INPLASY PROTOCOL

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Corresponding author:
JianLue Pan

771359972@qq.com

Author Affiliation:
Guangzhou University of Chinese Medicine, Guangzhou.

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None declared.

Commonly Traditional Chinese Medicine in treatment of Coronary Atherosclerotic Heart Disease with Anxiety and Depression: a network meta-analysis

Pan, J[1]; Huang, P[2]; Zhang, Y[3]; Huang, R[4]; Chen, Q[5]; Chen, H[6].

Review question / Objective: **Studies have shown that traditional Chinese medicine (TCM) preparations can effectively relieve anxiety and depression in Coronary Atherosclerotic Heart Disease (CAD) patients with anxiety and depression patients with high safety, because of their wide variety, clinical selection is difficult. So the object of study is to comparative the efficacy of Traditional Chinese Medicine preparation in the treatment of the patient by network meta-analysis, in order to select best medicine and further guide the clinical practice.**
Condition being studied: **The incidence of depression in CAD patients is as high as 14% ~ 47%, and patients with anxiety is as high as 20%, compared with the incidence of the population is significantly higher. Antidepressants may interact with multiple drugs for cardiovascular disease, and sometimes may cause adverse reactions when combined with cardiology drugs, increasing clinical uncertainty. TCM preparations are confirmed can have better effective in the patient by many researches.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 April 2021 and was last updated on 24 April 2021 (registration number INPLASY202140124).

INTRODUCTION

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METHODS

Search strategy: PubMed: (Coronary Heart Disease OR Coronary Diseases OR Ischemia, Myocardial OR Acute Coronary Syndrome OR Myocardial Infarction OR Angina Pectoris OR Stenocardia) AND (Depressions OR Depressive Symptoms OR Emotional Depression or Angst or Nervousness or Hypervigilance or Anxiousness or Social Anxiety) AND (wendan decoction OR yixinshu OR jieyuzhitong OR xinkeshu OR shuganjieyu OR Chaihu Longgu Muli decoction).

Participant or population: Patients with a definite diagnosis of coronary atherosclerotic heart disease with anxiety or depression.

Intervention: The intervention group was additionally treated with TCM preparation on the basis of the control group, including Wendan decoction, Yixinshu capsule, Jieyu Zhitong prescription, Xinkeshu tablet, Shugan Jieyu decoction or Chaihu Longgu Muli decoction.

Comparator: The control groups received standard treatment, including CAD secondary prophylactic drugs and anti-anxiety and depression drugs.

Study designs to be included: Randomized Controlled Trial or Controlled Clinical Trial, Clinical Trial.

Eligibility criteria: Inclusion criteria: 1)Patients with a definite diagnosis of coronary atherosclerotic heart disease with anxiety or depression.Age is 18 years to 80 years. 2)Sufficient sample size is required (N≥20) Exclusion criteria: 1) Repeated research; 2) the intervention is not a single traditional Chinese medicine preparation; 3)HAMA and HAMD scores at baseline were not recorded.

Information sources: The two authors will be independent to extract data from each study (PubMed, Cochrane Library, EMBASE, Web of Science, CINAHL, CNKI, WanFang, CBM, published from inception to 30st November 2020, the use of standardized data extraction, including research characteristics (such as the first author's name, year of publication, random method, randomized, blinded, lost to follow-up and hidden exit), the study of the characteristics of the object (included in the number of cases, for example) and outcomes measure(HAMA and HAMD). At the end of the intervention, the results of intentionality analysis (ITT) will be extracted preferentially.

Main outcome(s): Hamilton Anxiety(HAMA) scale.The effect measure was the difference of HAMA scores before and after intervention. Continuous variables were represented by mean different (MD) and the corresponding Standard Deviation (SD), and 95% confidence interval (CI) was used.

Additional outcome(s): Hamilton Depression(HAMD) scale.The effect measure was the difference of HAMD scores before and after intervention. Continuous variables were represented by mean different (MD) and the corresponding Standard Deviation (SD), and 95% confidence interval (CI) was used.

Quality assessment / Risk of bias analysis: The risk of bias in the included studies was assessed using the Cochrane Handbook 5.1.0 RCT Risk of Bias Assessment Tool. Specific criteria: 1. Whether random method is adopted; 2. Whether allocation concealment is adopted; 3. Whether the

participants and implementors are blind; 4, Whether the measurement results are blind, 5. Data integrity, 6. Whether there is selective reporting, 7. Each outcome was classified as low-risk, unclear, or high-risk for the presence of other biases. At the same time, the modified Jadad scale was used to evaluate the methodological quality of the included literatures. The specific criteria are shown in Attachment 1. Two evaluators will independently evaluate the quality. In case of disagreement, the third party will intervene to discuss and solve the problem.

Strategy of data synthesis: The bias of variance size parameter of heterogeneity (I^2) estimated from the NMA model using R V5.4 software was used to evaluate the statistical heterogeneity among studies. GEMTC14.3 based on the Bayesian framework was used for mesh meta-analysis, and the Markov chain Monte Carlo fitting consistency model was used for Bayesian inference. Four chains were set initially, and the number of iterations was set as 50 000 times. The first 20 000 times were used for annealing to eliminate the influence of initial values. The last 30 000 times were used for sampling, and PSRF was used to reflect the convergence degree of the model. When PSRF was close to or equal to 1, it indicated that the data had good convergence, and the consistency model was used for mesh meta-analysis.The surface area under the cumulative ranking curve (SUCRA) of different interventions was calculated by STATA15.The quality of evidence will be evaluated using Grade Pro 3.6 software for the quality of treatment effect evaluation through NMA.

Subgroup analysis: None.

Sensitivity analysis: When the heterogeneity of each study was large, the observation difference of low-quality studies were excluded, and the results of the network meta-analysis were compared with the consistent model and the non-consistent model.

Language: Chinese.

Country(ies) involved: China.

Keywords: Traditional Chinese Medicine, Coronary Atherosclerotic Heart Disease, Anxiety and Depression, Network Meta-analysis.

Contributions of each author:
Author 1 - JianLue Pan.
Author 2 - Pangning Huang.
Author 3 - Yuanwen Zhang.
Author 4 - RongFa Huang.
Author 5 - QiuCen Chen.
Author 6 - HuiBing Chen.