

## SYSTEMATIC REVIEW

## Sini decoction as an adjuvant therapy for angina pectoris: a systematic review of randomized controlled trials

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### Abstract

**OBJECTIVE:** To systematically assess the effects and safety of Sini decoction as an adjuvant therapy for patients with angina pectoris.

**METHODS:** We searched PubMed, Excerpt Medica Database, the Cochrane library, Wanfang Database, China National Knowledge Infrastructure Database,

China Science and Technology Journal Database from the date of its inception until August 1, in 2014. Available literatures were selected according to the inclusion criteria. Two reviewers finished data extraction, checked the data and assessed the methodological quality of studies, independently. The Review Manage Software 5.1.0 was used for data analysis.

**RESULTS:** Six trials involving 453 participants were eligible. None of the trials reported the mortality due to angina pectoris. The secondary outcomes showed that Sini decoction, together with nitroglycerin when necessary, may have some effects on reducing the number of angina attacks and the amount of nitroglycerin. But in terms of reducing the duration of angina and improvement of electrocardiogram, there were no statistical differences between Sini decoction group and isosorbide dinitrate group. Only one reported that no adverse events were found.

**CONCLUSION:** Based on this systematic review, Sini decoction can reduce the dosage of nitroglycerin, when compared with isosorbide dinitrate group. And there were not enough evidence in the papers to draw any conclusions for the safety of Sini decoction.

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**Key words:** Angina pectoris; Coronary disease; Sini decoction; Randomized controlled trial; Meta-analysis

### INTRODUCTION

Cardiovascular disease (CVD) and other noninfectious

chronic disease (NCD) has become one of the global concerns, especially in developing countries.<sup>1</sup> CVD is the primary cause of death worldwide. It is estimated that, up to 2030, there will be 23.3 million people dead due to CVD.<sup>2</sup> According to World Health Organization, about 4.23 million people died of Coronary Artery Heart Disease (CHD) every year.<sup>3</sup> The American Heart Association (AHA) study found that the heart attack caused by angina accounted for 18% and it also cost a lot.<sup>4</sup>

Angina pectoris (AP) with the symptoms of intense tightness or heavy pressure in the chest, radiating to the neck, jaw, shoulder, back, arm, and epigastric region can be caused by myocardial ischemia.<sup>5</sup> Nowadays, we usually treated the AP by drugs, intervention therapy and so on. The 2011 updated guidelines of the AHA recommended the following drugs for the secondary prevention in patients with coronary atherosclerosis, which were antiplatelet drugs, angiotensin-converting enzyme inhibitors (ACEI), angiotensin receptor blocker (ARB), aldosterone antagonists and B-Blocker. In addition, risk factors should also be controlled positively such as blood pressure, blood lipids, blood glucose and body weight, as well as combining with cardiac rehabilitation therapy.<sup>6</sup>

The Sini decoction is a recipe documented in the *On Harm Caused by Cold* a medical textbook in Traditional Chinese Medicine (TCM). It was originally used to treat shaoyin diseases in terms of TCM theory. In the 1960s, there were already some literature reporting the treatment of cold limbs with Sini decoction. But most of them were case reports mainly discussing their personal application and understanding of Pathogenesis.<sup>7-12</sup> Until 1970s, some articles began to report Sini decoction's effects on myocardial infarction or septic shock.<sup>13-19</sup> On the early 1980s, people tended to concern about the pharmacological effects of Sini decoction, such as protection of the myocardium, improvement of cardiac function, prevention of ischemia-reperfusion and so on.<sup>20-24</sup> Up to now, many clinical studies and animal experiments were related to Sini decoction for AP.<sup>25-40</sup> Moreover, those literatures indicated that Sini decoction were effective for the patients with AP, especially for yang deficiency syndrome or coagulated cold syndrome.<sup>35,38</sup> So far, there were lacking such a systematic review about Sini decoction, which is the classic recipe of TCM. Therefore, in order to answer the question whether our classic recipe of TCM is effective and safe as an adjuvant therapy, we conducted this systematic review as the objective evidence for clinical application and studies.

## METHODS

This systematic review had already been registered on PROSPERO (<http://www.crd.york.ac.uk/prospero/>). And the registration number is: CRD42014015036.

### Search strategy

We searched six electronic databases: PubMed (January

1966 to August 2014), Excerpt Medica Database (EMBASE) (January 1966 to August 2014), the Cochrane library (January 1966 to August 2014), Wanfang Database (January 1987 to August 2014), China National Knowledge Infrastructure Database (January 1979 to August 2014), China Science and Technology Journal Database (January 1989 to August 2014).

The search terms included Fuzi (*Radix Aconiti Lateralis Preparata*), Ganjiang (*Rhizoma Zingiberis*), stir-frying with liquid adjuvant Gancao (*Radix Glycyrrhizae*), Sini, CHD and angina. In the Chinese database, all the terms were used as the key words ("prepared common monkshood daughter root or dried ginger or glycyrrhiza or Sini decoction" and "CHD or angina"). In the English database, the search terms included "Sini decoction or Sini tang" as a MeSH term, and then "CHD or angina or AP" for a second retrieval. Studies published in both English and Chinese were retrieved. Additionally, citations of relevant systematic reviews were also searched for any potential studies that were missed in the electronic database.<sup>28-34</sup> A sample retrieval strategy for Pubmed was:

- #1 Search "Sini tang" [Supplementary Concept] (27)
- #2 Search "angina pectoris"[Mesh] or "angina stable" [Mesh] or "angina unstable" [Mesh] (47554)
- #3 Search #1 AND #2 (2)
- #4 Search "randomized controlled trial" [Publication Type ] (387312)
- #5 Search "controlled clinical trial" [Publication Type ] (88811)
- #6 Search "randomized controlled trials" [Mesh] (97040)
- #7 Search "random allocation" [Mesh](7)
- #8 Search "double blind method" [Mesh] (16)
- #9 Search "single-blind method" [Mesh] (20112)
- #10 Search #4 OR #5 OR #6 OR #7 OR #8 OR #9
- #11 Search "animals" [Mesh] (17785183)
- #12 Search #10 NOT #11 (2081)
- #13 Search "clinical trial" [Publication Type ] (796197)
- #14 Search "exp clinical trials" (no results)
- #15 Search "clin\$ adj25 trial\$". (no results)
- #16 Search ((singl\$ OR doubl\$ OR trebl\$ OR tripl\$) adj25 (blind\$ OR mask\$)) (no results)
- #17 Search "Random allocation" [Mesh] (82467)
- #18 Search "research design" [Mesh] (343867)
- #19 Search #13 OR #14 OR #15 OR #16 OR #17 OR #18 (1027986)
- #20 Search #19 NOT #11 (18833)
- #21 Search #20 NOT #11 (18833)
- #22 Search "comparative study" [Publication Type ] (1691637)
- #23 Search "expevaluation studies" (no results)
- #24 Search "follow up studies" [Mesh] (16)
- #25 Search "prospective studies"[Mesh] (15)
- #26 Search "control groups" or "volunteers"[Mesh] (12630)
- #27 Search #22 OR #23 OR #24 OR #25 OR #26 (1711379)

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