Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin: systematic review and economic evaluation
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CRD summary
This review suggested that spinal cord stimulation reduced chronic neuropathic pain of failed back surgery syndrome and complex regional pain syndrome type I. Selection criteria may need to be developed for critical limb ischaemia. Spinal cord stimulation may have short-term benefit for refractory angina. Several possible sources of bias made the reliability of the authors’ conclusions unclear.

Authors’ objectives
To evaluate the clinical and cost-effectiveness of spinal cord stimulation in the management of chronic neuropathic or ischaemic pain.

Searching
MEDLINE and Pre-MEDLINE, EMBASE, CINAHL, BIOSIS Previews, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials (CENTRAL), Science Citation Index, DARE, NHS EED, HTA database and HEED were searched. Search dates spanned 1900 to 2007. The search was without language restrictions, but studies were excluded if published only in a non-English language. Search terms were reported. National Research Register, Current Controlled Trials Register and MRC Clinical Trials Register and Google Scholar were also searched. Five key journals, websites of specific conditions causing chronic/neuropathic pain, industry submissions and relevant systematic reviews were searched to identify further studies.

Study selection
Published randomised controlled trials (RCTs) of adults with chronic neuropathic or ischaemic pain who had an inadequate response to medical or surgical treatment other than spinal cord stimulation were eligible for inclusion. In the eligible studies, spinal cord stimulation devices were compared with medical and/or surgical treatment that did not include spinal cord stimulation. Eligible outcomes were pain, health-related quality of life, physical and functional abilities, anxiety and depression, medication use and complications and adverse effects. Pregnant women or patients who had used spinal cord stimulation previously were excluded.

The included studies were of patients with failed back surgery syndrome, complex regional pain syndrome type I, critical limb ischaemia and refractory angina. Spinal cord stimulation (with or without conventional medical management, peroral analgesics or prostaglandin E1) was compared with a variety of surgical, pharmacological and physical treatments. All studies used spinal cord stimulation devices with an implantable pulse generator and non-rechargeable internal battery and were sponsored by industry. Most of the trials used validated outcome measurements. Follow-up ranged from six weeks to 60 months.

One reviewer selected papers for inclusion.

Assessment of study quality
Methodological quality was assessed using criteria based on those detailed in CRD Report No 4 (including randomisation, allocation concealment, eligibility criteria, baseline comparability, intention to treat and follow-up).

The number of reviewers involved in validity assessment was not reported.

Data extraction
Data were extracted by one author using a standardised form.

Methods of synthesis
Studies were combined in a narrative synthesis.

Results of the review
Eleven RCTs were included in the review (n=723, range 17 to 120): three were of neuropathic pain (n=214) and eight were of ischaemic pain (n=509). Method of randomisation and allocation concealment were each reported and deemed adequate in five trials. Three trials did not present intention-to-treat data. Power calculations were reported and sufficient patients were randomised in six trials. None of the trials were blinded.

Neuropathic pain (three RCTs):
Spinal cord stimulation appeared to be significantly more effective than conventional medical management (p<0.001 at six months, p=0.005 at 12 months) or reoperation (p=0.04) in reducing pain for patients with failed back surgery syndrome (two RCTs). A greater reduction in opiate use was seen with spinal cord stimulation compared with reoperation (one RCT). Spinal cord stimulation was more effective than conventional medical management in improving functional ability (p<0.001) and health related quality of life (p≤0.02 in seven of eight domains) (one RCT). There was no difference between spinal cord stimulation and reoperation in pain related to daily activities or neurological function. Medication use was similar for spinal cord stimulation and conventional medical management groups. Employment was not improved by spinal cord stimulation, conventional medical management or reoperation.

Spinal cord stimulation plus physical therapy was associated with more effective pain reduction than physical therapy alone at six months (p<0.001) and at two years (p=0.001), but not at five years (p=0.25) in patients with complex regional pain syndrome type I (one RCT).

Ischaemic pain (five RCTs):
Three of four trials suggested that spinal cord stimulation was effective in delaying refractory angina pain onset during exercise at short-term follow-up, although it was not more effective than coronary artery bypass graft. There was no evidence that pain relief in critical limb ischaemia was better with spinal cord stimulation than with conventional medical management (two of four RCTs).

Complication rates varied across trials, but these were usually minor.

Cost information
The analyses suggested that in patients with failed back surgery syndrome with inadequate response to medical or surgical treatment the estimated spinal cord stimulation incremental cost-effectiveness ratios (ICERs) were below £20,000 per quality adjusted life year (QALY) gained in year three onwards. In treatment of ischaemic pain the threshold analysis suggested the ICER of spinal cord stimulation in addition to conventional medical management was likely to be better than £30,000 per QALY gained for additional survival benefits that range from 5.58 to 82.8 days. Further results were reported.

Authors' conclusions
Evidence suggested that spinal cord stimulation was effective in reducing the chronic neuropathic pain of failed back surgery syndrome and complex regional pain syndrome type I. For ischaemic pain selection criteria may need to be developed for critical limb ischaemia. Spinal cord stimulation may have clinical benefit for refractory angina in the short term.

CRD commentary
The review question was supported by clearly defined inclusion criteria. A number of appropriate databases were searched. However, only studies published in English were included, so language and publication bias could not be ruled out. Validity assessment was performed using appropriate criteria and taken into consideration in the analysis. Where described, review processes were performed by only one reviewer, which increased the risk of bias and error. Narrative synthesis appeared appropriate considering the differences between study participants, comparators and outcomes. A number of possible sources of bias made the reliability of the authors’ conclusions unclear.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors stated that more RCTs were needed for other types of chronic neuropathic pain. For ischaemic pain, trials with larger populations and specific population subgroups were needed. Future RCTs should have longer follow-up and use validated health-related quality of life and pain measures. Multicentre collaboration should be used for forms of chronic pain with low prevalence rates to ensure adequate sample sizes. Trials that used exercise training to assess outcomes may be more valid if spinal cord stimulation was switched on during measurement. Trials without commercial interest were needed.

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