



A Systematic Review of the Cost-Utility of Spinal Cord Stimulation for Persistent Low Back Pain in Patients With Failed Back Surgery Syndrome

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Abstract

Study Design: Systematic Review.

Objectives: To review the literature surrounding the cost-effectiveness of implanting spinal cord stimulators for failed back surgery syndrome.

Methods: A systematic review was conducted inclusive of all publications in the Medline database and Cochrane CENTRAL trials register within the last 10 years (English language only) assessing the cost-effectiveness of Spinal Cord Stimulator device implantation (SCSdi) in patients with previous lumbar fusion surgery.

Results: The majority of reviewed publications that analyzed cost-effectiveness of SCSdi compared to conventional medical management (CMM) or re-operation in patients with failed back surgery syndrome (FBSS) showed an overall increase in direct medical costs; these increased costs were found in nearly all cases to be offset by significant improvements in patient quality of life. The cost required to achieve these increases in quality adjusted life years (QALY) falls well below \$25 000/QALY, a conservative estimate of willingness to pay.

Conclusions: The data suggest that SCSdi provides both superior outcomes and a lower incremental cost: effectiveness ratio (ICER) compared to CMM and/or re-operation in patients with FBSS. These findings are in spite of the fact that the majority of studies reviewed were agnostic to the type of device or innervation utilized in SCSdi. Newer devices utilizing burst or higher frequency stimulation have demonstrated their superiority over traditional SCSdi via randomized clinical trials and may provide lower ICERs.

Keywords

spinal cord stimulator, failed back surgery syndrome, cost effectiveness, quality of life, quality adjusted life years, cost benefit, lumbar interbody fusion, electric stimulation therapy, spinal cord, cost utility

Introduction

Low back pain (LBP) continues to burden patients and the health care system. Approximately 20% of adults currently have LBP¹ and 90% will experience LBP at some point in their life.² LBP is the most commonly cited reason for disability, lost work, and lost wages in industrialized nations.^{3,4} Comorbidities associated with chronic pain including depression, anxiety, and sleep disorders further add to this burden.⁵

Direct costs of LBP such as the cost of hospitalizations, surgeries, prescriptions, and physical therapy are estimated to be in the hundreds of billions of dollars per year in the US

alone.^{6,7} The indirect costs such as lost wages for missing work, emotional impact of chronic pain and any treatment or aid

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sought to help it, retraining for new jobs that are more tolerable for the patient, and even healthcare allocation opportunity costs are more difficult to calculate.⁷

Lumbar fusions for degenerative spondylolisthesis and associated LBP have risen significantly over the past 20 years.^{8,9} As many as 40% of patients who receive lumbar fusions may continue to have unsatisfactory relief of their symptoms.¹⁰ Patients with chronic back pain after a fusion surgery are deemed to have failed back surgery syndrome (FBSS). For some patients with apparent FBSS, there may be imaging findings, such as pseudarthrosis, fractures, or instrumentation failure, that could favor revision surgical treatment to improve symptoms. Nonsurgical treatments for patients with FBSS can include conventional medical management (CMM) including use of analgesics, physical therapy, and cognitive behavioral therapy, among others.¹¹ More interventional treatments for FBSS include medial nerve blocks, epidural injections, additional spinal fusion surgeries, or the implantation of a spinal cord stimulator (SCS).¹⁰ At least one high quality study found SCS device implantation (SCSdi) to provide superior patient satisfaction when compared to re-operation in patients with FBSS. Additionally, fewer patients in this study chose to cross-over from their SCS device to a re-operation, further establishing this treatment as patient-centric in addition to efficacious.¹² This study among others suggests SCSdi to be a safe and effective treatment option for patients with FBSS. However, it is important to also assess the costs of this procedure. Economic evaluation provides decision-making metrics such as incremental cost: effectiveness ratio (ICER) to evaluate against a common willingness-to-pay threshold. When the outcome of interest is quality-adjusted life years (QALY) instead of merely life years gained or specific clinical outcomes, the economic evaluation is called cost-utility analysis. The Cost-Utility and Cost-Effectiveness conveys the same meaning when the effectiveness is on utility measures such as QALY.

As such, direct and indirect ICER of this procedure versus CMM and/or re-operation has come in to question and requires further analysis. The aim of this manuscript was to review the cost-effectiveness of SCSdi compared to CMM and/or repeat/additional fusions in patients who continue to suffer from LBP after at least one lumbar fusion operation.

Methods

Eligibility Criteria

To be included in our analysis, the reviewed manuscript must provide novel data surrounding the cost-effectiveness of SCSdi in FBSS patients; the manuscript's abstract or title had to contain language suggestive of (1): implantation of SCS devices in FBSS patients, (2): either direct or indirect costs of the patients studied, and (3): a cohort of patients who received CMM and/or re-operation. We also reviewed and included any proposed trials that would meet these criteria when published. We excluded any publications that were replies or comments to other manuscripts. Manuscripts that did not provide novel data

surrounding our aims, but discussed previously published data in reviews was included in qualitative analyses but not in our quantitative analyses.

Information Sources

In April 2020, an electronic search of the Medline database and Cochrane CENTRAL trials register was performed to identify studies in the English language published in the past 10 years.

Search Strategy

We utilized the following phrases combined with "and" or "or" Boolean operators: "electrical stimulation," "spinal cord stimulation," "electric stimulation therapy," "spinal cord stimulator," "dorsal column stimulation," "dorsal column stimulator," "spinal fusion," "lumbar vertebrae," "low back pain," "failed back surgery syndrome," "back pain," "fbss," "cost effectiveness," "cost-benefit analysis, cost-utility analysis, quality of life, and QALY."

Study Selection

Four independent reviewers screened titles and abstracts from which we selected full-length articles. Reference texts within these full-length articles were also considered. We analyzed all 80 resulting publications for relevancy to our aims. Review of the title and abstract of these 80 studies resulted in 34 studies that met inclusion criteria and lacked the exclusion criterion. Four studies were not reviewed based on our exclusion criteria. The remaining 76 studies failed to meet inclusion criteria. Figure 1 depicts a flow chart summarizing our search methodology and findings.

Data Collection

We extracted the following items from each article: author, year, sample characteristics including sample size, objective patient outcomes, and length of follow-up. We extracted reported costs and quality of life improvements and broke them down by direct and indirect costs when available.

Risk of Bias Within Individual Studies

We assessed all reviewed studies for the utilization of randomization and blinding in their studies. We additionally reviewed the rates of inclusion/exclusion in each study and the percentage of patients who completed the study after selection in any prospective analyses. We utilized the ROBINS-I assessment tool for determination of likelihood of bias within each study.¹³ A risk of bias across the studies was not performed due to the variable nature of exchange rates of the currency utilized in each study. As such, we felt comparing effects and confidence intervals of the results to be inappropriate.

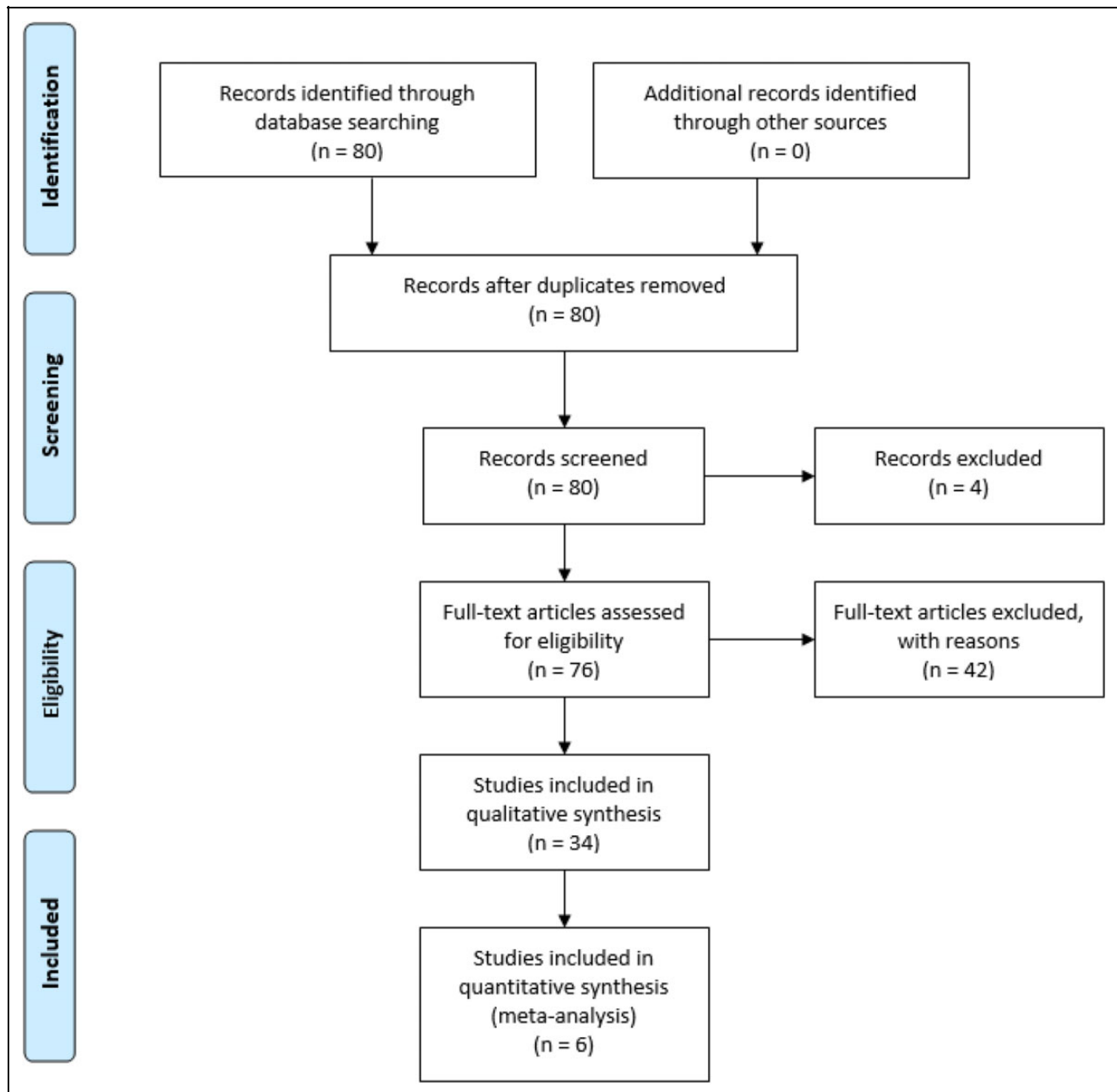


Figure 1. Flow diagram of search methodology and results.

Summary Measures

We made and reported comparisons between the difference in means between the groups within each study. No financial comparisons between studies were made due to the difference in currency used for each study and variable exchange rates before, during, and after the time of study.

Results

Adapted from: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for

Systematic Reviews and Meta-Analyses: The PRISMA Statement. *PLoS Med* 6(7): e1000097. doi:10.1371/journal.pmed.1000097¹⁴

Tables 1 and 2 provides a brief summary of the manuscripts that provided novel data surrounding the cost-effectiveness of one or more types of SCS compared to CMM and/or re-operation in patients with FBSS published from 2010-2020. The 6 manuscripts reviewed that provided novel information regarding the cost-effectiveness of SCSdi in FBSS patients were all retrospective analyses with one study having an additional prospective arm. These studies were all non-randomized and no blinding was utilized.

Table 1. Summary of Findings in Novel, Relevant Studies Published in the Last 10 Years.

Authors	Design	No. pts.	F/U	Pt. outcomes	CUA
Farber et al ¹⁵	Multicenter, retrospective	122,827	108 mo.	N/A	Data was purely cost related; 40% overall lower costs at 108 mo. compared to CMM
Zucco et al ¹⁶	Multicenter, observational, ambispective	80	24 mo.	50% increase in EQ-5D-3 L; 33% decrease in ODI	Total initial cost increase; €/QALY break even w/i 24 mo.
Annemans et al ¹⁷	Multicenter, retrospective	N/A	180 mo.	All 3 forms of SCS provided significant improvements in QALYs over CMM	Total initial cost increase w/ any SCS device; only direct costs assessed
Kumar and Rizvi ¹⁸	Single center, retrospective	335	240 mo.	SCS provided significant improvements in QALYs over CMM	Total cost increase at 240 mo.; \$CDN/QALY break even w/i 18 months
Hollingworth et al ¹⁹	Single center, retrospective	158	24 mo.	<10% of patients in any treatment group achieved pain relief	Total cost increase w/ SCS at 24 mo. of at least \$29 000 compared to usual care
Taylor et al ²⁰	Model-derived retrospective analysis	N/A	180 mo.	N/A	Total cost increase at 180 mo. w/ SCS; break even w/i 18 mo. compared to CMM; w/i 12 mo. compared to re-op

No. Pts. = number of patients; F/U = mean follow-up time; Pt. Outcomes = patient outcomes; CUA = Cost-utility analysis; HF10-SCS = 10 kHz High Frequency Spinal Cord Stimulation.

Table 2. Cost Utility Analysis in Novel, Relevant Studies Published in the Last 10 Years.

Authors	Cost/intervention/yr		QALYs/intervention/yr		Incremental Cost/QALY
	CMM	SCS	CMM	SCS	
Farber et al ¹⁵	\$10 103.9	\$9611	N/P	N/P	N/P
Zucco et al ¹⁶	€6567	€13 216	N/P	0.173*	€3222
Annemans et al ¹⁷	€5374	€5761	0.221	0.343	€3153
Kumar and Rizvi ¹⁸	\$CDN 7676	\$CDN 8322	0.173	0.242	\$CDN 9293
Hollingworth et al ¹⁹	\$19 151	\$18 195	N/P	N/P	\$USD 335 000
Taylor et al ²⁰	€5466	€5934	0.271	0.354	€5622

N/P = not provided in published work.

Five of the 6 studies demonstrated similar findings with respect to cost: on average, patients who underwent SCSdi incurred higher total medical costs to their insurer or national health service compared to patients who underwent CMM or re-operation. The bulk of this cost was within the first 12 months and was largely attributed to the cost of the device. One study by Farber et al, however, found conflicting results.¹⁵

Of the 5 studies listed in Table 1 that performed some form of a cost-effectiveness analysis, 4 found SCSdi to provide significantly lower ICER metrics.^{16,17,18,20} The break-even point where the difference in total costs was met by the savings per QALY was consistently found between 18-24 months across these studies. The single reviewed study that found SCS to be cost-ineffective had < 10% of patients who achieved satisfactory pain relief in any study arm, including CMM.¹⁹ This finding is much lower than the previously reported findings of 50-80% success with SCS devices. As such, it's difficult to determine the applicability of the findings within this study.

With respect to long-term cost savings, the data suggest 6,000 to 10 000 dollars in cost-savings per QALY to insurers

and national health services when comparing SCSdi to CMM and/or re-operation. Further, the overall medical costs of SCSdi was consistently found to be below \$25 000/QALY. In the study with the largest sample size and longest follow-up, reviewing the records of over 120 000 patients over 9 years, there was a reported decrease of over 50% in overall medical costs across the 9-year window for patients who underwent SCSdi compared to those managed with CMM and/or re-operations.¹⁵ The drawback to this finding is a lack of pain relief effectiveness reporting; the manuscript did not directly report intervention QALYs for these patients. Their analysis instead relied on previous reports and extrapolations of pain relief effectiveness from them.

All studies reviewed were retrospective with only one study having a prospective arm. As such, there was no randomization and with it a serious risk of bias judgements due to uncontrolled confounders in the pre-intervention portion of these studies. The studies, however, did utilize the same time frame for patients with limited exclusion criteria. The intervention groups in all novel studies reviewed were clearly defined and

non-interchangeable. The novel studies reviewed had few excluded patients reviewed with none reporting exclusions due to missing data. Taken together, we believe there was a low risk of bias post-intervention.

Discussion

SCS Technology and Cost-Effectiveness

The field of SCS devices has grown rapidly in the 40 years since its initial utilization. An estimated 30 000 to 50 000 devices are now implanted annually across the world.²¹ Naturally, the technology powering these devices continues to evolve and improve. Most notably, the types of delivery system used and the frequency and tonicity of the stimulation provided by the device are under heavy development. The use of a more novel paddle design and configuration has shown superior outcomes compared to traditional electrode size and placement.^{22,23} This is more than likely simply due to having a wider spread of effect and with it a higher chance of providing stimulation to the pathological area(s) of the spinal cord.

Additional technological improvements include the use of SCS devices that provide stimulation at much higher frequencies (10 000 vs. 50-100 Hz). A recent randomized trial demonstrated that not only do patients prefer the higher frequency SCS devices' lack of paresthesia compared to traditional stimulation devices, the higher frequency devices also provide superior and more durable pain relief.²⁴ A different stimulation method that also seemingly improves upon traditional stimulation methods provides SCS in a burst pattern rather than tonic stimulation.²⁵ A randomized study has also shown this stimulation pattern to be preferable to patients as well as able to provide better pain relief.²⁶ The burst stimulation method is more novel than the high-frequency method. As such, studies assessing its efficacy at time points greater than a year remain unpublished. Further research needs to be conducted to clarify if the burst method provides a non-inferior durability of pain relief that the high-frequency method shows. Literature that examined the cost-effectiveness of these more novel devices was not found. It is reasonable to hypothesize that these devices will provide even greater QALY/cost to patients and insurers than their predecessors.

Further, a parallel improvement in SCS cost-effectiveness would result from prolonging the battery life of non-rechargeable devices. As it currently stands, the published literature that compared the cost-effectiveness of non-rechargeable and rechargeable devices showed a slight benefit to rechargeable devices. This is largely due to having fewer replacements over the patient's lifetime and the associated surgical costs. The industry standard device longevity for non-rechargeable devices is ~4.5 years.²⁷ If a non-rechargeable device does not require replacement until after 4.5 years from initial implantation, it becomes more economical to utilize compared to the rechargeable models, given the initial device costs are similar. As such, if the cost of non-rechargeable devices could be maintained while simultaneously improving battery life, this would further improve cost-effectiveness of SCS devices.

Improving SCS Cost-Effectiveness With Refined Patient Selection

An alternative method to improving the cost effectiveness of SCS devices is further refining patient selection. Several studies have analyzed this; however, most of them utilize rather small sample sizes. Combining the findings from these studies, an ideal responder would not use tobacco,²⁸ be of normal weight,²⁹ and be free of psychiatric comorbidities other than anxiety.³⁰⁻³² The data surrounding which age group might better respond to SCS for LBP is mixed. One study suggested that younger patients fared worse²⁹ while another suggested older patients have inferior responses.³¹ One possible explanation for this disparity might be the finding that the efficacy of SCS decreases as latency between pain onset and treatment or the number of prior interventions increases.³³ As it also relates to patient selection, North et al found that patients who failed SCSdi and crossed over to re-operation failed to achieve adequate pain relief.¹² This cross-over resulted in inferior outcomes for patients of lesser pain-relief achieved and lower patient satisfaction, both coming at higher costs as well; a patient who did not respond to SCS and underwent subsequent re-operation ended up costing more than double the average patient who just had re-operation and over 5 times the amount of a patient just receiving SCSdi.

Improving SCS Cost-Effectiveness With More Encompassing Data Analysis

Often overlooked when comparing the cost of SCSdi to decompression and fusion surgeries are the indirect costs to patients. A particularly relevant indirect cost with respect to patients with LBP are side effects and unintended consequences from opioid use which may be difficult to fully estimate before reoperation. Estimates of the burden of opioid use in post-lumbar fusion patients suggest upward of 30 000 dollars in medical cost differences between patients who uses opioids in the short term after a surgery compared to those who use opioids for more than a year after surgery.³⁴⁻³⁷ The data surrounding the use of opioids after neuromodulation suggests either no difference or overall less opioid usage at 1 year post SCSdi compared to lumbar decompressions and fusions.^{38,39}

The field of SCS device implantation currently has 5 randomized controlled trials comparing the safety and efficacy of SCS device implantation compared to CMM and/or re-operation of the lumbar spine.^{12,24,40-42} While these studies all demonstrate the superior efficacy and safety profiles of SCSdi compared to both CMM and re-operation as far out as 120 months, they do not assess cost-effectiveness. It is clear that additional research will be needed to further delineate SCS effectiveness, patient-selection, and cost-effectiveness. Several multicenter randomized controlled trials have been proposed including the ESTIMET⁴³ and EVIDENCE⁴⁴ studies; their data remain unpublished. The execution and evaluation of results from these studies will help guide care for patients.

Limitations

This analysis relies on primarily retrospective, non-randomized data. The likelihood of confounders between patients who elect for SCSdi compared to those who do not is nearly guaranteed. As such, the presented data need to be considered thoughtfully. This review also lacks data from studies that are sure to alter the landscape either negatively or positively for SCSdi as an alternative for CMM. As these studies finish and are published, the conclusions made by this review may be made obsolete by technology. The efficacy, direct costs, or indirect costs are likely to be impacted by more manufacturers designing devices, improved technology, continued surgical experience, and compete against improvements to CMM as well.

Strengths

The primary strength of this analysis is its direct and narrow question. The number of manuscripts published that attempt to answer our proposed question of the cost-utility of SCSdi compared to CMM in FBSS patients is small. Additionally, the data found and presented in the studies were attained in a very uniform fashion, across a span of nearly a decade, and minimized bias when possible.

Conclusions

The literature suggests SCSdi is likely more expensive in the short term when compared to CMM or re-operation for patients with FBSS. This initial expense is likely negated by the improvements in quality of life SCSdi provides when compared to CMM or re-operation. The literature reported the cost/QALY for SCSdi to be lower than even the conservative estimate of \$25 000/QALY for an insurer's willingness to pay. The break-even point for the initial up-front costs seems to be ~24 months; one large analysis suggested there is more than a 50% reduction in overall medical cost-savings with SCSdi compared to CMM and/or re-operation.

Using the GRADE approach,⁴⁵ we believe the studies reviewed provide a moderate quality of evidence. We believe the strong likelihood of confounders being present greatly reduces the quality. However, this is partially offset by the striking consistency and large magnitude of effect on lower ICERs found across FBSS patients receiving SCS devices across different settings and time frames compared to FBSS patients who received CMM or secondary operations.

With the proposed large scale, multicenter, randomized controlled trials currently ongoing, it is likely we will see much more robust and applicable cost-effectiveness analyses that have greatly diminished if not absent confounders published in the coming years. These studies are also likely to include and differentiate the more novel high-frequency and burst devices as well as provide more encompassing costs of SCSdi compared to alternative treatments.

Declaration of Conflicting Interests

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