

What are the best *Salvia miltiorrhiza* injection classes for treatment of unstable angina pectoris? A systematic review and network Meta-analysis

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Abstract

OBJECTIVE: To undertake a systematic review and network meta-analysis (NMA) to compare the effectiveness among the different regimens of *Salvia miltiorrhiza* injection classes (SMICs) for unstable angina pectoris (UAP) treatment.

METHODS: A systematic retrieval was conducted in several literature databases to identify randomized controlled trials focusing on the different regimens of SMICs for UAP treatment until January 2016. The quality assessment was accomplished according to the Cochrane risk of bias tool. Pair-wise meta-analyses were carried out by RevMan 5.3. A random-effects model of NMA was used to compare the different regimens of SMICs with regard to efficacy by STATA 13.0.

RESULTS: A total of 111 studies involving 10 500

patients were included in the NMA. The methodological quality of included studies was not high. Current evidence shows that salvianolate (SI) is the optimal treatment for UAP in improving the total efficacy against UAP. Guanxingning (GXN) is the optimal treatment for UAP for improving the total effectiveness of electrocardiography.

CONCLUSION: SMICs have advantages in preventing cardiovascular events. GXN, SI, and Danhong had the greatest probability of being the best treatment in the total efficacy against UAP and for improving the total effectiveness of electrocardiography.

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Keywords: *Salvia miltiorrhiza*; Angina, unstable; Review; Network Meta-analysis

INTRODUCTION

Unstable angina pectoris (UAP) is a common coronary syndrome which has the characteristic of progressive deterioration. UAP can worsen readily and lead to myocardial infarction or sudden death.¹ Research has shown that ≈30% of patients with UAP develop myocardial infarction within 3 months.² Physicians trained in Traditional Chinese Medicine (TCM) consider UAP to belong to "thoracic obstruction" or "cardiodynia", the key pathogenesis of which is *Qi*-deficiency and blood stasis.³

Danshen (*Radix Salviae Miltiorrhizae*) is the dried root and rhizome of *Salvia miltiorrhiza*. Danshen (*Radix Salviae Miltiorrhizae*) is a common TCM and used widely to treat coronary heart disease and cerebrovascu-

lar disease. Danshen (*Radix Salviae Miltiorrhizae*) contains the lipid-soluble components tanshinone I, tanshinone II A, cryptotanshinone and dihydrotanshinone as well as the water-soluble components tanshinol and salvianolic acid B (SalB).⁴ Danshen (*Radix Salviae Miltiorrhizae*) can: relax coronary artery muscle directly; improve the microcirculation by promoting blood circulation; remove blood stasis; inhibit blood clotting; reduce blood viscosity; significantly improve the hyper-viscosity of blood; inhibit thrombogenesis.⁵

Danshen (*Radix Salviae Miltiorrhizae*) is bitter and gives a slightly cold sensation when it enters the heart and liver meridians. The major functions of this herb in TCM are activating blood circulation to disperse stasis, nourishing the heart to calm the mind, and tranquilizing the mind by nourishing the heart.⁶ Several traditional Chinese injections contain Danshen (*Radix Salviae Miltiorrhizae*), and are termed "Salvia miltiorrhiza injection classes" (SMICs). These include Danshen injection (DS), Danhong injection (DH), Salvianolate injection (SI), and Guanxinning injection (GXN), and are used widely for UAP treatment.

Several Meta-analyses⁷⁻¹⁷ have demonstrated that SMICs such as DH, SI and GXN, as adjuvant treatment for conventional treatment of UAP, are beneficial compared with conventional treatment alone in terms of the total efficacy against UAP, reducing fibrinogen content, adjusting blood lipid levels, and correcting T-wave inversion. However, the comparative effectiveness of SMICs with each other is not known, mainly because of the restrictions of using different interventions together.

"Network Meta-analysis" (NMA) is a method in which multiple treatments are compared using direct comparisons of interventions within randomized controlled trials (RCTs) and indirect comparisons across RCTs based on a common comparator.¹⁸⁻²⁰

To establish the optimal treatment for UAP, we did a comprehensive NMA to integrate all available information from RCTs to compare the effectiveness of SMICs.

METHODS

Inclusion criteria

Studies had to meet three main criteria. The first criterion was the type of study, which had to be a RCT reporting on the efficacy of SMICs as adjuvant treatment for UAP, regardless of blinding. The second criterion was the patient. The diagnosis of UAP was according to the 2014 American Heart Association/American College of Cardiology Guideline for the Management of Patients with Non-ST-Elevation Acute Coronary Syndromes²¹ or the diagnosis of UAP released by the cardiovascular-disease branch of the Chinese Medical Association in 2000.²² No limit was placed on age, sex, ethnicity or disease severity. The final criterion was interventions. These were classified according to recommendation from international guidelines for UAP treat-

ment.²³ The main drugs used in Western Medicine (WM) were antiplatelet agents, nitroglycerine, beta-blockers, long-acting calcium-channel blockers, and angiotensin-converting-enzyme inhibitors. We called these drugs, used alone or in combination, "chemotherapy" (CT). Eligible comparisons for our study were: SMICs plus CT versus CT; SMICs plus CT versus SMICs plus CT. None of participants received any other Chinese medicine, surgical procedure or acupuncture.

Exclusion criteria

The studies were excluded if they met the following criteria: (a) data were incorrect or incomplete; (b) participants had other serious diseases, such as acute myocardial infarction, severe heart failure, disturbance of blood coagulation, or disease of the liver or kidneys; (c) patients were undergoing surgery, acupuncture or other physical therapy; (d) treatment was combined with another herbal medicine in experimental or control groups; (e) studies do not meet the standard for evaluation of the curative effect.

Outcome measurements

Outcome measurements were: (a) total efficacy against UAP (significantly effective + effective); (b) total effectiveness of electrocardiography (ECG); (c) cardiovascular events.

According to guidelines for the criteria of the curative effect of UAP and ECG set by the Chinese Medicine Society²⁴, the efficacy criterion was classified as "significantly effective", "effective", and "invalid".

"Significantly effective" was documented if symptoms disappeared or improved significantly, the frequency of chest pain decreased to 80%, and ECG returned to normal. "Effective" was documented if symptoms were relieved, the frequency of chest pain decreased to 50%-80%, the ST-segment recovered ≥ 0.05 mV (but not to normal), the main lead T-wave changed from flat to vertical, or T-wave inversion was $> 50\%$. "Invalid" was documented if symptoms did not change or worsened, the frequency of chest pain did not decrease (or even increased), and ST-T waves did not change or worsened.

Data sources and search strategies

Two authors (Liu Shi and Zhang Dan) searched the following databases from inception to 31 January 2016: PubMed, The Cochrane Library, Embase, China National Knowledge Infrastructure Database (CNKI), Wanfang Database, China Science and Technology Journal Database (VIP) and China Biology Medicine disc (CBMdisc). Medical subject headings (MeSH) and free text words were used. No language or other restrictions were imposed. Apart from searching these electronic databases of works written in Chinese and English, we also searched RCTs at the Internet websites of related academic organizations. As an example, the search strategy employed for PubMed is shown as below.

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