Spinal cord stimulation for lower limb ischemic pain treatment

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CRD summary
This review assessed the efficacy of spinal cord stimulation (SCS) for the treatment of lower limb ischaemic pain. The authors found that SCS, alone or with prostanoids, may be suitable for patients unsuitable for revascularisation or that have persistent distal ischaemia and pain with a functioning revascularisation. However, the evidence provided does not appear strong enough to support these conclusions.

Authors' objectives
To assess the efficacy of spinal cord stimulation (SCS) for the treatment of lower limb ischaemic pain.

Searching
PubMed and the Cochrane Library were searched; the search terms were reported but the search dates were not. Papers written in English, French and Italian were eligible for assessment.

Study selection
Study designs of evaluations included in the review
Studies with a 6-month follow-up period were eligible for inclusion. Case reports and clinical trials with fewer than 20 participants were excluded. Randomised controlled trials (RCTs), multicentre trials and uncontrolled trials were included; the studies were both prospective and retrospective. The included studies had follow-up periods ranging from more than 8 months to 80 months.

Specific interventions included in the review
Studies that examined SCS were eligible for inclusion. The included studies evaluated SCS, either alone or in combination with medical treatment, peroral analgesic, prostaglandin or best medical treatment. The comparator treatments in studies that included a control group were medical treatment, peroral analgesic, prostaglandin and best medical treatment.

Participants included in the review
Patients with ischaemic pain in the limbs and angiographic exclusion of revascularisation were eligible for inclusion. Studies of patients with a mixed diagnosis of Buerger and Raynaud disease were excluded. The included patients were Fontaine stage IV and III, where reported, and some patients had diabetes, gangrene and atherosclerosis.

Outcomes assessed in the review
Studies that reported methods of pain evaluation and included means, percentages or statistics about pain were eligible for inclusion. Pain relief was the primary outcome assessed, with pain classified by rank and scale, the pain-rating index of the McGill pain questionnaire and a visual analogue scale.

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
The authors did not state that they assessed validity.

Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction.

Methods of synthesis
How were the studies combined?
The studies were synthesised narratively.
How were differences between studies investigated?
Heterogeneity was not formally investigated but tables containing individual study information were available for assessment.

Results of the review
Nineteen studies (n=1,657) were included: 4 RCTs (n=295), 3 multicentre studies which were either uncontrolled or details of controls were not reported (n=326) and 12 uncontrolled trials (n=1,036).

Three RCTs reported significantly greater long term pain reduction in the SCS group compared with control; the magnitude and statistical significance of these differences were unclear. One RCT reported no difference between the groups.

Pain relief was reported in 43 to 62% of patients in the three multicentre uncontrolled studies.

The extent of pain relief ranged from 14 to 77% in the uncontrolled trials.

Authors' conclusions
SCS, alone or in combination with prostanoids, may be suitable for patients unsuitable for revascularisation or that have persistent distal ischaemia and pain with a functioning revascularisation.

CRD commentary
The research question was clear and the inclusion criteria were explicit with regard to the intervention, participants, outcomes and study design. The authors searched two relevant databases, but only included English, Italian and French papers and made no attempt to identify unpublished studies. Some relevant studies might have been missed and the review may be subject to language and publication bias. Study validity was not assessed and the reliability of the included studies is therefore unclear. The authors did not specify how the data were extracted or how decisions on inclusions were made, so it is not known whether any steps were taken to minimise bias and error in the review process.

Very few study details were presented in the tables, in particular in relation to the intervention and included patients; this makes it difficult to determine the generalisability of the review findings. Although a narrative synthesis appears to have been appropriate given the differences between the studies, further details of the magnitude and statistical significance of the findings would have helped interpretation of the results. This review was poorly reported and the evidence provided does not appear strong enough to support the authors' conclusions, so should be treated with caution.

Implications of the review for practice and research
Practice: The authors stated that SCS implantation could be considered in certain patients that have previously been revascularised but have persistent pain and/or ulcers unresponsive to best medical treatment, and patients unsuitable for vascular reconstruction.

Research: The authors stated that SCS should be compared with emerging treatments such as gene therapy and cell implantation.

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Not stated.

Bibliographic details
Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.