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Systematic Review

Spinal Cord Stimulation for Patients with Failed Back Surgery Syndrome: A Systematic Review

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Background: Failed back surgery syndrome is common in the United States. Management of post lumbar surgery syndrome with multiple modalities includes interventional techniques, resulting in moderate improvement, leaving a proportion of patients in intractable pain. The systematic reviews of long-term benefits and risks of spinal cord stimulation (SCS) for patients with failed back surgery syndrome showed limited to moderate evidence and cost effectiveness. However, with the exponential increase in surgery in the United States, spinal cord implants are also increasing. Thus, the discussion continues with claims of lack of evidence on one hand and escalating increases in utilization on the other hand.

Study Design: A systematic review of SCS in patients with failed back surgery syndrome.

Objectives: This systematic review is undertaken to examine the evidence from randomized controlled trials (RCTs) and observational studies to evaluate the effectiveness of SCS in post lumbar surgery syndrome and to demonstrate clinical and cost effectiveness.

Methods: Review of the literature was performed according to the Cochrane Musculoskeletal Review Group Criteria as utilized for interventional techniques for randomized trials and the Agency for Healthcare Research and Quality (AHRQ) criteria for observational studies.

The 5 levels of evidence were classified as Level I, II, or III with 3 subcategories in Level II based on the quality of evidence developed by the U.S. Preventive Services Task Force (USPSTF).

Data sources included relevant literature of the English language identified through searches of PubMed and EMBASE from 1966 to December 2008, and manual searches of bibliographies of known primary and review articles.

Outcome Measures: The primary outcome measure was pain relief (short-term relief ≤ one-year and long-term > one-year). Secondary outcome measures of improvement in functional status, psychological status, return to work, and reduction in opioid intake were utilized.

Results: The indicated evidence is Level II-1 or II-2 for long-term relief in managing patients with failed back surgery syndrome.

Limitations: The limitations of this review included the paucity and heterogeneity of the literature.

Conclusion: This systematic review evaluating the effectiveness of SCS in relieving chronic intractable pain of failed back surgery syndrome indicated the evidence to be Level II-1 or II-2 for clinical use on a long-term basis.

Key words: Chronic low back pain, neuropathic pain, failed back surgery syndrome, FBSS, post lumbar surgery syndrome, electrical stimulation, spinal cord stimulation

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Spinal cord stimulation (SCS) introduced by Shealy et al in 1967 (1), is primarily implanted in the United States for failed back surgery syndrome (FBSS) and complex regional pain syndromes (CRPS) (2-12). Medicare spending for in-patient back surgery more than doubled over the decade, with an increase for lumbar fusion of 500%, from $75 million to $482 million, and lumbar fusion representing 47% of total spending for back surgery in 2003 in contrast to 14% in 1992 (13). In the year 2002, more than one million spinal procedures were performed in the United States with 400,000 cases being instrumented (13-19). Similarly, increases of 159% in spinal cord implants over a 10-year period from 1997 to 2006 have been reported in the Medicare population (20-24). Management of post lumbar surgery syndrome with numerous modalities of treatments including interventional techniques, results in moderate improvement, yet leaves a proportion of patients in intractable pain (6,25-35).

In the first decade after its introduction, SCS was extensively used and was claimed to have been applied indiscriminately to a diverse spectrum of pain diagnoses with poor follow-up of the patients leading to disrepute of this technology. During the past decade, there has been growing awareness that SCS might be a reasonably effective therapy for patients suffering from neuropathic pain for which there is no other alternative therapy (11). Multiple reasons described for the increased use of SCS include identification of relevant indications; improved design of electrodes, leads, and receivers/stimulators, resulting in improved success and reduction in incidence of re-operations for device failure; and introduction of the percutaneous electrode implantation facilitating trial stimulation (11,36,37).

The first systematic review of the long-term benefits and risks of SCS for patients with FBSS was performed by Turner et al in 1995 (2). However, this review has been criticized for including observational studies and methodological flaws. Subsequently, Turner et al (7) updated their review in 2004 to include data from 7 new studies including randomized controlled trials (RCTs) for the assessment of effectiveness and 15 studies for the assessment of adverse effects. They concluded that methodologically robust studies are needed to establish the effectiveness of SCS. The only randomized trial found a statistically significant moderate effect on pain, but no notable improvement in function. Taylor et al (3) performed a systematic review and analysis of prognostic factors of SCS for chronic back, leg pain, and FBSS, including one RCT (38), one cohort study, and 72 case studies. They reported that there was evidence of substantial statistical heterogenicity in the level of pain relief following SCS reported across case series studies. They also reported there were 4 principal prognostic factors to be predictive of an increased level of pain relief, including poor study quality score, short follow-up duration, multi-center (versus single center) studies, and including only those patients with FBSS versus chronic back and leg pain. Overall, they reported 43% of patients with chronic back and leg pain/FBSS experienced one or more complications following a SCS implant, even though no major adverse events were reported. They concluded that despite an increase in the number of studies, the level of evidence for the efficacy of SCS in chronic back and leg pain secondary to FBSS remains "moderate." Taylor et al (8) in a 2006 systematic review and meta-analysis of SCS in refractory neuropathic back and leg pain secondary to FBSS and CRPS concluded that the use of SCS in patients with refractory neuropathic pain of FBSS was Grade B evidence. They also noted that SCS not only reduces pain, improves quality of life, reduces analgesic consumption, and allows some patients to return to work, with minimally significant adverse events, but may also result in significant cost savings over time. Cochrane review for SCS for chronic pain (11) published in 2007 included multiple conditions including multiple sclerosis, CRPS, phantom pain, diabetic neuropathy, and post herpetic neuralgia, in addition to FBSS. They included 2 RCTs with 81 patients in total (39,40). They concluded that there is limited evidence in favor of SCS for FBSS and CRPS Type I and more trials are needed to confirm whether SCS is an effective treatment for certain types of chronic pain. In a reassessment of an evidence synthesis by the American College of Occupational and Environmental Medicine (ACOEM) guidelines Manchikanti et al (41) included 3 randomized trials (39,40,42).

Cost-effectiveness of SCS also has been performed specifically in FBSS (5,43). In a systematic review of the literature, Taylor et al (5) found initial health care acquisition costs were offset by a reduction in post implant health care resource demands and costs. Mean 5-year costs were $29,123 in the intervention group, compared to $38,029 in the control group for FBSS Bala et al (43) performed a systematic review of the cost-effectiveness of SCS for patients with FBSS and showed that, in terms of cost-effectiveness, 3 studies

met the inclusion criteria and offered the same conclusion and showed that, in terms of cost-effectiveness, SCS is more effective and less costly in the long-term, but there is an initial high cost associated with device implantation and maintenance. They also showed that SCS was effective in the treatment of FBSS in terms of pain reduction. Practice parameters for the use of SCS in the treatment of chronic neuropathic pain (12) provided a strength of recommendation of A for FBSS.

Thus, the discussion continues with claims of lack of evidence on the one hand and escalating increases in utilization on the other hand (41,44-47). This systematic review is undertaken to examine the evidence from the available literature of the effectiveness of SCS in post lumbar surgery syndrome.

Methods

Literature Search

A comprehensive literature search was conducted which included search of databases including PubMed and EMBASE from 1966 through December 2008, Cochrane database, Clinical Trial Registry, systematic reviews, narrative reviews, and cross-references to reviews published in the English language.

The search strategy emphasized chronic low back and lower extremity pain with a focus on SCS. Search terminology included post laminectomy syndrome, post surgery syndrome, FBSS, arachnoiditis, chronic low back pain, neuropathic pain, SCS, dorsal column stimulation.

Selection Criteria

Types of participants considered are patients with chronic low back pain of post lumbar surgery syndrome of at least 12 months duration. Types of interventions included surgically implanted, as well as percutaneously implanted, monopolar or multipolar, single or multi-channel, and ramped or intermittent stimulation devices.

Exclusion criteria included any types of pain other than post lumbar surgery syndrome.

Outcome Parameters

The following outcome measures were of documented pain relief at various points in time, functional assessment, and other outcomes including psychological improvement, return to work, change in opioid intake, and cost effectiveness. The follow-up criteria are a minimum of one-year with appropriate outcome measures of at least pain relief and functional status.

Review Criteria

The review focused on randomized trials and observational studies and reports of complications. The population of interest was patients suffering with FBSS. All studies providing appropriate management with outcome evaluations of 12 months or longer and statistical evaluations were reviewed. Reports without appropriate diagnosis, book chapters, and case reports were excluded.

Study Criteria

Two physicians evaluated each study for the stated criteria and a third physician resolved any disagreements.

If there was a conflict of interest with the reviewed manuscripts with authorship or any other type of conflict, the involved authors did not review the manuscripts for quality assessment, clinical relevance, evidence synthesis, or grading of evidence.

Methodologic Quality Assessment

The quality of each individual article used in this analysis was assessed by modified Cochrane review criteria with weighted scores (48) for randomized trials and the Agency for Healthcare Research and Quality (AHRQ) criteria for assessment of observational studies (49) with consensus-based weighted scoring developed by the guidelines committee of the American Society of Interventional Pain Physicians (ASIPP) and utilized in multiple evaluations (25,33,35,41,50-56).

Only the studies scoring at least 50 of 100 on weighted scoring criteria were utilized for analysis.

Observational studies were only included in the evidence synthesis if there were less than 4 randomized trials meeting the inclusion criteria.

Clinical Relevance

The clinical relevance of the included studies was evaluated according to 5 questions recommended by the Cochrane Back Review Group (57,58).

Each question was scored positive (+) if the clinical relevance item was met, negative (–) if the item was not met, and unclear (?) if data were not available to answer the question.

In the recent Cochrane review of "Injection Therapy for Subacute and Chronic Low Back Pain" (57), the authors considered a 20% improvement in pain scores (59) and a 10% improvement in functioning outcomes

(60) to be clinically important. This study utilized stricter criteria than previous systematic reviews. We also utilized strict methodologic quality assessment criteria (57) for inclusion and up to one year as short-term relief with long-term relief as longer than one year. Observational studies were also included with scores of 50 or more on a scale of 0 – 100 based on AHRQ criteria. This improves the generalizability of the systematic review as well as the intervention (61-65).

Analysis of Evidence

Qualities analysis was conducted using 5 levels of evidence, ranging from Level I to III with 3 subcategories in Level II, as illustrated in Table 1 (66).

Recommendations

Grading recommendations were based on Guyatt et al's criteria (67).

Outcome of the Studies

A study was judged to be positive if it was clinically relevant and effective, either with a placebo control or active comparator in randomized trials. This indicates that the difference in the effect for the primary outcome measure was statistically significant at the conventional 5% level. In a negative study, no difference between the study treatment and no improvement from baseline was reported. For observational studies, a study was judged to be positive if the intervention was effective, with outcomes reported at the reference point with positive or negative results.

Relief of 12 months or less was considered as short-term and relief of longer than 12 months was considered as long-term.

Results

A literature search was carried out for SCS as shown in Fig. 1.

Our search strategy yielded 6 randomized trials (38-40,68-70) and 25 observational studies (71-95) evaluating the effectiveness of SCS. In addition, 3 studies evaluated cost effectiveness (96-98).

Randomized Trials

Methodologic Quality Assessment

Of the 6 randomized trials, 2 met the inclusion criteria for methodological assessment and clinical relevance (39,68). Two of the manuscripts (38,42) were duplicates (39,68). One study (69) was a comparison of SCS electrode design, whereas the second study (70) was a study of SCS for axial low back pain comparing dual with single percutaneous electrodes. Both of them were of short-term follow-up, thus both studies were excluded from the methodologic quality assessment. Methodologic quality assessment criteria and clinical relevance criteria for randomized trials are illustrated in Tables 2 and 3.

The quality assessment criteria scores derived were 55 and 56 respectively for the randomized trials eligible to be included in the analysis (39,68).

Clinical Relevance Assessment

Both studies met clinical relevance criteria (39,68).

Study Characteristics

Kumar et al (42,68) compared SCS with conventional medical management (CMM) in patients with neuropathic pain secondary to FBSS with predominant

Table 1. *Quality of evidence developed by USPSTF.*

I:	Evidence obtained from at least one properly randomized controlled trial
II-1:	Evidence obtained from well-designed controlled trials without randomization
II-2:	Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group
II-3:	Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence
III:	Opinions of respected authorities, based on clinical experience descriptive studies and case reports or reports of expert committees

Adapted from the U.S. Preventive Services Task Force (USPSTF) (66).

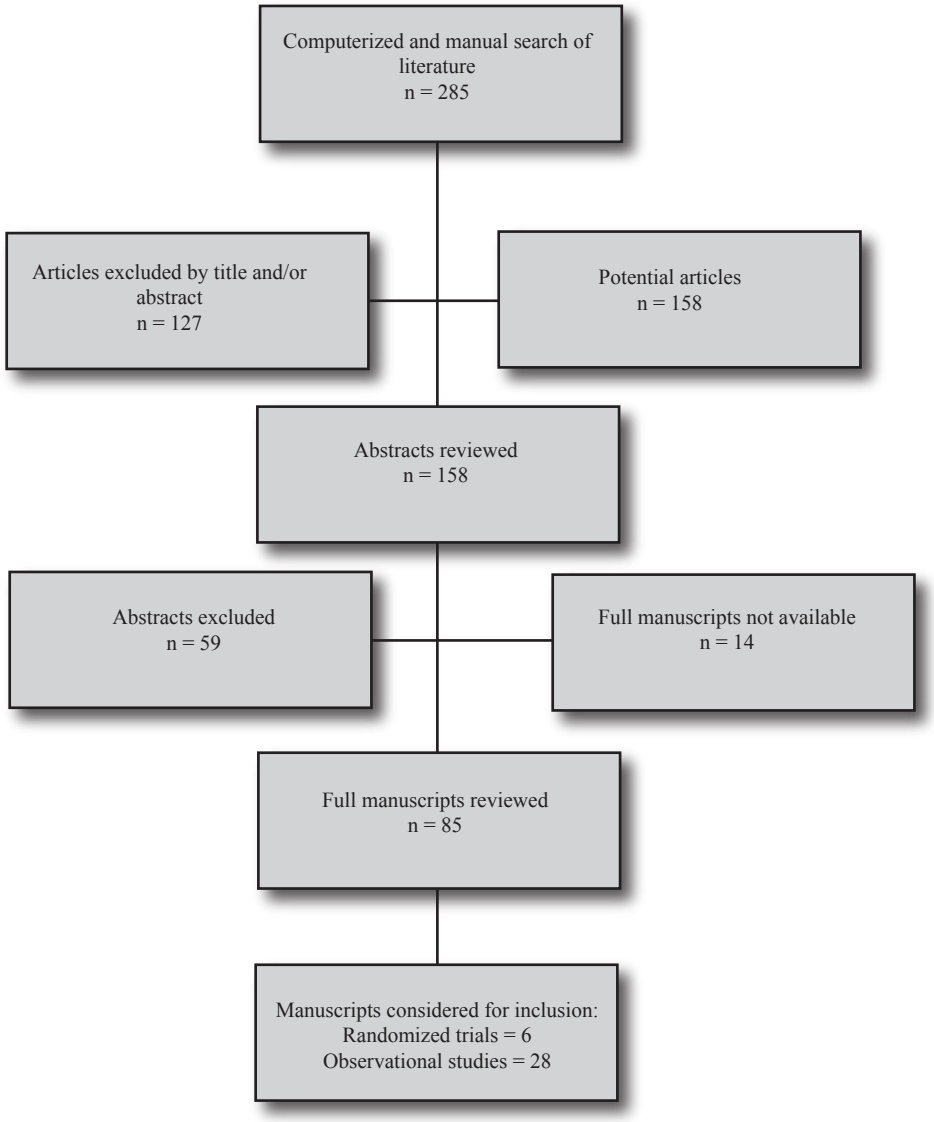

Fig. 1. *The flow diagram illustrating literature evaluating spinal cord stimulation.*

leg pain of neuropathic radicular origin. In both groups CMM was "actively managed." Of those who were randomized to medical management, by 12 months only 25% (16/48) remained in that arm, after 12 months, 28 elected to cross over to SCS. Five of those in the SCS group crossed over to the CMM group at 6 months, 4 because of inadequate pain relief. By 12 months, the protocol analysis showed 48% of the SCS group and 9% of the medical management group achieving at least 50% pain relief. By 24-month follow-up, 42 out of 52 randomized patients continuing SCS reported significantly improved leg pain relief, quality of life, and functional capacity; and 13 patients (31%) required a device-related surgical revision (68). At 24 months, of 46 out of 52 patients randomized to SCS and 41 of the 48 patients randomized to CMM who were available, the primary outcome was achieved by 34 (47%) out of 72 patients who received SCS as final treatment versus one (7%) of 15 for CMM. The authors concluded that compared with the medical management group, the

Table 2. *Methodological assessment of randomized clinical trials evaluating spinal cord stimulation in post lumbar surgery syndrome.*

CRITERION		WEIGHTED SCORE (points)	Kumar et al (68)	North et al (39)
Study population				
A	Homogeneity	2	2	2
B	Comparability of relevant baseline characteristics	5	4	2
C	Randomization procedure adequate	4	4	4
D	Drop-outs described for each study group separately	3	3	3
E	≤ 20% loss for follow-up	2	2	—
	≤ 10% loss for follow-up	2	—	—
F	> 50 subject in the smallest group	8	—	—
	> 100 subjects in the smallest group	9	—	—
Interventions				
G	Interventions included in protocol and described	10	10	10
H	Pragmatic study	5	5	5
I	Co-interventions avoided or similar	5	—	—
J	Placebo-controlled	5	—	—
Effect				
K	Patients blinded	5	—	—
L	Outcome measures relevant	10	10	10
M	Blinded outcome assessments	10	—	10
N	Follow-up period adequate	5	5	5
Data-presentation and analysis				
O	Intention-to-treat analysis	5	5	—
P	Frequencies of most important outcomes presented for each treatment group	5	5	5
TOTAL SCORE		100	55	56

Methodological criteria and scoring adapted from Koes BW et al. Efficacy of epidural steroid injections for low-back pain and sciatica: A systematic review of randomized clinical trials. *Pain* 1995; 63:279-288 (48).

Table 3. *Clinical relevance of randomized clinical trials evaluating the effectiveness of spinal cord stimulation.*

	Kumar et al (68)	North et al (39)
A) Are the patients described in detail so that you can decide whether they are comparable to those that you see in your practice?	+	+
B) Are the interventions and treatment settings described well enough so that you can provide the same for your patients?	+	+
C) Were all clinically relevant outcomes measured and reported?	+	+
D) Is the size of the effect clinically important?	-	-
E) Are the likely treatment benefits worth the potential harms?	+	+
TOTAL CRITERIA MET	4/5	4/5

+ = positive; - = negative

Scoring adapted from Staal JB et al. Injection therapy for subacute and chronic low-back pain. Cochrane Database Syst Rev 2008; 3:CD001824 (57).

spinal cord group experienced improved leg and back pain relief, quality of life, and functional capacity, as well as greater treatment satisfaction. The compliance rate in conventional treatment was low (33%), which raised questions by the authors of ACOEM guidelines (44). Medical management was criticized as being unstructured, with numerous potential confounders and utilization co-interventions (44). They also criticized the sharp reduction in the number who achieved the 50% pain relief target at 12 months, suggesting that the benefits, even if real, are not long-term. However, even at 24-month follow-up, 34 of 72 patients (47%) who received SCS as their final treatment achieved the primary outcome compared to 1 of 15 or 7% for CMM ($P = 0.02$). Overall improvement in leg pain relief and improvement in functional capacity were more robust ($P = 0.0001$ and $P = 0.0002$). Further, some of the criticisms related to inherent difficulties include lack of blinding which is difficult in SCS because of the paresthesia associated with treatment. The study did not blind outcome assessors and even though they reported that the groups were comparable, back pain scores in the control group were higher.

North et al (39) presented results of SCS versus repeated lumbosacral spine surgery for chronic pain in a RCT. Of the 99 patients from a consecutive series invited to participate in the study, 60 candidates consented to randomization and 50 proceeded to a treatment. The 39 patients who refused randomization chose to undergo reoperation. For an average of 3 years postoperatively, disinterested third party interviewers followed 50 patients selected for reoperation by standard criteria and randomized to SCS or reoperation. If the results of the randomized treatment were unsatisfactory, patients were allowed to cross over to the alternative. Success was based on self-reported pain relief and patient satisfaction. Among 45 patients (90%) available for follow-up, SCS was more successful than reoperation (9 of 19 patients versus 3 of 26 patients, $P \leq 0.01$). Patients initially randomized to SCS were significantly less likely to cross over than were those randomized to reoperation (5 of 24 patients versus 14 of 26 patients, $P = 0.02$). Patients randomized to reoperation required increased opiate analgesics significantly more often than those randomized to SCS ($P \leq 0.025$). However, other measures of activities of daily living and work status did not differ significantly. They concluded that SCS is more effective than reoperation as a treatment for persistent radicular pain after lumbosacral spine surgery, and in the great majority of patients, it obviates the need for reoperation. In summary, long-term success rates at 2.9 ± 1.1 years were for SCS, 47% versus reoperation 12% ($P \leq 0.01$). Some have criticized the study because reoperation is essentially a repeat of the same treatment, which in critics' opinions produced a potential bias in favor of the new treatment (44). However, long-term follow-up showed 15 of 29 in the successful group for SCS, while it was only 3 of 16 in the reoperation group. Further, the study was not blinded as blinding is difficult in SCS because of paresthesia associated with treatment. They used a disinterested third party for outcome assessment; this person was not blinded to treatment allocation. An additional limitation is that patients were randomized before the authorization from an insurance company was sought. As a result, 9 patients were not authorized by worker's compensation insurance to participate in the study and one other patient had a stroke; these 10 patients were excluded from the analysis. Moreover, it is not possible to assess the data reported from this study after a mean of 2.9 years as patients were allowed to crossover; which they did. Thus, groups assessed at the longest follow-up were no longer randomized groups. The comparability of the groups also has been questioned (43).

Both studies showed greater patient satisfaction with SCS treatment than with control treatment either in terms of satisfaction with pain relief and agreeing with the treatment or in terms of crossover to alternative treatment.

Observational Studies

Twenty-five observational studies (71-95) were considered for inclusion. Fifteen observational studies failed to meet inclusion criteria and therefore were excluded (80-83,85-95).

Methodologic Quality Assessment

The quality assessment criteria for observational studies are illustrated in Table 4. Of the 10 studies meeting the quality assessment criteria (71-79,84), the scores ranged from 37 to 62 with 9 of them meeting criteria for inclusion for the evidence synthesis.

Study Characteristics

Study characteristics are illustrated in Table 5. These studies are not only observational, but met with multiple deficiencies. Of all the observational studies, only one study had methodologic quality scoring of higher than 60 (76). These studies only assist in form-

Table 4. *Illustration of methodologic assessment of observational studies of spinal cord stimulation.*

CRITERION	Weighted Score (points)	Van Buyten et al (74)	Kumar and Toth (71)	De La Porte and Van de Kelft (73)	Devulder et al (72)	Fiume et al (75)	North et al (76)	Dario (77)	De La Porte and Siegfried (78)	Burchiel et al (79)	Ohnmeiss et al (84)
1. Study Question	2	2	2	2	2	2	2	2	2	2	2
• Clearly focused and appropriate question											
2. Study Population	8	5	5	5	5	5	5	5	5	5	5
• Description of study population	5	5	5	5	5	5	5	5	5	5	5
• Sample size justification	3	-	-	-	-	-	-	-	-	-	-
3. Comparability of Subjects	22	5	5	5	5	5	5	13	5	5	5
• Specific inclusion/ exclusion criteria for all groups	5	5	5	5	5	5	5	5	5	5	5
• Criteria applied equally to all groups	3	-	-	-	-	-	-	3	-	-	-
• Comparability of groups at baseline with regard to disease status and prognostic factors	3	-	-	-	-	-	-	3	-	-	-
• Study groups comparable to non-participants with regard to confounding factors	3	-	-	-	-	-	-	-	-	-	-
• Use of concurrent controls	5	-	-	-	-	-	-	-	-	-	-
• Comparability of follow-up among groups at each assessment	3	-	-	-	-	-	-	-	-	-	-
4. Exposure or Intervention	11	7	8	8	8	7	8	11	8	8	8
• Clear definition of exposure	5	5	5	5	5	5	5	5	5	5	5
• Measurement method standard, valid and reliable	3	2	3	3	3	2	3	3	3	3	3
• Exposure measured equally in all study groups	3	-	-	-	-	-	-	3	-	-	-
5. Outcome measures	20	11	20	18	13	12	20	15	15	15	15
• Primary/secondary outcomes clearly defined	5	2	5	3	5	3	5	5	5	5	5
• Outcomes assessed blind to exposure or intervention	5	2	5	5	-	5	5	-	-	-	-
• Method of outcome assessment standard, valid and reliable	5	2	5	5	3	2	5	5	5	5	5
• Length of follow-up adequate for question	5	5	5	5	5	2	5	5	5	5	5
6. Statistical Analysis	19	5	-	-	5	-	10	-	-	10	10
• Statistical tests appropriate	5	5	-	-	5	-	5	-	-	5	5

Table 4 (cont.). *Illustration of methodologic assessment of observational studies of spinal cord stimulation.*

CRITERION	Weighted Score (points)	Van Buyten et al (74)	Kumar and Toth (71)	De La Porte and Van de Kelft (73)	Devulder et al (72)	Fiume et al (75)	North et al (76)	Dario (77)	De La Porte and Siegfried (78)	Burchiel et al (79)	Ohnmeiss et al (84)
• Multiple comparisons taken into consideration	3	-	-	-	-	-	3	-	-	3	3
• Modeling and multivariate techniques appropriate	2	-	-	-	-	-	2	-	-	2	2
• Power calculation provided	2	-	-	-	-	-	-	-	-	-	-
• Assessment of confounding	5	-	-	-	-	-	-	-	-	-	-
• Dose-response assessment if appropriate	2	-	-	-	-	-	-	-	-	-	-
7. Results	8	8	8	8	8	2	5	5	5	5	5
• Measure of effect for outcomes and appropriate measure of precision	5	5	5	5	5	2	5	2	5	5	5
• Adequacy of follow-up for each study group	3	3	3	3	3	-	-	3	-	-	-
8. Discussion	5	5	5	5	5	2	5	3	5	5	5
• Conclusions supported by results with possible biases and limitations taken into consideration											
9. Funding or Sponsorship	5	5	5	5	5	2	2	2	5	2	2
• Type and sources of support for study											
TOTAL SCORE	100	53	58	56	56	37	62	56	50	57	57

Adapted and modified from West S et al. Systems to Rate the Strength of Scientific Evidence, Evidence Report, Technology Assessment No. 47. AHRQ Publication No. 02-E016 (49).

ing the conclusions regarding treatment effectiveness, and the results should be interpreted with caution keeping in mind their high risk of bias. Consequently, the results shown in these observational studies are more positive than the results from the RCTs. Partly, this is because the results in most cases are reported only for permanently implanted patients. In the studies that reported at least the number of patients who had an SCS trial, the percentage of patients who experienced failed SCS was over 47%. Generally, reporting was inadequate which prevents an appropriate assessment of methodologic quality. Further, when the relevant information was reported, the quality of these reports was in general relatively poor, scoring less than 60. As has been reported in systematic reviews and elsewhere, in accordance with current pain assessment standards, most observational reports showed pain relief using the threshold cutoff of 50% or more, even though they utilized a variety of methodologies. Some studies reported pain relief without reference to a specific cutoff figure using the wording such as poor, fair, good, or excellent. Some have equated good or excellent pain relief as the equivalent to the 50% or more cutoff. Consequently, significant heterogeneity was observed in the level of pain relief with SCS across studies. Pain relief was demonstrated in less than 60% of patients in 4 studies (71,73,76,79), whereas in 5 studies the response was 60% of the patients or more showing improvement (72,74,77,78,84).

Return to work was reported in 31% of the patients (74), 16% (73), and 25% (76), a 26% increase in working capacity (78) was reported, and 13% re-

Table 5. *Characteristics of observational studies of spinal cord stimulation.*

Study/ Methods	Participants	Intervention(s)	Outcome(s)	Result(s)	Conclusion(s) Positive = relief > 12 months
Van Buyten et al (74)	254 patients Over a 10-year period in a single center, 254 patients were subjected to trial period of SCS with an externalized pulsed generator. Of these, 217 of the patients showed satisfactory results justifying permanent implantation of the SCS system. The results were available to an independent physician in 153 patients.	SCS with externalized pulse generator	McGill Pain Questionnaire, VAS, quality of life, sleep disturbance, global patient assessment, pain medication intake and complications.	68% of the patients rated the result of the treatment as excellent to good after an average follow-up of almost 4 years. The resumption of work by 31% of patients who had been working before the onset of pain supports these positive findings.	Positive
Kumar and Toth (71)	Of the 221 patients with SCS for post laminectomy pain, 182 patients were considered for analysis of the effectiveness of SCS in post laminectomy pain, 153 men and 29 women were included.	All patients underwent trial stimulation of 3-to 7-days. Of the 182 patients included in the study, 165 patients (91%) experienced satisfactory initial pain relief and had their systems internalized.	Pain relief graded as poor, good, and excellent. 1) Greater than 75% relief (excellent). 2) 50% to 75% relief (good). 3) Less than 50% relief (poor)..	Minimum follow-up period was 8 months and the maximum follow-up period was 204 months. Average follow-up was 8.8 ± 4.5 years. After an average 8.8 ± 4.5 years of follow-up, 87 internalized patients (53%) continued to receive satisfactory pain relief. Of the 87 patients that were considered successful, 44% reported excellent pain relief and 56% reported good pain relief. Thus, out of the 182 patients in this study 48% of patients experienced 50% or greater long-term relief with SCS.	Negative
De La Porte and Van de Kelft (73)	78 patients with post laminectomy syndrome underwent trial stimulation, of these, 64 underwent an internalization of the system and they were followed every 3 months for a mean follow-up period of 4 years (range 1-7 years).	SCS	Pain relief graded as excellent, good, fair, poor, worse. Excellent with pain relief of 75% to 100%. Good 50% to 74% pain relief. Fair 25% to 49% pain relief. 0% to 24% poor pain relief.	Thirty-seven or 58% of the patients reported satisfactory relief of good to excellent at one-year. At final follow-up 35 patients (58%) continued to experience at least 50% of pain relief at the latest follow-up. Fifty-eight patients (90%) were able to reduce their medication, 39 patients (61%) increased. Fifty-three patients (83%) continued to use their device at the latest follow-up	Positive.
Devulder et al (72)	69 patients with chronic FBSS received SCS. All patients underwent trial stimulation over a period of 2 weeks, however data is not available on trial to permanent stimulation.	SCS	Pain relief, return to work, concomitant use of pain killing drugs. Very good relief more than 80% relief. Almost very good pain relief, 50% to 80% relief. Good relief 50%. Little relief 30% to 50%. Poor relief less than 30%.	Forty-three of 69 (77%) patients continued with the therapy and obtained good pain relief. Ten patients obtained better pain relief than during the trial procedure. Eleven patients have returned to work. The application of SCS cost on an average $3,660 per patient per year.	Positive

Table 5 cont. *Characteristics of observational studies of spinal cord stimulation.*

Study/ Methods	Participants	Intervention(s)	Outcome(s)	Result(s)	Conclusion(s) Positive = relief > 12 months
North et al (76)	A series of 50 patients with FBSS averaging 3.1 previous operations, who underwent spinal cord stimulator implantation.	SCS	Successful outcome was defined as 50% sustained relief of pain and patient satisfaction with the result, improvement in activities, return to work, reduction or elimination of analgesic intake.	Successful outcome was recorded in 53% of the patients at 2.2 years and in 47% of patients at 5 years postoperatively. 10 of 40 (25%) patients who were disabled preoperatively returned to work. Improvements in activities of daily living were recorded in most patients for most activities. Most patients reduced or eliminated analgesic intake.	Positive
Dario (77)	49 patients were included in the study from 1992 to 1997. 44 patients with 20 patients treated medically and 24 patients who did not respond to medical therapy, were treated with SCS implant, and 5 patients underwent further spine surgery.	1) Medical management with other interventions; 2) SCS; 3) Repeat surgery	Visual Analogue scale, pain disability index (PDI), Oswestry scales, leg pain, back pain, work status or daily activities, drug side effects, and use of analgesic medications. Follow-up ranged from 24 to 84 months with a mean of 42 months.	All but 2 patients treated with SCS demonstrated good results for their leg pain (17 of 24 or 71%); but not for back pain. 40% of the patients treated medically demonstrated good results on leg and low back pain. In other cases, good results were transitory and several therapeutic courses were necessary.	Positive
De La Porte and Siegfried (78)	94 patients suffering from low-back pain, with or without spread into the lower extremities.	SCS	Working capacity, and changes in medication, subjective improvement	The long-term results, based on a four-year follow-up, reveal a 60% subjective improvement of pain, a 40% substantial reduction of medication, and a 26% increase in working capacity.	Positive
Burchiel et al (79)	219 patients were entered at 5 centers throughout the United States. 45 patients or 64% of the sample included FBSS.	One hundred eighty-two patients were implanted with a permanent stimulating system. At the time of this report, complete 1-year follow-up data were available on 70 patients, 88% of whom reported pain in the back or lower extremities.	The average pain visual analogue scale, the McGill Pain Questionnaire, the Oswestry Disability Questionnaire, the Sickness Impact Profile, and the Back Depression Inventory. Overall success of the therapy was defined as at least 50% pain relief and patient assessment of the procedure as fully or partially beneficial and worthwhile.	All pain and quality-of-life measures showed statistically significant improvement during the treatment year. Therapy was shown in 55% of patients on whom 1-year follow-up was available. Complications requiring surgical intervention were reported by 17% (12 of 70) of patients. Medication usage and work status were not changed significantly.	Positive
Ohnmeiss et al (84)	40 patients with intractable leg pain with FBSS.	SCS	Sickness Impact Profile, Visual Analogue scale scores, pain status, walking, and overall lifestyle changes. Primary data collection periods were preoperative, 6 week after, and 12- and 24 month follow-up.	Significant improvements were shown in leg pain, sickness impact profile, walking capacity, overall lifestyle, and narcotic intake at 12- and 24-month follow-up in 70% of the patients.	Positive

ported entry into gainful employment (72), whereas one study (80) reported no change in the work status and the others did not report on this variable.

Opioid consumption was assessed across studies using a variety of definitions. Overall, 4 studies reported reduction in opioid intake (73,76,78,84) and in one study (79) there was no change.

Cost-Effectiveness:

Cost-effectiveness was evaluated in 2 systematic reviews (5,43) and 3 studies (96-98) yielding positive results. Manca et al (96) in a prospective, randomized, controlled, multicenter study of patients with FBSS (PROCESS) trial in evaluation of quality of life, resource consumption, and cost of SCS versus CMM in neuropathic pain patients with FBSS showed that the 6-month mean total health care cost in the SCS group (CAN$19,486; €12,653) was significantly higher than in the CMM group (CAN$3,994; €2,594), with a mean adjusted difference of CAN$15,395 (€9997) ($P \leq 0.001$). However, the gain in health-related quality of life (HRQoL) with SCS over the same period of time was markedly greater in the SCS group, with a mean EuroQol-5D (EQ-5D) score difference of 0.25 ($P \leq 0.001$) and 0.21 ($P \leq 0.001$), respectively at 3 and 6 months after adjusting for baseline variables. They concluded that the addition of SCS to CMM in patients with neuropathic leg and back pain results in higher costs to the health system, but also generates important improvements in patients' functional and health status over the same period.

Kumar et al (98) showed the mean cost for SCS therapy over 5 years of CAN$29,123 (inflation-adjusted CAN$30,852) in 2007 equivalent to US$24,799 and patient cost of CAN$41,964 or US$33,722 inflation adjusted for 2007 for conventional pain therapy. During the first 2.5 years, the cost for SCS was higher than conventional pain therapy owing to the initial high cost of implantable devices. After this period, however, the cost for SCS remained significantly lower than that for conventional pain therapy, whereas quality of life results showed a 27% improvement for the SCS group compared with a 12% improvement for the conventional pain therapy group. Sixty percent of the SCS patients reported being very satisfied with therapy, whereas 28% were satisfied and 12% were unsure. In contrast, 15% of the SCS group (9 patients) returned to work, whereas none of the conventional pain therapy group did, which was attributed to superior pain control and lower drug intake. They also showed that the lifespan of the electrode and the battery life of the pulse generator improved by 25%. The payoff period would decrease from 2.5 years to 2.3 years. Finally the authors concluded that despite the initial high cost, SCS is a cost-effective strategy in that it leads to significant cost savings and increased quality of life in the long-term. Consequently, it is hypothesized that if a societal perspective were considered, SCS would be more cost-effective as more people return to work compared with those treated with conventional pain therapy.

North et al (97) performed cost effectiveness and cost utility analysis based on a randomized, controlled trial (39). The data for the first 42 patients was collected by a disinterested third party in a randomized, controlled, crossover trial. With a 3.1 year follow-up, 13 of 21 patients (62%) crossed to reoperation versus 5 of 19 patients (26%) that crossed to SCS ($P \leq 0.025$). The mean cost per success was US$117,901 for crossovers to SCS. No crossovers to reoperation achieved success despite a mean per-patient expenditure of US$260,584. The mean per-patient cost was US$31,530 for SCS versus US$38,160 for reoperation (intention to treat), US$48,357 for SCS versus US$105,928 for reoperation (treated as intended), and US$34,371 for SCS versus US$36,341 for reoperation (final treatment). SCS was dominant (more effective and less expensive) in the incremental cost-effectiveness ratios and incremental cost-utility ratios. A bootstrapped simulation for incremental costs and quality-adjusted life years confirmed SCS's dominance, with approximately 72% of the cost results occurring below U.S. policy makers' "maximum willingness to pay" threshold. The authors concluded that SCS was less expensive and more effective than reoperation in selected FBSS patients and should be the initial therapy of choice compared to reoperation. Thus, SCS is most cost-effective when patients forego repeat operation and finally, if SCS should fail, reoperation is unlikely to succeed.

Effectiveness

Of the 2 randomized trials evaluating SCS, both showed positive results for short- and long-term relief (39,68). Of the 9 observational studies meeting the inclusion criteria with methodologic quality assessment of 50 or higher, all of them showed positive results for short- and long-term relief, except for Kumar and Toth (71).

Table 6. *Results of published studies of effectiveness of spinal cord stimulation in post lumbar surgery syndrome.*

Study	Study Characteristics	Methodological Quality Scoring	Patients	Pain Relief		Results	
				≤ 12 mos.	> 12 mos.	Short-term ≤ 12 mos.	Long-term > 12 mos.
Kumar et al (68)	RA	55	SCS=52 CMM=48	48% vs 9%	58% vs 17%	P	P
North et al (39)	RA	56	SCS=24 Reoperation=26	SCS 9/19 Reoperation 3/26	SCS 9/19 Reoperation 3/26	P	P
Van Buyten et al (74)	O	53	254	–	68%	P	P
Kumar and Toth (71)	O	58	182	–	48%	P	N
De La Porte and Van de Kelft (73)	O	56	78	–	58%	P	P
Devulder et al (72)	O	56	69	–	77%	P	P
North et al (76)	O	62	50	–	53%	P	P
Dario (77)	O	56	49	–	71%	P	P
De La Porte and Siegfried (78)	O	50	94	–	60%	P	P
Burchiel et al (79)	O	57	219	–	55%	P	P
Ohnmeiss et al (84)	O	57	40	–	70%	P	P

RA = randomized; O = observational; SCS = spinal cord stimulation; CMM = conventional medical management; *;* vs = versus; *P = positive*

Table 6 illustrates the results of effectiveness studies for SCS.

Level of Evidence

The indicated evidence for SCS is Level II-1 or II-2 for long-term relief in managing patients with FBSS.

Recommendations

Based on Guyatt et al's criteria (67), the recommendation for SCS is 1B or 1C/strong recommendation with a caveat that the may change when higher quality evidence becomes available.

Discussion

This systematic review evaluating the effectiveness of SCS in relieving chronic intractable pain of post lumbar surgery syndrome indicated the level of evidence of II-1 or II-2 with 1B or 1C/strong recommendation for clinical use on a long-term basis. This assessment included 2 randomized trials (39,68) and 10 observational studies (71-79,84) meeting stringent inclusion and methodologic quality assessment criteria.

The previous systematic reviews of SCS for FBSS identified multiple studies and provided variable evidence. In fact, the results of this review are similar to

the previous evaluations with most of the studies included being the same. In this systematic review we were able to identify only one study by Kumar et al (42) which was included in the reassessment of evidence synthesis of ACOEM guidelines (41), but not in other studies evaluating the effectiveness of SCS. The study is limited by only one additional randomized trial with a total of 2 randomized trials for a procedure which involves escalating use and cost to the health care system in the United States. Consequently, this review may be criticized for using observational studies, however, the evidence is obtained from randomized trials and the addition of observational studies has not contaminated the evidence synthesis, but only increased the strengths of the analysis. The advantages and disadvantages of observational studies, randomized trials, and systematic reviews in pragmatic trials have been well described (61-65).

SCS or neurostimulation has been used to treat chronic intractable pain for 40 years by stimulating nerve fibers in the spinal cord. The resulting impulses in the fibers may inhibit the conduction of pain signals to the brain according to the pain gate theory proposed by Melzack and Wall in 1965 (99) and the sensation of pain is thus blocked. While SCS may reduce pain, it will not eliminate it as it masks the sensation of pain by producing tingling sensations or numbness. Consequently, the sympatholytic effect of SCS is one of its most obvious and interesting of the therapeutic properties considered in managing neuropathic pain secondary to FBSS and other conditions. A retrospective study by Hord et al (100) found that patients with CRPS who responded to smpathetic nervous blocks tended to do better with SCE than those with sympathetically independent neuropathic pain. Yet, no deleterious acute cardiovascular effects were demonstrated (101). SCS is applied through the electrical generator that delivers pulses by means of electrodes placed in the epidural space adjacent to a targeted spinal cord area presumed to be causing the pain. The leads containing electrodes may be implanted by laminectomy or percutaneously. Further, the number and type of leads (unipolar, bipolar, or multipolar) and the parameters of stimulation (amplitude pulse wide electrode sensation) may vary depending on the nerve roots involved and the intensity of the pain being experienced by the patient. An implanted or external battery supplies the power through an external radio-frequency transmitter; however, both sources of power are equipped with a computerized telemetry system that allows transcutaneous programming of the specific pattern of stimulation.

FBSS, defined as persistent back and/ or leg pain after spine surgery, is a growing phenomenon in the U.S., where the likelihood that a person with back pain will undergo operative therapy far exceeds the rest of the world (102). Also known as postlaminectomy syndrome, this umbrella term overlies a constellation of different symptoms and etiologies, the latter of which includes recurrent herniation, arachnoiditis, instability, epidural fibrosis, spinal stenosis, traumatic neuritis (battered root syndrome), juxtafusional discogenic pain, sacroiliac joint pain, and many others (13-19,103-108). Since a significant percentage of these patients experience some form of neuropathic pain, and the success rate of repeat back surgery declines in parallel with the number of reoperations, many of these individuals may be good candidates for SCS. Although recent advances in SCS technology have improved coverage in patients with axial spine pain using dual electrodes (109,110), individuals with predominantly neuropathic extremity pain are still widely acknowledged to be the best candidates for this treatment (108).

In 1983, De Le Porte and Siegfried (78) described the role of SCS in managing lumbosacral spinal fibrosis, also better known as arachnoiditis. The first report of arachnoiditis as a pathological process was described in 1903 (111). Subsequently, Mendel and Adler (112) renamed the condition "meningitis serosa spinalis." Over the years others have referred to inflammation and scarring of the arachnoid lining by a variety of different terms such as "chronic spinal meningitis" (113), "adhesive spinal arachnoiditis" (114), "meningitis serosa circumscripta" (115), and "spinal meningitides with radiculomyelopathy" (116). The first publication implicating disc surgery as a cause of arachnoiditis dates back to 1951 (117). Since then, "arachnoiditis" or "epidural arachnoiditis" has generally been used to describe the persistence of back pain after spine surgery in the absence of recurrent arachnoiditis. In carefully selected patients, refractory to conventional modalities, SCS is considered to be the treament of choice for postsurgical arachnoiditis.

Currently, the selection protocols for SCS implantation stipulate a screening period using temporary percutaneous placement of leads and an external generator (11). Medicare regulations use the following criteria to determine whether or not a candidate is suitable for SCS (118). Adapted from a sample policy from Trailblazer Health Enterprises, LLC:

- To treat chronic pain caused by documented lumbosacral arachnoiditis that has not responded to medical management.
- To treat intractable pain caused by nerve root injuries, including those associated with post surgery syndrome (FBSS).
- The implantation of the stimulator is used only as a last late resort (if not a last resort).
- Other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have not proved to be satisfactory or are judged unsuitable or contraindicated for the given patients.
- Patient has undergone careful physical and psychological screening, evaluation, and diagnosis by a multidisciplinary team prior to implantation. All facilities, equipment, and personnel required for the proper diagnosis, treatment, training, and follow-up must be available.
- Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation.

Practice parameters for the use of SCS in neuropathic pain have also described selection criteria, relative contraindications, and screening procedures (2). Most of these guidelines consider a 3- to 8-day trial period adequate to simulate the anticipated response to the definitive procedure and offer meaningful prognostic information as to whether SCS will succeed or fail. After the trial period the electrode should be rountinely explanted, so that patient and physican expectation bias do not skew interpretation of the screening trial. A successful screening trial results in at least 50% patient-reported pain relief both at rest and in the face of provocative physical activity, along with stable or reduced analgesic consumption and patient satisfaction. If adequate coverage does not occur during the screening trial, a repeat trial may be considered with different lead placement and settings.

Whereas the exact mechanism(s) by which SCS exerts its analgesic effects remain poorly understood, one likely explanation involves the inhibition of pain transmission in the dorsal horn of the spinal cord (36,119,120). For reasons that also elude current understanding, SCS seems to be more effective in treating neuropathic pain than pain resulting from ongoing tissue damage (i.e. nociceptive pain). Estimates regarding the prevalence of neuropathic pain in subjects with chronic back pain generally range between 10% to 19% (121,122) though this percentage is considerably higher in those who have been treated with prior surgery.

The cost-effectiveness analysis in this review augers favorably for the use of SCS in patients with FBSS. However, more evidence is still needed to deterine at which point in the treatment continuum SCS should be considered, who are the best candidates for this treatment, and to further refine the optimal stimulation parameters.

SCS is not a risk-free endeavor. Taylor et al (3) reported that 43% of patients with chronic back and leg pain/FBSS experienced one or more complications with SCS, with the majority of these due to electrode or lead problems (27%). Infections (6%), generator problems (6%), extension cable problems (10%), and other issues, such as cerebrospinal fluid leaks (7%), accounted for most of the remainder. On the positive side, no neurologic-related complications were reported in this systematic review. Recently, a case report was published describing a patient who experienced acute renal failure during a trial of SCS (123).

Conclusion

The results of this systematic review evaluating SCS in FBSS indicates a level of evidence of II-1 or II-2 with a 1B or 1C/strong recommendation for clinical use on a long-term basis.

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