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## Original Article

# Efficacy of combining traditional Chinese medicine fumigation with Western medicine for diabetic peripheral neuropathy: A systematic review and meta-analysis

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## ABSTRACT

**Objective:** A systematic review and meta-analysis was conducted to evaluate the effectiveness of supplementing Western medicine with Traditional Chinese medicine (TCM) fumigation in patients with diabetic peripheral neuropathy.

**Methods:** The China Biomedical Literature, Chinese full-text periodical, China National Knowledge Infrastructure, WanFang, PubMed, Embase, and Cochrane Library databases were searched for relevant randomized controlled trials published from inception through May 2015. The methodological quality of eligible studies was evaluated using the Cochrane Risk Bias Assessment tool, and summarized effects were calculated using Reviewer Manager 5.1 software. Subgroup analysis was conducted based on the duration of intervention.

**Results:** The initial search identified 312 relevant studies, of which 40 randomized controlled trials involving 3497 patients were eligible for analysis. The results indicated that TCM fumigation significantly improved the curative effects [risk ratio (RR) = 1.34, 95% CI (confidence interval): 1.29–1.39], common peroneal motor nerve conduction velocity [standard mean difference (SMD) = 2.93, 95% CI: 2.26–3.61], common peroneal sensory nerve conduction velocity (SMD = 2.23, 95% CI: 1.46–3.01), and plasma viscosity (SMD = –1.02, 95% CI: –1.35–0.69) compared to Western medicine alone (all  $p < 0.01$ ). A subgroup analysis indicated that the curative effects were significant after 15 days (RR = 1.31, 95% CI: 1.21–1.42), 30 days (RR = 1.33, 95% CI: 1.26–1.40), and 60 days (RR = 1.50, 95% CI: 1.32–1.71) of combined treatment (all  $p < 0.01$ ).

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**Conclusion:** TCM fumigation significantly improves the clinical outcomes of diabetic peripheral neuropathy, though further confirmatory studies are needed.

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## 1. Introduction

Diabetic peripheral neuropathy (DPN) is the most common chronic complication of diabetes mellitus [1]. It is the main contributor to diabetic foot ulcers, which are responsible for the majority of non-traumatic amputations, and ultimately increases the risk for mortality in diabetic patients [2,3]. The pathogenesis of DPN is not well understood, and current Western medicines fail to adequately treat this condition [4]. However, Traditional Chinese medicine (TCM) offers considerable advantages over Western medicine for the treatment of chronic diseases and their associated complications. For example, previous work has shown that TCM fumigation promotes local circulation of blood and lymphatic fluids via stimulation of blood vessels and nerves [5]. Nonetheless, data demonstrating the benefits obtained from TCM fumigation in DPN patients are inconclusive. This systematic review and meta-analysis of randomized controlled trials was conducted in order to evaluate the efficacy of TCM fumigation compared to Western medicine alone in the treatment of patients with DPN.

## 2. Materials and methods

The search and screening of all potential studies, extraction of data, assessment of study quality, and analysis and reporting of results in this study were all in accordance with the Preferred Reporting Items for Systematic Review and Meta-analysis [6] and Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [7]. All analyses were conducted on data extracted from previously published studies; therefore, ethical approval and informed consent were not required.

### 2.1. Literature search

Two investigators (L. Zhang and X. Tian) independently searched for potential studies that compared Western medicine and TCM fumigation with Western medicine alone for treatment of DPN listed in PubMed, EMBASE, the Cochrane Central Register of Controlled Trials, Google Scholar, [Clinicaltrials.gov](http://clinicaltrials.gov) (<http://clinicaltrials.gov>), China Biomedical Literature, Chinese full-text periodical, Wanfang, and China National Knowledge Infrastructure databases up through May 2015. The following search terms were used: “diabet\*” OR “diabetes mellitus” (Mesh) AND “peripheral neuropathy” OR “neuritis” (Mesh) OR “peripheral nerve” OR “peripheral neur\*” AND “Traditional Chinese medicine fumigation” OR “fumigation\*” OR “fumigation” (Mesh) OR “embalm wash” OR “drug

fumigation” AND “randomized controlled trial” (publication type) OR “randomized controlled trials as topic” (Mesh) OR “random\*” AND human NOT animal. The reference lists of topic-related reviews and eligible studies were also searched to include any latent articles and guarantee the recall ratio. Only studies published in English or Chinese languages were eligible. Any discrepancies that occurred during the search and selection of literature were resolved by discussion with a third investigator (Y. Ma).

### 2.2. Selection criteria

Selection criteria were specified *a priori* according to the PICOS acronym: population, all diabetic patients with DPN were eligible [8]; interventions and comparisons, studies comparing the efficacy of Western medicine (methycobal, alprostadiol, alpha lipoic acid, ligustrazine, vitamin B1, vitamin B6, or epalrestat) plus TCM fumigation or alone; outcomes, the outcomes included in this study were total effect rate (defined as self-conscious symptom and tendon reflection improvement, electromyography nerve conduction velocity increase <5 m/s, or the traditional Chinese medicine syndrome integral reduce 30% or higher), nerve conduction velocity, vibration perception threshold, and plasma viscosity; study design, only randomized controlled trials were included. Any discrepancies that occurred between authors concerning the eligibility of a study were resolved by consulting a third author (Y.-H. Jing) or by consensus.

### 2.3. Data extraction

The total effective rate and nerve conduction velocity were extracted as primary outcomes, and vibration perception threshold and plasma viscosity were specified as secondary outcome measures of interest in this study. Relevant data were independently extracted from eligible full-text articles by two investigators (L. Zhang and F.-J. Meng) using a pre-designed standardized data extraction form. If essential information from an included study was incomplete, the corresponding author of the original study was contacted. Any discrepancies that occurred between authors concerning the extracted data were resolved by consulting a third author (L. Zhang).

### 2.4. Quality assessment

The Cochrane Risk of Bias tool released by the Cochrane Collaboration was used to assess the methodological quality of each of eligible study [7]. Six domains, including selection, performance, detection, attrition, reporting, and other biases,

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