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SYSTEMATIC REVIEW

Danshenchuanxiongqin injection in the treatment of unstable angina pectoris: a systematic review and Meta-analysis

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Abstract

OBJECTIVE: To evaluate systematically the efficacy and safety of Danshenchuanxiongqin Injection (DCI) in the treatment of unstable angina pectoris (UAP).

METHODS: Randomized controlled trials (RCTs) regarding DCI used for treating UAP were searched in English and Chinese electronic databases from inception to January 2014. Two reviewers independently retrieved RCTs and extracted relevant information. The Cochrane risk of bias method was used to assess the quality of included studies, and a Meta-analysis was conducted with Review Manager 5.2 software.

RESULTS: Eleven RCTs involving 1034 participants were included. The methodological quality was relatively passable. The Meta-analysis indicated that the combined use of DCI and conventional treatment with Western Medicine (WM) was more efficacious in the outcomes of total effective rate [Relative Risk (RR) = 1.27, 95% *CI* (confidence interval; 1.18, 1.35), $P < 0.000\ 01$], the total effective rate of ECG [RR = 1.40, 95% *CI* (1.18, 1.66), $P < 0.000\ 01$], total cholesterol [Mean difference (MD) = − 0.58, 95% *CI* (− 0.83, − 0.33), $P < 0.000\ 01$], total triglycerides [MD = − 0.36, 95% *CI* (− 0.54, − 0.17), $P = 0.0001$], and the number of ST-segment depression [MD = − 0.36, 95% *CI* (− 0.54, − 0.17), $P = 0.0001$]. There were two adverse drug reactions reported in one study.

CONCLUSION: Based on the systematic review, DCI combined with WM appeared to be efficacious in the treatment UAP. However, the evidence of DCI for treating UAP requires large-scale and double-blind RCTs to substantiate these findings.

Key words: Danshenchuanxiongqin injection; Angina, unstable; Review; Meta-analysis

INTRODUCTION

Unstable angina pectoris (UAP) is a series of clinical syndromes, which belongs to ischemic cardiovascular and cerebrovascular diseases.[1] It has the characteristics with severe chest pain, long duration, poor efficacy of nitrates, and easily deteriorating into AMI or sudden death.[2] Therefore, UAP has been one of research hotspots in recent years.

Modern medical research has shown that the pathological basis of UAP is local coronary artery with ischemic lesion,[3] which is mainly related to vascular endothelial injury, platelet activation barriers, inflammation response, vasospasm, thrombosis formation and other relevant factors.[4,5] Currently, the conventional therapy with Western Medicine (WM) includes anti-ischemia, anti-thrombosis, thrombolysis and lipid-lowering, however, the treated patients may have headaches, heart palpitations, or other side effects that caused by the overdose.[6-8] In view of this, to explore an efficacious, safe, convenient and economical treatment measure is very important.

In Traditional Chinese Medicine, UAP can be treated by invigorating *Qi* and promoting blood circulation. [9] Danshenchuanxiongqin injection (DCI) is a phytochemical drug that synthesized by Ligustrazine Hydrochloride (chemical name: 2,3,5,6 - tetramethyl pyrazine hydrochloride), which is extracted from Chuanxiong (*Rhizoma Chuanxiong*), and tanshinol [chemical name: β-(3, 4- dihydroxyphenyl) lactic acid], which is extracted Danshen (*Radix Salviae Miltiorrhiae*). Modern research has shown that tanshinol can increase coronary blood flow, improve microcirculation, promote open collateral circulation, reduce extent of myocardial ischemia, and protect the ischemic myocardium. At the same time, it can improve blood rheology index, increase the hypoxia tolerance, anti-peroxidation of lipid, reduce free radicals, and so on. Ligustrazine is a new calcium antagonist, which can inhibit the production of free radical, improve the activity of endogenous superoxide dismutase, inhibit platelet aggregation and fibrosis, and regulate the lipid Metabolism.[10-12] The two active ingredients are combined to have strong efficacy on dilating coronary arteries, reducing blood viscosity, improving hemodynamics and microcirculation, regulating the platelet function and anticoagulation.[13]

There was one systematic review[14] regarding DCI in the treatment of angina pectoris, but it may lack some preciseness that drugs used in control groups had big difference. Therefore, it is necessary to assess the current trials to systematically review the potential effect and safety for the use of DCI in the treatment of UAP.

MATERIALS AND METHODS

This study was conducted according to the Cochrane practice, including pre-specified objectives, search strategy, inclusion and exclusion criteria, quality assessment, data collection and Meta-analysis.

Study search

Randomized controlled trials (RCTs) were respectively retrieved by searching the following databases from January 1979 to January 2014: China National Knowledge Infrastructure (CNKI), Wanfang Database, China Science and Technology Journal Database (VIP), Chinese Biomedical Literature Database (CBM), PubMed, and Cochrane Library. No limit placed on published language.

Different search strategies were combined as follows: for English databases, such as PubMed, the search terms included ("Danshenchuanxiongqin" [Full text] OR "danshen chuanxiongzine" [Full text] OR "danshenchuanxiongqin" [Full text] OR "danshenchuanxiongzine" [Full text] OR "salviae miltiorrhizae and ligustrazine" [Full text]) AND ("Unstable angina pectoris" [MeSH terms] OR "angina" [MeSH terms] OR "pectoris" [MeSH terms] OR "preinfarction angina" [MeSH terms] OR "preinfarction anginas"); for Chinese databases, such as CNKI, the search terms included ("Danshenchuanxiongqin" [MeSH terms]) AND "Bu Wen Ding Xin Jiao Tong" [MeSH terms] OR "Bu Wen Ding Xing Xin Jiao Tong" [MeSH terms]).

Inclusion criteria

Studies met the following criteria were included. RCTs regarding DCI in the treatment of UAP were included, regardless of blinding. The diagnostic criterion of UAP was determined by Branch of Chinese Medical Society of Cardiology in 2000, which including the frequency of chest pain paroxysm, the duration, the activity thresholds induced angina, and the abnormal ST-segment of ECG. [15] No limit was placed on patients' age, gender, and races. The experiment group and control group were both given the WM therapy, such as anti-ischemia, anti-thrombosis, thrombolysis and lipid-lowering. Based on the treatment that used in the control group, DCI was given to the experiment group. The efficacy criterion was "clinical guidelines for cardiovascular system drugs", which was determined by Ministry of Health Pharmaceutical Council in 1993.[16] The primary outcomes were the total clinical effective rate and the total effective rate of electrocardiogram (ECG). The total effective rate = (number of patients of significantly effective + number of patients of effective) / total number × 100 %. Significantly effective was determined when the same degree of exertion did not cause UAP, at least reduce over 80%, or the improvement of angina degree is over grade Ⅱ. Effective was determined by the number of angina episode decreased by 50%-80%, or the improvement of angina degree in grade Ⅰ-Ⅱ. Invalid was determined that the number of angina episode decreased within 50%, or the improvement of angina degree within grade Ⅰ, even no improvement. The total effective rate of ECG = (number of patients of significantly effective + number of patients of effective) / total number × 100%. Significantly effective was determined when ECG moves down, and the recovery of ST-segment is over 0.1mV or return to normal at resting. Effective was determined when the recovery of ST-segment is in 0.05-0.1 mV or the inverted T-wave is lighter than 50%. Invalid was determined when ECG is the same as that before treatment at resting. Secondary outcomes were hemorheology indicators, such as total cho-