

RESEARCH ARTICLE

Efficacy of Traditional Chinese Medicine in patients with acute myocardial infarction suffering from diabetes mellitus

Dai Guohua, Gao Wulin, Bi Dongxue, Liu Chunhua, Liu Yuhan, Wang Ning, Zhao Chen

Dai Guohua, Department of Cardiology, the Affiliated Hospital of Shandong University of Traditional Chinese Medicine, Jinan 250000, China

Gao Wulin, Bi Dongxue, Liu Chunhua, Liu Yuhan, Wang Ning, First Clinical Medical College, Shandong University of Traditional Chinese Medicine, Jinan 250000, China

Zhao Chen, Institute of Traditional Chinese Medicine, Tianjin University of Traditional Chinese Medicine, Tianjin 300000, China

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Correspondence to: Prof. Dai Guohua, Department of Cardiology, the Affiliated Hospital of Shandong University of Traditional Chinese Medicine, Jinan 250000, China. daigh2017@163.com

Telephone: +86-531-68616065

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Abstract

OBJECTIVE: To investigate the "real world" effectiveness of Traditional Chinese Medicine (TCM) in patients with acute myocardial infarction suffering from diabetes mellitus (AMI+DM patients).

METHODS: This was a retrospective cohort study. During hospitalization, the "exposure group" was defined as patients who had a TCM injection for ≥ 7 d. During follow-up, the definition of the exposure group was application of a Chinese patent medicine or decoction of Chinese medicine for ≥ 28 d. General information (age, sex, contact details), TCM use and endpoint events of AMI+DM patients during hospitalization and follow-up were collected. The correlation between TCM and the end-point

events of AMI + DM patients was analyzed using a multiple logistic regression method.

RESULTS: A total of 479 AMI + DM patients were enrolled and 345 cases were followed up. During hospitalization, TCM, age, hypertension and use of an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) were associated with cardiac death. During follow-up, TCM was associated with cardiac death. TCM was a relevant factor for a composite endpoint of re-infarction and stroke. TCM, anti-thrombotic therapy and lipid-lowering therapy were related to acute heart failure. TCM, anti-thrombotic therapy, anti-MI therapy and ACEI/ARB use exhibited a strong correlation with re-hospitalization due to cardiovascular disease.

CONCLUSION: TCM reduced the prevalence of cardiac death during hospitalization, and cardiac death, a composite endpoint of re-infarction and stroke, acute heart failure and re-hospitalization due to cardiovascular disease during follow-up.

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Keywords: Myocardial infarction; Diabetes mellitus; Death; Medicine, Chinese traditional; Cohort studies

INTRODUCTION

Acute myocardial infarction (AMI) is a common, acute and severe cardiovascular disease that is prone to various types of serious complications and which can increase mortality risk. With extensive application of thrombolysis and interventional therapy, the preva-

lence of mortality of AMI has been reduced considerably worldwide.¹

However, the effect of thrombolysis and interventional therapy is poor if AMI patients also suffer from diabetes mellitus (DM). This combination of diseases is not conducive to reperfusion and establishment of a collateral circulation owing to damage to the microcirculation and arteriole narrowing. Such patients are more likely to suffer from heart failure, arrhythmia, shock and other complications.² Therefore, improvement of the prognosis of AMI patients suffering from DM (i.e., AMI+DM patients) is a focus of clinical research.

Traditional Chinese Medicine (TCM) has been used widely in the treatment and secondary prevention of AMI and DM. TCM can improve the prognosis of AMI and DM,^{3,4} suggesting that TCM could improve the prognosis of AMI + DM patients. The true benefit of TCM on AMI + DM patients has not been shown clearly.

In the present study, we investigated the effect of TCM and the endpoint events of AMI + DM patients. In this way, our study focused on the "real world" effectiveness of TCM for AMI + DM patients.

MATERIALS AND METHODS

Design of our cohort study

The study protocol was approved by the Medical Ethics Committee of the Affiliated Hospital of Shandong University of TCM (Shandong, China).

Injections of Chinese herbal extracts ("TCM injections") were the main treatment for AMI + DM patients during hospitalization. The "exposure group" comprised patients who underwent application of a TCM injection ≥ 7 d. The exposure group was subdivided into the "low-exposure group" (who had a TCM injection for 7-13 d) and a "high-exposure group" (who had a TCM injection for ≥ 14 d).

During follow-up, TCM treatment for AMI+DM patients was Chinese patent medicines and decoctions of Chinese medicines. During follow-up, the definition of the exposure group was application of Chinese patent medicine or decoction of Chinese medicine for ≥ 28 d. Subdivision of the exposure group led to a low-exposure group (application of Chinese patent medicine or decoction of Chinese medicine for ≥ 28 d and < 3 months), medium-exposure group (≥ 3 months and < 6 months) and high-exposure group (≥ 6 months).

It has been reported that the prevalence of endpoint events in AMI patients treated with TCM is 2%, and that the prevalence of endpoint events in AMI patients not treated with TCM is 17%.⁵ According to the formula for calculation of the sample size of cohort studies,⁶ the estimated sample size was 168 cases. Hence, 263 AMI patients needed to be enrolled in our study if the in-hospital mortality was 20% and loss to follow-up was $< 20\%$.

Patients

According to the diagnostic criteria of MI and DM,^{7,8} AMI + DM patients aged 40-87 years were recruited from the Affiliated Hospital of Shandong University of TCM as well as other specialist TCM hospitals in China: Zibo Hospital, Rizhao Hospital, Jinan Hospital, Qingdao Hospital, Jining Hospital, Weihai Hospital, and Weifang Hospital. This recruitment was from 1 January 2008 to 31 December 2014.

The inclusion criteria were patients: (a) with acute myocardial infarction and diabetes mellitus; (b) hospitalized from January 1, 2008 to December 31, 2014.

The exclusion criteria were patients: (a) with previous MI (patients with recurrent MI were not excluded); (b) who had received percutaneous coronary intervention or coronary artery bypass grafting previously; (c) without contact information or current address; (d) who had serious non-cardiovascular diseases (e.g., cancer, mental illness).

Interventions

According to guidelines for the treatment of MI and DM,⁷ use of conventional Western Medicines such as anti-thrombosis drugs, anti-MI drugs, lipid-lowering drugs, angiotensin-converting enzyme inhibitors (ACEIs) and angiotensin receptor blockers (ARBs) were recorded. The TCM injections employed during hospitalization were Shengmai, Danhong, and Ligustrazine.

During follow-up, Chinese patent medicines (Suxiao Jiuxin pills, Compound Danshen Dropping pills, Qishen Yiqi Dropping pills, Xuefu Zhuyu capsules) and decoctions of Chinese medicines (Shengmaisan, Xuefu Zhuyu, Gualou Xiebai Banxia) were used.

Outcome

Identification numbers of patients were retrieved through the medical record information management system (MRIMS) of the particular TCM hospital. Patients who met the included criteria were enrolled. General information such as age, sex, contact details, complications, TCM use, and endpoint events (e.g., cardiac death, cardiac shock, acute heart failure, re-infarction, stroke) were collected through the MRIMS from 1 July 2014 to 30 June 2015. The TCM use and endpoint events of AMI + DM patients discharged from a particular TCM hospital were followed up through telephone conversations and outpatient clinics from 1 July 2015 to 31 September 2015.

There were three potential biases in the present study: patient recruitment was not comprehensive; the information collected was inaccurate; there was recall bias at follow-up. To reduce the effect of such biases, a series of measures were adopted: patients who met the inclusion criteria were retrieved through the MRIMS; a double-entry test was used to ensure the accuracy of the data; researchers were trained to ensure that follow-up results were reliable.

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