Original Article

Spinal Cord Stimulation: A Valuable Treatment for Chronic Failed Back Surgery Patients

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Abstract
Spinal cord stimulation (SCS) has been used in the treatment of "chronic failed back surgery syndrome" for many years. To evaluate long-term results and cost effectiveness of SCS, we interviewed 69 patients treated during a period of 13 years. Twenty-six patients stopped using SCS; there was no clear explanation for this unsatisfactory result in 10. Forty-three patients continued with the therapy and obtained good pain relief. Electrode breakage either spontaneous or due to a procedure to obtain better stimulation paresthesias was more frequent in the radiofrequency-coupled system group than in the battery group (mean ± SEM 2.81 ± 2.0 versus 1.42 ± 1.51, respectively; P = 0.0018). Ten patients obtained better pain relief than during the trial procedure. Some still need opioid analgesics, but 11 of the 16 who require these drugs obtained a synergistic effect when concomitantly using the stimulator. Eleven patients have returned to work. In our center, the application of SCS costs on average $3660 per patient per year. Although this seems expensive, it may be a cost-effective treatment if other therapies fail. J Pain Symptom Manage *1997;13:296–301. © U.S. Cancer Pain Relief Committee, 1997.*

Key Words
Spinal cord stimulation, failed back surgery syndrome, outcome, chronic pain

Introduction

Lumbar discectomy is followed by unrelieved sciatic pain in 7%–15% of patients.[1] Pain may be difficult to treat in this chronic failed back surgery syndrome (CFBSS). Instability of the lumbar spine as an etiological factor can be treated surgically.[2,3] In the absence of such instability or other treatable problems, pain persists. Although some patients develop fibrosis in the affected nerve root where before there had been a disc herniation, there is not always an association between epidural fibrosis and sciatica in the lumbar postdiscectomy syndrome.[4] Cooper et al. found that the periradicular fibrosis and vascular abnormalities associated with herniated intervertebral discs can occur without inflammatory cell infiltration and represent an important etiopathological factor predisposing to intraneural and perineural fibrosis, and hence

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to chronic pain symptoms, after disc herniation.[5] Regardless of the etiology of the pain, some patients are very disabled, and their return to work appears impossible.

Spinal cord stimulation (SCS) can be considered if pain persists despite conservative treatment and there are no significant psychological antecedents or comorbidities. We present 69 patients with CFBSS implanted with SCS, who were managed over a period of 13 years. These patients were assessed by the authors in terms of return to work, drug intake, patients' pain evaluation (using a verbal pain-rating scale), and medical costs for each year they used the stimulator. We sought to conclude whether SCS implants are worthwhile and to examine the evolution of their outcomes.

Methods

In our department, 102 spinal cord stimulators have been implanted during a period of 13 years for the treatment of chronic pain. Stimulators were implanted in 69 patients with CFBSS. Implantation was only considered when no other surgical option was seen as potentially curative. None of the patients was psychologically impaired, and all had undergone a trial stimulation with a temporary electrode during a 2-week period. In our country, a long trial period associated with sufficient pain relief is requested for reimbursement of the neurostimulator. All patients obtained considerable pain relief during the trial. This relief was determined by a decline in the verbal pain score of more than 50%; an increase in daily activities; a decrease in drug intake, and/or an improvement in sleep pattern. Implantation was not done if the results of trial stimulations were poor.

The final SCS population with permanent implanted electrodes comprised 102 patients. For this paper we only considered the 69 patients with CFBSS. Twenty-seven patients were implanted with a radiofrequency-coupled system (RF), and 42 received a battery system. The RF system was used if the patient required a relatively high voltage (more than 4 V) or if the amplitude needed numerous adjustments depending on the patient's position. The older battery stimulators were equipped with only two preprogrammed amplitudes.

1 Name of the patient..... implant date.....

2 Do you still use the stimulator?... Since when..... and why?.....

3 Do you obtain pain relief by using the stimulator?.....

4 How much pain relief do you obtain?
4 poor < 30%..... 1 almost very good 50-80%.....
3 little 30-50%.....0 Very good > 80%.....
2 good relief (50%)

5 Do you still take other drugs?

6 What drugs do you need?

7 Do you obtain better pain relief by the stimulator and by using drugs?

8 What activities can you perform?

9 Can you return to work?

10 Did you obtain better pain relief during the trial procedure than now?

Fig. 1. Questionnaire.

To evaluate long-term effectiveness, an independent reviewer telephoned the 102 patients and asked about: activities such as return to work, stimulator use, effectiveness, and concomitant use of pain-killing drugs (Figure 1). The patients rated their pain relief using a verbal pain scale [0 = very good relief (more than 80% relief); 1 = almost very good relief (50%–80%); 2 = good relief (50%); 3 = little relief (30%–50%); and 4 = poor relief (less than 30%)]. A category score (0 = good pain relief, no need for medication; 1 = good pain relief and the use of non-opioid drugs; 2 = good pain relief and use of "weak" opioid; 3 = good pain relief and the use of "strong" opioid; 4 = little pain relief; and 5 = stopped stimulation) was used for evaluation by the reviewer. The reviewer also asked about patients' pain relief during the trial procedure and the relief obtained now. If the stimulation had been stopped, the reason for this was sought.

We examined possible correlations between these outcomes and both the type of stimulator and the gender of the patients. We also attempted to calculate the cost per year for patients using the stimulator and for those who stopped. This amount was obtained by calculating the costs of the materials (battery system, electrode, etc.) and hospital stays for each patient. Hospital stays for implantation

Table 1
Patient Population, Stimulator System, and Results

System	N	Age (years) Mean ± SD	Present situation			Return to work	
			In use	Cont.	Intermitt.		"Weak" opioids
Battery SCS	42	52 ±9.8	28	18	10	7	3
RF SCS	27	49.8±9.1	15	14	1	4	1
Total	69	43	32	11	11	4	

N, total number; SD, standard deviation; cont., continuous use; intermitt., intermittent use; RF SCS, radiofrequency-coupled SCS; SCS, spinal cord stimulation.

were estimated as 14 days (trial procedure included) and as 3 days for electrode revision. Costs for battery replacements were calculated as a 1-day stay. Costs for drugs were not considered, as they were used by stimulator users as well as by those who stopped stimulation. Statistical analysis employed the non-parametric Spearman correlation and the non-parametric signs test. A P value less than 0.05 was considered significant.

Results

The mean age of the 69 patients with CFBSS and SCS was 51.1 ± 9.6 years. The population comprised 34 women (age, 49.5 ± 9.0 years) and 35 men (age, 52.7 ± 9.9 years). There was no significant difference in age between the men and women ($P = 0.15$). Forty-two patients received a battery system (age: 52.0 ± 9.8 years), and 27 patients (age, 49.8 ± 9.1 years) received a radiofrequency-coupled (RF) system (Table 1). Nineteen patients were implanted with Cordis neurostimulators (Cordis, Miami, US) (19/69); the remainder, who were treated since 1988, received Medtronic (Minneapolis Inc.) systems.

Forty-three patients still used the stimulator (28 battery and 15 RF-coupled systems). The average period of use was 4.9 ± 3.3 years. No significant difference was found between the battery and the RF systems ($P = 0.68$).

Eleven patients returned to work. Fourteen used the stimulator as the only instrument to alleviate their pain (12 battery and 2 RF). Eleven patients used a non-opioid drug together with SCS, 16 patients used a "weak" opioid, and two a "strong" opioid together with the stimulator (Table 2).

A positive correlation was found between the category score and the patient's pain evaluation ($P = 0.014$). This condition was not detected in the radiofrequency group alone ($P = 0.059$).

The electrodes were implanted at the level where the best stimulation paresthesias could be obtained. Forty-five electrodes were placed between the seventh and eleventh thoracic vertabrae. At first, the electrodes were implanted neurosurgically and fixed to the dura to prevent dislocation, and a "mini-laminectomy" was necessary for electrode introduction. Later, with the Medtronic systems, the electrodes were introduced, if possible, percutaneously (27 of 69 cases). Neurosurgical fixations were required where percutaneous introduction was too difficult.

Multiple electrode reinterventions were needed. The battery systems need significantly fewer electrode interventions than the RF sys-

Table 2
Patient Population, Stimulator System, and Results

Pain treatment	N	Battery	RF	Intermittent use	Continuous use	Pain relief trial SCS versus now		
						Better	=	Worse
Only stimulator	14	12	2	6	8	1	9	4
Stim. + non-opioid	11	6	5	2	9	5	4	2
Stim. + "weak" opioid	16	8	8	2	14	7	5	4
Stim. + strong opioid	2	2	0	0	2	1	1	0
Total	43	30	15	10	33	14	19	10

SCS, spinal cord stimulation; Stim., stimulator.

Table 3
Reinterventions (Electrode and Battery) and Continued Use Afterward

Electrode reinterventions	Patient	New electrodes	Still use the stimulator
Battery system	25/42	60	19/25
RF system	23/27	67	13/23
Total	48/69		32/48
Battery reinterventions		Newbatteries	
Battery system	31/42	66	20

RF, radiofrequency-coupled.

tems (60 electrodes for 42 battery patients versus 67 electrodes for 27 RF patients, $P = 0.0018$) (Table 3). The RF patients were those with poor stimulation quality. They could only obtain paresthesias using higher amplitudes or by continuously changing their parameters. This might explain different reinterventions to obtain a better paresthesia overlap. The Spearman correlation showed no relationship between the frequency of reintervention and the final category score ($P = 0.8$). As noted, there was no correlation between the category score and the patient evaluation in the RF group; this indicated that reinterventions could not ameliorate patients' satisfaction for the RF group.

We found a positive correlation between the duration of SCS use and the category score ($P = 0.0002$). This relationship was less strong among female patients ($P = 0.055$).

Fourteen of the patients still using the stimulator reported that pain relief was better during the trial stimulation period than in the present (14/43). Conversely, ten patients reported better pain relief than during the trial, and 19 described the same perceived degree of pain relief as during the trial (Table 2). Higher category scores were associated with better pain relief in the present than during the trial ($P = 0.014$). There was no apparent correlation between the patient's age and the category score. With the RF system, however, there appeared to be a slight negative correlation, the older the patient the worse the score ($P = 0.03$).

Twenty-six patients no longer used the stimulator. Three died of another disease, three could not be contacted, two obtained pain relief after orthopedic back surgery, and two became pain free spontaneously and no longer needed the device. Six patients never had the painful area adequately overlapped by stimulation paresthesias, which might explain the failure to obtain pain relief. Another ten patients, however, had good overlap but never attained sufficient pain relief. Eleven patients reported synergy in pain- relieving effects between the use of SCS and a "weak" opioid.

Our population of 69 patients totalled 341 years of neuro-stimulator use. In aggregate, each year of stimulation cost $3660 per patient. If we consider only those patients who continued to use the device, 1 year of stimulation cost $3400. If we recalculate the cost and only consider the materials implanted in a day-surgery setting, the price could be reduced to $3030 for each patient each year and to $2730 for every successful user.

Discussion

Applying electrical current to the spinal cord was first described by Shealy et al.[6] The CFBSS was one of the first indications for such treatment. Later, SCS was used for various other indications, such as motor disorders, cancer pain, and ischemic pain.[7-12] The physiological mechanisms of SCS remain obscure, although the gate control theory of Wall and Melzack attempted to explain the induced analgesia.[13] It has been shown that various neurotransmitters are released during stimulation, and, depending upon the condition, this release might explain its effects.[14-19] For example, gamma-aminobutyric acid (GABA) is probably important for pain relief and is released in the dorsal horn by electrical spinal cord stimulation.[17]

Questions remain about whether the use of SCS is a rational investment for patients with CFBSS, a ver complex pain syndrome. Patients may have nerve destruction, and frequently there is fibrosis around the affected nerve root.[5] As in all chronic pain syndromes, psychological impairment can be present and may be an important prognostic factor for the

success of SCS in chronic back and leg pain.[20-22] Such complexities complicate efforts to predict the outcome of this technique. Nevertheless, the implantation of a SCS system is a nondestructive technique, and moreover, a prospective study has shown that SCS can yield better outcomes in this syndrome than reoperation.[23]

Our results also show that SCS can relieve pain adequately and allow some patients to return to work. Some patients gained relief from the electrical stimulation alone, and others apparently experienced synergistic effects from SCS and opioids. Analgesia due to systemic opioids is believed to be partly the result of the activation of medullary neurons projecting to the spinal cord,[24] which might explain the observed synergy.

In our center, the long-term use of SCS is expensive. The high cost cannot be explained by longer hospital stays, as surgery in a 1-day setting also costs $3030 per patient. Much of the expense comes from electrode reinterventions, especially the cost of materials. This observation suggests that only those patients with stable stimulation parameters should be implanted. In this context, we can agree with observations by North et al. about the superiority of multichannel stimulators.[25] These devices provide the opportunity to change the electrode combinations so that optimal paresthesia conditions can be achieved.

We cannot precisely explain the finding of better category scores in men than women. We can only speculate that our observations correspond with the report by Wright et al. that elderly women are at greater risk of lower back pain than are men.[21] We also found that women in the RF group obtained a worse category score than men. Their mean age was greater than that of the men, but the difference was not statistically significant ($P = 0.11$). Nevertheless, we judge that age may be a negative prognostic factor.

The appreciation of pain relief during stimulation may vary as a function of time. In some patients, we can assume that tolerance is present, especially in those no longer experiencing pain relief, but others observed the contrary effect. This subjective feeling might have been influenced by natural healing, as two patients did not need the stimulator after a few years.

It is obvious, considering the costs involved, that strict criteria for patient selection should be maintained. SCS should only be used if surgery is contraindicated and would produce a yet more negative outcome. In two of our patients, SCS was insufficient, and final relief was obtained by surgical reintervention (one decompressive laminectomy and one fixation of the vertebrae). In these cases, SCS would be a waste of money in the long term. We also note that whenever SCS analgesia becomes poor but is not correlated with bad paresthesia overlap, the patients stop using the stimulation.

We found an increase in the cost when failures were taken into account. A patient who benefits from the stimulation costs $3400 as compared with $3660 for the whole SCS population studied. Burchiel et al. also found that patients who report poor pain relief soon after implant substantially increase the cost/benefit ratio of the procedure as a whole.[20] We found the same result, but still argue that SCS should not be abandoned immediately if poor analgesia is the result of bad paresthesia overlap. Reinterventions are indicated as long they can improve the quality of the stimulation paresthesias. The battery systems may be more attractive in this regard, as reintervention is statistically less frequent than for the RF systems.

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