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SYSTEMATIC REVIEW

Efficacy and safety of puerarin injection in treatment of diabetic peripheral neuropathy: a systematic review and Meta-analysis of randomized controlled trials

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Abstract

OBJECTIVE: To systematically evaluate the clinical efficacy and safety of puerarin injection in the treatment of diabetic peripheral neuropathy (DPN).

METHODS: Randomized controlled trials investigating the efficacy of puerarin injection on DPN were searched for in China National Knowledge Infrastructure Database, Chinese Scientific Journals Database, Wanfang Database, Chinese Biomedical Literature Database, PubMed, and Cochrane Library from establishment to April 30. Two reviewers independently retrieved and extracted the information. The included studies were assessed by the Cochrane risk of bias and analyzed by Review Manager 5.2 software.

RESULTS: Twenty-two studies involving 1664 participants were included. The quality of the studies was found to be relatively low. Meta-analysis showed that puerarin injection combined with western medication was more effective than conventional therapy for DPN in terms of total effective rate, nerve conduction velocity (NCV), and hemorheology index. Six adverse drug reactions (ADRs) from puerarin injection were reported in two studies. Reactions included facial flushing, palpitations, and pain at infusion locations. However, no serious ADRs were reported.

CONCLUSION: Puerarin injection was effective for the treatment of DPN. Puerarin can improve the total effective rate, correct NCV that was decreased by diabetes, and improve the hemorheology index. Puerarin was also relatively safe clinically. However, since the articles included in the study were not high-quality, more studies should be conducted to strengthen their findings.

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Key words: Puerarin; Diabetic neuropathies; Treatment outcome; Meta-analysis; Randomized controlled trials

INTRODUCTION

Diabetic peripheral neuropathy (DPN) is one of the most common neuropathies caused by diabetes mellitus (DM). Its prevalence is 30%-90%.[1] DPN is one of the most debilitating factors in DM patients.[2] The clinical symptoms of DPN are intermittent, persistent limb pain, featuring burning or chisel-like sensations. The symptoms are often aggravated at rest or at night.

Patients may develop hypoesthesia or suffer paresthesia with numbness or electric shock-like sensations.[3] Some studies showed that both the relationships between prevalence and course and prevalence and severity of DM were not obvious.[4] If patients with DPN can be diagnosed earlier, then given timely positive blood glucose control and necessary foot care, they can avoid foot ulcers, gangrene, amputation, and other serious consequences.[5]

For Western Medicine, no effective therapy is available for the treatment of DPN. Methylcobalamin and neurotrophin are usually used clinically, but they are expensive and have a long course of treatment.[2] Traditional Chinese Medicine (TCM) provides an option for DPN treatment and has shown certain advantages over Western Medicine. TCM physicians consider the pathology of DPN to be a stasis syndrome. The key of the pathogenesis is Yang deficiency and collateral stasis. After the 1990s, puerarin injection has been used for the treatment of DPN. Puerarin is one of the flavonoids extracted from Gegen (*Radix Puerariae Lobatae*).[6] Modern pharmacological studies[7] have confirmed that puerarin can lower blood sugar, significantly improve microcirculation, expand the coronary arteries, reduce platelet aggregation and blood viscosity, and improve the sensitivity of insulin receptors.

Therefore, this systematic review aimed to evaluate the efficacy and safety of puerarin injection for the treatment of DPN to provide a scientific basis for its use.

METHODS

Database searched

Two reviewers searched the following databases from establishment to April 30, 2013: China National Knowledge Infrastructure, Wanfang Data, Chinese Scientific Journals Database, Chinese Biomedical Literature Database, PubMed, and Cochrane Library. The search terms were "Puerarin injection" and "diabetic peripheral neuropathy." Studies published in English or Chinese were considered.

Inclusion criteria

Studies that met the following criteria were included: randomized controlled trials (RCTs) administering puerarin for DPN, irrespective of publishing language, and DPN caused by DM including both type Ⅰ and type Ⅱ. Cases were excluded if the DPN was caused by other diseases. Age, sex, and race were not limited. The diagnostic criteria of DM were World Health Organization diagnostic criteria for diabetes (1999), or American Diabetes Association diagnostic criteria (1997). The diagnostic criteria of DPN followed the "Diabetes TCM Prevention Guide: diabetic peripheral neuropathy" released by Association of Chinese Medicine in 2007.[3] All participants blood glucose levels and nerve conduction velocity (NCV) indexes were available.[8]

Intervention measures

Both the control and experimental groups received primary treatment to strictly control blood glucose, improve microcirculation, correct metabolic disorders, dilate blood vessels, and nourish nerves. In the control group, the conventional medications for DPN were methylcobalamin, PGE 1, vitamin B, and nimodipine. The therapy for the experimental group was puerarin injection combined with the medications of the control group. The main interventions were puerarin *vs* Western Medicine, puerarin + Western Medicine *vs* Western Medicine. The therapy for the experimental group did not include any other TCM medications.

Outcomes

Primary outcome was the total effective rate. The total effective rate=(the number of patients with significant effect + the number of patients with effect)/ total number of patients. A "significant effect" meant that limb pain, numbness, and fatigue were significantly reduced, nighttime sleep was improved, and NCV from electromyography increased >5 m/s or returned to normal. An "effect" meant that the symptoms mentioned above were relieved, and NCV compared with pre-treatment increased <5 m/s. "Failure" meant that the symptoms did not improve, and there were no changes in NCV. Secondary outcomes included hemorheology index with glycosylated hemoglobin (HbA1c), fibrinogen (Fb), and plasma viscosity (η_p). The NCV index of peroneal nerve and median nerve included the motor nerve conduction velocity (MNCV) and sensory nerve conduction velocity (SNCV). The number of adverse drug reactions (ADR)/adverse drug events (ADE) occurred was counted.

Data extraction and quality assessment

For the included studies, data were extracted independently by two reviewers according to the inclusion criteria, intervention measures, and outcomes. Disagreement was resolved through discussion or assistance by a third researcher. Data included study type, patient characteristics, and information about treatment. We assessed the risk of bias of the included trials strictly according to the Cochrane risk of bias tool, which included random sequence generation, allocation concealment, blinding of participants and research staff, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias. For each item, there were three choices: low risk of bias, unclear, and high risk of bias. When inadequate information was presented in the article and we were unable to explicitly judge the item with "high, low or unclear."

Statistical analysis

The Revman 5.2 software[9] package was used to analyze data. Relative risk (*RR*) was used for dichotomous data and mean difference (*MD*) was used for continuous variables, both with 95% confidence interval (95%

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