Spinal cord stimulation for failed back surgery syndrome: a decision-analytic model and cost-effectiveness analysis

Taylor R J, Taylor R S

Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The use of spinal cord stimulation (SCS) in patients with failed back surgery syndrome (FBSS).

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The patient population studied had FBSS, which was defined as chronic back and leg pain after technically and anatomically adequate lumbosacral surgery.

Setting
The setting was secondary care. The economic study was carried out in the UK.

Dates to which data relate
The effectiveness evidence was drawn from studies published in the years 2001 to 2005. The resources used were drawn from a single study in 2002 (Kumar et al. 2002, see 'Other Publication of Related Interest' below for bibliographic details). Euro prices for 2003 were used.

Source of effectiveness data
The effectiveness data were derived from a review or synthesis of completed studies.

Modelling
A 2-year decision analytic model was designed to assess the costs and outcomes at 2 years. In addition, a Markov extension was added to the tree, which was capable of performing a lifetime analysis based on the average patient life expectancy. Thus, the purpose of the model was two-fold: a short-term combination of the utility and costs, and an extrapolation or combination of the utility and costs over the lifetime of the patient, using observational evidence.

Outcomes assessed in the review
The outcomes assessed, or input parameters for the model, were:

the probability of receiving an implant for SCS after trial screening:
the annual probability of having a complication following SCS;
the annual probability of failing SCS from year 2 onwards;
the probability of achieving satisfactory pain relief with SCS in the first 2 years post-implant;
the annual decrement in annual probability of achieving satisfactory pain relief with SCS from year 2 onwards;
the probability of achieving satisfactory pain relief with CMM in the first 2 years of receiving treatment;
the annual probability of having a complication following CMM; and
the annual decrement in annual probability of achieving satisfactory pain relief with CMM from year 2 onwards.

Battery life of the SCS implant was also assessed.

**Study designs and other criteria for inclusion in the review**
The authors searched for clinical effectiveness estimates derived from randomised controlled trials (RCTs), or systematic review evidence.

**Sources searched to identify primary studies**
Not reported.

**Criteria used to ensure the validity of primary studies**
Not reported.

**Methods used to judge relevance and validity, and for extracting data**
The authors found only one RCT of SCS. This randomised FBSS patients to either SCS or re-operation (Taylor et al. 2005, see 'Other Publications of Related Interest' below for bibliographic details). The authors appear to have chosen another RCT in their indirect comparison, which was based on length of follow-up over 2 years (FBSS patients randomised to either CMM or re-operation). No justification was provided for the choice of study supplying long-term complication and pain relief data for SCS; the implication was that only one study existed.

**Number of primary studies included**
The authors reported that three primary studies or references, along with a personal communication from the authors of one of the studies (Kumar et al. 2002) in 2003, provided the effectiveness evidence.

**Methods of combining primary studies**
The studies were not combined.

**Investigation of differences between primary studies**
The authors did not investigate any differences between the primary studies, or how these differences affected the estimate of the effectiveness of the technology. They appear to have been restricted by the low number of available studies for inclusion.

**Results of the review**
The probability of receiving an implant for SCS after trial screening was 0.80.
The annual probability of having a complication following SCS was 0.18.

The annual probability of failing SCS from year 2 onwards was 0.02.

The probability of achieving satisfactory pain relief with SCS in the first 2 years post-implant was 0.474.

The annual decrement in annual probability of achieving satisfactory pain relief with SCS from year 2 onwards was 0.06.

The probability of achieving satisfactory pain relief with CMM in the first 2 years of receiving treatment was 0.0583.

The annual probability of having a complication following CMM was set to zero in the absence of data.

The annual decrement in annual probability of achieving satisfactory pain relief with CMM from year 2 onwards was also set to zero in the absence of data.

The battery life of the SCS implant was 4 years.

Measure of benefits used in the economic analysis
Quality-adjusted life-years (QALYs) were used in the economic analysis. The utility estimates in patients with FBSS could not be found, so utilities reported in the Beaver Dam study (Fryback et al. 1993, see 'Other Publications of Related Interest' below for bibliographic details) were used. These focused on patients who reported an "episode of severe back pain" in the past 12 months. Patient utility associated with satisfactory and unsatisfactory pain outcomes was imputed, along with the utility loss associated with an SCS-related complication, based on a method adapted from Malter et al. 1996 (see 'Other Publications of Related Interest' below for bibliographic details).

Direct costs
One single-study Canadian study (Kumar et al. 2002) was identified as having undertaken a comprehensive examination of health care costs associated with SCS and CMM in FBSS patients. The patterns of health care resource use and costs were considered reflective of European clinical practice. These were directly used in the model following agreement from a clinical advisory panel. Costs, but not quantities, were reported for SCS implantation and year 1 costs, SCS complications, SCS reimplantation, annual maintenance costs of SCS from year 2 onwards, CMM in year 1, and annual maintenance costs of CMM from year 2 onwards. The costs were reflated, using EU-15 health care price inflation rates, to 2003 prices. Discounting was not applied although it was relevant over a lifetime analysis.

Statistical analysis of costs
The costs were treated deterministically.

Indirect Costs
The indirect costs were not included.

Currency
Euros (Euro). Prices were converted from Canadian dollars (Can$) based on purchasing power parity, but the precise rate was not reported.

Sensitivity analysis
The authors aimed to examine the effect of data limitations in the assessment of SCS efficacy and long-term disease process. One-way sensitivity analyses were conducted. The parameters investigated were the SCS screening, complication and failure rates, SCS effectiveness, CMM complication rate, SCS screening pass rate, battery life and life expectancy. Most ranges were assumptions, but alternative SCS effectiveness data was drawn from a case series...
study. A multi-way sensitivity analysis was also performed for a "best-case" SCS scenario.

**Estimated benefits used in the economic analysis**
In the base-case, the incremental benefits were 0.066 QALYs per patient after 2 years and 1.12 QALYs over a typical lifetime (36 years).

**Cost results**
The total SCS cost per patient was Euro 16,250 over 2 years and Euro 75,758 over a lifetime. The total CMM cost per patient was Euro 13,248 over 2 years and Euro 122,725 over a lifetime.

Therefore, the incremental cost of SCS over CMM was Euro 3,002 over 2 years and Euro -46,967 over a lifetime.

The costs of adverse effects and maintenance costs were dealt with in the costing.

**Synthesis of costs and benefits**
The estimated benefits and costs were combined in incremental cost-utility ratios. The incremental cost per QALY gained for SCS over CMM was Euro 45,819 over 2 years. SCS was dominant (reduced costs for increased effectiveness) in comparison with CMM in the lifetime analysis, and this result held true in all sensitivity analyses. In the short-term, however, the incremental cost-effectiveness ratios varied widely, reflecting the uncertainty in model parameters. The results were particularly sensitive to changes in SCS effectiveness and measures of utility, as would be expected.

**Authors’ conclusions**
Compared with conventional medical management (CMM), spinal cord stimulation (SCS) was cost-saving to the health care system and more effective over a patient’s lifetime. This finding was robust and supported other cost studies examining SCS. SCS has the potential to be cost-effective in the short-term, but the current paucity of SCS data increased uncertainty in the model estimates.

**CRD COMMENTARY - Selection of comparators**
Although no explicit justification was given for the comparator, it appears to have represented current practice in the authors’ setting. You should decide whether it is an appropriate comparator in your own setting.

**Validity of estimate of measure of effectiveness**
The authors did not state that a systematic review of the literature had been undertaken. However, they did state that only one RCT of SCS had been completed, and that they had consulted published systematic reviews of cost and effectiveness. The authors used data from the available studies selectively and did not combine estimates. The authors used an indirect comparison to estimate the effectiveness for the comparators from two RCTs with re-operation as the common link. This approach is legitimate but, because the analysis was not described, it was unclear whether the authors sufficiently controlled for differences in the two studies, or considered their impact on the results.

**Validity of estimate of measure of benefit**
The estimation of benefits was modelled using utility estimates from a single study of back pain. The methods or instruments used to derive the values in the original study were not discussed, and may or may not have been appropriate. The authors acknowledged that utility values measured in the population of interest, FBSS patients, were essential to the analysis but are currently lacking.

**Validity of estimate of costs**
All the categories of cost relevant to the health care perspective adopted were included in the analysis. As the costs and the quantities were not reported separately, it was unclear whether all relevant costs were included. The resource use quantities for both comparators were obtained from a single Canadian study. The authors were careful to address European applicability by convening an expert panel, which approved the Canadian study as accurately reflecting European clinical practice. Appropriate currency conversions and inflations were performed as the costs were transformed from year 2000 Canadian dollars to year 2003 Euros. It was not explained why the corresponding European costs were not collected directly; perhaps the authors did not wish to produce a country-specific study. Sensitivity analyses of the costs and quantities were not conducted. Discounting over patient lifetimes ought to have been applied but was not used in the model.

**Other issues**

The authors made appropriate comparisons with other studies, noting that theirs was the first to combine the costs and outcomes of SCS. The issue of generalisability to other settings was not addressed. The authors did not present their results selectively. The study was concerned with FBSS patients and this was reflected in the scope of the conclusions. No description of the "typical" FBSS patient was given, but an average life expectancy of 36 years was applied in the model. The authors reported a number of data limitations to their study. First, the assessment of SCS efficacy. Second, the quantification of utility values. Third, the long-term disease process. Fourth, the derivation of the costs. They also acknowledged the uncertainty introduced into the model and the resultant variability in cost-effectiveness results, particularly in the short term.

**Implications of the study**

The authors indicated that the long-term benefits of SCS in terms of lower costs and superior effectiveness made the therapy clearly attractive to policy-makers for the treatment of FBSS patients. The optimum short-term decision is unclear and the authors recognised that further empirical data is needed for precise estimates of cost-effectiveness. They particularly recommended further research to collect utility values in FBSS patients, and to assess how these values change with SCS in comparison with CMM. Research to quantify the variation in health care resources and costs across settings was also recommended.

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**Bibliographic details**


PubMedID 16110715

**Other publications of related interest**


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Subject indexing assigned by NLM

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