

# INPLASY PROTOCOL

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None declared.

## Effects of triple semicircular canal plugging on hearing in Meniere's patients: a systematic review and meta-analysis

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**Review question / Objective:** Effects of triple semicircular canal plugging on hearing in Meniere's patients.**P:** Meniere's disease, **I:** semicircular canal **OR S:** Case-control studies, randomized controlled studies, cross-sectional studies, cohort studies, case-control and non-randomized controlled studies.

**Condition being studied:** The preservation of cochlear function after semicircular canal occlusion is the key to popularize and apply semicircular canal occlusion. Since there is currently no study on the effect of treatment of trisemicircular canal obstruction on the hearing of patients with Meniere's disease, in order to better understand the effect of TSCP on the hearing of patients, this study conducted a meta-analysis on the postoperative hearing loss rate of patients with Meniere's disease treated by TSCP.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 April 2023 and was last updated on 19 April 2023 (registration number INPLASY202340067).

### INTRODUCTION

**Review question / Objective:** Effects of triple semicircular canal plugging on hearing in Meniere's patients.**P:** Meniere's disease, **I:** semicircular canal **OR S:** Case-control studies, randomized controlled studies, cross-sectional studies, cohort

studies, case-control and non-randomized controlled studies.

**Rationale:** Studies were analyzed and extracted in accordance with PRISMA flowchart. The studies were screened and extracted conducted a scientific literature search in each English (PubMed, EMBASE, Scopus, Clinical Trials, Web of Science, and

Cochrane Library) and Chinese (CNKI,Wan Fang and Wei Pu) databases. The Stata 17 software was used for data analysis as well as risk of bias assessment. The random effects model was accustomed analyze the chosen articles. Also, subgroup analysis, sensitivity analysis, and publication bias were performed during this meta-analysis.

**Condition being studied:** The preservation of cochlear function after semicircular canal occlusion is the key to popularize and apply semicircular canal occlusion. Since there is currently no study on the effect of treatment of trisemicircular canal obstruction on the hearing of patients with Meniere's disease, in order to better understand the effect of TSCP on the hearing of patients, this study conducted a meta-analysis on the postoperative hearing loss rate of patients with Meniere's disease treated by TSCP.

## METHODS

**Search strategy:** According to the topic of the article, it can be divided into P: Meniere's disease, I: semicircular canal OR S: Case-control studies, randomized controlled studies, cross-sectional studies, cohort studies, case-control and non-randomized controlled studies. Use subject words + free words for literature search. Among them, subject words are connected by AND, AND free words are searched by OR connection, namely P(subject words OR free words) AND I(subject words OR free words) and S(Case-control studies, randomized controlled studies, cross-sectional studies, cohort studies, case-control and non-randomized controlled studies.). Subject words and free words are as follows.

**Participant or population:** Inclusion criteria include: (a). Three semicircular canal obstruction in the treatment of Meniere's disease was the main study, and the postoperative effects on hearing were reported; (b). The research methods were randomized controlled experiment; non-randomized controlled experiment; Cohort studies, retrospective studies, case-control studies; (c). Diagnosed as Meniere's

disease according to the 1995 American Criteria for Diagnosis of Meniere's Disease in Otolaryngology, Head and Neck Surgery (AO-HNS)(Monsell et al., 1995) ; (d). All patients received conservative treatment for at least 6 months, including medication (betaestine 12 mg tid, hydrochlorothiazide 25 mg bid), lifestyle changes, and tympanoid steroids; (e). Postoperative follow-up time was more than 6 months; (f). The final result of the data is expressed as a percentage or frequency; (g). Hearing function was measured using a pure tone audiometer and assessed against the four-tone mean  $(a+b+c+d)/4$  compiled by the 1995 AO-HNS standard (a, b, c and d at 0.5, 1, 2 and 3 KHZ hearing levels, respectively). The worst hearing levels 6 months before surgery were compared with the worst hearing levels 6 months after surgery. A change of 10 decibels or more was considered "better" or "worse," and a change of less than 10 decibels was considered "no change."

**Intervention:** This study was an observational meta-analysis, and intervention measures were not applicable.

**Comparator:** No comparator.

**Study designs to be included:** Case-control studies, randomized controlled studies, cross-sectional studies, cohort studies, case-control and non-randomized controlled studies.

**Eligibility criteria:** 2.2. Eligibility criteria Inclusion criteria include: (a). Three semicircular canal obstruction in the treatment of Meniere's disease was the main study, and the postoperative effects on hearing were reported; (b). The research methods were randomized controlled experiment; non-randomized controlled experiment; Cohort studies, retrospective studies, case-control studies; (c). Diagnosed as Meniere's disease according to the 1995 American Criteria for Diagnosis of Meniere's Disease in Otolaryngology, Head and Neck Surgery (AO-HNS)(Monsell et al., 1995) ; (d). All patients received conservative treatment for at least 6 months, including medication (betaestine

12 mg tid, hydrochlorothiazide 25 mg bid), lifestyle changes, and tympanoid steroids; (e). Postoperative follow-up time was more than 6 months; (f). The final result of the data is expressed as a percentage or frequency; (g). Hearing function was measured using a pure tone audiometer and assessed against the four-tone mean  $(a+b+c+d)/4$  compiled by the 1995 AO-HNS standard (a, b, c and d at 0.5, 1, 2 and 3 KHZ hearing levels, respectively). The worst hearing levels 6 months before surgery were compared with the worst hearing levels 6 months after surgery. A change of 10 decibels or more was considered "better" or "worse," and a change of less than 10 decibels was considered "no change." Exclusion criteria include: (a). Patients with normal hearing; (b). Previous cases of Meniere's surgery for second and second operations; (c). Republished literature; (d). Postoperative hearing status was not reported; (e). Poor general condition can not tolerate surgery; (f). Reviews, reviews, case reports, and articles on animal subjects.; (g). Letters to the editor, conference papers, books, editorials and notes.

**Information sources:** We searched English databases PubMed, Web of Science, Embase, Cochrane Library, Clinical Trials, Scopus and Chinese databases: Wanfang, CNKI, VIP, To identify relevant studies published as of December 2020.

**Main outcome(s):** The primary endpoint was defined as the rate of hearing loss, which was assessed using AAO-HNS guidelines. Mean pure tone auscultation (PTA) threshold changes were calculated and classified as "hearing loss" (postoperative threshold 10 dB above preoperative level) or "severe hearing loss" (postoperative threshold 20dB above preoperative level).

Secondary endpoints were defined as vertigo control rates and assessed using AAO-HNS guidelines. Categories A/B are grouped together, representing either "Complete vertigo Control" or "Substantial vertigo Control". "These categories are lumped together because Category B is generally considered successful because it

represents a substantial reduction (99 to 60 percent) in vertigo attacks.

**Quality assessment / Risk of bias analysis:** The quality of the seven articles included in this meta-analysis was assessed using the revised Newcastle-Ottawa Quality Assessment Scale (NOS) for cross-sectional studies.

**Strategy of data synthesis:** We used Stata 17 software to perform the meta-analysis calculations. The random effects model was used to analyze SE. The rates of hearing loss and vertigo control after TSCP operation were calculated respectively. The effect size and 95% CI for each study are presented as forest maps. Heterogeneity was assessed using Cochran's Q test ( $p < 0.05$ ) and I<sup>2</sup> statistics recommended in the Cochrane Manual to determine heterogeneity in estimates of hearing loss rates and vertigo control rates. Heterogeneity is low, medium, and high if the cut-off points for I<sup>2</sup> values are 25%, 50%, and 75% or higher.

**Subgroup analysis:** We performed a subgroup analysis of the pooled effect size for hearing loss and vertigo control, including 7 studies on the effects of follow-up time and disease duration on the rate of hearing loss and vertigo control after trisemicircular canal obstruction.

**Sensitivity analysis:** We also performed a sensitivity analysis of the included literature to assess the robustness and reliability of the pooled incidence. Egger's regression model is used to quantify publication bias, and numerical methods are adopted to evaluate the impact of failure safety assessment bias.

**Language restriction:** No Language limit.

**Country(ies) involved:** China (Fengdu County People's Hospital & Otolaryngology Department).

**Keywords:** Meniere's diseases, triple semicircular canal plugging, hearing loss, vertigo control, Systematic review, Meta-analysis.

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