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

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Objectives: The aim of this study was to develop a decision-analytic model to assess the cost-effectiveness of spinal cord stimulation (SCS), relative to nonsurgical conventional medical management (CMM), for patients with failed back surgery syndrome (FBSS).
Methods: A decision tree and Markov model were developed to synthesize evidence on both health-care costs and outcomes for patients with FBSS. Outcome data of SCS and CMM were sourced from 2-year follow-up data of two randomized controlled trials (RCTs). Treatment effects were measured as levels of pain relief. Short- and long-term health-care costs were obtained from a detailed Canadian costing study in FBSS patients. Results are presented as incremental cost per quality adjusted life year (QALY) and expressed in 2003 Euros. Costs were discounted at 6 percent and outcomes at 1.5 percent.
Results: Over the lifetime of the patient, SCS was dominant (i.e., SCS is cost-saving and gives more health gain relative to CMM); a finding that was robust across sensitivity analyses. At a 2-year time horizon, SCS gave more health gain but at an increased cost relative to CMM. Given the uncertainty in effectiveness and cost parameters, the 2-year cost-effectiveness of SCS ranged from €30,370 in the base case to €63,511 in the worst-case scenario.
Conclusions: SCS was found to be both more effective and less costly than CMM, over the lifetime of a patient. In the short-term, although SCS is potentially cost-effective, the model results are highly sensitive to the choice of input parameters. Further empirical data are required to improve the precision in the estimation of short-term cost-effectiveness.

Keywords: Spinal cord stimulation, Cost-effectiveness, Decision-analysis, Modeling

Failed back surgery syndrome (FBSS) is defined as chronic back and leg pain after technically and anatomically adequate lumbosacral surgery (14). FBSS is common throughout the developed world, but especially in the United States, where more lumbosacral surgery is done per capita than any other country (26).

There is randomized controlled trial evidence that spinal cord stimulation (SCS) is an effective method for the management of chronic pain management in FBSS patients in comparison to re-operation (18;19;21) However, reimbursement of health-care technologies in many countries now also requires evidence of acceptable cost-effectiveness (6).

A recent systematic review identified several studies that have assessed the costs of SCS in patients with FBSS (24). These studies consistently show that the initial health-care acquisition costs of SCS implantation are offset in the long

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run by a reduction in postimplant health-care resource demand and costs. A formal economic evaluation focusing on whether or not the additional health benefit of SCS, in FBSS patients, is worth its additional cost in the short-term has not been addressed to date. Such an economic evaluation should be based upon comparing SCS to accepted current medical management for FBSS, that is, nonsurgical conventional medical management that includes analgesic drugs and physical therapy (13). This study describes a decision-analytic model designed to compare SCS with conventional medical management (CMM) in FBSS patients and reports the preliminary model cost-effectiveness results based on current best evidence.

METHODS

Our model took a health-care perspective and assessed the cost-effectiveness of SCS compared CMM in FBSS, as an incremental cost per quality cost per quality-adjusted life year (QALY). It was assumed that the probability of survival was equivalent for CMM and SCS-treated patients. Therefore, the incremental cost per QALY of SCS, compared with CMM, was driven by differences in health-care costs and utility (quality of life) gain.

Model Structure

The conceptual basis of the cost-effectiveness model is summarized in Figure 1 and can be summarized as (i) quantification of pain relief associated with SCS and CMM from randomized controlled trial (RCT) evidence, (ii) imputation of utility (quality of life) associated with this level of pain relief, (iii) short-term combination (2-year) of utility and costs, and (iv) extrapolation and combination of utility and costs over the lifetime of the patient using observational evidence.

A decision tree was developed to examine the costs and outcomes of SCS and CMM at 2 years. A Markov extension to this decision tree enabled costs and outcomes to be determined over the lifetime of the patient (Figure 2). The structure of this model was developed from a previously published disease model framework for FBSS patients used in the assessment of the costs of intrathecal morphine therapy (5). The model was developed using decision-analytic software (DATA-PRO Release 2, TreeAge Software, Inc., Williamstown, MA).

Patients undergoing SCS could experience four possible health states: (i) satisfactory pain relief with no complications; (ii) satisfactory pain relief with complications; (iii) unsatisfactory pain relief with no complications; and (iv) unsatisfactory pain relief with complication. Investigators have conventionally chosen an improvement of 50 percent, or more, to indicate a satisfactory level of pain relief (22). This analysis follows this convention. The model structure is summarized in Figure 2.

It was assumed that CMM patients do not experience either short- or long-term complications (see derivation of clinical effectiveness parameters) and, therefore, could undergo only two possible health states: (i) satisfactory pain relief and (ii) unsatisfactory pain relief.

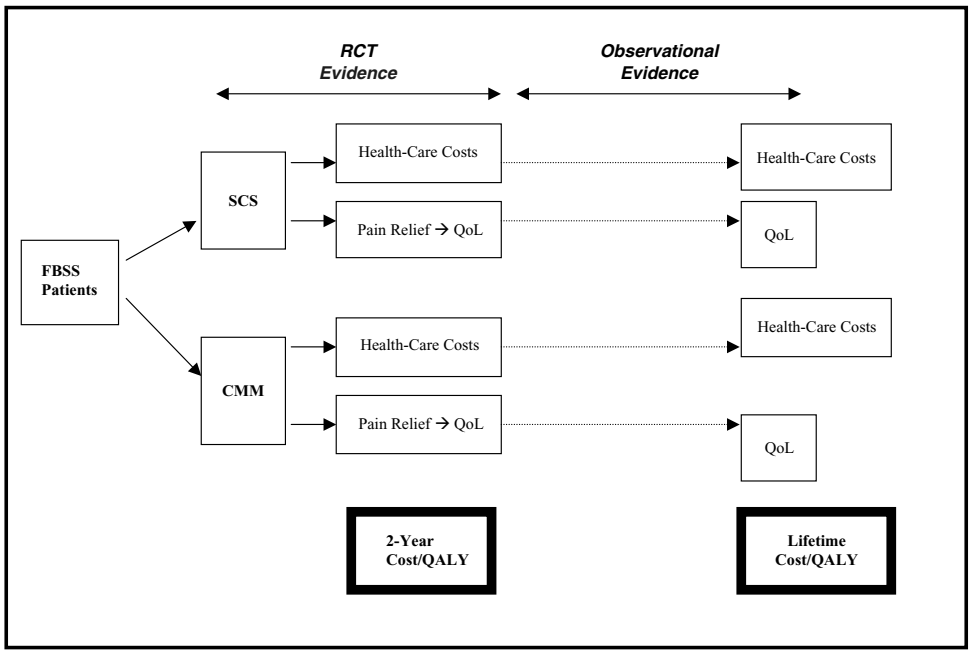

Figure 1. Schematic summary of spinal cord stimulation (SCS) cost-effectiveness analysis. RCT, randomized control trial; FBSS, failed back surgery syndrome; CMM, conventional medical management; QoL, quality of life; QALY, quality-adjusted life year.

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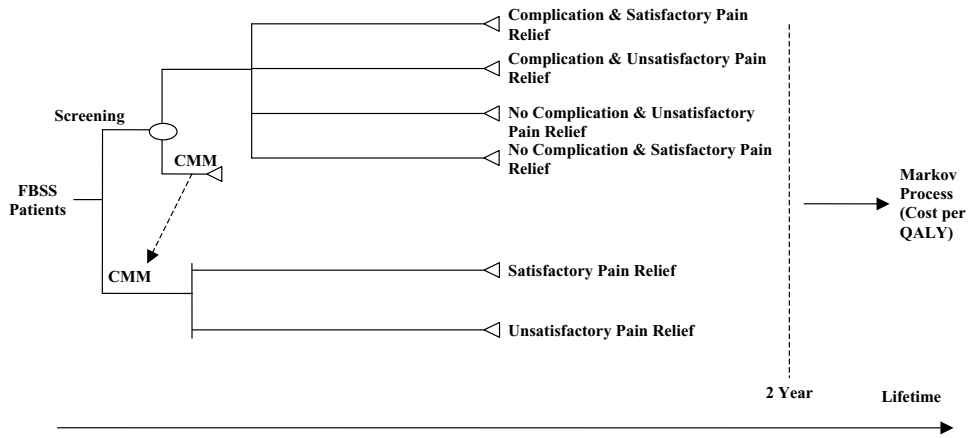

Figure 2. Summary of spinal cord stimulation (SCS) cost-effective model structure. FBSS, failed back surgery syndrome; CMM, conventional medical management; QALY, quality-adjusted life year.

On entering the decision tree, FBSS patients could undergo either SCS screening (i.e., a short test period to assess if SCS would be effective or not) or CMM. Those patients who achieved satisfactory pain relief with testing underwent SCS implantation, and patients who failed underwent CMM. All patients then achieved satisfactory pain relief, or unsatisfactory pain relief over a 2-year period of follow-up. During this period, SCS patients could either experience a complication in this period or "fail" (i.e., undergo a stimulator explant and then switch to CMM).

After this initial 2-year period, patients then enter a Markov process for the period of their lifetime. The structure of the model, to the right of each Markov node (triangles in Figure 2), consists of 4-year cycles that depend on the node at which a patient enters. For example, a patient undergoing SCS who has experienced satisfactory pain with no short-term complications will accrue the relevant costs and utility at year 2. On entering the Markov process, this patient will progress to year 3 and either (i) continue to experience satisfactory pain relief with no long-term complications, (ii) continue to experience satisfactory pain relief with a complication, or (iii) experience failure and move to a strategy for CMM for remainder of their lifetime. Each of these states results in the patient accruing a different (transitional) cost and utility for that cycle. The number of yearly cycles experienced by a patient, after an SCS implant, was determined by the stimulator battery life. This process continues over the life expectancy of the patient. According to their 2-year outcome, CMM patients remained in either satisfactory or unsatisfactory pain over the duration of their lifetime.

Derivation of Model Parameters of Clinical Effectiveness

To minimize bias, clinical effectiveness estimates were derived from an RCT, or systematic review evidence. The one RCT of SCS to date to randomize FBSS patients to either SCS or re-operation had a mean follow-up of 2.5 years (18;19;21). To compare SCS with CMM, the method of indirect comparisons was used (2). The indirect method is based on comparing the results of two or more studies where there is a common comparator (in this case re-operation). An RCT of CMM versus re-operation in patients with chronic leg and back pain (CLBP) was identified with 2-year follow-up data (7). Using this indirect approach, it was estimated that the proportions of patients who achieved satisfactory pain relief were 47.4 percent and 5.8 percent for SCS and CMM, respectively.

The proportion of FBSS patient undergoing implantation after SCS testing was estimated to be 80 percent (25). It was estimated that there was a 6 percent absolute reduction in the proportion of patients reporting satisfactory levels of pain relief each year after SCS implantation (25). Based on an overall rate of 43 percent of patients experiencing one or more complication over an average period of 28-months across studies, an annual rate of 18 percent rate of complications with SCS per year was assumed (25).

We failed to find any studies that reported the long-term rate of complications and changes in pain relief associated with the use of CMM in FBSS patients. However, one RCT reported no complications with CMM in patients with CLBP over a 2-year follow-up period (7). Therefore, for the purposes of this study, the rate of complications and the loss in pain relief with CMM were both set to zero. These values were chosen to underestimate the cost-effectiveness of SCS relative to CMM. The importance of these assumptions was assessed by several sensitivity analyses.

Derivation of Model Health Utility Values

Health-related quality of life was not collected in the two RCTs used to estimate the magnitude of pain relief with SCS versus CMM. A detailed literature search, therefore, was conducted to identify utility estimates in patients with FBSS. Although several studies in back pain exist, none considered FBSS patients specifically (3;8–10;12). The utility values

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reported from the Beaver Dam study were selected for the purposes of this report, as this study focused on patients who reported "an episode of severe back pain" in the past 12-months and, therefore, were deemed to be the closest to FBSS (8).

Estimates of the patient utility associated with satisfactory and unsatisfactory pain outcome were imputed based on a method adapted from Malter et al. (16). Utility values of 0.83 and 0.59 were estimated to be associated with satisfactory and unsatisfactory pain relief, respectively.

Given the fundamental basis of the imputation of utilities to the results of this decision-analytic model, we sought to validate these utility values. Individual patient data was obtained from the principal author of an RCT of SCS in type I complex regional pain syndrome (CRPS) patients (11). Analysis of the utility and pain relief data from the Kemler trial supported the above imputed utility values. The utility loss associated with an SCS-related complication was taken as −0.05 utility units (16).

Derivation of Model Costs

From a systematic review of SCS cost studies (24), one particular study was identified to have undertaken a comprehensive examination of the costs associated with SCS and CMM in patients with FBSS (13). This study was conducted in a single Canadian center.

To assess the issue of European applicability, a Clinical Reference Panel, composed of a group of clinicians working with SCS across Europe, was asked to judge if the level of key health-care resource utilization identified for SCS and CMM in this study was reflective of their own clinical setting. With few exceptions, the group judged the Canadian pattern of resource utilization, for both SCS and CMM, to be similar to their own. Therefore, the pattern of health-care resource and costing from the Canadian study were directly used in this study. Health-care costs were converted from Canadian dollars (at 2000 prices) to Euros (at 2003 prices), based on both purchasing parity power and European (EU-15) health-care price inflation rates.

Cost-Effectiveness Reporting and Sensitivity Analyses

The model results are calculated and reported as incremental cost per QALY ratios. Several univariate and multivariate sensitivity analyses were undertaken across the plausible range of key parameter values that reflected uncertainties in the data sources, extrapolation, and analytic methods (1). Costs were discounted at 6 percent and outcomes at 1.5 percent, in accordance with current guidance (17).

RESULTS

The values of the effectiveness, utility, and cost parameters used in the model base case are summarized in Table 1. The incremental cost-effectiveness ratios for SCS compared with CMM at 2 years and over the duration of the patient lifetime are described below.

2-Year Analysis

Table 2 shows the base case costs and utilities for SCS and CMM at 2 years. SCS was associated with higher cost (+€3,002) and a higher utility gain (+0.066), with an incremental cost-effectiveness ratio for SCS of €45,819 per QALY.

In a one-way sensitivity analysis, the cost-effectiveness of SCS appeared to be highly sensitive to changes, in both the level of SCS effectiveness and SCS annual complication rate (Table 3). The incremental cost-effectiveness ratio was insensitive to changes in the proportion of patients being implanted with SCS after screening. In the "best case" multivariate analysis, with a complication rate of 18 percent for CMM patients, the incremental cost-effectiveness ratio was estimated to be €30,370 per QALY.

Life-Time Analysis

Table 4 shows the base case costs and utilities for SCS and CMM over the lifetime of an average 36-year-old FBSS patient. In this analysis, SCS was dominant, that is, both reduced costs (−€46,967 per patient) and improved utility (+1.12 QALYs per patient), relative to CMM. This finding was robust to all one-way sensitivity analyses (Table 5).

DISCUSSION

In this study, a decision-analytic model was developed to assess the cost-effectiveness SCS for patients with FBSS. We believe this report to be the first study to have combined the outcomes and costs of SCS for FBSS within a formal economic evaluation.

Over the lifetime of the patient, compared with conventional medical management, SCS was found to be both cost-saving to the health-care system and more effective, a findings that was robust to the plausible range of model parameter values and assumptions. This finding supports the previous studies that have examined the costs of SCS alone (24). In a short-term, 2-year analysis, the effectiveness of SCS was found to be superior and health-care costs to be higher relative to CMM. Given the uncertainty in model effectiveness and cost parameters, the short-term cost incremental cost-effectiveness of SCS could range from €30,370, in the best case scenario, to €63,511, in the worst case scenario.

Study Limitations

As with any decision-analytic model, the results and conclusions of this study are dependent on the quality of data upon which the model is based. In this study, there are four potential data limitations: assessment of SCS efficacy, quantification of utility values, long-term disease process,

Table 1. Base Case Model Parameter Values and Sources

Parameter description	Value	Source (Ref.)
SCS clinical probabilities		
Probability of receiving SCS implant after trial screening	0.80	Taylor et al. (25)
Annual probability of having a complication following SCS	0.18	Taylor et al. (25)
Annual probability of failing SCS from year 2 onward	0.02	Kumar et al. (personal communication, 2003)
Probability of achieving satisfactory pain relief with SCS in first 2 years postimplant	0.474	North et al. (21)
Annual decrement in annual probability of achieving satisfactory pain with SCS from year 2 onward	0.06	Taylor et al. (25)
SCS costs		
SCS implantation and year 1 costs	€14783[a]	Kumar et al. (13)
Costs of SCS complication	€1600[a]	Kumar et al. (13)
Reimplantation costs	€5516[a]	Kumar et al. (13)
Annual maintenance costs of SCS from year 2 onward (does not include reimplantation costs)	€895[a]	Kumar et al. (13)
CMM clinical probabilities		
Probability of satisfactory pain relief with CMM within first 2 years of onset of treatment	0.0583	Fritzell et al. (7) [based on analysis of individual patient data]
Annual probability of having a complication following CMM	0.00	Set to conservative value
Annual decrement in annual probability of achieving satisfactory pain with SCS	0.00	Set to conservative value
CMM costs		
Costs of CMM in year 1	€7269[a]	Kumar et al. (13)
Annual maintenance costs of CMM from year 2 onward	€5979[a]	Kumar et al. (13)
Utility values		
Utility value assigned to unsatisfactory pain relief with CMM or SCS	0.59	Malter et al. (16), Fryback et al. (8)
Utility value assigned to satisfactory pain relief with CMM or SCS	0.83	Malter et al. (16), Fryback et al. (8)
Utility loss assigned to SCS complication	−0.05	Kuntz et al. (14)
SCS settings		
Battery life	4 years	Kumar et al. (13)
Patient life expectancy	36 years[b]	North (20)

[a] Costs converted from 2001 Can$ to 2003 Euros.
[b] Based on average age in patients in SCS RCT.
SCS, Spinal cord stimulation; CMM, conventional medical management.

and derivation of costs. These limitations are discussed below.

To date, no RCT has directly compared SCS and CMM in FBSS patients. The treatment effect, therefore, was estimated from an indirect comparison of RCTs. Indirect comparison has been shown to be a valid method for estimating efficacy, when no head-to-head evidence exists (23). However, a particular difficulty in the indirect comparison performed in this study was that of the difference in population of the two RCTs that were used: CLBP in the RCT of re-operation versus CMM (7) and FBSS in the RCT of re-operation versus SCS (19;21). However, as the primary indication for treatment in both RCTs was back and leg pain, an indirect comparison was deemed reasonable.

Despite a comprehensive literature review, no studies reporting utility values in FBSS patients were identified. Therefore, in this study, utility values were imputed from the level of pain relief. As this method failed to take into account other patient outcomes, such as improvements in functionality, it could be argued that the true utility gain associated with SCS

Table 2. 2-Year Base Case Cost-Effectiveness Analysis of SCS and CMM for FBSS (Costs in 2003 Euros)

	SCS costs (€)	CMM costs (€)	Incremental costs (€)	SCS utility	CMM utility	Incremental utility	ICER
Base case[a]	16,250	13,248	3,002[a]	0.670	0.604	0.066[a]	€45,819/QALY

[a] 80% of patients screened receive SCS; 18%/year SCS complication rate; SCS/CMM efficacy, 0.474/0.058 achieve ≥50% pain relief; 2%/year SCS failure rate; battery life, 4 years.
SCS, Spinal cord stimulation; CMM, conventional medical management; FBSS, failed back surgery syndrome; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life year.

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Table 3. Sensitivity Analysis on 2-Year Cost-Effectiveness of SCS for FBSS (costs in 2003 Euros)

	SCS costs (€)	CMM costs (€)	Incremental cost	SCS utility	CMM utility	Incremental utility	ICER
One-way sensitivity analysis							
SCS screening rate							
100%	17,000	13,248	+€3,752	0.686	0.604	+0.082	€45,819/QALY
50%	15,124	13,248	+€1,876	0.645	0.604	+0.041	€45,819/QALY
SCS complication rate							
0%/year	16,047	13,248	+€2,799	0.684	0.604	+0.079	€35,022/QALY
10%/year	16,160	13,248	+€2,912	0.676	0.604	+0.072	€40,487/QALY
30%/year	16.385	13,248	+€3,137	0.660	0.604	+0.056	€56,107/QALY
SCS failure rate							
0%/year	16,148	13,248	+€2,900	0.669	0.504	+0.065	€44,330/QALY
5%/year	16,403	13,248	+€3,155	0.670	0.504	+0.066	€48,045/QALY
SCS effectiveness from case series[a]	16,250	13,248	+€3,002	0.70	0.60	+0.09	€32,283/QALY
CMM[b]	16,138	13,339	+€2,799	0.675	0.631	+0.044	€63,511/QALY
Multi-way sensitivity analysis							
Best case[c]	16,619	13,248	+€3,371	0.739	0.649	+0.090	€37,456/QALY
CMM**	16,619	13,339	+€3,280	0.739	0.631	+0.108	€30,370/QALY

[a] 62% pain relief at 2-year follow-up.
[b] 18% complications.
[c] 100% of patients screened receive SCS; 0%/year SCS complication rate; SCS/CMM efficacy, 62%/24.5 achieve ≥50% pain relief; 0%/year failure rate.
SCS, Spinal cord stimulation; FBSS, failed back surgery syndrome; CMM, conventional medical management; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life year.

Table 4. Base Case Lifetime Cost-Effectiveness Analysis of SCS for FBSS (Costs in 2003 Euros)[a]

	SCS costs (€)	CMM costs (€)	Incremental cost (€)	SCS utility	CMM utility	Incremental utility	ICER
Base case	75,758	122,725	−46,967	15.91	14.79	+1.12	SCS dominant

[a] 80% of patients screened receive SCS; 18% complication rate/year for SCS; SCS/CMM efficacy, 0.474/0.245 achieve ≥50% pain relief; 6% reduction/year in SCS patients achieving ≥50% pain relief; 2% failure rate/year for SCS; battery life, 4 years; life expectancy, 36 years.
SCS, Spinal cord stimulation; FBSS, failed back surgery syndrome; CMM, conventional medical management; ICER, incremental cost-effectiveness ratio.

Table 5. Sensitivity Analysis on Lifetime Costs and Outcomes of SCS for FBSS (Costs in 2003 Euros)

	SCS costs (€)	CMM costs (€)	Incremental cost (€)	SCS utility	CMM utility	Incremental utility	ICER
One-way sensitivity analysis							
SCS screening pass rate							
100%	64,016	122,725	−58,709	16.19	14.79	+1.4	SCS dominant
50%	93,371	122,725	−29,354	15.49	14.79	+0.7	SCS dominant
Battery life							
2 years	170,873	216,534	−45,661	13.67	10.87	+2.8	SCS dominant
Life expectancy							
4 years	20,711	25,206	−4,495	2.23	1.95	+0.28	SCS dominant
SCS failure rate							
0%/year	71,006	122,725	−51,719	16.92	14.79	+2.13	SCS dominant
5%/year	80,095	122,725	−42,630	14.85	14.79	+0.06	SCS dominant
SCS complication rate							
0%	74,040	122,725	−48,685	16.09	14.79	+1.31	SCS dominant
10%	74,994	122,725	−47,731	15.99	14.79	+1.20	SCS dominant
30%	76,904	122,725	−45,822	15.79	14.79	+1.00	SCS dominant
SCS effectiveness from case series[a]	74,758	122,725	−46,967	16.07	14.79	+1.29	SCS dominant

[a] 62% pain relief at 2-year follow-up.

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was underestimated. However, two factors support the approach taken here. First, in view of the fact that the principle indication for SCS in FBSS is pain, it was considered reasonable to assume that a key driver of the utility change in FBSS patients will be the magnitude of pain relief. Second, when the imputation method was applied to individual patient utility values reported by direct assessment, the results were very similar.

To quantify the long-term costs and outcomes of SCS and CMM, extrapolation was required from the 2-year RCT results. Several long-term (i.e., up to 8 years) observational studies have reported outcomes (efficacy and complications) associated with SCS in patients with FBSS (25). In the absence of such evidence for CMM, it was assumed that there was both no decrement in pain relief over time and no complications with CMM. Although recognized to be highly conservative, these assumptions were made so that they underestimate (rather than overestimate) the cost-effectiveness of SCS compared with CMM.

Costs in this study were from the previous literature rather than, and in particular, from the only detailed cost analysis (13). Although costs from this study were converted to 2003 Euros, it is possible that the pattern of health-care resource utilization reported by the study based in a single Canadian center might be unrepresentative of that incurred in a European setting. However, the pattern of Canadian health-care utilization was judged to be similar to European levels by a clinical expert panel.

CONCLUSIONS

SCS was found to be both more effective and less costly than CMM over the lifetime of a patient. In short-term, although SCS is potentially cost-effective, the model results are highly sensitive to the choice of input parameters. Further empirical data are required to improve the precision in the estimation of short-term cost-effectiveness.

POLICY IMPLICATIONS

In view of its lower health-care costs and superior effectiveness, SCS is clearly highly attractive for health-care policymakers as a long-term therapy for the management of FBSS patients. At the moment, the policy decision in the short-term is less clear: currently, there is uncertainty in model effectiveness and costs inputs. Indeed, the incremental cost-effectiveness of spinal cord stimulation in this study was found to vary widely: the incremental costs per QALY of SCS spans a range that include values above and below what is currently deemed to represent good value for money in the United Kingdom, that is, less than €50,000 (22). To improve the precision in estimation of the cost-effectiveness of SCS, the collection of further empirical data is required. Collection of utility values in FBSS patients, and assessment of how these values change with SCS, compared with CMM, is required in future research studies. In addition, studies are required to quantify the potential variation in health-care costs of SCS and CMM across centers, and countries. An ongoing, multicentered, randomized controlled trial (PROCESS) is an example of one such study that should address many of these issues (4).

CONTACT INFORMATION

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