Spinal cord stimulation in severe angina pectoris: a systematic review based on the Swedish Council on Technology assessment in health care report on long-standing pain

Borjesson M, Andrell P, Lundberg D, Mannheimer C

CRD summary
This review assessed the use of spinal cord simulation for the treatment of severe angina pectoris. It concluded that spinal cord simulation improved angina symptoms, functional capacity and quality of life, with few complications and no negative impact upon survival. The review was poorly reported and may be prone to bias. The authors’ conclusions are difficult to verify.

Authors' objectives
To determine the efficacy of spinal cord simulation for the treatment of severe angina pectoris.

Searching
Medline, EMBASE and The Cochrane library were searched for the period 1966 to May 2007. Search terms were reported.

Study selection
Controlled studies of spinal cord simulation for the treatment of angina pectoris were eligible for inclusion. Studies were excluded if they dealt with mechanistic or acute phases of treatment, or if they were case studies or reviews. Studies were excluded from the analysis of efficacy if they were deemed to be of low quality (a score of 0 or 1 on a modified version of the Jadad 5-point scale). The included studies compared spinal cord simulation with placebo, waiting list, coronary artery bypass graft (CABG) or percutaneous myocardial laser revascularisation (PMR) in patients with severe angina. The outcomes reported related to angina symptoms, quality of life, functional status, complication rate and mortality. Follow-up ranged from four weeks to five years, where stated.

At least two reviewers independently assessed the studies for inclusion.

Assessment of study quality
Study quality assessment was assessed using a modified Jadad scale, which included five questions that covered allocation concealment, patient or assessor blinding, use of control group, randomisation and withdrawal rates. Studies that received scores of 0 or 1 were deemed low quality, those with scores of 2 or 3 were deemed medium quality and studies with scores of 4 or 5 were deemed high quality.

The authors did not state how the validity assessment was performed.

Data extraction
The authors extracted data on angina symptoms, functional status, quality of life, mortality and complications of treatment.

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

Methods of synthesis
The studies were described narratively in text and in tables. Studies for the main analysis were ungrouped, but some grouping of comparisons with PMR or CABG was conducted. Results were presented in terms of whether spinal cord simulation increased or decreased outcomes compared with comparators.

Results of the review
Ten studies (n=331 patients) were included in the review: six randomised controlled trials (RCTs); two follow-ups of one of the RCTs; and two controlled studies. All of the studies were assessed as medium or high quality: four studies received scores of 4 (high quality), two received scores of 3 (medium quality) and the remaining two studies received a score of 2 (medium quality).

**Spinal cord simulation versus any comparator:**

Four high-quality studies (n=201) showed that, compared with control groups, spinal cord simulation led to an improvement in angina symptom scores as measured by the number of angina attacks, consumption of nitrates and/or improvement of angina severity as measured by the Canadian Cardiovascular Society scale. The same four studies indicated that spinal cord simulation improved functional status as measured by improved treadmill/exercise test or increased walking time on six-minute walk test.

Three high-quality studies (n=97) demonstrated that compared with control groups spinal cord simulation improved quality of life (QoL) as measured by a variety of QoL questionnaires (such as Seattle Angina Questionnaire and EuroQol).

One medium- and one high-quality study (n=161) indicated that when spinal cord simulation was compared with CABG, spinal cord simulation had fewer deaths than CABG. When spinal cord simulation was compared to an external control group, there was no difference in mortality.

Two medium- and four high-quality studies (n=282) demonstrated low complication rates. The most common adverse event associated with spinal cord simulation was electrode dislocation, which occurred with lesser frequency in newer studies than in older studies.

**Spinal cord simulation versus PMR:**

One high quality study indicated that compared with PMR, spinal cord simulation had significantly longer time to angina after three months treatment and a greater reduction in angina pain. Functional status, as measured by six-minute walk test, was not significantly improved with spinal cord simulation.

**Spinal cord simulation versus CABG:**

One high-quality study indicated that compared with CABG, spinal cord simulation had lower morbidity and mortality rates. Angina symptoms, as measured by angina attacks and nitro consumption, were similar between groups.

**Authors’ conclusions**

There was strong evidence that spinal cord simulation improved symptoms, quality of life and functional capacity in patients with severe angina. There was some limited evidence to indicate that spinal cord simulation was not associated with negative effects on mortality. Complication rates were found to be acceptable.

**CRD commentary**

The review addressed a broadly defined question. Several relevant databases were searched, but the restriction to published literature may have meant that relevant unpublished studies were missed. Publication bias was not assessed. Study selection was performed in duplicate, which minimised error and bias. It was unclear how validity assessment and data extraction were performed, which may have introduced bias into the analysis. The validity assessment tool was limited and may not have been the most reliable tool upon which to judge the quality of included studies. The authors’ conclusions appeared to be based on general trends for increases or decreases in outcomes associated with spinal cord simulation with little consideration of the different comparators or patient populations studied within each of the controlled studies. Heavy reliance upon the validity assessment tool as an indication of trial quality, poor reporting of methodology and a lack of detail about the comparability of patient populations in the individual trials made the authors’ conclusions difficult to verify.

**Implications of the review for practice and research**

**Practice:** The authors did not state any implications for practice.
Research: There was a need for more RCTs of spinal cord simulation in the treatment of angina pectoris that aimed to capture data on efficacy, morbidity, mortality, safety and economic factors.

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