INPLASY

Surgical Outcomes of Continuous Irrigating Mode versus Conventional Endoscopic Techniques in Chronic Suppurative Otitis Media: A Systematic Review and Meta-Analysis

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ADMINISTRATIVE INFORMATION

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Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 October 2025 and was last updated on 28 October 2025.

INTRODUCTION

Review question / Objective The core objective of this systematic review and meta-analysis is to systematically synthesize evidence from randomized controlled trials (RCTs) worldwide that compare continuous irrigation endoscopic ear surgery (CIEES) with conventional endoscopic surgery for the treatment of chronic suppurative otitis media (CSOM), and to scientifically evaluate the clinical value of CIEES.

Condition being studied In this document, the "Condition being studied" specifically refers to Chronic Suppurative Otitis Media (CSOM)—a common clinical chronic infectious disease of the middle ear, whose diagnosis must comply with internationally or nationally recognized criteria.

METHODS

Participant or population The target population of this study consists of patients with clinically confirmed Chronic Suppurative Otitis Media (CSOM). Specifically, in all randomized controlled trials (RCTs) included in the analysis, participants must meet internationally or nationally recognized diagnostic criteria for CSOM and undergo either Continuous Irrigation Endoscopic Ear Surgery (CIEES) or conventional endoscopic surgery. There are no restrictions on age or gender, though baseline demographic characteristics of participants must be clearly documented in the studies.

Diagnostic Criteria for the Disease

Presence of persistent tympanic membrane perforation with a disease duration of ≥ 2 months;

Recurrent otorrhea (suppuration) with a cumulative duration of ≥ 6 months. For patients in the acute infection phase, inclusion is permitted only after infection control;
Pure-tone audiometry results indicating mild to moderate conductive or mixed hearing loss (severe sensorineural hearing loss, defined as an average air-conduction threshold > 80 dB HL, is excluded);
Temporal bone computed tomography (CT) or otoscopic examination ruling out other middle ear pathologies, such as middle ear cholesteatoma, middle ear malignancy, and congenital middle ear malformation.
Population Scope Limitations
No upper or lower age limit; however, included studies must clearly report the age distribution of participants (e.g., the age range of the included population in the literature is 18–77 years, with a mean age of 42.2 ± 8.6 years);
No gender restrictions, and the gender composition must be reported (e.g., in the literature, there are 218 male cases, accounting for 54.0%, and 186 female cases, accounting for 46.0%);
Baseline clinical characteristics (e.g., degree of hearing loss, disease duration, presence of other comorbidities, etc.) must be clearly retrievable to ensure baseline comparability between the two groups (CIEES group and conventional endoscopic surgery group).

Intervention Intervention
I. Intervention in the Experimental Group: Continuous Irrigation Endoscopic Ear Surgery (CIEES)
Patients in the experimental group all underwent **Continuous Irrigation Endoscopic Ear Surgery (CIEES), a technique characterized by "continuous normal saline irrigation during surgery". The specific operational standards and technical key points are as follows:
Core Operational Principle: The entire surgery is performed under transcanal endoscopic visualization. A dedicated irrigation device delivers sterile normal saline to the middle ear cavity at a constant pressure (the included studies do not specify a unified pressure value, but all mention "gentle continuous perfusion") to achieve real-time cleaning of the surgical field and environmental regulation. The irrigating fluid is promptly drained through the surgical area's drainage channel, forming an "irrigation-drainage" cycle to prevent the accumulation of blood and secretions.
Basic Surgical Procedure: Consistent with the control group, all patients underwentendoscopic type I tympanoplasty—tragal cartilage-perichondrium was used as the graft to repair persistent tympanic membrane perforations. Only one included study (Xiao Zhaoqiu et al., 2024) adopted the "underlay grafting technique", while the others used the "dissection technique". However, all studies clearly stated that: except for "continuous irrigation", the experimental group was identical to the control group in terms of graft selection, tympanic membrane repair steps, and intraoperative instrument use. This ensures that the only variable in the intervention is "continuous irrigation".
Requirements for Irrigation Parameters: Included studies were required to detailedly describe irrigation-related details (e.g., the irrigating fluid was sterile normal saline, and the coordinated operation method between the irrigation device and the endoscope). However, there was no mandatory unification of specific parameters such as irrigation pressure and flow rate (slight differences existed among different studies based on the surgeons' experience, but all emphasized "no impact on the stability of middle ear anatomical structures").

Intervention in the Control Group: Conventional Endoscopic Surgery
Patients in the control group all underwenconventional endoscopic surgery i.e., "transcanal endoscopic tympanoplasty without continuous irrigation". The only difference in specific operations from the experimental group is the "absence of intraoperative irrigation steps", while the rest of the procedure is fully consistent:
Consistency in Surgical Method Like the experimental group, all patients underwentendoscopic type I tympanoplasty. There were no differences in graft type (tragal cartilage-perichondrium), tympanic membrane perforation repair technique (dissection technique or underlay technique, consistent with the corresponding experimental group study), or intraoperative endoscope model and visualization operation standards.
Difference in Surgical Field Cleaning Method: Without continuous irrigation, if blood or secretions obscured the visual field during surgery, "intermittent wiping of the endoscope lens" or "local suction with an aspirator" was required to clear the view. This is the core difference in the operational process between the control group and the experimental group, directly related to differences in efficiency indicators such as "intraoperative lens-wiping frequency" and "operative duration".
Key Control Points for Interventions
To ensure that the "only variable" between the two groups' interventions is "continuous irrigation", all included studies strictly followed the following

control principles to avoid confounding factors affecting efficacy evaluation: Consistency of Operating Team: In the same study, surgeries in the experimental group and control group were all performed by the same team of surgeons (or the surgeons' experience levels were verified to be statistically identical), eliminating the interference of "surgeon operational proficiency" on surgical outcomes.
Homogeneity of Postoperative Care: Patients in both groups received the same postoperative care plan, including the use of anti-infective drugs (e.g., oral antibiotics), guidance on surgical ear protection (avoiding water entry, avoiding forceful nose-blowing), and follow-up time points (reexaminations at 1 week, 1 month, and 3–6 months postoperatively). This ensures a consistent postoperative recovery environment, and outcome differences are only explained by differences in interventions.
Documentation Requirements for Interventions: Included studies were required to detailedly describe the specific steps of the two groups' surgeries in the methodology section, especially clarifying the implementation details of "continuous irrigation" (e.g., start time, duration, model of the irrigation device) and the cleaning method of the control group, ensuring that the interventions are reproducible and verifiable.

Comparator The comparator in this study is conventional endoscopic type I tympanoplasty without continuous irrigation. Its operational specifications are fully consistent with those of the experimental group (CIEES), with the only difference being in the "method of surgical field cleaning".

Study designs to be included This study systematically assessed the 6 included randomized controlled trials (RCTs) across 6 core bias domains using the Cochrane Risk of Bias 2.0 tool (RoB 2.0). Meanwhile, it integrated details of study designs and data completeness to comprehensively determine the overall quality level of the included studies.

Eligibility criteria Rct.

Information sources China National Knowledge Infrastructure (CNKI): As the academic database covering the widest range of disciplines in China, it includes a large number of clinical studies on endoscopic surgery for Chronic Suppurative Otitis Media (CSOM) published in Chinese core journals.
Wanfang Data Knowledge Service Platform (Wanfang Data): It supplements some scientific and technological journals and dissertations not included in CNKI. In particular, it has comprehensive coverage of small-scale Randomized Controlled Trials (RCTs) conducted by local hospitals, which can reduce regional publication bias.
PubMed: The world's largest biomedical literature database, it contains a large number of Randomized Controlled Trials (RCTs) and systematic reviews in the field of otology published in international journals, and serves as a core source for obtaining high-quality English-language studies.

Main outcome(s) The main outcomes of this study include intraoperative lens-wiping frequency and operative duration related to surgical efficiency, the incidence of postoperative complications related to postoperative safety, as well as postoperative tympanic membrane healing rate, average air-conduction threshold, and air-bone gap related to postoperative functional recovery.

Quality assessment / Risk of bias analysis In this systematic review and meta-analysis (focused on "comparing the surgical efficacy of continuous irrigation mode versus conventional endoscopic techniques in chronic suppurative otitis media [CSOM]"), the inclusion of study designs adheres to the principle of "high alignment with the research question, while balancing evidence strength and clinical practicality".

Strategy of data synthesis Overall, one study was rated as moderate quality, and the remaining five were rated as low quality.

Subgroup analysis No.

Sensitivity analysis In this study, sensitivity analysis was conducted by sequentially excluding studies of different quality, changing the effect size pooling model, removing potential outlier studies, and adopting different missing data handling methods. The results showed no significant changes in the pooled effect sizes of the main outcome indicators, indicating that the conclusion that "CIEES is superior to conventional endoscopic surgery" is robust.

Country(ies) involved China - Taihe Hospital, Hubei University of Medicine.

Keywords Chronic Suppurative Otitis Media (CSOM)、Continuous Irrigation Endoscopic Ear Surgery (CIEES)、Conventional Endoscopic Surgery、Tympanoplasty、Randomized Controlled Trial (RCT)、Systematic Review.

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