Moxibustion for diarrhea in children: a protocol for systematic review and meta-analysis

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Abstract

Background: Infantile Diarrhea is a common and frequent digestive tract disease in children. The causes of this disease are relatively complex and the onset time is relatively long. At present, there is no specific treatment method in Western medicine. Moxibustion is a simple and painless external treatment. However, due to the lack of high-quality evidence to support the effectiveness and safety of moxibustion for pediatric diarrhea. Therefore, the purpose of this study is to verify the effectiveness and safety of moxibustion in the treatment of pediatric diarrhea.

Methods: We will use PubMed, Cochrane Library, Wan Fang Database, Web of Science, China National Knowledge Infrastructure Database, Chinese Science Journal Database, China Biomedical Literature Database to carry out a progressive search of diseases. The study will be screened according to eligibility criteria, and quality of the study will be assessed by using the Cochrane Risk of Bias Tool.

Results: Through this study, we will systematically evaluate the effectiveness and safety of moxibustion in the treatment of pediatric diarrhea.

Conclusion: The results of this study will provide reliable evidence of the safety and effectiveness of moxibustion in the treatment of infantile diarrhea, and provide a therapeutic basis for the future clinical application.

Ethics and dissemination: Since this paper does not involve ethical issues, it does not need to pass the review of the ethics committee. It can only collect relevant literature and study.

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Abbreviation: Mesh = medical subject headings.

Keywords: children, diarrhea, moxibustion, random, systematic review and meta-analysis

1. Introduction

Infantile diarrhea is a digestive tract syndrome caused by multiple pathogens and factors. Its clinical manifestations are increased stool frequency, or changes in the nature and shape of stool, as well as feces containing substances such as mucus, pus, and blood.\textsuperscript{1,2} Long-term diarrhea is prone to dehydration, electrolyte disturbance and other symptoms, and too long duration can cause growth retardation, and even death in children.\textsuperscript{3,4} According to records, children who die of diarrhea every year in the world are mostly due to dehydration and electrolyte disturbance caused by diarrhea.\textsuperscript{5,6} At present, most clinical drugs are mainly used to protect intestinal mucosa, intestinal microecological agents and prevent dehydration, and side effects will inevitably occur in the process of drug use.\textsuperscript{7} Therefore, it is necessary to seek a safer and more effective alternative therapy.

Traditional Chinese medicine deem that the disease site of diarrhea in children is in the spleen, stomach, and large intestine, dysfunction of the spleen in transportation is the key, and invigorating spleen is the external treatment that makes the maladjusted function operate normally, and has the effects of warming the meridian and dissipating cold, promoting blood circulation and dredging collateral, preventing disease and health care, etc.\textsuperscript{8} In addition, moxibustion therapy can also promote gastrointestinal peristalsis and repair of gastrointestinal mucosa while inhibiting intestinal hypermotility through bidirectional regulation.\textsuperscript{9,10} A large number of studies have proved that moxibustion, as an external treatment of traditional Chinese
medicine, can not only make the children do not resist at the same
time, but also make the effect of the exact.

2. Methods

2.1. Study registration

This Agreement was registered on the International Platform for
Registrar System Review and Meta-Analysis Protocols
(INPLASY) on March 24, 2021 and last updated on March
24, 2021 (Registration No. INPLASY202130091).

2.2. Database

We will search PubMed, Web of Science, Cochrane Library,
China National Knowledge Infrastructure (CNKI), Wanfang
Database, China Scientific Journals Database (VIP), and China
Biomedical Literature Database (CBM) databases. The included
literatures are limited to Chinese and English publications, and
the time limit will be January 31, 2021.

2.3. Search strategy

Moxibustion, Infantile, diarrhea, and random were used as the
key words, and the method of “subject word + free word” was
adopted to conduct the retrieval on PubMed. Table 1 shows a
draft search strategy using PubMed.

2.4. Inclusion and exclusion criteria

2.4.1. Types of studies. Only publications in Chinese and
English as the first language were included in this study, and only
randomized controlled trials were included. The experimental
group was moxibustion therapy or moxibustion combined with
other therapies, and the control group was other therapies except
moxibustion therapy. Other designs such as non-randomized
controlled trials, animal studies, individual cases, and reviews
will be excluded.

2.4.2. Types of participants. All the children included were
diagnosed with diarrhea, regardless of gender, age, race,
nationality, or severity. The inclusion criteria in China were
based on the “Chinese Diarrhoeal Disease Diagnosis and
Treatment Program” revised by the Ministry of Health of the
People’s Republic of China in 1998.[111]

2.4.3. Types of intervention. The moxibustion methods in the
experimental group could be traditional moxibustion, heat-
sensitive moxibustion, needle warming moxibustion and other
types of moxibustion therapy. The control group received one of
the following treatments: conventional drug treatment, no
treatment, or placebo.

2.4.4. Types of outcomes. The curative effect such as cure rate,
apparent efficiency, effective rate, and inefficiency will be the
main evaluation indexes.

2.5. Data extraction and analysis

2.5.1. Data extraction. The titles and abstracts of the included
studies were reviewed independently by 2 investigators, and the
full texts were read if necessary. The studies were screened for
study design, interventions, methods, the index of measures,
results, and methodological content such as hidden grouping and
blind method. If there is any disagreement, the data will be
verified by a third investigator. If the literature information is
incomplete, the original author will be contacted to obtain the
data. Figure 1 is the flow chart of preliminary screening.

2.5.2. Risk assessment of the included literature. The authors
use the Cochrane collaboration of bias risk assessment tools to
evaluate each other law quality, and the bias risk assessment
included in the study are available from the following aspects: the
formation of sequence, allocation concealment, the result data is
imperfect, the interpretation of the results, the wrong data
coding, and other bias. The bias can be divided into 3 risks: high
risk, low risk, and uncertain risk.

2.6. Summary statistics

2.6.1. Heterogeneity analysis. I² test was used to test the
heterogeneity of the study. If \( P > .10 \) and \( I^2 \leq 50\% \), no statistical
difference is considered, fixed effect model will be used. If \( P \leq .10 \)
and \( I^2 > 50\% \), the heterogeneity is considered to be high, and the
random effect model will be adopted.

2.6.2. Publication bias. RevMan 5.4 was used to draw funnel
plots to detect publication bias. When the funnel plots were
symmetrical, it was considered that there was no publication bias;
when the scatter points on the funnel plots were asymmetrical, it
was the other way around.

2.6.3. Subgroup analysis. In the case of sufficient literature data,
subgroup analysis can be conducted according to the severity of
diarrhea or the intervention mode of moxibustion therapy.

1. The severity of diarrhea (such as duration, frequency of stools,
associated symptoms, etc.)
2. Types of moxibustion (such as Heat-sensitive moxibustion,
needle warming moxibustion, traditional moxibustion, etc.).

2.6.4. Sensitivity analysis. According to the outcome indicators
of the data, literatures were excluded one by one in terms of method
quality, sample size, data missing, measurement, etc to see whether
the heterogeneity was changed. If the results of the sensitivity
analysis are consistent, the results are relatively robust. On the
contrary, it is not robust and should be treated with caution.

3. Discussion

Diarrhea in children is a common clinical digestive tract disease,
which can occur throughout the year, especially in summer and
autumn. Its clinical manifestations are mainly characterized by increased stool frequency, thin stools, failure to dissipate grains, or even watery symptoms.\textsuperscript{11,12} The causes of its occurrence are mainly related to factors such as irregular diet, perception of exogenous pathogenic factors, spleen, and stomach weakness. Children’s constitution is delicate, vulnerable to the invasion of disease evil, injury to the diet, spleen and stomach weakness, and the spleen and stomach transport dysfunction.\textsuperscript{13} As a category of external treatment, moxibustion therapy of traditional Chinese medicine has the characteristics of simple operation, convenient use, significant curative effect and less toxic and side effects, and plays the role of treating diseases, enhancing physical fitness, and preventing diseases before diseases.\textsuperscript{14,15} Western medicine in the treatment of pediatric diarrhea in the clinical use of gastrointestinal mucosal protectant, antibiotics and other drugs, the effect is more limited but also with certain side effects.\textsuperscript{16,17} The process of medication is also facilitated by making children resist. Therefore, it is of great significance to explore moxibustion as a safe and effective external therapy that is easy to be accepted by children and their parents.

**Author contributions**

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