.
21 ((endolymphatic or labyrinth*) and (HYDROPS or SYNDROME)).tw.
22 ((AURAL or LABYRINTH*) and VERTIGO).tw.
23 (COCHLEA* and HYDROPS).tw.
24 22 or 21 or 23 or 19 or 20
25 18 or 10
26 25 and 24

CINAHL (EBSCO)	Web of Science/BIOSIS Previews (Web of Knowledge)	CAB Abstracts (Ovid)
S1 (MH "Meniere's Disease") S2 TX Meniere* S3 TX endolymphatic or labyrinth* S4 TX HYDROPS or SYNDROME S5 S3 and S4 S6 AURAL or LABYRINTH* S7 TX VERTIGO	#1 TS=(MASTOIDECTOMY or MASTOIDOTOMY or SURG* or OPERAT* or LABYRINTHECTOM* or LABYRINTHOTOM* or COCHLEAECTOM* or COCHLEOSACCULOT* or GROMMET* or EDSS* or TUBULATION) #2 TS=((endolymphatic or sac) and shunt)	1 exp Surgery/ 2 (MASTOIDECTOMY or MASTOIDOTOMY or SURG* or OPERAT* or LABYRINTHECTOM* or LABYRINTHOTOM* or COCHLEAECTOM* or COCHLEOSACCULOT* or GROMMET* or EDSS* or TUBULATION).tw. 3 ((endolymphatic or sac) and shunt).tw.

(Continued)

S8 S6 and S7
S9 TX COCHLEA* and HYDROPS
S10 S1 or S2 or S5 or S8 or S9
S11 (MH "Surgery, Operative")
S12 TX MASTOIDECTOMY or MASTOIDOTOMY or SURG* or OPERAT* or LABYRINTHECTOM* or LABYRINTHOTOM* or COCHLEAECTOM* or COCHLEOSACCULOT* or GROMMET* or EDSS* or TUBULATION
S13 S11 or S12
S14 S10 and S13

#3 TS=(endolymphatic and (SURG* or DECOMPRES* or drainage))
#4 TS=(ventilat* and tub*)
#5 TS=(VESTIBULAR and (SURG* or SECTION or RESECT* or NEURECTOM* or NEUROTOM* or EXCISION or EXERESIS or RADICULECTOMY))
#6 TS=(saccus and surg*)
#7 TS=(MIDDLE and EAR and (VENTILATION or TUBE*))
#8 TS=(TYMPAN* and TUBE*)
#9 #8 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1
#10 TS=((endolymphatic or labyrinth*) and (HYDROPS or SYNDROME))
#11 TS=((AURAL or LABYRINTH*) and VERTIGO)
#12 TS=(COCHLEA* and HYDROPS)
#13 #12 OR #10 OR #11
#14 #13 AND #9

4 (endolymphatic and (SURG* or DECOMPRES* or drainage)).tw.
5 (ventilat* and tub*).tw.
6 (VESTIBULAR and (SURG* or SECTION or RESECT* or NEURECTOM* or NEUROTOM* or EXCISION or EXERESIS or RADICULECTOMY)).tw.
7 (saccus and surg*).tw.
8 (MIDDLE and EAR and (VENTILATION or TUBE*)).tw.
9 (TYMPAN* and TUBE*).tw.
10 6 or 3 or 7 or 9 or 2 or 8 or 1 or 4 or 5
11 (ENDOLYMPHATIC and SAC).tw.
12 (VESTIBULAR or SACCUS).tw.
13 11 or 12
14 neurectomy/
15 (NEURECTOMY or NEURONECTOMY or NEUROTOMY or EXCISION or EXERESIS or RADICULECTOMY or SURG* or OPERAT* or DECOMPRESS* or SECTION or DRAINAGE).tw.
16 14 or 15
17 16 and 13
18 meniere*.tw.
19 ((endolymphatic or labyrinth*) and (HYDROPS or SYNDROME)).tw.
20 ((AURAL or LABYRINTH*) and VERTIGO).tw.
21 (COCHLEA* and HYDROPS).tw.
22 18 OR 19 OR 20 OR 21
23 17 or 10
24 23 and 22

WHAT'S NEW

Date	Event	Description
23 November 2012	New citation required but conclusions have not changed	No new studies identified by the searches in November 2012.
7 November 2012	New search has been performed	New searches. We retrieved a total of 178 references, but none met the criteria for inclusion in the review.

HISTORY

Protocol first published: Issue 3, 2005
Review first published: Issue 1, 2010

Date	Event	Description
15 October 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

Peter Paul van Benthem initiated the review, wrote the first draft and performed the study selection and data extraction following the first search.
Hans Giard and Hendrik Verschuur helped with the process of drafting the final protocol.
Bas Pullens incorporated the original and latest search (to November 2012) on which he performed study selection and data extraction, wrote the second draft of the review and updated the review.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- None, Not specified.

External sources

- None, Not specified.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Following the release of RevMan 5 and the new *Cochrane Handbook for Systematic Reviews of Interventions* (Handbook 2011) in 2008, we revised our planned quality assessment system as outlined in the protocol and adopted the Cochrane Collaboration 'Risk of bias' tool.

INDEX TERMS

Medical Subject Headings (MeSH)

Endolymphatic Sac [*surgery]; Mastoid [*surgery]; Meniere Disease [*surgery]; Middle Ear Ventilation; Randomized Controlled Trials as Topic

MeSH check words

Humans