INPLASY

Protocol for a Systematic Review and Meta-Analysis of the Prognostic Impact of Aural Fullness in Sudden Sensorineural Hearing Loss

INPLASY202640063

doi: 10.37766/inplasy2026.4.0063

Received: 18 April 2026

Published: 18 April 2026

Hou, JB; Han, CJ; Jin, YL; Zhang, R; Qiao, Y.

Corresponding author:
Jiabin Hou

houjiabin_2026@foxmail.com

Author Affiliation:
Department of Otorhinolaryngology Head and Neck Surgery, Xijing Hospital, Air Force Medical University.

ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Data extraction.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202640063

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 April 2026 and was last updated on 18 April 2026.

INTRODUCTION

Review question / Objective To systematically evaluate the impact of concomitant aural fullness on the prognosis of patients with sudden sensorineural hearing loss (SSNHL), and to provide evidence-based reference for clinical prognostic risk stratification and the formulation of individualized diagnosis and treatment strategies.

Condition being studied Sudden sensorineural hearing loss (SSNHL), defined as acute-onset sensorineural hearing loss occurring within 72 hours, meeting any of the following authoritative diagnostic criteria: 1) 2019/2012 American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) clinical practice guideline: ≥30 dB HL hearing threshold shift across at least 3 consecutive pure-tone frequencies; 2) 2015 Chinese Medical Association (CMA) guideline for diagnosis and treatment of sudden deafness: ≥20 dB HL hearing threshold shift across at least 2 consecutive pure-tone frequencies; 3) Diagnostic criteria for acute low-frequency sensorineural hearing loss (ALHL, a recognized subtype of SSNHL): ≥30 dB HL average hearing threshold loss at two consecutive low-frequency bands (250 Hz and 500 Hz). This study aims to investigate the impact of concomitant aural fullness at disease onset on hearing prognosis in SSNHL patients after standardized treatment.

METHODS

Search strategy Systematic searches were conducted in PubMed, Cochrane Library, Web of Science, and Embase databases from inception to April 15, 2026.
Search terms:
Disease: Sudden sensorineural hearing loss, Hearing Loss, Sudden, Sudden Hearing Loss
Exposure/Outcome: aural fullness, feeling of ear fullness, aural pressure, aural occlusion, ear fullness, Outcomes, prognosis, Prognostic, risk factors

Searches combined MeSH terms and free words; references of included studies and relevant systematic reviews were manually supplemented.

Participant or population Patients diagnosed with SSNHL according to authoritative criteria:
AAO-HNS criteria: ≥30 dB HL threshold shift in 3 consecutive frequencies within 72 hours;
Chinese 2015 criteria: ≥20 dB HL threshold shift in 2 consecutive frequencies;
ALHL: ≥30 dB HL average hearing loss at 250 Hz and 500 Hz.
No restrictions on age, gender, or ethnicity.

Intervention SSNHL patients with concomitant aural fullness symptom at disease onset, who received standardized comprehensive treatment for SSNHL. The core treatment is glucocorticoid administration (including systemic regimens: prednisone, methylprednisolone sodium succinate, dexamethasone; and local targeted regimens: intratympanic dexamethasone injection, retroauricular dexamethasone injection), with optional adjuvant therapies consistent with mainstream SSNHL clinical guidelines, including ginkgo biloba extract, batroxobin, neurotrophic drugs, prostaglandins, hyperbaric oxygen therapy and other conventional supportive treatments.

Comparator SSNHL patients without concomitant aural fullness symptom at disease onset, who received the same standardized comprehensive treatment regimen for SSNHL as the exposure group.

Study designs to be included Observational studies, including cohort studies (CS) and case-control studies (CC); only English-language studies with Newcastle-Ottawa Scale (NOS) score ≥6 points were included.

Eligibility criteria Additional Inclusion Criteria:
1. Studies with complete data for calculating the odds ratio (OR) and 95% confidence interval (CI) of hearing recovery outcomes;
2. Studies with standardized treatment regimens consistent with international SSNHL clinical guideline
Additional Exclusion Criteria:
1. Studies with unavailable full text, duplicate publication, incomplete or erroneous data;
2. Randomized controlled trials, crossover trials, self-controlled before-after studies, case reports, andsingle-arm uncontrolled case series;
3. Studies including a large number of secondary or recurrent SSNHL cases;
4. Studies with significant heterogeneity in treatment regimens between the exposure and controlgroups.

Information sources PubMed, Cochrane Library, Web of Science, Embase (from database inception to April 15, 2026).

Main outcome(s) Improvement rate (effective rate): the proportion of patients with pure-tone average (PTA) improvement ≥10 dB HL or ≥15 dB HL after standardized treatment (evaluated by Siegel criteria, AAO-HNS criteria, or Chinese 2015 criteria).

Additional outcome(s) Complete hearing recovery rate (cure rate): the proportion of patients with hearing threshold returning to normal/baseline level, PTA <25 dB HL, or threshold within 10 dB HL of normal hearing.

Quality assessment / Risk of bias analysis The methodological quality and risk of bias of all included observational studies were independently assessed by three reviewers using the Newcastle-Ottawa Scale (NOS) (full score: 9 points). Studies with a NOS score ≥ 6 were defined as high-quality and eligible for inclusion. The assessment covered three core domains: selection of study participants, comparability between study groups, and ascertainment of exposure/outcome. Discrepancies were resolved through discussion with a fourth senior reviewer. We also evaluated potential selection bias, performance bias, and reporting bias in the included studies.

Strategy of data synthesis All statistical analyses wil be performed using RevMan 5.4 and Stata 16 software. For dichotomous outcomes (hearing improvement rate and cure rate), the pooled odds ratio (OR) with 95% confidence interval (CI) will be calculated using the Mantel-Haenszel method.
Heterogeneity across studies will be tested by Cochran's Q test and quantified by the I" statistic:
• $I^2 < 50\%$ (low heterogeneity): fixed-effects model will be applied;
• $50\% \leq I^2 < 75\%$ (moderate heterogeneity): random-effects model will be used, withsubgroup/ sensitivity analyses to explore heterogeneity sources;
• $I^2 \geq 75\%$ (high heterogeneity): if no clear clinical source of heterogeneity can be identified, pooled effect size calculation will be abandoned, and only qualitative systematic review will be performed.
Publication bias will be evaluated by Begg's rank correlation test and Egger's linear regression test when the number of included studies > 10; the

trim-and-fill method will be used for correction if significant publication bias is detected.

Subgroup analysis Predefined subgroup analyses were conducted to explore heterogeneity and verify the robustness of results, stratified by:
Diagnostic criteria for SSNHL: 3 consecutive frequencies ≥30 dB HL, 2 consecutive frequencies ≥20 dB HL, and acute low-frequency hearing loss (ALHL);
Hearing efficacy evaluation criteria: ΔPTA ≥10 dB HL, ΔPTA ≥15 dB HL, and ΔPTA ≥15 dB HL with final PTA ≤45 dB HL.

Sensitivity analysis We will perform the following sensitivity analyses to verify the robustness of the pooled results:
1. Leave-one-out analysis: sequentially exclude each individual study and re-calculate the pooled effect size to identify studies that may dominate the overall result;
2. Exclusion of low-quality studies: re-analyze the data after excluding studies with NOS score = 6 to test the stability of results;
3. Change of effect model: switch between fixed-effects and random-effects models to assess the impact of model selection on the pooled results;
4. Change of outcome definition: re-analyze the effective rate using different threshold definitions (ΔPTA≥10 dB HL vs. ≥15 dB HL) to verify the consistency of results.

Language restriction Only English-language published studies were included in this systematic review and meta-analysis.

Country(ies) involved China.

Keywords Sudden sensorineural hearing loss; Aural fullness; Meta-analysis; Concomitant symptoms; Prognosis.

Contributions of each author

Author 1 - Jiabin Hou.
Email: houjiabin_2026@foxmail.com
Author 2 - Chunji Han.
Author 3 - Yulian Jin.
Author 4 - Rui Zhang.
Author 5 - Yan Qiao.