

# Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin: systematic review and economic evaluation

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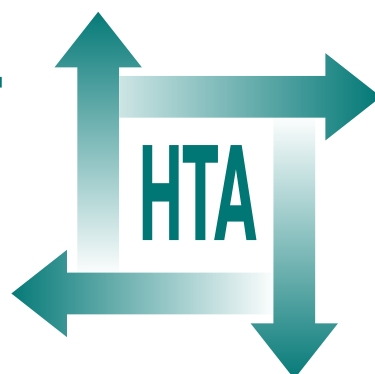
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## *Executive summary*

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## Executive summary

### Background

Chronic pain is a cause of physical and emotional suffering. Spinal cord stimulation (SCS) modifies the perception of pain by stimulating the dorsal columns of the spinal cord, and may relieve neuropathic or ischaemic pain.

### Objectives

This report addressed the question ‘What is the clinical and cost-effectiveness of spinal cord stimulation in the management of chronic neuropathic or ischaemic pain?’

### Methods

A systematic review of the literature sought clinical and cost-effectiveness data for SCS in adults with chronic neuropathic or ischaemic pain with inadequate response to medical or surgical treatment other than SCS. Comparators were medical or surgical treatment appropriate to condition. Thirteen electronic databases were searched from inception, including MEDLINE (1950–2007), EMBASE (1980–2007) and the Cochrane Library (1991–2007). In addition, relevant journals were hand-searched and appropriate websites for specific conditions causing chronic neuropathic/ischaemic pain were browsed. Clinical outcomes sought included pain, health-related quality of life (HRQoL) and adverse effects. Data were available from randomised controlled trials (RCTs) and were included. Heterogeneity precluded meta-analysis, so a narrative synthesis was presented.

Economic analyses were performed to model the cost-effectiveness and cost-utility of SCS in patients with neuropathic or ischaemic pain.

In patients with neuropathic pain, a two-stage model was developed to explore the cost and health outcomes associated with a 15-year time period of treatment using a UK NHS perspective. A decision tree was used to model the first 6 months of treatment. The decision tree model was extended by a Markov model used to determine

the cost and health outcomes over a 15-year time horizon. Data from RCTs were used to determine efficacy and results were presented in terms of incremental cost-effectiveness ratios (ICERs). The model evaluated the cost-effectiveness of treatment in two indications: failed back surgery syndrome (FBSS) and complex regional pain syndrome (CRPS) type I. For FBSS there were two comparators, conventional medical management (CMM) and reoperation. For CRPS the comparator was CMM. Detailed reviews were undertaken to obtain the most recent evidence on costs and utility measures for the different health states modelled. UK-specific data were used.

For ischaemic pain, a mathematical model was developed to explore the cost and health outcomes of SCS in refractory angina using a UK NHS perspective. The analysis estimated the ICERs of SCS plus CMM in comparison with coronary artery bypass grafting (CABG), percutaneous coronary intervention (PCI), or CMM. A threshold analysis was presented because of the dearth of direct clinical evidence. This analysis attempted to clarify the impact of overall survival benefit of SCS on cost-effectiveness and cost-utility levels of acceptability.

### Results

From approximately 6000 citations identified, 11 RCTs were included in the clinical effectiveness review: three of neuropathic pain and eight of ischaemic pain. Comparators were relevant to UK practice. Good quality, adequately powered trials were available for the neuropathic conditions FBSS and CRPS type I, and they suggested that SCS was more effective than CMM or reoperation in reducing pain. The main limitation of the ischaemic pain trials was small sample sizes, meaning that most of the trials may not have been adequately powered to detect clinically meaningful differences. Trial evidence failed to demonstrate that pain relief in critical limb ischaemia (CLI) was better for SCS than for CMM. Trial evidence suggested that SCS was effective in delaying refractory angina pain onset during exercise at short-term follow-up, although not more so than

CABG for those patients eligible for that surgery, although SCS was a relatively safe alternative to CABG. Complication rates varied across trials, but were usually minor.

The results for the neuropathic pain model, over a 15-year time horizon, a device longevity of 4 years and a device cost of £7745, suggested that the cost-effectiveness estimates for SCS in patients with FBSS who had inadequate responses to medical or surgical treatment were below £20,000 per quality-adjusted life-year (QALY) gained. In patients with CRPS who had had an inadequate response to medical treatment the ICER was £25,095 per QALY gained.

When the SCS device costs varied from £5000 to £15,000, the ICERs ranged from £2563 per QALY to £22,356 per QALY for FBSS when compared with CMM and from £2283 per QALY to £19,624 per QALY for FBSS compared with reoperation. For CRPS the ICERs ranged from £9374 per QALY to £66,646 per QALY.

If device longevity (1 to 14 years) and device average price (£5000 to £15,000) were varied simultaneously, ICERs were below or very close to £30,000 per QALY when device longevity was 3 years and below or very close to £20,000 per QALY when device longevity was 4 years. Sensitivity analyses were performed varying the costs of CMM, device longevity and average device cost, showing that ICERs for CRPS were higher.

In the ischaemic model, it was difficult to determine whether SCS represented value for money when there was insufficient evidence to demonstrate its comparative efficacy. The threshold analysis suggested that the most favourable

economic profiles for treatment with SCS were when compared to CABG in patients eligible for PCI, and in patients eligible for CABG and PCI. In these two cases, SCS dominated (it cost less and accrued more survival benefits) over CABG.

## Discussion

Clinical effectiveness was demonstrated for SCS over CMM in reducing pain for FBSS and CRPS type I, from good-quality trials. It is unclear whether this can be generalised to other forms of neuropathic pain. Evidence from small trials failed to demonstrate that pain relief in CLI was better for SCS than for CMM, and suggested that SCS was effective in delaying angina pain onset short-term. Trials of other types of neuropathic pain, or subgroups of ischaemic pain, may be useful.

## Conclusions

Evidence suggested that SCS was effective in reducing the chronic neuropathic pain of FBSS and CRPS type I. For ischaemic pain, there may need to be selection criteria developed for CLI, and SCS may have clinical benefit for refractory angina in the short term.

## Publication

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# NIHR Health Technology Assessment Programme

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