Spinal cord stimulation for complex regional pain syndrome: a systematic review of the clinical and cost-effectiveness literature and assessment of prognostic factors

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CRD summary
This review concluded that spinal cord stimulation is effective for complex regional pain syndrome (CRPS) type I (high-quality evidence) and type II (low-quality evidence). The reliability of these conclusions is unclear because the supporting evidence was limited, even for CRPS type I.

Authors' objectives
To assess the use of spinal cord stimulation (SCS) for complex regional pain syndrome (CRPS), its clinical and cost-effectiveness, and prognostic indicators of therapeutic success.

Searching
MEDLINE, CINAHL, EMBASE, the Cochrane Database of Systematic Reviews, the Cochrane Controlled Trials Register, the Centre for Reviews and Dissemination's HTA database, ongoing trials registers (National Research Register, MRC Clinical Trials Register, U.S. National Institutes of Health Clinical Trials Register), and specialist economic databases (NHS EED and HEED) were searched up to 1 January 2002. There was no language restrictions. The bibliographies of selected articles were checked and experts in the field were contacted for further studies.

Study selection
Study designs of evaluations included in the review
Both randomised and non-randomised, controlled and uncontrolled studies were eligible for inclusion. When multiple reports of the same case series existed, only the study with the largest series was eligible for inclusion. Mixed case series that included non-CRPS patients were eligible for inclusion provided the results were reported separately. Single case reports were not eligible for inclusion.

One RCT was included. Blinding was not feasible because of the nature of the intervention. Twenty-five case series were included.

Specific interventions included in the review
Interventions that used SCS, unilateral or bilateral, by itself or in conjunction with other therapies, were eligible for inclusion. Studies of subdural SCS were excluded because it is not current practice.

Participants included in the review
Studies involving patients diagnosed with CRPS types I and II were eligible for inclusion. The one randomised controlled trial (RCT) involved patients with CRPS type I of at least 6 months' duration. Case series involved patients with both type I and II CRPS, with an average age of 47 years and a median pain duration of 5.7 years.

Outcomes assessed in the review
Studies evaluating any type of benefits, adverse effects, or costs of CRPS were eligible for inclusion. All included studies evaluated pain relief. Other outcomes reported were functional capacity, complications and health-related quality of life.

How were decisions on the relevance of primary studies made?
Two reviewers independently decided on study inclusion or exclusion using a standardised form. Although it was stated that a good level of agreement between reviewers on study inclusion was found, it was not stated how differences were resolved.
Assessment of study quality
The RCT was evaluated using a modified version of the Jadad scale. Case series were evaluated using a 7-point scale developed especially for this review. A single reviewer conducted the evaluations.

Data extraction
A single reviewer extracted the data using a standardised form.

Methods of synthesis
How were the studies combined?
The results of case series were combined using a random-effects model of meta-analysis when the outcomes were evaluated in a sufficiently similar fashion to make that possible.

How were differences between studies investigated?
Before analysis of the studies, several patient and study factors were pre-defined and a meta-regression analysis of the association of subgroups with pain outcomes was conducted.

Results of the review
Twenty-six studies were included: 1 RCT (n=54) and 25 case series (n=500).

The RCT was judged to be of a high quality (score of 3 on a Jadad scale of 5). The case series were generally of a poor quality with a median score of 2 on a 7-point scale; they often did not report outcomes in a usable form.

RCTs.
The RCT compared an SCS plus physical therapy group with a group receiving only physical therapy. Pain relief: differences between the mean changes in the SCS group and the control group were statistically significant at 6 months (-2.4, standard deviation, SD=2.5 versus 0.2, SD=1.6; p<0.001) and at 12 months (-2.7, SD=2.8 versus 0.4, SD=1.8; p<0.001).

Functional status: there was no significant difference.

Health-related quality of life: the results were not statistically significant.

Complications: at 2 years post-intervention, 38% of patients receiving SCS had experienced complications requiring operation.

Case series.
Pain relief: the proportion of patients with at least 50% pain relief averaged 67% (95% confidence interval, CI: 51, 84). Seven studies used a visual analogue scale (VAS) score to assess pain relief. The pooled mean change in VAS score was -4.7 (95% CI: -6.0, -3.4).

Functional status: three case series reported improvement following SCS implantation, but different reporting of outcomes and use of different questionnaires made a pooled analysis impossible.

Health-related quality of life: the two case series which assessed this both reported statistically significant improvements.

Complications: SCS complications were reported in eight studies, with 33% of patients reporting at least one complication, the commonest being electrode issues (20%). None of the complications were considered serious.

Predictors of SCS success for pain relief: none found to be statistically significant across studies in the multivariate meta-regression analysis.
Cost information
An economic analysis, which the authors judged to be well conducted, was done in association with the RCT. It reported a mean cost of $23,480 (in 1998 U.S. dollars) per quality-adjusted-life-year at the 12-month follow-up. Although 12-month costs for SCS plus physical therapy ($10,200) were higher than for physical therapy alone ($6,000), the lifetime projected costs were $60,800 lower. The mean cost per quality-adjusted life-year was approximately $23,480.

Authors' conclusions
SCS appeared effective for CRPS types I and II. Evidence for effectiveness was of high quality for type I CRPS but of low quality for type II CRPS.

CRD commentary
The review addressed a clear question. Inclusion criteria for the participants, interventions, outcomes and study design were defined. The literature search was comprehensive and not restricted by language. Two reviewers independently selected studies for inclusion, whilst a single reviewer conducted the quality assessment and data extraction. Validity was assessed appropriately, but the quality of most of the included studies was very low. The authors mentioned the potential for publication bias but did not use any formal method to assess it. Blinding was not feasible for valid reasons; however, lack of blinding can still lead to an overestimation of treatment effect. Thus, the authors were likely to have overestimated the strength of the evidence in the one RCT relating to CRPS type I and underestimated the likelihood of bias. Conclusions on CRPS type II were based on low-quality case series. The reliability of the reviewers' conclusions is therefore uncertain.

Implications of the review for practice and research
Practice: The authors stated that data from the RCT support the conclusion that SCS combined with physical therapy is an appropriate and effective treatment for patient with CRPS type I who have failed medical therapy. Caution should be applied in the routine use of SCS in type II patients until supporting evidence of sufficient quality becomes available.

Research: The authors stated the need for an RCT of SCS for CRPS type II. In addition, future case series studies of SCS for CRPS need to be better conducted in a number of respects, such as independent assessment of the outcomes and more complete reporting including adverse events and/or complications.

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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.