

INPLASY PROTOCOL

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Conflicts of interest:

None declared.

Efficacy and Safety of TCMI in Patients With diabetes mellitus complicated by coronary heart disease: A Systematic Review and Network Meta-Analysis

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Review question / Objective: The aim of this meta-analysis of randomized controlled trials is to evaluate the efficacy and safety of traditional Chinese medicine injection(TCMI) for diabetes mellitus complicated by coronary heart disease, to better inform clinical practice.

Condition being studied: Diabetes is one of the most important non-communicable diseases threatening global human health. International Diabetes Federation (IDF) statistics show that the number of diabetic patients worldwide has reached 370 million in 2011, of which 80% are in developing countries. It is estimated that China will have 550 million diabetes patients worldwide by 2030. There are many complications of diabetes and will involve microvascular and large vessels, of which about 70% of sugar and urine glucose will be accompanied by coronary heart disease. Data has shown that the possibility of cardiovascular disease in diabetic patients is four times that of non-diabetic patients. Cardiovascular disease is one of the leading causes of death in patients with type 2 diabetes. Studies have shown that supplementation and replacement therapy have advantages in improving symptoms and reducing side effects in patients with diabetic coronary heart disease. In recent years, traditional Chinese medicine injection has attracted more and more attention due to its exact efficacy and low toxicity. Danhong injection, Shenmai injection and Gualoupi injection are widely used in the treatment of diabetes mellitus complicated with coronary heart disease in China.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 December 2021 and was last updated on 28 December 2021 (registration number INPLASY2021120125).

INTRODUCTION

Review question / Objective: The aim of this meta-analysis of randomized

controlled trials is to evaluate the efficacy and safety of traditional Chinese medicine injection(TCMI) for diabetes mellitus

complicated by coronary heart disease, to better inform clinical practice.

Rationale: According to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

Condition being studied: Diabetes is one of the most important non-communicable diseases threatening global human health. International Diabetes Federation (IDF) statistics show that the number of diabetic patients worldwide has reached 370 million in 2011, of which 80% are in developing countries. It is estimated that China will have 550 million diabetes patients worldwide by 2030. There are many complications of diabetes and will involve microvascular and large vessels, of which about 70% of sugar and urine glucose will be accompanied by coronary heart disease. Data has shown that the possibility of cardiovascular disease in diabetic patients is four times that of non-diabetic patients. Cardiovascular disease is one of the leading causes of death in patients with type 2 diabetes. Studies have shown that supplementation and replacement therapy have advantages in improving symptoms and reducing side effects in patients with diabetic coronary heart disease. In recent years, traditional Chinese medicine injection has attracted more and more attention due to its exact efficacy and low toxicity. Danhong injection, Shenmai injection and Gualoupi injection are widely used in the treatment of diabetes mellitus complicated with coronary heart disease in China.

METHODS

Search strategy: (1).PubMed:"Coronary Diseases"、"Diabetes"、"Traditional Chinese medicine"、"Injection" (2).The China National Knowledge Infrastructure (CNKI):"diabetes with coronary heart disease "、"Traditional Chinese medicine"、"Injection". And so on.

Participant or population: Patients who were diagnosed with diabetes mellitus complicated by coronary heart disease,

and there's no limitation on nationality, race, gender, age, disease duration.

Intervention: Traditional Chinese medicine injection conventional with western medicine. Traditional Chinese medicine injection include Danshen injection, Shenmai injection, Gualoupi injection, Shengmai injection, Shenfu injection, Shuxuetong injection, Ciwujia injection, Dengzhanxin injection, Gegen injection, Chuanxiangqin injection.

Comparator: Usual care and medications such as Hypoglycemic drugs, Statins Antihypertensive drugs and so on.

Study designs to be included: Only RCTs

Eligibility criteria: (1) Participants: patients who were diagnosed with diabetes mellitus complicated by coronary heart disease, and there's no limitation on nationality, race, gender, age, disease duration; (2) Interventions and comparisons: the treatment group was given traditional Chinese medicine injection with conventional western medicine, and the control group adopted conventional western medicine alone. Also, the conventional western medicine treatment must be consistent between treatment and control group. (3) Outcomes: the primary outcomes of this network meta-analysis were total effective rate, the duration of angina pectoris pain, and the secondary outcomes levels of fasting blood glucose, post-prandial 2-hour plasma glucose, total cholesterol, triglycerides, high-density lipoprotein cholesterol, and low-density lipoprotein cholesterol, as well as frequency of angina attacks, the effective rate of electrocardiogram, stable angina pectoris of CCS classification. Moreover, the safety outcomes were all-cause mortality and Adverse events. In this network meta-analysis, RCT which included one of the primary outcomes was sufficient. (4) Study design: only RCTs were taken into our consideration.

Information sources: PubMed, Web of Science, Embase, the China National Knowledge Infrastructure (CNKI), the

Chinese Biological Medicine Literature Service System (CBM), the Chinese Scientific Journal Full-text Database (VIP), and the Wan-fang Database(WF).

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Main outcome(s): Total effective rate, the duration of angina pectoris pain.

Additional outcome(s): Levels of fasting blood glucose, post-prandial 2-hour plasma glucose, total cholesterol, triglycerides, high-density lipoprotein cholesterol, and low-density lipoprotein cholesterol, as well as frequency of angina attacks, the effective rate of electrocardiogram, stable angina pectoris of CCS classification.

Data management: NoteExpress was used to manage retrived literatures stata 16.0 was used to perform network meta-analysis and make graphs.

Quality assessment / Risk of bias analysis: Cochrane risk of bias tool and GRADE assessment.

Strategy of data synthesis: It followed the Preferred Reporting Items for Systematic Review and Meta- Analysis(PRISMA).

Subgroup analysis: First: age=60; Second: stable angina pectoris of CCS classification.

Sensitivity analysis: The total of patients in trials with case numbers ≥ 100 trials.

Language: No language limitation.

Country(ies) involved: China.

Keywords: network meta-analysis, traditional Chinese medicine, injection, Diabetes mellitus, coronary heart disease.

Contributions of each author:

Author 1 - Du haixia - conceived and designed the study.

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Author 2 - Shen hailiang - extracted and analyzed the data.