INPLASY PROTOCOL

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Review question / Objective: As a common cardiovascular disease, the morbidity and mortality of CHD are increasing year by year. In recent years, many RCTs have proved that compared with conventional therapy, the combination of traditional Chinese medicine injections for promoting blood circulation and removing blood stasis can improve clinical efficacy. However, there is still a lack of direct comparative study between different kinds of traditional Chinese medicine injections. Therefore, based on the network meta-analysis, this study compares the curative effects of various traditional Chinese medicine injections for promoting blood circulation and removing blood stasis in treating CHD to provide a reference for clinical medication.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 29 March 2021 and was last updated on 29 March 2021 (registration number INPLASY202130103).

INTRODUCTION

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Condition being studied: Coronary heart disease(CHD) refers to heart disease caused by coronary artery atherosclerosis. causing stenosis or occlusion of lumen, leading to myocardial ischemia and hypoxia or necrosis. This disease is the most common type of organ diseases caused by atherosclerosis, which seriously endangers human health. According to the World Health Organization statistics, at present, the death toll of CHD has exceeded the sum of all tumour deaths, becoming the first cause of death. Clinically, many patients with CHD often have no apparent symptoms in the early stage. Still, once the condition occurs, severe cases will lead to myocardial infarction and even sudden death. Preventing the occurrence and further development of angina pectoris of CHD has become one of the urgent medical problems. In recent years, due to the rapid growth of medical technology, people turn to revascularization to treat stable angina pectoris of CHD by western medicine. However, while these treatments improve symptoms and prognosis, there are also some problems such as expensive interventional surgery, postoperative restenosis, adverse drug reactions, etc. However, in treating diseases, traditional Chinese medicine(TCM) mainly adopts the principle of syndrome differentiation and treatment, so it is a research topic with practical significance and broad prospects to treat CHD and angina pectoris from the direction of TCM. At present, TCM injections for promoting blood circulation and removing blood stasis have been widely used in the clinical treatment of CHD. Moreover, the theory and practice of promoting blood circulation and removing blood stasis in treating CHD have been widely affirmed, and the combination with western medicine can improve the clinical curative effect. Studies have shown that the method of promoting blood circulation and removing blood stasis can resist platelet aggregation, remove oxygen free radicals, improve blood circulation and hemorheology of patients. Promoting blood circulation and removing blood stasis provides a new approach and perspective for CHD treatment and has practical application value. There are Danhong injection, Xuesaitong injection, Dengzhanxixin injection and Salvianolate injection for treating CHD. In recent years, several systematic evaluations suggest that combining TCM and western medicine can improve clinical efficacy and effect treating both the symptoms and root causes. However, some differences between different studies are different, and there is still no direct comparative study between different kinds of TCM injections. Therefore, in this study, the efficacy of various TCM injections for promoting blood circulation and removing blood stasis on CHD was compared and ranked by network Meta-analysis to provide a basis for clinical drug selection.

METHODS

Participant or population: Patients diagnosed as CHD according to clinical standards will be included.

Intervention: The treatment group included Danhong injection, Xuesaitong injection, Dengzhanxixin injection and Salvianolate injection combined with routine treatment.

Comparator: The control group was given routine treatment, which could be combined with placebo or other TCM treatments.

Study designs to be included: Randomized controlled trials (RCTs) of Treating CHD with Chinese Medicine Injection for Promoting Blood Circulation and Removing Blood Stasis will be included in this review. The literature language is limited to Chinese and English.

Eligibility criteria: (1)The control group was treated with TCM injection other than intervention measures, and the intervention

measure is the study of combining multiple drugs; (2)Documents with similar original data and repeated publication; (3)Research on incomplete data reporting, duplicate data or inability to extract data; (4)Animal experimental literature; (5)Case report, conference papers and summaries; (6)CHD with other complications; (7)No RCT.

Information sources: Two researchers independently searched PubMed, Web of Science, the Cochrane Library, Embase, China National Knowledge Infrastructure, the Chongqing VIP Chinese Science and Technology Periodical Database, Wanfang Database, and China Biomedical Literature Database. The search time is from the establishment of each database to February 2021. We will also manually retrieve from the following databases: Chinese Clinical Trial Register, conference papers, and unpublished studies or references.

Main outcome(s): This study's primary outcome indicators are the total effective rate of improving angina pectoris symptoms and the improvement of the electrocardiogram.

Quality assessment / Risk of bias analysis: According to the bias risk evaluation standard of randomized controlled trials provided by Cochrane Handbook, the literature quality evaluation is carried out, which includes the following seven aspects: random method, assignment concealment, blind method of subjects, blind method of result evaluation, data integrity, selective report, and other bias. According to the specific scoring rules, the two researchers evaluated three types: "low risk", "high risk", and "uncertain risk". Researchers independently complete and cross-check, and if there are differences, they will be resolved through discussion or assistance by a third researcher.

Strategy of data synthesis: The software Revman 5.3 and stata16.0 were used for data analysis. RevMan 5.3 was used to evaluate the quality of the included literature. Stata 16.0 software is used for direct meta-analysis and network metaanalysis based on frequency framework. In the network Meta-analysis, the network group command is used to preprocess the data, the network evidence diagram and the "comparison-correction" funnel diagram are drawn, the different interventions are compared in pairs, and the optimal probability ranking curve surface under the cumulative ranking curve (SUCRA) is calculated to rank the efficacy. The higher the SUCRA value, the better the intervention level in the network. A SUCRA value of 100% indicates that the treatment is the most effective in the network. An inconsistency check is performed when there is a closed loop. If there is evidence of direct comparison and indirect comparison at the same time, that is, there are closed loops, the consistency of each closed loop is evaluated by using the inconsistency factor (IF) and its 95% CI, and 95% CI contains 0 as good consistency; otherwise, it is considered that the closed loop has obvious inconsistency.

Subgroup analysis: If heterogeneity is observed in the study, we will use subgroup analysis for analysis.

Sensitivity analysis: We consider sensitivity analysis for methodological quality, and test the robustness of the results by excluding the risk of low quality and high bias.

Country(ies) involved: China.

Keywords: coronary heart disease, protocol, systematic review, traditional Chinese medicine injections, network meta-analysis

Contributions of each author:

Author 1 - Langlang Huang -Conceptualization, Data curation, Investigation, Writing – original draft, Writing – review & editing.

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