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Nebulized Chinese Herbal Medicine for Pediatric Pneumonia: A Meta-Analysis Running title：Nebulized Chinese Herbal Medicine for Pediatric Pneumonia

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Completed but not published.

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 25 February 2026 and was last updated on 25 February 2026.

INTRODUCTION

Review question / Objective Nebulized Chinese Herbal Medicine for Pediatric Pneumonia: A Meta-Analysis
Running title：Nebulized Chinese Herbal Medicine for Pediatric Pneumonia.

Condition being studied The condition under investigation is pediatric pneumonia. Pneumonia remains a leading cause of morbidity and mortality in the pediatric population worldwide, posing a significant threat to global child health, particularly among children under five years of age. The condition is diagnosed based on clinical and/or radiological findings in pediatric patients (age ≤ 18 years). The management of pediatric pneumonia primarily involves antimicrobial therapy; however, the escalating challenge of antibiotic resistance and the potential for adverse effects necessitate the exploration of effective adjuvant treatments. This review focuses on pediatric patients with pneumonia receiving conventional Western medical therapy, with or without adjunctive nebulized Chinese herbal medicine.

METHODS

Participant or population The participants addressed in this review are pediatric patients (age ≤ 18 years) with a clinical and/or radiological diagnosis of pneumonia. Studies involving patients with severe underlying diseases (e.g., congenital heart disease, immunodeficiency, chronic lung disease), critical severe pneumonia, or those with severe dysfunction of other organs were excluded.

Intervention The intervention evaluated is nebulized inhalation of any form of Chinese herbal medicine (compound formula or single herb), used as an adjunct to conventional Western medical therapy. Studies administering Chinese herbs via

non-nebulized routes (e.g., intravenous, oral) were excluded.

Comparator The comparator is the identical conventional Western medical therapy as received by the experimental group, administered with or without a placebo nebulization.

Study designs to be included Only randomized controlled trials (RCTs) were included. Non-randomized studies, observational studies, reviews, case reports, conference abstracts, and animal experiments were excluded.

Eligibility criteria Inclusion criteria were structured according to the PICOS framework:
Participants: Pediatric patients (age ≤ 18 years) with a clinical and/or radiological diagnosis of pneumonia.
Interventions: Nebulized inhalation of any form of Chinese herbal medicine (compound formula or single herb) as an adjunct to conventional Western medical therapy.
Comparisons: Identical conventional Western medical therapy as the experimental group, with or without a placebo nebulization.
Outcomes: Studies reporting at least one of the following: total clinical effective rate, incidence of adverse reactions, time to improvement of symptoms and signs (fever, cough, rales resolution time), time to radiographic improvement, or hospital stay duration.
Study design: Randomized controlled trials (RCTs).
Exclusion criteria included:
Patients with severe underlying diseases (e.g., congenital heart disease, immunodeficiency, chronic lung disease), critical severe pneumonia, or severe dysfunction of other organs.
Studies administering Chinese herbs via non-nebulized routes (e.g., intravenous, oral).
Studies not reporting any of the specified relevant outcomes.
Non-randomized studies, observational studies, reviews, case reports, conference abstracts, and animal experiments.

Information sources A comprehensive search was conducted in electronic databases including PubMed, Cochrane Library, Web of Science, Embase, China National Knowledge Infrastructure (CNKI), Wanfang Data Knowledge Service Platform, VIP Chinese Journal Database, and Chinese Biomedical Literature Database (CBM) from inception to November 1, 2025. No language restrictions were applied during the search.

Main outcome(s) The main outcomes are:
Primary outcomes:
Total clinical effective rate (dichotomous outcome, analyzed using odds ratio [OR] with 95% confidence interval [CI])
Incidence of adverse reactions
Secondary outcomes:
Time to improvement of symptoms and signs (continuous outcomes, analyzed using standardized mean difference [SMD] with 95% CI):
Fever resolution time
Cough resolution time
Rales resolution time
Time to radiographic improvement
Hospital stay duration
For continuous outcomes (symptom resolution time, hospital stay), the standardized mean difference was employed due to potential differences in measurement scales across studies. Heterogeneity was assessed using the I^2 statistic, with fixed-effects models used when $I^2 \leq 50\%$ and random-effects models when $I^2 > 50\%$.

Quality assessment / Risk of bias analysis The methodological quality of each included randomized controlled trial was independently assessed by two reviewers using the revised Cochrane Risk of Bias tool (RoB 2) for randomized trials. Disagreements were resolved through discussion or by consulting a third reviewer.
The RoB 2 tool evaluates the risk of bias across five domains:
Bias arising from the randomization process
Bias due to deviations from intended interventions
Bias due to missing outcome data
Bias in measurement of the outcome
Bias in selection of the reported result
Judgments for each domain were made as "Low risk of bias," "Some concerns," or "High risk of bias," based on the detailed criteria and signaling questions provided in the RoB 2 handbook. The overall risk of bias for each study was determined according to the Cochrane RoB 2 guidance, synthesizing the judgments across the five domains using the following algorithmic logic:
If all domains were judged as 'Low risk', the overall risk was Low.
If one or more domains were judged as raising 'Some concerns' but no domain was judged as 'High risk', the overall risk was judged as having Some concerns.
If any domain was judged as 'High risk', the overall risk of bias for the study was deemed High, irrespective of judgments in other domains.
The risk of bias graph was generated using RevMan 5.4 software.

Strategy of data synthesis All meta-analyses and heterogeneity tests were performed using Stata 17.0 software.

For dichotomous outcomes (e.g., total effective rate), the odds ratio (OR) with a 95% confidence interval (CI) was used as the effect measure. For continuous outcomes (e.g., symptom resolution time, hospital stay), the standardized mean difference (SMD) with a 95% confidence interval was employed due to potential differences in measurement scales across studies.
Heterogeneity among studies was assessed using the I^2 statistic. If $I^2 \leq 50\%$ and $P \geq 0.1$, heterogeneity was considered acceptable, and a fixed-effects model was used for data pooling. If $I^2 > 50\%$ and $P < 0.1$, significant heterogeneity was considered present, and a random-effects model was employed.
When a sufficient number of studies were included (typically ≥10), potential publication bias was assessed using Egger's test and visual inspection of funnel plots, performed using Stata 17.0 software.
The conduct and reporting of this review adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.

Subgroup analysis No subgroup analysis was reported in this manuscript.

Sensitivity analysis Sensitivity analyses were performed for symptomatic outcomes. For the resolution time of respiratory symptoms, a sensitivity analysis excluding the study by Dong et al., a potential source of heterogeneity, resulted in a more homogeneous set of studies ($I^2 = 0.0\%$), confirming the robustness of the primary finding that adjunctive nebulized Chinese herbal medicine accelerates the resolution of respiratory symptoms.

For fever resolution time, a sensitivity analysis performed by removing the study by Dong et al., which contributed substantially to the heterogeneity, yielded a consistent but more precise effect estimate (SMD = -1.31, 95% CI) with no residual heterogeneity ($I^2 = 0.0\%$).

Country(ies) involved China.

Keywords Pneumonia; Drugs, Chinese Herbal; Nebulizers and Vaporizers; Randomized Controlled Trial; Meta-Analysis.

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