INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Traditional Chinese medicine for the treatment of Paediatric Pneumonia: An overview of systematic reviews

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Review question / Objective: **This study aimed to reassess the methodological quality, risk of bias, quality of reporting and quality of evidence of SRs/MAs to provide a more substantial reference for the treatment of paediatric pneumonia with TCM.**
Eligibility criteria: **(1)Study: SRs/MAs of RCTs reporting the effects of TCM on outcome indicators in children with pneumonia;**
(2)Participants: Paediatric pneumonia as determined based on diagnostic criteria, with no restrictions on age, race, type of pneumonia and duration and severity of disease in children;
(3)Intervention: Treatment groups such as TCM monotherapy and TCM combined with Western medicine (WM), control groups such as WM and placebo, in which WM refers to the use of antibiotic and antiviral drugs and/or symptomatic supportive treatment (antipyretic, phlegm, cough, asthma, oxygenation, rehydration, nutrition and correction of water–electrolyte and acid–base balance disorders); the form of treatment or route of administration, dose of medication, frequency of administration and duration of medication were not included in both groups;
(4)Outcomes: The primary outcome index was the total effective rate of TCM and other outcome indices included relevant clinical symptom indices (fever subsidence time, cough disappearance time and lung rale disappearance time), average hospitalization time, laboratory test indices (CRP, IL-6 and TNF-α levels), lung X-ray infiltrates disappearing time and adverse reactions.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 September 2022 and was last updated on 01 April 2023 (registration number INPLASY202290048).

INTRODUCTION

Review question / Objective: **Multiple systematic reviews (SR) have been conducted to assess Efficacy and safety of traditional Chinese medicine (TCM) in children with pneumonia. Here, we aimed to provide an overview to assess the methodological quality and quality of evidence for SR to provide convincing data**

on CHM for the treatment of childhood pneumonia(including mycoplasma pneumonia, viral pneumonia, and other common types of pneumonia).

Rationale: At present, modern treatment of paediatric pneumonia is based on antiviral and antibacterial drugs combined with conventional symptomatic supportive therapy. The long-term inappropriate use of some antimicrobial drugs can induce resistance in the causative strains and adversely affect the prognosis of children with pneumonia. Recent in-depth studies on the treatment of paediatric pneumonia have demonstrated that TCM can effectively improve clinical symptoms, shorten the disease course and reduce antibiotic abuse in children and is safe for clinical application. Several systematic reviews (SRs) or meta-analyses (MAs) have evaluated the potential benefits of TCM in paediatric pneumonia. This study aimed to re-evaluate SRs/MAs reported on the efficacy of TCM in the treatment of paediatric pneumonia based on RCTs, providing a basis for clinical decision-making in the treatment of paediatric pneumonia using TCM.

Condition being studied: Several meta-analyses (MAs) and systematic reviews (SRs) have assessed the efficacy and safety of traditional Chinese medicine (TCM) in the treatment of paediatric pneumonia. Although clinical studies have reported the benefits of TCM, the efficacy of existing TCM approaches warrants further validation.

METHODS

Search strategy: The search terms mainly included TCM, Chinese herbology,Chinese herb medicines TCM and WM, decoction, granules, patent medicine, pill, powder, capsule, extract, injection, acupuncture, needling, auricular acupuncture, moxibustion, point application therapy, massage, cupping therapy, infant, child, adolescent, pneumonia, pneumonia with dyspnea and cough, bronchopneumonia, mycoplasma pneumonia, viral pneumonia, community-acquired pneumonia, bacterial pneumonia, lobar pneumonia, respiratory syncytial virus pneumonia, severe pneumonia, Meta-analysis, meta-analysis, systematic evaluation and systematic review

Participant or population: Paediatric pneumonia as determined based on diagnostic criteria, with no restrictions on age, race, type of pneumonia and duration and severity of disease in children.

Intervention: Treatment groups such as TCM monotherapy and TCM combined with Western medicine (WM).

Comparator: Control groups such as WM and placebo, in which WM refers to the use of antibiotic and antiviral drugs and/or symptomatic supportive treatment (antipyretic, phlegm, cough, asthma, oxygenation, rehydration, nutrition and correction of water–electrolyte and acid–base balance disorders); the form of treatment or route of administration, dose of medication, frequency of administration and duration of medication were not included in both groups.

Study designs to be included: SRs/MAs of RCTs reporting the effects of TCM on outcome indicators in children with pneumonia.

Eligibility criteria: (1)Study: SRs/MAs of RCTs reporting the effects of TCM on outcome indicators in children with pneumonia;
(2)Participants: Paediatric pneumonia as determined based on diagnostic criteria, with no restrictions on age, race, type of pneumonia and duration and severity of disease in children;
(3)Intervention: Treatment groups such as TCM monotherapy and TCM combined with Western medicine (WM), control groups such as WM and placebo, in which WM refers to the use of antibiotic and antiviral drugs and/or symptomatic supportive treatment (antipyretic, phlegm, cough, asthma, oxygenation, rehydration, nutrition and correction of water–electrolyte and acid–base balance disorders); the form of treatment or route of administration, dose

of medication, frequency of administration and duration of medication were not included in both groups;
(4)Outcomes: The primary outcome index was the total effective rate of TCM and other outcome indices included relevant clinical symptom indices (fever subsidence time, cough disappearance time and lung rale disappearance time), average hospitalization time, laboratory test indices (CRP, IL-6 and TNF-α levels), lung X-ray infiltrates disappearing time and adverse reactions.

Information sources: PubMed, Embase, Cochrane Library, China Biomedical Literature Database, China National Knowledge Infrastructure, Wan Fang Database of China.

Main outcome(s): Total effective rate, fever subsidence time, cough disappearance time, lung rale disappearance time, average hospitalization time, CRP, IL-6, TNF-α levels, lung X-ray infiltrates disappearing time and adverse reactions

Additional outcome(s): Two evaluators independently screened the literature and extracted and cross-checked the information. In case of disagreement, a third evaluator was consulted to assist in the judgement. Authors were contacted to supplement missing information. Articles were initially screened based on the title and abstract. After excluding irrelevant articles, the full text was analysed to determine the final inclusion. Data extraction included the following aspects: (1) basic information: title, first author, year of publication, number of included cases, quality evaluation tools, interventions and their specific details; (2) outcome indicators and outcome data of interest and relevant findings; (3) key elements of quality evaluation: AMSTAR 2 scale, ROBIS tool, PRISMA 2020 statement, GRADE system and other evidence quality evaluation tool entries.

Data management: Descriptive analysis was performed to evaluate the SRs/MAs included in this overview. Risk ratios (RRs), odds ratios (ORs), 95% confidence intervals (CIs), weighted mean differences (WMDs) and standard mean differences (SMDs) were estimated to summarise the outcomes. The I2 statistic was used to detect heterogeneity among the included SRs/MAs.

Quality assessment / Risk of bias analysis: The ROBIS tool was used to assess the risk of bias incorporated into the systematic evaluation, which was conducted in three stages: (1) assessing the fit between the target problem and the proposed solution in the systematic evaluation; (2) determining the level of risk of bias in the systematic evaluation development process and (3) determining the risk of bias in the systematic evaluation. Each stage of the ROBIS tool contains several landmark questions, and the responses to these questions are categorised as yes, probably yes, no, probably not and no information. The risk of bias in the included studies was classified as low, high or unclear.

Strategy of data synthesis: Descriptive analysis was performed to evaluate the SRs/MAs included in this overview. Risk ratios (RRs), odds ratios (ORs), 95% confidence intervals (CIs), weighted mean differences (WMDs) and standard mean differences (SMDs) were estimated to summarise the outcomes. The I2 statistic was used to detect heterogeneity among the included SRs/MAs.

Subgroup analysis: Type of disease, treatment.

Sensitivity analysis: We provide a narrative description of the included SRs. Tabulate all the primary and secondary outcomes, and extract the pooled effect size. The risk ratio (RR) and 95% confifidence interval (CI) were used to summarize the dichotomous variables, and the weighted mean difference (WMD) or standard mean deviation (SMD) and 95% CI were used to summarize the continuous data. Obtain the heterogeneity of each included SR, which is detected by the I2 and Chi2 tests.

Country(ies) involved: China.

Keywords: Traditional Chinese medicine, Paediatrics, Pneumonia, Systematic review, Overview.

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