



Spinal cord stimulation for chronic pain

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Conflict of Interest

None

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Spinal chord stimulation for chronic pain

Question

1. **What are the effects of spinal cord stimulation in people with chronic low back and leg pain and failed back surgery syndrome?**
2. **What are the effects of spinal cord stimulation in people with intractable ischaemic limb pain?**
3. **What are the effects of spinal cord stimulation in people with intractable angina pectoris?**

Summary

Chronic back pain and non-ischaemic leg pain: We found insufficient evidence that spinal cord stimulation improves functional disability, work status, or healthcare and medication use compared with other treatments or placebo in people with failed back surgery syndrome, other chronic back pain, or chronic non-ischaemic leg pain.

Ischaemic limb pain: Two RCTs have found no evidence that adding spinal cord stimulation to conventional analgesia improves limb survival or pain compared with analgesia alone, although the trials may have been underpowered to detect a clinically important difference. We found no evidence of effects on quality of life, functional status or healthcare use.

Intractable angina: We found weak evidence from a single RCT that spinal cord stimulation may reduce intensity and frequency of anginal symptoms and medication use in people with intractable angina pectoris. The study found that quality of life was improved, although it is unclear whether the tools assessing quality of life were valid. Further controlled trials with greater power and validated outcome measures are needed.

Background

Spinal cord stimulation has been used since the 1980s to treat patients with intractable pain syndromes including the failed back surgery syndrome (chronic low back pain which has failed to respond to surgical treatment), and ischaemic cardiac and limb pain. The technique is believed to inhibit chronic pain by stimulating large diameter afferent nerve fibres in the spinal cord. According to the pain gate theory proposed by Melzack and Wall in 1965, ascending impulses in these fibres may inhibit the conduction of pain signals to the brain.

The implantation procedure involves placing electrodes in the epidural space, along with an implantable controller that allows alteration of parameters such as pulse width, duration and intensity of stimulation. Repetitive electrical impulses are then delivered to the spinal cord.

Search Methods

Primary sources: Medline 1966 to date; Embase 1980 to date; Cochrane 2001 issue 1; NHS Centre for Research and Dissemination; Database of Abstracts of Reviews of Effectiveness; NHS Health Technology Assessment Database; NHS Economic Evaluation database; TRIPS database; Monash University database. Search date: June 2001.

Evidence found

Chronic back pain and non-ischaemic limb pain: We found one systematic review¹ and two subsequent case series^{2,3}

examining effects of spinal cord stimulation in people with chronic pain syndromes, most commonly the failed back surgery syndrome. The systematic review found no controlled trials, but identified 39 case series from a combination of Medline and hand searches and from a spinal cord stimulation manufacturers' archives. Failed back surgery syndrome was not precisely defined in the articles reviewed, but appeared to refer to chronic back or leg pain that has not responded to surgical intervention.

Ischaemic limb pain: We found one narrative review article, which was excluded because of poor methods (see below).⁴ We found two RCTs.^{5,6} The first compared spinal cord stimulation plus analgesia versus conventional analgesia alone in 51 people with atherosclerotic (n=41) or diabetic (n=10) lower limb ischaemia of more than two weeks duration, which was associated with rest pain or ulceration, or had failed to respond to bypass surgery.⁵ Main outcomes were limb amputation rates and pain relief at 18 months. The second RCT compared spinal cord stimulation plus 'best medical treatment' versus best medical treatment alone in 120 people with rest pain of more than two weeks duration, ankle systolic pressure <50mmHg, absent ankle pulses or ulceration.⁶ Main outcomes were limb survival, pain and analgesic use over a period of two years.

Intractable angina: No systematic reviews were identified. We found one small RCT⁷ and four poor quality case series.⁸⁻¹¹ The RCT

compared the effect of spinal cord stimulation with an inactive implanted stimulator on exercise capacity, quality of life and ischaemia in 25 people with angina pectoris after six weeks treatment.

Quality of Evidence Found

Chronic back pain and non-ischaemic leg pain: The systematic review examined studies concerning patients with failed back surgery syndrome who underwent spinal cord stimulation for pain relief.¹ The quality of the review was excellent, although the studies that it found were of poor quality. Search methods of the review were clearly reported, and studies were independently appraised by two investigators. The synthesis reported outcomes, methodology, patient demographic characteristics and follow up and also highlighted heterogeneity among included studies. Methodological problems with included studies were identified, and results tabulated. Dropout rates in included studies were not stated. Given the poor quality and heterogeneity of study design, it may not have been appropriate to attempt to combine study results. Combined results appear to have been calculated from mean percentages rather than individual patient data, which may skew the final results. The main combined outcome measure (proportion of patients with $\geq 50\%$ pain relief) may not be validated outcome tool for this condition.

The case series design of the included and subsequent studies is intrinsically weak, because it lacks a control group, and is prone to

selection bias. It is an even weaker design for evaluating spinal cord stimulation for chronic back and leg pain because endpoints, such as degree of pain relief, may be difficult to evaluate and because the untreated prognosis is variable. Dropout rates were high in some cases, and people who dropped out were not always accounted for in the analyses. Inclusion and selection criteria were not generally stated, and sample populations were heterogeneous for underlying diagnosis. The clinical importance of significant results is open to dispute.

Ischaemic limb pain: The narrative review did not state its search or appraisal methods, and was therefore excluded in favour of evidence from RCTs.⁴ The trials were of generally good quality.^{5,6} Both randomised treatment allocation. Treatment groups were balanced for potential confounders, and analysis was by intention to treat. Neither trial was blinded, although blinding is difficult when comparing invasive versus non-invasive strategies. The first trial only just achieved its recruitment target, and may not have had adequate power to detect a clinically important difference in outcome between groups.⁵ It was not clear whether the outcome assessment for pain, a visual analogue scale, had been previously validated. The second trial had higher power and used standard instruments such as the McGill Pain Questionnaire and EuroQol to assess subjective outcomes.⁶

Intractable angina: The RCT was of fair quality.⁷ It was unblinded but

randomised appropriately with analysis by intention to treat. There were no dropouts. Treatment groups were balanced for most relevant variables. However, there was no power calculation and the sample size was small. The reliability and validity of the outcome measures were also not reported.

The results from the case series should be viewed with caution as they lack controls or comparators, randomisation and blinding and generally have small sample sizes.⁸⁻

¹¹ There also tends to be a large dropout rate, with dropout unaccounted for in the analyses.

Study Results

Chronic back pain and non- ischaemic leg pain: The review found that there was disparity in outcome measurements, heterogeneity of patient populations and poor data presentation in the included case series.¹ Efficacy of spinal cord stimulation could not be compared with other pain treatments, placebo or no treatment because of the lack of good quality RCTs. The review concluded that there is insufficient evidence relating to the efficacy of spinal cord stimulation on patient work status, functional disability and healthcare and medication use. Complications are stated as 'surprisingly frequent,' occurring in 20-75% of patients across studies (mean frequency 42%), but were generally considered minor. The review combined data from case series, and found that ≥50% pain relief was achieved in 59% of patients, although this average is unlikely to be reliable because methods of pain

measurement varied, and study populations were heterogeneous. The two more recent case series found that spinal cord stimulation was associated with statistically significant pain relief, functional improvement and reduced narcotic use in failed back surgery syndrome compared with baseline assessment.^{2,3} However the quality of these studies is poor and the clinical importance of these effects is not clear.

Ischaemic limb pain: Neither trial found any significant improvement in limb survival with spinal cord stimulation plus analgesia compared with analgesia alone, although power may have been inadequate to demonstrate clinically important effects.^{5,6} Both trials found that spinal cord stimulation reduced pain from baseline, although effects compared with conventional treatment were conflicting. The higher quality study found that pain was significantly reduced from baseline in both trial arms, although it found no significant difference between treatments.⁶ The smaller study found that pain assessed using a coarse visual analogue scale (rated from 1 – 5) was significantly reduced from baseline throughout the trial only in the spinal cord stimulation arm. The trial did not compare pain relief between treatments.

Intractable angina: The RCT found that, compared with control, spinal cord stimulation significantly increased exercise duration and time to angina on exercise testing (median exercise duration after 6 weeks 533s with stimulation v 447s

with control; median time to angina 319s v 246s); and decreased frequency of anginal attacks (median after six weeks 2.4 per day v 3.2 per day with control), sublingual nitrate consumption (median after 6 weeks 1.6 tablets per day v 2.6 with control), and quality of life on a linear analogue scale.⁷ It is not clear whether the subjective scales used had been previously validated, so the clinical importance of the quality of life results is not certain.

The case series found that spinal cord stimulation decreased pain from baseline in patients with chronic angina.⁸⁻¹¹

Conclusions

Chronic back pain and non-ischaemic leg pain: One high quality systematic review has found insufficient evidence on the effects of spinal cord stimulation for failed back surgery syndrome. We found insufficient evidence on the effects in people with other chronic back pain or non-ischaemic leg pain. Treatment awaits evaluation in controlled trials with well-defined inclusion and exclusion criteria, to assess efficacy and adverse effects in clinically applicable patient populations.

Ischaemic leg pain: We found two RCTs, which suggested that spinal cord stimulation plus conventional analgesia significantly improve pain compared with baseline assessment in people with chronic lower limb ischaemia unsuitable for or unresponsive to bypass surgery. However, the studies found no evidence that adding spinal cord stimulation to conventional

analgesia improved pain or limb survival compared with analgesia alone over a period of 18-24 months. Functional effects remain unclear.

Intractable angina: We found weak evidence from one small RCT that spinal cord stimulation may be effective for reducing intensity and frequency of anginal symptoms. Further trials are needed to confirm or refute this finding. Functional effects remain unclear.

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