INPLASY PROTOCOL

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None declared.

Quality of life after spinal cord stimulation for the treatment of painful diabetic neuropathy: a systematic review and meta-analysis

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Review question / Objective: **(1) participants: participants had PDN in the lower extremities for more than 1 year, and the intensity of 5 cm or more on a 10-cm visual analogue scale (VAS); (2) interventions: patients received SCS plus conventional medical management (CMM); (3) comparison: patients who only received CMM; (4) outcomes: The primary outcomes were percentage of participants with 50% pain relief and VAS. The secondary outcome included the EuroQol 5-Dimension Questionnaire (EQ-5D-5L) and the EuroQoL Visual Analogue Scale (EQ VAS). Safety outcomes include all adverse events and the neurological assessment; (5) study type: randomized controlled trial (RCT) study design.**
Condition being studied: **Spinal cord stimulation (SCS) has been shown to significantly reduce pain in patients with neuropathic pain, such as chronic low back pain and failed back surgery syndrome. Currently, results from several randomized clinical trials demonstrate the effectiveness of SCS for painful diabetic neuropathy (PDN). However, the results of these studies are inconclusive.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 October 2022 and was last updated on 07 October 2022 (registration number INPLASY2022100028).

INTRODUCTION

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METHODS

Search strategy: Two investigators independently and separately searched MEDLINE, Embase, the Cochrane Central Register of Controlled Trials (CENTRAL) and ClinicalTrials.gov to identify relevant studies published up to September 1, 2022. In addition to this, references to relevant literature were screened to ensure that the required literature could be searched more comprehensively. Various combinations of the following Medical Subject Headings (MeSH) terms and keywords were used in the screening process: spinal cord stimulation, SCS, diabetic peripheral neuropathy, painful diabetic neuropathy or PDN.

Participant or population: Participants had PDN in the lower extremities for more than 1 year, and the intensity of 5 cm or more on a 10-cm visual analogue scale (VAS).

Intervention: Patients received SCS plus conventional medical management (CMM).

Comparator: Patients who only received CMM.

Study designs to be included: Randomized controlled trial.

Eligibility criteria: The exclusive criteria were as follow: (1) review, comment, letter, case report, or animal experiments; (2) lack of extractable data; (3) patients with atherosclerotic lesions, infections, treatment with anticoagulants or known coagulation disorders; (4) language: not published in English.

Information sources: MEDLINE, Embase, the Cochrane Central Register of Controlled Trials (CENTRAL) and ClinicalTrials.gov .

Main outcome(s): The primary outcomes were percentage of participants with 50% pain relief and VAS.

Additional outcome(s): The secondary outcome included the EuroQol 5-Dimension Questionnaire (EQ-5D-5L) and the EuroQoL Visual Analogue Scale (EQ VAS). Safety outcomes include all adverse events and the neurological assessment.

Quality assessment / Risk of bias analysis: The risk of bias for included RCTs was assessed using the Cochrane Collaboration tool,[19] including selection bias, performance bias, detection bias, attrition bias, reporting bias, and other potential biases. Each bias criterion was categorized as "low", "high", or "unclear". Two investigators independently assessed the quality of the study. Discrepancies were resolved by consensus or by another independent investigator.

Strategy of data synthesis: Version 5.3 of Review Manager was used to evaluate the data. For dichotomous outcomes, risk ratio (RR) was analyzed with 95% confidence intervals (CI). For continuous outcomes, mean difference (MD) was analyzed with 95% CI. Cochrane's Q test and I2 were calculated to explore heterogeneity. Two-tailed tests were performed, and $P < 0.05$ was considered to be statistically significant.

Subgroup analysis: NA.

Sensitivity analysis: Cochrane's Q test and I2 were calculated to explore heterogeneity. For data with significant heterogeneity ($P \leq 0.1$ and $I2 \geq 50\%$), random-effects model was used. For data without significant heterogeneity ($P > 0.1$ and $I2 < 50\%$), fixed-effects model was used.

Language restriction: English.

Country(ies) involved: China.

Keywords: meta-analysis; painful diabetic neuropathy; quality of life; spinal cord stimulation.

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