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<http://www.journaltcm.com>Effectiveness and safety of Shenmai injection in treatment of shock: A Meta-analysis<sup>☆</sup>Li Xiaoli<sup>a</sup>, Shen Yi<sup>b</sup>, He Fan<sup>c</sup>, Zhu Yinchao<sup>d</sup>, Li Fudong<sup>c,\*</sup><sup>a</sup> Department of Gynecology, The Second Affiliated Hospital of Zhejiang University School of Medicine, Hangzhou, 310009, China<sup>b</sup> Department of Epidemiology and Health Statistics, School of Public Health, Zhejiang University, Hangzhou, 310058, China<sup>c</sup> Department of Public Health Surveillance and Advisory, Zhejiang Provincial Center for Disease Control and Prevention, Hangzhou, 310051, China<sup>d</sup> Institute of Non-Communicable Disease Control and Prevention, Ningbo Municipal Center for Disease Control and Prevention, Ningbo, 315010, China

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## ABSTRACT

**Objective:** To evaluate the effectiveness and safety of Shenmai injection for shock.**Methods:** Randomized controlled trials (RCTs) that evaluated the therapeutic effect of Shenmai injection on shock (including septic shock, cardiogenic shock, hypovolemic shock, neurogenic shock and anaphylactic shock) were included in this analysis. The major electronic databases were searched until May 2015. The methodological quality of the trials was assessed according to the Cochrane Handbook. Review Manager 5.3 and Stata 12.0 software were applied for data analysis.**Results:** Thirty RCTs involving 2038 participants were included. The methodological quality of the trials was generally passable. The combined use of Shenmai injection and conventional medicine was significantly more effective at managing shock compared to conventional medicine alone in the outcomes of total effective rate [risk ratio (RR) 1.25, 95% confidence interval (CI) 1.18–1.31] and mortality rate [risk difference (RD) –0.10, 95% CI –0.17 to –0.02]. Likewise, improvements were observed in other metrics. Three trials reported adverse events, but no trial reported serious adverse effects.**Conclusions:** Our results indicated the potential effectiveness of Shenmai injection combined with conventional medicine treatment for shock. However, further rigorously designed trials are needed to collect and weigh up all the evidence for the use of Shenmai injection.

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## 1. Introduction

Shock is a life-threatening, generalized form of acute circulatory failure associated with inadequate oxygen utilization by the cells [1,2]. It was reported that up to one-third of patients admitted to the intensive care unit were in shock [3]. Shock can result in multiorgan failure and a high mortality rate, making immediate intervention necessary [4]. Traditional Chinese Medicine (TCM) has been believed with potential effects for treating shock. In China, Shenmai, a kind of traditional Chinese herbal medicine, is usually used as a complementary treatment to recommended western treatments for shock [5]. It is a mixture of two herbal components: Renshen (*Radix Ginseng*) and Maidong (*Radix Ophiopogonis Japonici*)

[6]. These herbs are combined but there is no standard proportion for each herb. There are commonly four forms of Shenmai, including capsule, powder, oral liquid and injection.

Several trials have shown that Shenmai injection might have therapeutic potential for patients with shock. Nevertheless, the quality of these studies, as well as the efficacy and safety of Shenmai injection, has not been evaluated systematically, which is valuable for clinical practice and required for TCM to receive approval in international medical fields. Therefore, we conducted this Meta-analysis to assess the benefits and adverse effects of Shenmai injection plus conventional medicine treatment versus conventional medicine for the treatment of shock in adult patients.

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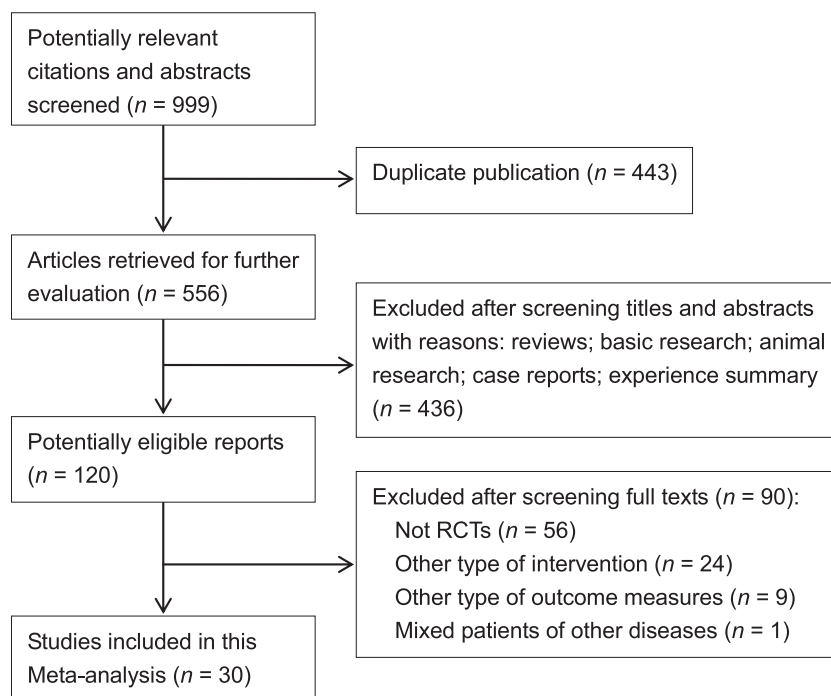


Fig. 1. Flow diagram of studies identification.  
RCTs: randomized controlled trials.

## 2. Methods

### 2.1. Eligibility criteria

Types of study design: randomized controlled trials (RCTs) to evaluate Shenmai injection for shock, irrespective of allocation concealment and blinding status were included in this analysis. The trials using randomization methods (either clear description or unclear description), are included.

Types of participants: the trials included participants regardless of gender, age and ethnic group. In each included trial, shock was clearly diagnosed according to the guideline [7] developed in 2006, and each type of shock was considered, such as septic shock, cardiogenic shock, hypovolemic shock, neurogenic shock and/or anaphylactic shock.

Types of interventions: shenmai injections plus conventional medicine treatment was compared with conventional medicine alone. Shenmai was defined in this review as the products derived from Renshen (*Radix Ginseng*) and Maidong (*Radix Ophiopogonis Japonici*). Trials were included regardless of dosage and duration of treatment.

Types of outcome measures: the primary outcome measures included total effective rate and mortality rate. The secondary outcome measures included heart rate, blood pressure, urine volume, Killip classification and left ventricular ejection fraction (LVEF). The number and type of adverse events in each study were also noted. The criteria for clinical effect were based on "Consensus on circulatory shock and hemodynamic monitoring" [8], which was developed by the European Society of Intensive Care Medicine. The total effective rate = number of patients who respond to the therapy effectively/total number of patients × 100%. Effectiveness was defined as recovery of symptoms and signs of shock after the therapy.

### 2.2. Search strategy

We systematically searched the following electronic databases from each database's inception to May 2015: PubMed, the

Cochrane Library, EBSCO–MEDLINE Complete, BIOSIS, BioMed Central, Web of Knowledge; and four Chinese databases: China National Knowledge Infrastructure Database (CNKI), VIP Journal Integration Platform, Wanfang Database and Chinese Biomedical Literature Database. Different search strategies were combined as follows: for English databases, such as PubMed, the search terms included ("Shenmai" [Title/Abstract] OR "Shen-mai" [Title/Abstract] OR "Shen mai" [Title/Abstract] OR "Panax and Ophiopogon" [Title/Abstract]) AND ("shock" [MeSH terms]); for Chinese databases, such as CNKI, the search terms included ("Shenmai" [Abstract] OR "Renshen and Maidong" [Abstract]) AND ("Xiu Ke" [Subject]). The specific search procedure varied in some cases according to the different interface settings of each database. No language restrictions were applied. We also searched references in published articles, reviews and relevant articles. Finally, we searched the websites of grey literature (<http://www.opengrey.eu/>, <http://www.greylit.org/home>) to include unpublished studies.

The search strategy for PubMed is as follows:

- #1 "Shenmai" [Title/Abstract]
- #2 "Shen-mai" [Title/Abstract]
- #3 "Shen mai" [Title/Abstract]
- #4 "Panax and Ophiopogon" [Title/Abstract]
- #5 "Shock" [MeSH terms]
- #6 #1 OR #2 OR #3 OR #4
- #7 #6 AND #5

### 2.3. Study selection and data extraction

Two researchers screened the titles, abstracts and the full texts independently using a standardized screening guide. Initially, abstracts were screened to exclude obviously ineligible reports then the full texts were reviewed for all the remaining studies. Any disagreement was resolved by discussion. Characteristics and information of each included study was obtained for further description, quality assessment and data analysis.

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