INPLASY PROTOCOL

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Review Stage at time of this submission: **Data analysis.**

Conflicts of interest: **No.**

Traditional Chinese Medicine Injection Combined with Conventional Western Medicine in Treating Coronary Heart Disease after PCI: A Protocol systematic review and meta analysis of overview

Xu, XM[1]; Yang, WN[2]; Chen, X[3]; Kong, YX[4]; Wang, J[5]; Zheng, JH[6].

Review question / Objective: **P: Coronary heart disease after PCI; I: Traditional Chinese Medicine Injection Combined with Conventional Western Medicine; C: Conventional Western Medicine; O: Clinical Efficacy and Cardiovascular Adverse Events; S: A Systematic Review and Meta-Analysis.**
Condition being studied: **With the continuous development of PCI technology, the treatment technology of coronary heart disease has been constantly improved. However, interventional therapy has also led to a series of new problems in postoperative cardiovascular adverse events. There are many specific treatments and research results on prevention and treatment of complications and improvement of prognosis after PCI for coronary heart disease at home and abroad. Meta-analysis studies have shown that Chinese medicine injection assisted PCI for coronary heart disease can improve the clinical efficacy and reduce the occurrence of adverse cardiovascular events. Due to the lack of direct comparison of different traditional Chinese medicine injections, clinicians can't judge their therapeutic value correctly, and it is difficult to select the best auxiliary medicine of traditional Chinese medicine based on the combination of traditional Chinese medicine injections and conventional western medicine in clinic.this research using the greatest advantage of the network Meta-analysis method over the direct comparison meta-analysis, sorting the advantages and disadvantages of its indirect comparison of the efficacy and safety indexes of different traditional Chinese medicine injections combined with conventional western medicine in the treatment of coronary heart disease PCI, so as to provide the best treatment scheme and evidence-based medical evidence for clinical practice.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 July 2020 and was last updated on 20 July 2020 (registration number INPLASY202070087).

INTRODUCTION

Review question / Objective: **P: Coronary heart disease after PCI; I: Traditional Chinese Medicine Injection Combined with Conventional Western Medicine; C: Conventional Western Medicine; O: Clinical Efficacy and Cardiovascular Adverse Events; S: A Systematic Review and Meta-Analysis.**

Rationale: By consulting seven authoritative medical literature database and collecting relevant data, the clinical research results of traditional Chinese medicine injection combined with conventional western medicine in the treatment of coronary heart disease after PCI were obtained. The literature was selected in strict accordance with inclusion and exclusion criteria, and the quality of the literature adopted in this paper was evaluated by using the Jadad scale and Cochrane bias risk assessment tools.

Condition being studied: With the continuous development of PCI technology, the treatment technology of coronary heart disease has been constantly improved. However, interventional therapy has also led to a series of new problems in postoperative cardiovascular adverse events. There are many specific treatments and research results on prevention and treatment of complications and improvement of prognosis after PCI for coronary heart disease at home and abroad. Meta-analysis studies have shown that Chinese medicine injection assisted PCI for coronary heart disease can improve the clinical efficacy and reduce the occurrence of adverse cardiovascular events. Due to the lack of direct comparison of different traditional Chinese medicine injections, clinicians can't judge their therapeutic value correctly, and it is difficult to select the best auxiliary medicine of traditional Chinese medicine based on the combination of traditional Chinese medicine injections and conventional western medicine in clinic.this research using the greatest advantage of the network Meta-analysis method over the direct comparison meta-analysis, sorting the advantages and disadvantages of its indirect comparison of the efficacy and safety indexes of different traditional Chinese medicine injections combined with conventional western medicine in the treatment of coronary heart disease PCI, so as to provide the best treatment scheme and evidence-based medical evidence for clinical practice.

METHODS

Search strategy: Through the physical library access to relevant medical databases, such as CNKI, Wangfang, VIP, CBM, PubMed, Cochrane Library and EMBASE.Chinese keywords of this study include percutaneous coronary intervention, PCI, PCI for acute myocardial infarction, PCI for coronary heart disease, stent intervention, Danhong injection, etc.The search time limit for English search terms, including Percutaneous Coronal Intervention, Coronal Intervention, Percutaneous, Danhong Injection, etc., is from the establishment of the database to January 31, 2020. (CNKI, Wangfang, VIP, CBM) #1= percutaneous OR conary intervention OR PCI for acute myocardial infarction OR PCI for coronary heart disease or stent intervention or PCI after OR AMI OR PCI (subject) #2= Danhong injection OR Danshen polyphenolate injection OR Shengmai injection OR Danshen ligustrazine injection OR Shuxuetong injection OR Xuesaitong injection OR Shenmai injection OR Shenfu injection OR tanshinone IIA injection OR ginkgolide meglumine injection OR Shenqi Fuzheng injection OR Yinxindamo injection OR Xinmailong injection OR compound Danshen injection OR Salvia miltiorrhiza injection, snakegourd peel injection, Xuebijing injection, breviscapine injection, safflower yellow injection, breviscapine injection, puerarin injection, Rhodiola rosea injection, Ixeris sonchifolia injection, Shenqi Fuzheng injection, tanshinone injection, Yiqifumai injection, Shenkang injection, Yinxingdamo injection, ligustrazine injection, safflower yellow sodium chloride injection and breviscapine injection Glucose injection OR acanthopanax senticosus injection OR ginseng glycopeptide injection OR ginseng polysaccharide injection OR salvianolic acid injection OR chuanshentong injection OR Danxiang glucose infusion OR Danxiang Guanxin injection (theme) #3=#1 AND #2 (subject) (PubMed, Cochrane Library,EMBASE) #1=Percutaneous Coronary Intervention OR CoronaryIntervention,Percutaneous OR

Coronary Interventions,Percutaneous OR Intervention,Percutaneous Coronary OR Interventions, Percutaneous Coronary OR Percutaneous Coronary Interventions OR Percutaneous Coronary Revascularization OR Coronary Revascularization, Percutaneous OR Coronary Revascularizations, Percutaneous OR Percutaneous Coronary Revascularizations OR Revascularization, Percutaneous Coronary OR Revascularizations, Percutaneous Coronary [Title/Abstract] #2=Injections OR Injection OR Injectables OR Injectable[Title/Abstract] #3=#1 AND #2.

Participant or population: Patients have been diagnosed with coronary heart disease, and have undergone coronary angiography and PCI without limitation of sex, age, course of disease or co-morbidity diagnosed, But the baseline characteristics of each study should be consistent.

Intervention: Intervention measures: The treatment group was treated with traditional Chinese medicine injection (traditional Chinese medicine injection, traditional Chinese medicine powder injection, etc.) combined with conventional western medicine;The control group was treated with conventional western medicine alone.

Comparator: The control group was only used for routine western medicine treatment, including vasodilator, ACEI/ARB, calcium antagonist, beta blocker, anti-platelet aggregation, anticoagulation and lipid regulation.

Study designs to be included: Inclusion criteria: RCTs Exclusion criteria: Non-RCTs.

Eligibility criteria: Inclusion criteria:According to the suggestions of a cardiologist, we designed the inclusion criteria as follows: All subjects have been diagnosed with coronary heart disease, and have undergone coronary angiography and PCI. Intervention measures: The treatment group was treated with traditional Chinese medicine injection (traditional Chinese medicine injection, traditional Chinese medicine powder injection, etc.) combined with conventional western medicine; The control group was treated with conventional western medicine alone. Randomized controlled clinical trial (RCT). Outcome indicators (clinical efficacy, cardiovascular adverse events) include at least one of them. Exclusion criteria: the research object without stent; In the treatment group, non-traditional Chinese medicine injection (traditional Chinese medicine decoction, Chinese patent medicine, such as compound, unilateral or traditional Chinese medicine extract, etc.) and external treatment with traditional Chinese medicine (such as cupping and hot moxibustion, etc.); Non-randomized controlled trials, such as animal experiments, cell experiments, systematic evaluation, meta-analysis, etc. Severe arrhythmia, stubborn hypertension and severe failure of target organ function.

Information sources: Through the physical library access to relevant medical databases, such as CNKI, Wangfang, VIP, CBM, PubMed, Cochrane Library and EMBASE. Chinese keywords of this study include percutaneous coronary intervention, PCI, PCI for acute myocardial infarction, PCI for coronary heart disease, stent intervention, Danhong injection, etc.The search time limit for English search terms, including Percutaneous Coronal Intervention, Coronal Intervention, Percutaneous, Danhong Injection, etc., is from the establishment of the database to January 31, 2020.

Main outcome(s): Clinical efficacy and cardiovascular adverse events.

Additional outcome(s): Clinical results will be eligible, includingLVEF, BNP, NT-probNP, NO,ET-1, CRP,SOD, et al.

Data management: NoteExpress, Review Manager5.3 and software Stata15.

Quality assessment / Risk of bias analysis: The quality of literature adopted in this paper was evaluated by Jadad Scale and Cochrane Biased Risk Assessment Tool.Risk of bias assessment was conducted by two independent authors. When there were differences in extracting data or evaluating ROB, the third author solved the differences. According to Cochrane svstematic Review Manual, This paper systematically evaluates the research quality from seven dimensions.ROB's evaluation areas include stochastic equilibrium generation, allocation concealment, participants and personnel blindness, result evaluation blindness, incomplete data, selective reporting and other biases. Rob is divided into three grades: high, low and unclear. According to the analysis of RevMan5.3 statistical software, there are 58 related biased risk documents adopted in this paper, and the results show that 17 are of high quality, the remaining 41 are of low quality;This shows that the evaluation indexes of the included research literature are mostly low risk, and the overall risk is low.

Strategy of data synthesis: In this paper, software Stata15 is used to draw the network diagram of relevant evidence, and r software gemtc installation package is used to make meta-analysis of relevant Meta.The data are binary classified variables, Risk ratio (RR) was used for binary data and mean difference (MD) was used for continuous data, with confidence interval of 95%.According to the calculated rank value, the therapeutic effect of each treatment measure was predicted.In this study, $P < 0.05$ and 95%CI were used as the standards with statistical significance.In this study, 10 or more meta-analyses will be funneled to analyze their publication bias in strict accordance with systematic evaluation.

Subgroup analysis: Sub-group analysis defined by gender, age, research type, intervention measures and outcome indicators, severity of illness or intervention period, and sensitivity analysis stratified by the quality included in the trial will be used.

If there are sufficient sources, heterogeneity or publication bias will be detected.

Sensibility analysis: If perceptual analysis is needed, we will do it.

Language: Chinese and English.

Country(ies) involved: China.

Keywords: coronary artery disease; Percutaneous coronary intervention; Chinese medicine injection; Cardiovascular adverse events; Meta-analysis.

Contributions of each author:
Author 1 - Xiangmei Xu - The authors participated in the development of selection criteria and risk bias assessment strategies, collected data, and drafted manuscripts.
Author 2 - Wenna Yang - The author has made some modifications to the paper.
Author 3 - Xuan Chen - The author provides statistical expertise.
Author 4 - Yixuan Kong.
Author 5 - Jie Wang.
Author 6 - Jinghui Zheng - The author reads, gives feedback and approves the final manuscript.