What is the evidence on efficacy of spinal cord stimulation in (subgroups of) patients with critical limb ischemia

Klomp HM, Steyerberg EW, Habbema JD, van Urk H

CRD summary

The authors stated that spinal cord stimulation probably did not improve limb survival in patients with critical limb ischaemia. The review findings reflected the data presented, but the lack of information about review methods, small amount of evidence available and poor quality of some of the primary studies mean the authors' conclusions may require a degree of caution.

Authors' objectives

To evaluate the efficacy of spinal cord stimulation on patients with critical limb ischaemia.

Searching

PubMed and (unspecified) registers of controlled trials were searched. A Google search was completed. Bibliographies of relevant articles were checked. Search terms were reported.

Study selection

Randomised controlled trials (RCTs) that compared spinal cord stimulation with any conservative therapy for treating adults with chronic severe peripheral vascular disease were eligible for inclusion. Primary outcome measures in the review were mortality and limb survival.

Participants in the review were patients with critical limb ischaemia unsuitable for further vascular reconstruction. Controls received optimal medical treatment, which was similar across the studies. The review reported limb survival at 12 months, mortality rate, quality of life and pain scores. Duration of follow-up ranged from 12 to 24 months.

The authors stated neither how the papers were selected for the review nor how many reviewers performed the selection.

Assessment of study quality

The following quality criteria were assessed: reporting of study setting; methods of randomisation and allocation concealment; blinding; and rates of accrual and follow-up.

The authors did not state how the assessment was performed.

Data extraction

Data were extracted on event rates in the two groups of each study and were expressed as relative risks with 95% confidence intervals.

The authors stated neither how data were extracted for the review nor how many reviewers performed the data extraction.

Methods of synthesis

Studies were combined using a random-effects model to calculate pooled relative risks and risk differences, with 95% confidence intervals.

Results of the review

Five RCTs were included in the review (n=332, range 37 to 120). None were blinded. One study met all quality criteria apart from blinding, two met one or more quality criteria and two met none.

There was no statistically significant difference between spinal cord stimulation and optimal medical treatment for limb survival at 12 months (five RCTs) or mortality (five RCTs). Neither quality of life nor pain scores were significantly improved in the intervention group (one RCT).

Authors' conclusions

Spinal cord stimulation probably did not improve limb survival in patients with critical limb ischaemia.

CRD commentary

The objectives and inclusion criteria of the review were clear. Only two databases were searched, so some studies may have been missed. It was not stated whether the search was restricted by language, so the review may have been subject to language bias. The review may also have been subject to publication bias; no formal test for publication bias was reported. No search dates were reported. It was unclear whether steps were taken to minimise the risk of reviewer bias and error in study selection, data extraction and validity assessment, such as having more than one reviewer make decisions independently. Few details were reported about the individual studies (such as dropout rate, results of validity assessment and details of medical intervention). These factors make it difficult to assess the reliability of the findings. Some studies met none of the review's quality criteria, yet study quality was not taken into account in the interpretation of results. The time-point for measuring mortality rate was not stated. The review findings reflected the data presented, but the lack of information about review methods, small amount of evidence available and poor quality of some of the primary studies mean the authors' conclusions may require a degree of caution.

Implications of the review for practice and research

Practice: The authors did not state any implications for practice.

Research: The authors stated that a well-powered RCT would be required to detect any clinical benefit associated with spinal cord stimulation in particular patient subgroups.

Funding

The Dutch Fund for Investigative Medicine Grant OG-90053 (Health Insurance Council).

Bibliographic details

Klomp HM, Steyerberg EW, Habbema JD, van Urk H. What is the evidence on efficacy of spinal cord stimulation in (subgroups of) patients with critical limb ischemia. Annals of Vascular Surgery 2009; 23(3): 355-363

PubMedID

19128928

DOI

10.1016/j.avsg.2008.08.016

Original Paper URL

http://www.annalsofvascularsurgery.com/article/S0890-5096(08)00322-1/abstract

Indexing Status

Subject indexing assigned by NLM

MeSH

Aged; Aged, 80 and over; Amputation; Critical Illness; Electric Stimulation Therapy /methods; Evidence-Based Medicine; Extremities /blood supply; Female; Gangrene /etiology; Humans; Ischemia /complications /mortality /surgery /therapy; Kaplan-Meier Estimate; Male; Middle Aged; Proportional Hazards Models; Risk Assessment; Risk Factors; Skin Ulcer /etiology; Spinal Nerves; Time Factors; Treatment Failure

AccessionNumber

12009105755

Date bibliographic record published
05/08/2009

Date abstract record published
02/12/2009

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.