

INPLASY PROTOCOL

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None declared.

Effects of acupuncture on pain in diabetic peripheral neuropathy: a systematic review and meta-analysis of randomized controlled trials

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Review question / Objective: The purpose of this review is to determine the efficacy and safety of acupuncture on diabetic peripheral neuropathy (DPN) pain compared with analgesics or sham acupuncture. Randomized controlled trials are the only types of studies included in this review.

Condition being studied: Diabetic peripheral neuropathy (DPN) is a common complication of type 1 and 2 diabetes. It is also the main cause of lower limb amputation and disability in patients with diabetes. Epidemiological evidence shows that up to 50% of patients with diabetes developed neuropathy during their long-term course of disease. The cause of DPN is not completely clear, but older age, longer diabetic duration and worse postprandial glucose control has been proved to be closely related to DPN. Distal symmetric polyneuropathy is the most typical manifestation of DPN, and about 10% to 30% of the affected patients may experience symptoms of neuropathic pain. Pain can be described as burning pain, electrical or stabbing sensations, parasthesiae, hyperasthesiae, and deep aching pain of the feet and lower limbs at night. This irreversible and unbearable pain greatly affects patients' sleep and quality of life.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 05 September 2022 and was last updated on 05 September 2022 (registration number INPLASY202290019).

INTRODUCTION

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METHODS

Participant or population: Participants must be clinically diagnosed as having DPN and must not be < 18 years old. No limit to the gender, race and other basic information of the participants.

Intervention: Manual acupuncture (MA) and electroacupuncture (EA).

Comparator: DPN routine medication or usual care, sham acupuncture, laser acupuncture, transcutaneous electrical nerve stimulation (TENS).

Study designs to be included: Randomized controlled trials.

Eligibility criteria: 1) Other types of research such as observation studies, animal studies, conference summaries. If the sample size of the RCT study is less than 10, it will be excluded. 2) Non-penetrating acupuncture types (e.g. TENS, acupuncture

pressure). Acupuncture combined with moxibustion or traditional Chinese Medicine (TCM) decoction, western medicine. The control group included acupuncture treatment (such as the study of comparing different acupuncture points). 3) Pain-related outcome measurements have not been clearly reported. 4) Using languages other than Chinese and English. Duplicate articles.

Information sources: Pubmed, Embase, Cochrane Library and Clinicaltrials.gov, the China National Knowledge Infrastructure (CNKI), Wanfang database, the Chinese Biomedical Database (SinoMed).

Main outcome(s): The main outcome was pain relief, assessed as dichotomous (effective proportion of patients with pain relief) and continuous (pain score) variables.

Quality assessment / Risk of bias analysis: Cochrane Collaboration's Risk of Bias tool is used to assess the offset risk included in the RCT study.

Strategy of data synthesis: We calculated the relative risk (RR) and 95% confidence interval (CI) for binary outcomes. For continuous data, the mean difference (MD) and 95% CI were calculated. If the result measurements were different, the standardized mean difference (SMD) was calculated. $P < 0.05$ was considered to be statistically significant. The I² test was used to evaluate the heterogeneity between studies. We defined I² $> 50\%$ to represent significant heterogeneity, and meta-analysis used a random effect model, whereas a fixed effect model was used. We used a funnel chart to evaluate the publication offset (at least 10 studies were included). All operations were done in Review Manager 5.3.

Subgroup analysis: We performed subgroup analyses as needed for the study, such as by patient's disease duration (10 years) or type of acupuncture used (manual acupuncture or electroacupuncture).

Sensitivity analysis: We performed sensitivity analysis by omitting one study at a time to observe their impact on the pooled effects. All operations were done in Review Manager 5.3.

Country(ies) involved: China.

Keywords: DPN pain; Acupuncture; Systematic Review; Meta-analysis.

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