

## SYSTEMATIC REVIEW

## Safety and effectiveness of Traditional Chinese Medicinal herbs for diabetic foot: a systematic review and Meta-analysis

Chen Shuo, Ma Jianwei, Xu Limei, Niu Tianhui, Dong Jing, Liu Wenjun, Han Qi

**Chen Shuo**, Beijing Drum Tower Hospital of Traditional Chinese Medicine, Beijing 100009, China

**Ma Jianwei, Xu Limei, Niu Tianhui, Dong Jing, Liu Wenjun**, Department of Traditional Chinese Medicine General Hospital of the Air Force PLA, Beijing 100042, China

**Han Qi**, Department of Dalian Medical University, Dalian 116027, China

**Supported by** Capital Characteristic Clinical Application Research Subject: the Clinical Study of Comprehensive Therapy of Traditional Chinese Medicine Combine and Western Medicine to Improve the Efficacy of the Early to Mid-term Diabetic Foot (No. Z121107001012011)

**Correspondence to: Prof. Ma Jianwei**, Department of Traditional Chinese Medicine General Hospital of the Air Force PLA, Beijing 100042, China. [mjw8166@163.com](mailto:mjw8166@163.com)

**Telephone:** +86-15611161118

**Accepted:** January 9, 2017

### Abstract

**OBJECTIVE:** To evaluate the safety and effectiveness of traditional Chinese medicinal herbs (TCMHs) as an adjunctive treatment for diabetic foot (DF).

**METHODS:** The sources used were PubMed (1966 to August 2015), the Cochrane Library (1988 to August 2015), the Excerpta Medica Database (1974 to August 2015), Wiley (1807 to August 2015), Ovid (1988 to August 2015), ClinicalTrials.gov (1993 to August 2015), the Cochrane Central Register of Controlled Trials (1966 to August 2015), China Science and Technology Journal Database (1994 to August 2015), ChiCTR (2007 to August 2015), SinoMed (1978 to August 2015), the China National Knowledge Infrastructure (1984 to August 2015), Wanfang Data Knowledge Service Platform (1998 to Au-

gust 2015), and the Traditional Chinese Medical Literature Analysis and Retrieval System (TCMLARS) (1984 to August 2015). Studies were identified and selected, and the data were extracted by two independent reviewers. The Cochrane Risk of Bias tool was used to assess the quality of studies. Revman 5.2 software was used for data synthesis and analysis.

**RESULTS:** Sixteen studies were included based on the selection criteria. Of these, seven studies had low bias risk and one had high bias risk. In the overall analysis, TCMHs resulted in a significantly higher total effective rate (*OR* 5.08; 95% *CI* 3.50 to 7.36; *P* < 0.000 01), cure rate (*OR* 2.12; 95% *CI* 1.63 to 2.77; *P* < 0.000 01), and shorter time to ulcer healing (*SMD* - 0.64; 95% *CI* - 0.89 to - 0.40; *P* < 0.000 01) when compared with non-TCMHs treated DF. The analysis also revealed that significantly fewer amputations occurred in TCMHs patients (*OR* 0.36; 95% *CI* 0.20 to 0.65; *P* = 0.0007). Sensitivity analysis indicated that the findings of the Meta-analysis were robust to study quality, and the funnel plot of the Egger test showed no publication bias.

**CONCLUSION:** TCMHs intervention appears to be more effective for DF, with a similar safety profile, when compared with non-TCMHs treatments, although this result requires further verification with more well-designed studies.

© 2017 JTCM. This is an open access article under the [CC BY-NC-ND license](#).

**Keywords:** Diabetic foot; Medicine, Chinese Traditional; Randomized controlled trial; Meta-analysis

## INTRODUCTION

Diabetic foot (DF), a common and serious complication of diabetes, is the major cause of amputation and death.<sup>1</sup> As the world is facing an epidemic of type 2 diabetes and an increasing incidence of type 1 diabetes,<sup>2,3</sup> the International Diabetes Federation chose to focus on the global burden of DF disease in 2005. The lifetime risk of a person with diabetes developing a foot ulcer could be as high as 25%,<sup>4</sup> and it is believed that every 30 s a lower limb is lost somewhere in the world due to diabetes.<sup>5</sup>

Conventional therapies for DF include foot care, glucose control, improving blood supply, providing nutrients to the nerve cells, management of infection, and debridement. However, treatment outcomes are lackluster. Even with the comprehensive treatment regimens available, only 24% or 30% of diabetic foot ulcers (DFUs) heal within 12 or 20 weeks respectively, and patients are prone to serious complications, including wounds, osteomyelitis, cellulitis, and amputation.<sup>6-8</sup> Up to 40% of DFUs may require amputation, and after a major amputation, 50% patients will require another major amputation within two years.<sup>9-11</sup> The relative mortality after amputation is around 50%, which is second only to lung cancer (86%), and higher than colorectal (39%) or breast cancer (23%).<sup>12</sup>

In China, traditional medicinal herbs (TCMHs) have been used for the treatment of DF, including internal treatment, external treatment, and combined treatment using traditional Chinese and Western Medicine, which has achieved good clinical efficacy.<sup>13</sup> However, the safety and effectiveness of TCMHs for the treatment of DF have not been confirmed by strong evidence-based medicine. Therefore, based on a systematic review and meta-analysis, this study aimed to evaluate the safety and effectiveness of TCMHs as an adjunctive treatment for DF, in order to provide a theoretical basis for this clinical practice.

## MATERIALS AND METHODS

### *Search principle*

Complying with the guidelines from the Cochrane Collaboration,<sup>14</sup> the following electronic databases were searched from their inception through August 2015: PubMed (1966 to August 2015), the Cochrane Library (1988 to August 2015), the Excerpta Medica Database (EMBASE) (1974 to August 2015), Wiley (1807 to August 2015), Ovid (1988 to August 2015), ClinicalTrials.gov (1993 to August 2015), the Cochrane Central Register of Controlled Trials (1966 to August 2015), China Science and Technology Journal Database (VIP) (1994 to August 2015), ChiCTR (2007 to August 2015), SinoMed (CBM) (1978 to August 2015), the China National Knowledge Infrastructure (CNKI) (1984 to August 2015), Wanfang Data Knowl-

edge Service Platform (1998 to August 2015), and the Traditional Chinese Medical Literature Analysis and Retrieval System (TCMLARS) (1984 to August 2015). The search terms used were as follows: "Chinese herbal medicine" or "herb" or "East Asian traditional" or "drugs Chinese herbal" and "diabetic foot" or "diabetic leg ulcer" or "diabetic wounds" and "therapy" and "Random control trail (RCT)". The search strategy was adjusted for each database. In addition, the references of relevant articles and proceedings were examined for additional relevant literature. We did not limit based on publication language or type, including conference proceedings and theses, as long as they met our inclusion criteria. The retrieved articles were imported into Endnote X6 (Endnote X6 THOMSON USA Connecticut) for document management and analysis. For example, the PubMed database retrieval strategy is shown as below.

```
#1 Randomized controlled trial pt
#2 Controlled clinical trial pt
#3 Randomized tiab
#4 Trial tiab
#5 Randomly tiab
#6 Groups tiab
#7 Drug therapy sh
#8 Placebo tiab
#9 #1 OR#2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8
#10 Diabetic foot
#11 Diabetic leg ulcer
#12 Diabetic wounds
#13 #10 OR #11 OR #12
#14 Chinese herbal medicine
#15 Herb
#16 East asian traditional
#17 Drugs chinese herbal
#18 #14 OR #15 OR #16 OR #17
#19 #9 OR #13 AND #18
```

### *Study selection*

RCTs were adopted when comparing TCMHs combined with conventional therapy in the treatment group with conventional therapy alone in the control group for patients with DF. Conventional therapy was defined as standard DF treatment with or without controlling glucose, improving blood supply, supplying nutrients to the nerve cells, prescribing antibiotics, and debridement. In addition, the study had to report on effectiveness and/or safety indicators. Effectiveness outcomes included total effectiveness rate, complete healing rate, amputation rate, change in ulcer size, and ulcer healing time. The safety profile included adverse events such as diarrhea, itchy skin, edema, pain, bleeding, localized wound infection, and abnormal liver or kidney function occurring during the trials. Total effectiveness rate, cure rate, adverse events and the amputation rate were taken as primary outcomes. Sufficient details had to be reported to allow the calculation of the

Download English Version:

<https://daneshyari.com/en/article/8818189>

Download Persian Version:

<https://daneshyari.com/article/8818189>

[Daneshyari.com](https://daneshyari.com)