INPLASY PROTOCOL

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None declared.

Efficacy and safety of traditional Chinese medicine decoction in the treatment of Acute pancreatitis in Elderly Patients: A protocol for systematic review and network meta-analysis

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Review question / Objective: **Efficacy and safety of traditional Chinese medicine decoction in the treatment of Acute pancreatitis in Elderly Patients: A protocol for systematic review and network meta-analysis.**
Eligibility criteria: **Inclusion criteria Randomized controlled trial (RCT) studies meeting the population, intervention, comparison, outcome, and study type (PICOS) criteria: 1. Participants: Patients with a confirmed diagnosis of acute pancreatitis, aged 60 years or older. 2. Interventions: The experimental group was treated with TCM decoction alone or combined with conventional western medicine. The use of TCM decoction is limited to oral administration regardless of course of treatment and dosage. 3. Comparators: The control group was treated with conventional western medicine recommended by internationally authorized clinical guidelines or placebo. 4. Outcome: The primary outcomes were the effectiveness rate, VAS scores for abdominal pain, VAS scores for nausea/vomiting, and time to first defecation. The secondary outcomes were the level of serum amylase, mortality, and adverse reactions. 5. Type of study: We will include randomized controlled trials (RCTs) of TCM for acute pancreatitis published in Chinese or English, regardless of blinding or allocation concealment. Exclusion criteria 1. The experimental group was treated with TCM decoction combined acupuncture, moxibustion, and other traditional Chinese medicine methods are excluded. 2. Studies for which data could not be extracted accurately. 3. Studies with inconsistent outcome indicators.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 July 2022 and was last updated on 04 August 2022 (registration number INPLASY202270119).

INTRODUCTION

Review question / Objective: **Efficacy and safety of traditional Chinese medicine decoction in the treatment of Acute pancreatitis in Elderly Patients: A protocol for systematic review and network meta-analysis.**

Rationale: Acute pancreatitis is a common cause of acute abdomen, elderly acute pancreatitis patients are more likely to with complications. Mortality in the elderly patients was higher than young and middle-aged patients. Although many studies have shown that traditional Chinese medicine are effective for the treatment of acute pancreatitis, however, the efficacy and safety of different traditional Chinese medicine decoction for Acute pancreatitis in elderly patients is not fully clarified. In addition, due to many traditional Chinese medicine decoction are available to treat Acute pancreatitis, the selection of appropriate decoction has become a pressing issue. This study aimed to use the method of network meta-analysis to compare the effectiveness and safety of different Chinese medicine decoctions for elderly Acute pancreatitis patients.

Condition being studied: Acute pancreatitis (AP) is a common cause of acute abdomen and one of the leading causes of hospitalization . The estimated incidence of AP is approximately 34 per 100000 people worldwide, and the case fatality rate ranges from 15 to 30% . Epidemiological studies and systematic reviews have shown that the incidence of AP is increasing globally . Based on the Revised Atlanta Classification (RAC), AP severity can be categorized into three types: mild, moderately severe, and severe. 80%-85% of cases are mild, whereas 15%-20% are severe . Although most APs are mild, the mortality rate of severe pancreatitis can be as high as 30% . The well-established causes of AP are biliary disease, alcohol consumption, hypertriglyceridaemia (HTG) and endoscopic retrograde cholangio-pancreatography (ERCP) . Mortality rates are similar among several etiologies of AP . Furthermore, elderly patients are more likely to with complications . A retrospective comparative study comparing epidemiology and outcomes between elderly and young and middle-aged acute pancreatitis patients showed the elderly patients had a higher proportion of system inflammatory reaction syndrome, multiple organ dysfunction syndrome (MODS), and shock. Mortality in the elderly group was 1.69%, while the young and middle-aged group had a mortality rate of only 0.72%. Therefore, it is necessary to determine strategies for the treatment and prevention of AP in elderly patients. Traditional Chinese medicine (TCM) has been successfully used to treat AP for many years. Numerous clinical studies and systematic reviews have confirmed that proprietary Chinese medicines can significantly improve clinical symptoms and potentially ameliorate disease progression. The traditional Chinese medicine commonly used in the treatment of AP include Dachaihu decoction, Dachengqi decoction, etc. Clinical evidence suggests that TCM decoctions can significantly improve clinical symptoms and potentially ameliorate disease progression [9-10]. TCM decoctions are recommended by guidelines as it improves symptom burden, and contributes to rapid recovery of gastrointestinal function [11]. Although there are many types of Traditional Chinese medicine decoctions in clinical application, little evidence compared the clinical efficacy and safety of a variety of TCM decoctions in elderly AP patients. As a statistical method to directly and indirectly compare the effects of two or more treatments and allows ranking of different treatments, Network meta-analysis (NMA) has an advantage to make comparison of the interventions that have not been compared directly in the studies. Therefore, the purpose of this study is to evaluate the effectiveness and safety of different TCM decoctions in elderly patients with acute pancreatitis through NMA and to contribute to clinical decision-making in treatment.

METHODS

Participant or population: Patients with a confirmed diagnosis of acute pancreatitis, aged 60 years or older.

Intervention: The experimental group was treated with TCM decoction alone or combined with conventional western medicine. The use of TCM decoction is limited to oral administration regardless of course of treatment and dosage.

Comparator: The control group was treated with conventional western medicine recommended by internationally authorized clinical guidelines or placebo.

Study designs to be included: We will include randomized controlled trials (RCTs) of TCM for acute pancreatitis published in Chinese or English, regardless of blinding or allocation concealment.

Eligibility criteria: Inclusion criteria Randomized controlled trial (RCT) studies meeting the population, intervention, comparison, outcome, and study type (PICOS) criteria: 1. Participants: Patients with a confirmed diagnosis of acute pancreatitis, aged 60 years or older. 2. Interventions: The experimental group was treated with TCM decoction alone or combined with conventional western medicine. The use of TCM decoction is limited to oral administration regardless of course of treatment and dosage. 3. Comparators: The control group was treated with conventional western medicine recommended by internationally authorized clinical guidelines or placebo. 4. Outcome: The primary outcomes were the effectiveness rate, VAS scores for abdominal pain, VAS scores for nausea/vomiting, and time to first defecation. The secondary outcomes were the level of serum amylase, mortality, and adverse reactions. 5. Type of study: We will include randomized controlled trials (RCTs) of TCM for acute pancreatitis published in Chinese or English, regardless of blinding or allocation concealment. Exclusion criteria 1. The experimental group was treated with TCM decoction combined acupuncture, moxibustion, and other traditional Chinese medicine methods are excluded. 2. Studies for which data could not be extracted accurately. 3. Studies with inconsistent outcome indicators.

Information sources: We will search several databases, including PubMed, Embase, Web of Science, Cochrane Library, China National Knowledge Infrastructure (CNKI), Wan Fang Database (Wan Fang), Chinese Biomedical Literature Database (CBM), VIP Database for Chinese Technical Periodicals (VIP), Medline, and Clinical Trial Register (CTR) for eligible RCTs. Published trial will be from their inception to June 2022.

Main outcome(s): The effectiveness rate, abdominal pain, nausea/vomiting, and time to first defecation.

Additional outcome(s): The secondary outcomes: the level of serum amylase, mortality, adverse reactions.

Quality assessment / Risk of bias analysis: Two reviewers will independently assess risk of bias based on the following domains from recommendations from the Cochrane handbook: 1. Adequate sequence generation; 2. Allocation concealment; 3. Blinding; 4. Incomplete outcome data and how it was addressed; 5. Selective reporting of the outcome; 6. Any other biases. results of bias assessment will be presented in a figure and a graph indicating low, high or unclear risk of bias for each of the 6 items in each trial. Sensitivity analysis will be conducted based on the bias assessment to assess robustness of results.

Strategy of data synthesis: Stata 14.0 software and Markov chain–Monte Carlo method will be used to conduct Bayesian meta-analysis. Three Markov chains will be used for simulation. The number of iterations will be set at 50,000 (the first 20,000 are used for annealing to eliminate the effect of the initial value, and the last 30,000 are used for sampling). The reticular diagram will be drawn by Stata 15.0 software to show the direct and indirect comparison between different interventions. The relative odds ratio (OR) and its 95% confidence interval (CI) are calculated to evaluate the consistency of each closed loop. If the lower limit of 95% CI is equal to 1, indicating good consistency. If relative OR is close to 1, direct and indirect evidence are consistent, the fixed effect model will be adopted for analysis. Otherwise, the closed-loop is considered to have obvious inconsistencies, the random effect model will be used for analysis. WinBUGS 1.4.3

will be used to rank the efficacy of different interventions.

Subgroup analysis: Because different degrees of disease severity have been shown to have different prognoses, the subgroup analysis was based on disease severity (mild, moderately severe, or severe). In cases of significant heterogeneity among the included studies, subgroup analysis was performed based on the type of TCM decoction or other factors.

Sensitivity analysis: Sensitivity analysis will be conducted by excluding each qualified study.

Country(ies) involved: China.

Keywords: Traditional Chinese medicine decoction, acute pancreatitis, elderly patients, protocol, network meta-analysis.

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