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Systematic Evaluation and Meta-analysis of Characteristic TCM Therapy for Acute Gastroenteritis

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Review question / Objective: **To systematically evaluate the clinical effect of treating acute gastroenteritis with characteristic traditional Chinese medicine (TCM) therapy and characteristic TCM therapy combined with conventional Western medicine therapy. Methods A literature search to identify studies of characteristic TCM therapy acute gastroenteritis was conducted in CNKI, Wanfang, VIP and PubMed. Using the required inclusion and exclusion criteria, the two researchers screened the literature and data performed extraction, and RevMan 5.4 was used for meta-analysis. Results A total of 29 studies were selected that included 3155 cases: 1646 in the treatment group and 1509 in the control group. The total effective rate of the treatment group was higher than that of the control group (OR=5.24, 95% CI [3.98, 6.89], P<0.00001), and the treatment group showed greater reduction in the VAS score and the number of intestinal sounds, greater reduction in the duration of adverse symptoms, shorter time to symptom remission, shorter time to the disappearance of symptoms and higher patient satisfaction scores than the control group, with significant differences.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 June 2021 and was last updated on 02 June 2021 (registration number INPLASY202160008).

INTRODUCTION

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Condition being studied: In recent years, characteristic TCM therapy has attracted increasing attention, and many researchers are committed to clinical research on acute gastroenteritis.To explore the efficacy of characteristic TCM therapy for the improvement of Acute gastroenteritis, we finally systematically collected 29 clinical studies examining 3155 cases for acute gastroenteritis and evaluated efficacy of all the therapies through pairwise meta-analyses. Until now, there is no relevant analysis for characteristic TCM therapy. In our study, we found that the treatment of acute gastroenteritis with characteristic TCM therapy or integrated traditional TCM therapy and Western medicine can improve the symptoms of the digestive tract symptoms and have a positive effect on patients's quality of life better.

METHODS

Participant or population: Patients who met the Chinese and Western medicine diagnostic criteria for acute gastroenteritis.

Intervention: Test group: Characteristic TCM therapy alone or combined with conventional Western medicine therapy. Control group: Conventional Western medicine treatment or other Western medicine approaches based on conventional treatment or blank control.

Comparator: conventional Western medicine therapy.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: Full texts, reviews, articles with serious errors in data and articles reporting animal experiments, studies other than RCTs, and the use of combination drugs or interventions other than TCM therapy and conventional treatments for symptoms were excluded.This study was carried out in strict accordance with the Cochrane Collaboration's bias risk assessment tool, and quality assessment was conducted using RevMan 5.4 "bias risk assessment". The main factors that were evaluated were (1) method of randomization; (2) allocation concealment; (3) double-blinding; (4) blinding to outcome assessment; (5) integrity of outcome data; (6) publication bias; and (7) other biases. The risk of bias and the quality of the included studies were evaluated.

Information sources: CNKI, Wanfang, Weipu and PubMed were searched using the key words "traditional Chinese Medicine therapy", "acupuncture", "moxibustion", "TCM hot compress", "acute gastroenteritis" and so on. Additionally, the reference lists of selected studies were manually searched for relevant articles. The search period was from the creation of the database to May 2020.

Main outcome(s): Total effective rate; VAS score; time to symptom improvement; number of bowel sounds; time to relief of diarrhea, abdominal pain and vomiting; serum WBC count; time to disappearance of diarrhea, abdominal pain and vomiting; and patient satisfaction score.

Quality assessment / Risk of bias analysis: A total of 29 studies were included, all randomized controlled trials. (1) Random grouping: 22 papers mentioned random number table method for grouping; Were rated as low risk; 5 papers did not adopt random grouping method; Are rated as

high risk. The other two papers did not carry out random method description and rated as unknown risk. (2) Random concealment :22 studies were double-blind and rated as low risk; Others did not mention the blind method of description and allocation of hidden, rated as unknown risk. (3) Subject-blind method :20 studies mentioned double blindness, which were described in detail and rated as low risk; The other 9 articles are not mentioned, rated as unknown risk. (4) Outcome measure blindness :20 studies mentioned double-blind method, which was rated as low risk; The other 9 papers were not mentioned, and all were rated as unknown risks. (5) Data integrity: 2 papers were rated as high risk because of missing data; 3 articles did not mention, so it was rated as unknown risk; The data of 24 papers were complete without loss, so they were all rated as low risk. (6) Selective reporting:3 studies rated high risk; 1 paper was rated as low risk; The remaining 25 were rated as unknown risk. (7) Other bias :24 studies were not mentioned and rated as low risk, while 5 studies were unknown and rated as unknown risk.

Strategy of data synthesis: Literature screening Two researchers screened the studies independently according to the screening criteria. If it was impossible to determine whether a study met the inclusion criteria, consensus was reached through discussion by the researchers or assessment by a third party. Screening process: (1) The retrieved studies were double-checked with NoteExpress; (2) Duplicated studies were eliminated, and studies that clearly did not meet the inclusion criteria upon reading were eliminated; (3) If it was still unclear whether a study met the inclusion criteria after the full text was read, it was screened again to determine whether it should be included. 1.4 Study data processing The collected data, including the main authors, number of cases, intervention measures, course of treatment, year, outcome indexes, etc., were extracted to an Excel sheet. 1.5 Evaluation of the quality of the included literature This study was carried out in strict accordance with the Cochrane Collaboration's bias risk assessment tool, and quality assessment was conducted using RevMan 5.4 "bias risk assessment". The main factors that were evaluated were (1) method of randomization; (2) allocation concealment; (3) double-blinding; (4) blinding to outcome assessment; (5) integrity of outcome data; (6) publication bias; and (7) other biases. The risk of bias and the quality of the included studies were evaluated. In this study, RevMan 5.4 software, provided by the Cochrane Collaboration, was used for the meta-analysis. A subgroup analysis was conducted to determine possible heterogeneity among the included data studies. The I2 test was used to evaluate the statistical heterogeneity of the studies, and a rate of 50% was used as the standard for analysis. The degree of heterogeneity was small, and the fixed effects model was used for the statistical analysis. A random effects model was selected for sensitivity analyses and subgroup analyses due to the large degree of heterogeneity within subgroups.

Subgroup analysis: 1.VAS score 2.the number of intestinal sounds 3. the duration of adverse symptoms 4.time to symptom remission 5.time to the disappearance of symptoms 6.patient satisfaction scores.

Sensitivity analysis: OR=5.24, 95% CI [3.98, 6.89], P<0.00001.

Country(ies) involved: China.

Keywords: Characteristic traditional Chinese medicine therapy; Acute gastroenteritis; Meta-analysis.

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