

## TREATMENT OF CHRONIC PAIN WITH SPINAL CORD STIMULATION VERSUS ALTERNATIVE THERAPIES: COST-EFFECTIVENESS ANALYSIS

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**Received,** August 20, 2001.

**Accepted,** February 19, 2002.

**OBJECTIVE:** There is limited available research measuring the cost-effectiveness of spinal cord stimulation (SCS), compared with best medical treatment/conventional pain therapy (CPT). The purpose of this study was to tabulate the actual costs (in Canadian dollars) for a consecutive series of patients treated with SCS in a constant health care delivery environment and to compare the costs with those for a control group treated in the same controlled environment.

**METHODS:** We present a consecutive series of 104 patients with failed back syndrome. Within this group, 60 patients underwent SCS electrode implantation, whereas 44 patients were designated as control subjects. We monitored these patients for a 5-year period and tabulated the actual costs incurred in diagnostic imaging, professional fees paid to physicians, implantation (including the costs for hardware), nursing visits for maintenance of the stimulators, physiotherapy, chiropractic treatments, massage therapy, and hospitalization for treatment of breakthrough pain. From these data, the cumulative costs for each group were calculated for a 5-year period. An analysis of Oswestry questionnaire results was also performed, to evaluate the effects of treatment on the quality of life.

**RESULTS:** The actual mean cumulative cost for SCS therapy for a 5-year period was \$29,123/patient, compared with \$38,029 for CPT. The cost of treatment for the SCS group was greater than that for the CPT group in the first 2.5 years. The costs of treating patients with SCS became less than those for CPT after that period and remained so during the rest of the follow-up period. In addition, 15% of SCS-treated patients were able to return to employment, because of superior pain control and lower drug intake. No patients in the control group were able to return to employment of any kind.

**CONCLUSION:** SCS is cost-effective in the long term, despite the initial high costs of the implantable devices.

**KEY WORDS:** Chronic pain, Cost-effectiveness analysis, Spinal cord stimulation

*Neurosurgery* 51:106-116, 2002

DOI: 10.1227/01.NEU.0000017314.03296.44

www.neurosurgery-online.com

Chronic benign pain in general, and back pain in particular, has generated interest because of its persuasive nature and the high treatment costs, loss of earnings, reduced productivity, and individual suffering involved. Spinal cord stimulation (SCS) has proven to be an effective therapeutic modality for the treatment of certain chronic pain syndromes (4, 5, 7, 11, 14, 19-21, 24). Our experience with SCS for the treatment of chronic benign pain encompasses two decades (14). Common indications for SCS include failed back syndrome, pain associated with peripheral vascular disease, peripheral neuropathies, multiple sclerosis, and complex regional pain syndrome I (1, 9, 12, 13, 15). Patients who received SCS in our series were all gated

through multidisciplinary pain clinics, where traditional modalities of pain relief had failed. Although the literature recognizes that SCS has its place in the treatment of chronic intractable pain, there are few data to measure the cost-effectiveness of SCS in chronic pain therapy. The financial pressures on third-party payers with advances in medical technology have increased the need for physicians to include cost-effectiveness as a parameter in treatment planning.

The purpose of this study was to evaluate the costs of SCS therapy, compared with conventional pain therapy (CPT), for a consecutive series of 104 patients with failed back syndrome. In this group, 60 patients underwent SCS, whereas 44 patients

continued treatment with conservative treatment modalities. To quantify the effects of these treatments on the quality of life, the Oswestry questionnaire (6) was administered at the time of patient enrollment into the study and during the follow-up period.

Our data suggest that the cumulative costs of SCS therapy are bimodal, with an initially high component for 2.5 years because of the requirement for expensive implantable hardware. After that period, the costs of CPT were greater than those of SCS therapy through 5 years. We made no attempt to attribute monetary values to the degree of pain relief, the benefits of a return to employment, improvements in the quality of life, or reductions in workman's compensation benefits, where applicable, because of multiple variable factors and the subjectivity that such calculations would impose. Such considerations would increase the advantages of SCS over CPT.

## PATIENTS AND METHODS

### Patient Selection

We have a large database that includes data for 350 patients who have undergone SCS in the past 20 years. For this study, we extracted data for consecutive patients with failed back syndrome. One hundred twenty-two patients were included in that category. All patients were initially gated through a multidisciplinary pain clinic, where conservative methods had failed. The patients were then referred for SCS therapy. While these patients were awaiting trial stimulation, 18 patients either moved or refused to participate in the study and thus were lost to follow-up monitoring. Because none of those 18 patients received further treatment of any kind, they did not incur further expense to the system. Therefore, we did not factor in anticipated costs for the purposes of this study.

These exclusions left a working group of 104 patients who were monitored for a minimum of 5 years. The data were derived from chart reviews and follow-up appointments, supplemented with telephone interviews. The patients were then subdivided into two groups, i.e., Group A (with implants, SCS group) and Group B (without implants, CPT/control group). The groups were matched with respect to age, sex, mean number of operations performed before enrollment into the study (3.3 operations), and time away from work since injury (minimum of 1 yr), and all patients were evaluated by the same multidisciplinary pain specialist group.

Group A consisted of 60 patients (57.7%; 28 female patients [47%] and 32 male patients [53%]), with a mean age of 52.3 years. After evaluations and successful trials, these patients underwent permanent SCS electrode implantation, and they continued to achieve more than 50% pain relief throughout the 5-year follow-up period. There were no explanations of the system because of loss of pain control; although four patients exhibited slight decreases in efficacy during the follow-up period, they continued to be quite comfortable and satisfied with the stimulation program.

The control group design was necessarily limited by practical considerations for human experimentation. An ideal control group would be composed of patients who were referred for SCS and responded favorably to trial stimulation but were then randomly assigned to the implant-treated group (surgical treatment, Group A) and a control group (Group B) in which the functioning electrode was removed after trial stimulation. In that event, the patients in the control group would have undergone surgical procedures specifically designed not to benefit the patients, which is an ethically intolerable situation. To maintain consistency in as many parameters as possible, including the use of a surgical procedure, our control group (medical treatment, Group B) was defined as patients who were referred for SCS but did not undergo electrode internalization. Internalization was not performed because those patients did not achieve more than 50% pain relief from their stimulators, despite stimulation-induced paresthesia covering the territory of the pain. The failure to achieve pain control may be attributable to nonspecific reasons. This control group constitutes a reasonable sample for comparisons between long-term surgically treated and conservatively treated patients with similar causes for their pain.

Group B consisted of 44 patients (42.3%; 21 female patients [48%] and 23 male patients [52%]), with a mean age of 51.4 years. This group was treated with conservative/noninterventional therapies, was matched with Group A, and was monitored every 6 months (in a manner similar to that for Group A) during the 5-year study period.

### Cost Calculations

The costs tabulated in this study are actual costs based on year 2000 prices, in Canadian dollars. The costs incurred in the treatment of patients who underwent SCS were calculated under the following headings: 1) hardware used in SCS, 2) professional fees, 3) radiological investigations, 4) hospital admissions, 5) drugs, 6) nursing contacts, and 7) electrode or pulse generator replacement during the 5-year follow-up period. The costs of treatment for patients who were monitored with medical treatment were calculated in a similar manner, using the following parameters: 1) physician and other health care professional fees, 2) drugs, 3) radiological investigations (computed tomographic [CT]/magnetic resonance imaging [MRI], myelographic, and x-ray studies), 4) alternative therapies (massage, physiotherapy, and chiropractic treatments), and 5) hospital admissions for treatment of breakthrough pain.

### Effects of the Canada Health Act

To non-Canadian readers, the cost calculations presented in this article may seem low, compared with their experience in the United States or western European countries. The lower financial costs are attributable to differences in pricing by the manufacturer of the implantable devices used and tight regulation (by the provincial or federal government) of the fee schedules for various professional organizations. However,

the cost comparisons between SCS and CPT are valid on a relative basis. It is important to note that, in Canada, the health care system is universal, accessible, comprehensive, portable, and publicly funded and is governed by the Canada Health Act, which was enacted in 1984 by the federal government and is administered by each province for its subjects. The Canada Health Act outlines necessary requirements that provincial health care insurance plans must fulfill. Under this act, hospitals are prohibited from adding any premium to the actual cost of any implantable device.

### Costs of Implantable Devices

The costs for implantable devices were calculated from the year 2000 price list provided by the manufacturer (Medtronic of Canada, Ltd., Mississauga, ON, Canada), as charged to Canadian hospitals. We used the actual prices charged to hospitals by the manufacturer, because no increases in the prices to patients are permissible under Canadian law. The implantable devices used in SCS treatment consisted of an electrode, pulse generator, and connector cord. The pulse generator needed to be replaced after 3.5 to 4.5 years (the average lifespan of its battery). Some designs are externally powered and do not require periodic battery replacement; however, those devices have poor patient acceptance because of the inconvenience of carrying the transmitter on the belt and the use of antennae, which frequently cause skin rashes and allergic reactions. For our calculations, we observed that the frequency of pulse generator replacement was, on average, once every 4 years. Our study also revealed that the electrode required replacement once every 5 years, on average, because of fracture, migration, or fibrosis. The cost associated with electrode replacement was amortized for a 5-year period, because there was no identifiable average electrode lifespan.

### Costs Associated with Iatrogenic Complications

The following iatrogenic complications were observed: 1) superficial infections that resolved with antibiotic treatment, without explantation; 2) infections that required explantation and treatment with antibiotics, followed by reimplantation; and 3) respiratory complications that required antibiotic treatment and prolonged hospital stays. In the first 1 year after implantation, we observed four infections. In two cases, the infections were superficial and resolved with intravenously administered antibiotics. The other two cases required explantation, followed by antibiotic therapy and reimplantation. Eight cases involved minor respiratory complications, such as atelectasis or pneumonia. These were treated with appropriate antibiotics as indicated, in conjunction with respiratory therapy.

### Medical Personnel Costs

Physicians and other health care professionals in Canada are paid on a fee-for-service basis. The fee schedules for various professional bodies are controlled by the provincial governments, after negotiation with the professional licensing bodies. The fees paid to the various physicians and surgeons

in the study were derived from the year 2000 payment schedule for the Saskatchewan Medical Association.

### Nursing and Allied Health Care Professional Costs

The costs of nursing contacts for the maintenance of patients enrolled in the SCS group were derived from the hourly wages paid to the health care workers, as determined by the nursing union contract. Each patient contact was equated to 1 hour of wage. A similar approach was used for social worker involvement. The costs of physiotherapy, chiropractic treatment, massage therapy, and acupuncture were determined on the basis of the fee schedules approved by the respective associations.

### Costs of Investigations

The costs of various imaging procedures (CT, MRI, myelographic, and x-ray studies) were provided by the finance department of the Regina Health District.

### Hospitalization Costs

The daily hospitalization cost, as approved for the institution at which the study was conducted, was \$627. This was the exact amount paid to the hospital by the government of Saskatchewan in the year 2000. No markup is chargeable to patients, according to Canadian law.

### Pharmacotherapy Costs

The pharmacotherapy costs that the patients paid for pain management were determined by using the Saskatchewan Health Formulary (Table 1). The drugs commonly used by patients in our series included antidepressants, benzodiazepines, opioids, nonsteroidal anti-inflammatory drugs, analgesics, and muscle relaxants. These costs were determined on a monthly basis, allowing a prefixed, government-approved, pharmacy markup schedule (over wholesale prices) and a flat rate for dispensing (Table 1), according to the current pharmaceutical standards of practice. In our province, the government approves the wholesale price of each drug, the allowable markup for each drug, and the chargeable dispensing fees.

**TABLE 1. Formulae used in the calculation of costs for pharmacotherapy<sup>a</sup>**

A. Wholesale cost of a particular medication/mo = wholesale cost of medication/pill × number of pills consumed/patient/d × 30 d/mo
B. Pharmacy markup schedule (over wholesale cost)
\$0–6.31, 30% markup
\$6.32–15.81, 15% markup
\$15.81–200.00, 10% markup
C. Dispensing fee for each drug for 1-mo supply = \$7.15

<sup>a</sup> Total cost/mo/medication = Cost A + Cost B + Cost C.

**Cumulative Cost Calculations**

*Group A*

The actual cumulative costs were determined via data collection under the following headings (*Tables 2 and 3*): 1) professional costs (medical consultation fees and surgical costs);

**TABLE 2. Evaluation and implantation cost<sup>a</sup>**

	Unit cost (\$)	Average unit frequency (d)	Average unit cost (\$)	Average cost/patient (\$)
<b>Consultation</b>				
Psychiatrist	108			
Social worker	84			
General practitioner	44			426
Neurosurgeon	57			
Neurologist	85			
Orthopedic surgeon	48			
<b>Investigations</b>				
CT scans	465	1.7	822	
MRI scans	1045	1.1	1184	2390
X-rays	36	5.6	202	
Myelograms	135	1.4	182	
<b>Surgery</b>				
<i>Anesthesia</i>				
Implantation	192			
Internalization	93			
<i>Neurosurgical professional fees</i>				
Implantation	593			1156
Internalization	216			
Assistant surgeon	62			
<b>Pulse generators</b>				
Itrel III	5825			
Itrel II	5675			6110
X-trel	7650			
<b>Electrodes</b>				
Resume	1595			1595
Pisces-Quad	1595			
In-line connector	625			625
<b>Complications</b>				
Explantation	236	2	472	
IV antibiotic treatment	56	2	112	308
Reimplantation	8617	2	17,234	
Respiratory complications	153	4	612	
Antibiotics for superficial infections	14	2	28	
Hospital admission	627	6.9		4326
<b>Total</b>				<b>16,936</b>

<sup>a</sup> CT, computed tomographic; MRI, magnetic resonance imaging; IV, intravenous.

2) costs of various imaging investigations; 3) costs of implantable equipment (electrode, pulse generator, and in-line connector); 4) costs of treatment of iatrogenic complications (infections); 5) costs of pharmacotherapy to control breakthrough pain; 6) hospital admission costs for implantation, if needed; 7) SCS maintenance costs, calculated by adding fees associated with physician contacts, nursing contacts, electrode changes because of fracture, malfunction, or shifting (with the associated professional costs and hospital charges for treatment of the pathological condition), and pulse generator changes (with the associated professional costs and hospital charges); and 8) physician contact costs (statistical analysis for our series revealed that patients with functional implants visited a family physician four times/yr and a neurosurgeon twice/yr). After we determined the yearly costs, we extrapolated the cumulative costs for a period of 5 years (*Tables 2–4*).

*Group B*

The actual cumulative costs were determined via data collection under the following headings (*Table 5*): 1) costs of evaluations by various health care professionals, including family physicians, orthopedic surgeons, psychiatrists, social workers, neurologists, and neurosurgeons; 2) imaging costs (CT, MRI, x-ray, and myelographic studies) required initially and during episodes of pain flare-up (in our series, it was observed that patients required one CT study and one MRI study every 2 yr); 3) pharmacotherapy costs, calculated as outlined for Group A; 4) costs of alternative therapies (physiotherapy, chiropractic treatments, massage therapy, and acupuncture); and 5) costs of intermittent hospitalization for treatment of acute breakthrough pain (in this series we observed that patients experiencing breakthrough pain required an average of 3 d of hospitalization/yr). It should be noted that surgical costs, including the costs of hardware for trial stimulation and hospital charges for that time, were not included for Group B.

**Evaluation of Quality of Life and Patient Satisfaction**

To determine the effects of SCS treatment on the quality of life and function, we administered the Oswestry disability questionnaire (6) at the time of enrollment into the study and every 1 year during the follow-up period. The results were then averaged for a 5-year period. With a separate questionnaire, patients who underwent SCS were questioned regarding their satisfaction with the treatment, whether they would undergo a repeat procedure for the same degree of benefit, and whether they would recommend this procedure to their friends and relatives with similar pain problems.

**RESULTS**

**Group A**

Sixty patients were included in Group A. Calculations of the average initial costs of implantation for the patients who received permanent SCS implants are summarized in *Table 2*.

**TABLE 3. Costs of spinal cord stimulation maintenance**

Description	Unit cost (\$)	Unit (frequency)	Cost (\$)	5-yr cost (\$)
Physician contacts				
<i>Family physician</i>	44	4 visits/yr	176	
<i>Neurosurgeon</i>	57	2 visits/yr	114	
<i>Total</i>			290	1450
Nursing contacts for stimulation parameter optimization and counseling	30	3.1 visits/yr	92	460
Pharmacotherapy for pain flare-ups	302			1510
Electrode change <sup>a</sup>	1595	1	1595	1595
Professional costs for electrode change <sup>a</sup>				
<i>Anesthesia</i>	93			
<i>Neurosurgeon</i>	275			
<i>Hospital charge</i>	75			
<i>Total</i>	443			443
Pulse generator replacement <sup>b</sup>	6005	1		6005
Professional fees for pulse generator change <sup>b</sup>				
<i>Anesthesia</i>	284			
<i>General practitioner consultation</i>	44			
<i>Neurosurgeon consultation</i>	57			
<i>Neurosurgeon</i>	202			
<i>Assistant surgeon</i>	62			
<i>Hospital charge</i>	75			
<i>Total</i>	724			724
<b>Total (5-yr cost)</b>				<b>12,187</b>

<sup>a</sup> Once in every 5-year period.

<sup>b</sup> Once in every 4-year period.

**TABLE 4. Costs of treating a patient with chronic pain with stimulation for 5 years**

Data	Costs (\$)
<i>Table 2</i>	16,936
<i>Table 3</i>	12,187
<b>Total (Table 2 + Table 3)</b>	<b>29,123</b>

The types of pulse generators used in this study included Itriel II, Itriel III, and X-trel (Medtronic, Inc., Minneapolis, MN). Thirty-nine patients (65%) received Itriel II pulse generators, 14 (23%) received Itriel III pulse generators, and 7 (12%) received X-trel pulse generators. The average pulse generator cost was \$6110. The electrodes used in this series were either Resume or Pisces-Quad electrodes (Medtronic, Inc.), with an average price of \$1595. The average cost for the in-line connectors was \$625. The initial imaging costs (before implantation) for x-rays, myelograms without CT scans, CT scans, and MRI scans of the

lumbar spine were \$202, \$182, \$822, and \$1184, respectively, totaling \$2390. Professional costs, which included costs for initial assessments by a primary care physician and consultation services rendered by an orthopedic surgeon, psychiatrist, social worker, neurologist, and neurosurgeon, totaled \$426. The costs of surgery and anesthesia for implantation were \$1156 for each implantation and anesthesia procedure. The average cost for treatment of iatrogenic complications was \$308. The hospital charges during the study period were \$627/d, with an average hospital stay of 6.9 d/patient, totaling \$4326. These costs totaled \$16,936/patient in the year of implantation (Table 2).

Maintenance costs included costs for follow-up monitoring by a family physician, a neurosurgeon, and a neuromodulation nurse and the costs of medications used during flare-up periods (Table 3). Patients with functional implants visited their family physicians four times/yr and a neurosurgeon twice/yr, at a total cost of \$290/yr. Neuromodulation nursing contact costs for implant maintenance (optimization of stimulator parameters) were \$92/yr/patient; an average of 3.1 contacts/yr were required. The cost of medications for the treatment of breakthrough pain was \$302/yr. Our records

**TABLE 5. Annual medical resource use by patients who have undergone nonsurgical chronic care<sup>a</sup>**

Therapy description	Unit cost (\$)	Average unit (frequency)	Cost/yr (\$)	5-yr cost (\$)
Physician visits (24 visits/yr with family physician)	22	24	528	2640
Specialist consultation				
1 visit with neurologist	85	1	85	425
1 visit with neurosurgeon	57	1	57	285
1 visit with orthopedic surgeon	48	1	48	240
1 visit with psychiatrist/psychologist	108	1	108	540
Social worker	21	4 h	84	420
Hospitalization for breakthrough pain	627	3 d	1881	9405
Medications (antidepressants, anti-inflammatory agents, benzodiazepines, muscle relaxants, opioids) <sup>b</sup>	861		861	4305
Alternative therapies				
Physiotherapy	30	57.6	1736	8680
Chiropractic treatment	22	17.2	373	1865
Massage therapy	40	10.1	404	2020
Acupuncture	35	10.6	371	1855
Total for alternative therapies			2884	14,420
Total maintenance cost (Cost A + Cost B + Cost C + Cost D + Cost E)				6536
Initial diagnostic procedures <sup>c</sup>				
CT scans, lumbar spine	465	1.8	825	825
MRI scans, lumbar spine	1045	1.0	1071	1071
X-rays, lumbar spine	36	6.8	244	244
Myelograms	135	1.4	189	189
Total for diagnostic procedures			2329	2329
Total			8865	35,009
Diagnostic procedures precipitated by flare-ups during study, CT and MRI scans, lumbar spine <sup>d</sup>	1510	2	3020	3020
Total (5-yr)				38,029

<sup>a</sup> CT, computed tomographic; MRI, magnetic resonance imaging.

<sup>b</sup> Derived from chart review.

<sup>c</sup> For establishing diagnosis and entry into the study.

<sup>d</sup> Performed once every 2 years.

revealed that SCS patients required, on average, one electrode change during the 5-year study period (precipitated by fracture, shifting, or nonfunction); the associated costs of surgery for replacement were \$2038 (cost of the electrode [\$1595] + professional costs [\$368] + hospital costs [\$75]). The pulse generator also needed to be replaced an average of once every 4 years, at a cost of \$6729, because of battery power depletion.

To determine the cumulative costs, we projected these calculations for a 5-year period by determining the following average costs per patient per year (Tables 2 and 3): Cost a, costs of the initial evaluation (\$426) and investigations (\$2390); Cost b, cost of implantation (\$13,812; hardware costs, \$8330; surgi-

cal fees, \$1156; hospitalization costs, \$4326); Cost c, cost of treatment of iatrogenic complications (\$308); Cost d, SCS maintenance cost (\$684; physician, \$290; nursing contacts, \$92; drugs, \$302); Cost e, cost of electrode replacement (once every 5 yr) (\$2038; for purposes of calculation, this was amortized for a 5-yr period at \$408/yr); Cost f, cost of pulse generator replacement (once every 4 yr) (\$6729; pulse generator, \$6005; surgical fees, \$649; hospital costs, \$75). Therefore, the cumulative costs were as follows (Table 6): Year 1, Cost a + Cost b + Cost c + amortized Cost d; Year 2, Year 1 cost + Cost c + amortized Cost d; Year 3, Year 2 cost + Cost c + amortized Cost d; Year 4, Year 3 cost + Cost c + amortized Costs d + e;

**TABLE 6. Actual annual costs of spinal cord stimulation and conventional pain therapy for 5 years<sup>a</sup>**

Year	Actual costs (\$)		Cumulative costs (\$)	
	SCS	CPT	SCS	CPT
1	18,028	8865	18,013	8865
2	1092	7291	19,120	16,156
3	1092	7291	20,212	23,447
4	7819	7291	28,013	38,738
5	1092	7291	29,123	38,029
Total	29,123	38,029		
Average	5825	7606		

<sup>a</sup> SCS, spinal cord stimulation; CPT, conventional pain therapy.

Year 5, Year 4 cost + Cost c + amortized Cost d. At the end of a 5-year period, the average cumulative cost for this group was \$29,123.

During the 5-year study period, none of these patients underwent lumbar spine surgery. Therefore, no extra costs were attributable to such procedures.

**Group B**

The control group consisted of 44 patients. This group required a greater number of physician visits per year for assessments, as well as to obtain prescriptions for pharmacotherapy or referrals to allied health care professionals. The average number of family physician visits was 24/patient/yr, with an average yearly cost of \$528. In addition, each patient sought consultations with various specialists (a neurosurgeon, an orthopedic surgeon, a neurologist, a psychiatrist/psychologist, and a social worker) an average of five times/yr, with a cost of \$910/yr. On average, each patient initially required 1.8 CT scans, 1.0 MRI scan, 6.8 x-rays of the lumbar spine, and 1.4 myelograms. Therefore, the average initial imaging costs for this group were \$2329. In addition, during the follow-up period, each patient required CT/MRI studies once every 2 years, on average, with a cost of \$1510. This group also required hospitalization an average of 3 d/yr, because of acute pain exacerbations, at a cost of \$1881. The cost of pharmacotherapy for pain averaged \$861/yr (Table 5). The average numbers of visits to physiotherapists, chiropractors, massage therapists, and acupuncturists were 57.6, 17.2, 10.1, and 10.6 visits/yr, respectively, yielding a total cost of \$2884/patient/yr.

To determine the cumulative costs, we projected these calculations for a 5-year period by determining the following average costs per patient per year (Table 5): Cost a, cost of investigations (\$2329); Cost b, cost of maintenance (total, \$6536; pharmacotherapy, \$861; physician contacts, \$910; alternative therapies, \$2884; hospitalization for treatment of break-

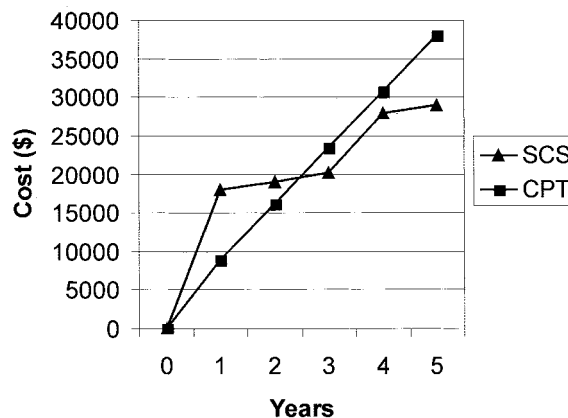
through pain, \$1881); Cost c, cost of secondary investigations every 2 years (costs of CT and MRI scans, \$1510 × 2 = \$3020, amortized for a 4-yr period as \$755/yr, allocated to the second, third, fourth, and fifth years of the follow-up period). Therefore, the cumulative costs per patient for Group B were as follows (Table 6): Year 1, Cost a + Cost b; Year 2, Year 1 cost + Cost b + amortized Cost c; Year 3, Year 2 cost + Cost b + amortized Cost c; Year 4, Year 3 cost + Cost b + amortized Cost c; Year 5, Year 4 cost + Cost b + amortized Cost c. At the end of a 5-year period, the cumulative costs for this group were \$38,029/patient.

Figure 1 demonstrates that the costs of SCS therapy are greater than those of CPT in the first 2.5 years, because of the initial high costs of the implantable devices. After that period, SCS treatment becomes economically favorable for patients who respond positively to SCS. Although the costs of pulse generator replacement in the fourth year tend to bring the two curves closer, CPT remains relatively more expensive. With projection of these data for a 10-year period, these savings are magnified (Fig. 2).

**Quality of Life Considerations**

Although the cost of therapy may dictate which methods are used for the treatment of chronic pain, patient quality of life is equally important, if not more important. Patient functioning and quality of life were measured by using the Oswestry disability questionnaire (6). The questionnaire indicated a 27% improvement in quality of life for the SCS group, compared with 12% improvement for the control group.

For assessment of patient satisfaction with SCS, an additional questionnaire was used. The responses were graded into three groups, i.e., very satisfied, satisfied, and unsure. Thirty-six patients (60%) reported being very satisfied, 17 patients (28%) reported being satisfied, and 7 patients (12%) were unsure. Because SCS was the only modality that had given the very satisfied and satisfied groups comfort and allowed reductions of drug usage, the patients noted that they



**FIGURE 1.** Graph illustrating the cumulative costs of SCS versus CPT for a 5-year period. The 2.5-year payoff period should be noted.

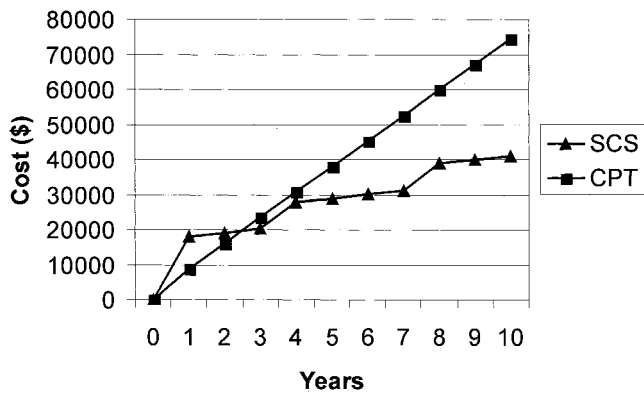


FIGURE 2. Graph illustrating the cumulative costs of SCS versus CPT projected for a 10-year period.

would recommend this procedure to relatives or friends with similar pain problems.

A benefit of SCS treatment in addition to the cost savings was that nine patients (15%) in Group A were able to return to some form of gainful employment, compared with none in Group B. Drug intake was also reduced with SCS. Preoperatively, the average cost for drug therapy for pain was \$78/mo (this cost was calculated from our patient records before enrollment and is not presented in the tables); postoperatively, the cost decreased to \$25/mo. The average pharmacotherapy cost for the control group was higher, i.e., \$861/yr (\$72/mo).

Statistical Analyses

The actual yearly costs for SCS and CPT for the 5-year period are summarized in Table 6 and Figure 3, which indicate that the average yearly costs for SCS are less than the mean yearly costs for CPT. In an effort to provide realistic costs to hospital administrators for budgeting, we added a net present value of 5% (inflation factor) to the actual costs; these adjusted costs are presented in Table 7. Once again, the mean CPT costs are much higher than the mean SCS costs.

We observed that, in Tables 6 and 7, the Year 1 cost for SCS therapy (\$18,028) is much higher than the costs for the remain-

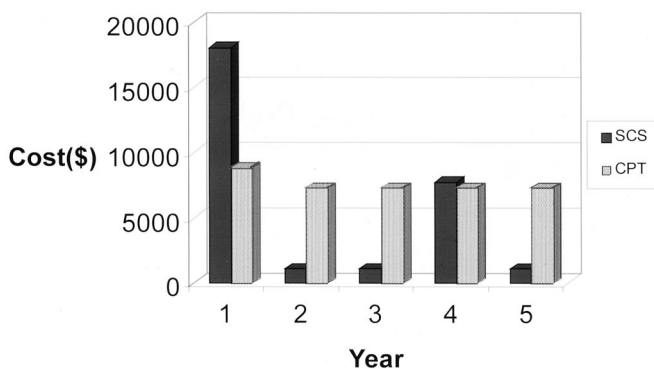


FIGURE 3. Bar graph illustrating the yearly noncumulative costs of SCS versus CPT for a 5-year period.

TABLE 7. Inflation-adjusted annual costs of spinal cord stimulation and conventional pain therapy for 5 years (including 5% inflation)<sup>a</sup>

Year	SCS cost (\$)	CPT cost (\$)
1	18,028.00	8865.00
2	1147.99	7664.81
3	1206.88	8057.80
4	9134.94	8470.93
5	1333.77	8905.24
Total	30,851.58	41,963.78
Average	6170.32	8393.00

<sup>a</sup> SCS, spinal cord stimulation; CPT, conventional pain therapy.

ing years, particularly Years 2, 3, and 5. This observation may affect analysis of the data and may represent an outlying point in the data set. To provide a reasonable analysis, we redistributed some of the cost from Year 1 to Years 2, 3, and 5. Table 8 and Figure 4 present the adjusted costs. We transferred \$9000 from Year 1 and added \$3000 to each of Years 2, 3, and 5. Importantly, this transfer had no effect on the total or mean costs. It can be observed in Tables 7 and 8 that the mean yearly costs remained the same, at \$6170.32. Therefore, we used the data in Table 8 for further analysis.

We claim that the mean yearly cost of CPT is higher than the mean yearly cost of SCS. A statistical hypothesis-testing procedure was used to examine this conjecture. In this case, the null hypothesis (H<sub>0</sub>) was that the average costs for the two procedures were the same. The research or alternative hypothesis (H<sub>a</sub>) was that the mean annual SCS costs were less than the CPT costs. In other words, the null and alternative hypoth-

TABLE 8. Redistributed adjusted annual costs of spinal cord stimulation and conventional pain therapy for 5 years (including 5% inflation)<sup>a</sup>

Year	SCS cost (\$)	CPT cost (\$)
1	9028.00	8865.00
2	4147.99	7664.81
3	4206.88	8057.80
4	9134.94	8470.93
5	4333.77	8905.24
Total	30,851.58	41,963.78
Average	6170.32	8393.00

<sup>a</sup> SCS, spinal cord stimulation; CPT, conventional pain therapy.

eses are as follows:  $H_0$ , there is no difference between the mean costs of the two treatment modalities;  $H_a$ , the mean cost of SCS is less than the mean cost of CPT.

The hypothesis test for comparing two population means was investigated with the pooled, two-sample, Student's *t* test. First, we assumed that the population variances were equal. The analysis was performed by using Minitab statistical software (Minitab, Inc., State College, PA), which formulated a *P* value of 0.04. This provided evidence of a significant difference between the average treatment costs for SCS and CPT procedures. It should be noted that the pooled *t* procedures assumed that the population variances were homogeneous. We also performed analysis with unequal population variances; in that situation, the *P* value was 0.58, and thus we reject the null hypothesis of equality of the mean costs at a 5.8% level of significance. In both cases, we reject the null hypothesis. There is sufficient evidence to conclude that the mean yearly cost of SCS is less than the mean yearly cost of CPT. SCS is thus cost-effective, compared with CPT, for the 5-year period. From *Tables 6* and *8*, it can be safely extrapolated that the mean treatment cost for SCS will continue to be significantly smaller than the average treatment cost for CPT as the number of years increases.

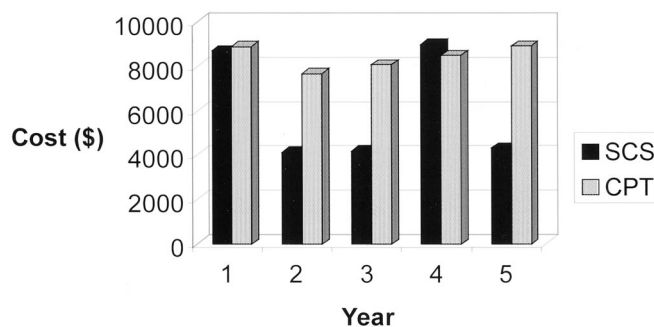
### Sensitivity Analysis

In this study, we tabulated data from actual patient files, for patients monitored within a constant delivery environment. There are three possible variables that must be considered, i.e., 1) the clinical efficacy rate for SCS, 2) the complication rate associated with SCS, and 3) the lifespans of the pulse generator battery and the electrode.

These variables are less applicable in our case than in other published studies, in which theoretical models of medical resource utilization were used. The clinical efficacy rate has remained stable for the past 10 years but may improve in the future, with the development of more effective patient screening. In our study, no operative procedures were required, except for those related to hardware complications. This incidence has remained constant in all published studies in the past decade, leaving only two variables that may affect costs in the foreseeable future, namely the lifespan of the electrode and the battery life of the pulse generator. The manufacturers are actively pursuing improvement of these items. If the manufacturers were to improve the function of these two components by 25% in the future, the payoff period would decrease from 2.5 years to 2.3 years.

## DISCUSSION

Shealy et al. (22, 23) were the first to advocate the application of electrical current to the spinal cord to relieve pain. The physiological mechanism by which SCS relieves pain is partially explained by the gate theory proposed by Melzack and Wall (18). In early years, many patients with chronic pain underwent SCS; however, because the selection criteria were poorly defined, the results were far from satisfactory (7). In



**FIGURE 4.** Bar graph illustrating the redistributed adjusted costs of SCS versus CPT for a 5-year period, including 5% inflation.

subsequent years, indications were clarified by the work of Lazorthes et al. (16), Winkelmueller (25), Gybels et al. (8), Kim et al. (10), North et al. (20, 21), Kumar et al. (14), Meglio et al. (17), and Barolat et al. (1), and SCS has become an important mode of treatment for failed back syndrome. We attempted to match the two groups with respect to the cause of their pain as much as possible. However, Group B could have a slightly higher proportion of patients with nociceptive pain and Group A patients with lumbosacral rhizopathy. With the increasing costs of medical technology, it is necessary for physicians to provide evidence that SCS is a cost-effective method of treatment, compared with nonsurgical therapies.

To date, there have been only two published studies (2, 3) on the cost-effectiveness of SCS, to our knowledge. Bell et al. (3) demonstrated that, among patients who responded favorably to SCS, the estimated payoff period was 2.1 years. However, in that study, Bell et al. (3) developed theoretical models of medical resource utilization for the two groups of patients (SCS and CPT). Their cost calculations were based on the anticipated use of resources, as determined from clinical literature, retrospective data sets, expert opinions, and published diagnostic and therapeutic protocols. The drawback of that study was that all calculations were based on presumptions, rather than actual recorded costs for the treatment of the two groups. Bel and Bauer (2) monitored 14 patients for the relatively short period of 2 years and concluded that the treatment of chronic pain with SCS was cost-effective, compared with conventional therapy, because the cost of electrode implantation was quickly compensated for by a drastic reduction in drug utilization and increased reentry into the workforce after surgery. That study was limited because of the small number of patients and the short follow-up period, and it failed to provide data for calculation of the recovery period for the high costs of implantable devices used in SCS treatment, compared with CPT.

We designed our study to allow monitoring of a large number of patients in the two groups (SCS and CPT) for a 5-year period and to address some of the flaws in those earlier reports. We recorded the actual costs incurred in the treatment of both groups of patients, increasing the validity of our results. The absolute derived costs may not be directly com-

parable to those encountered and may be lower than those in the United States or Europe. This difference is a consequence of the nature of the medical delivery system in Canada and differences in pricing by the manufacturer in different countries, which limit absolute costs. Because the same economic scale was applied to the various factors that modulate therapy for both of our study groups, our conclusions remain valid on a relative basis.

The cumulative cost for the SCS group for the 5-year period was \$29,123/patient (Table 4), compared with the control group figure of \$38,029/patient (Table 5). The higher costs for the non-surgically treated group are attributable to the patients' greater utilization of health care resources for drug therapy, rehabilitation services, and other therapies for pain control (Table 5). Figure 1 indicates that the costs of CPT exceed those of SCS, on a monthly basis, at 2.5 years. In the SCS group, costs are higher in the first 2 years because of the high costs of the implantable devices. After 2.5 years, the costs of primary treatment with SCS become less than those for the control group. This cost benefit is maintained throughout therapy, despite the periodic increases in expenses attributable to the costs associated with hardware manipulation and replacement of the pulse generator (because of depletion of its battery power) (Fig. 1).

Our analysis indicates that additional cost savings could result from improvements in the effectiveness of SCS therapy. These improvements might be achieved via more effective patient selection criteria and technological advances in the equipment used. The manufacturers need to focus on methods to improve the longevity of the pulse generator and the durability of the electrode.

## CONCLUSIONS

Patients with chronic pain secondary to failed back syndrome who respond to SCS therapy can achieve significant cost savings, compared with a control group. Additional benefits may include an increased rate of work rehabilitation, increased pain control, and a better quality of life. A coordinated approach to the treatment of this disabling ailment can result in better utilization of scarce health care funds.

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## Acknowledgment

No financial support was received for the generation of this submission. We have no personal or institutional interest in the devices described in this article.

## COMMENTS

Kumar et al. presented two groups of patients treated by spinal cord stimulation (SCS) and conventional chronic pain therapy (CPT), respectively. They compare the cost-effectiveness of both treatments. In the age of science and technology, these types of cooperative studies are very important in evaluating the real value of surgical methods, which usually seem very expensive. In the presented series, SCS is

shown as not only an effective method but also a cost-effective treatment in comparison with CPT. The most important benefit of SCS was that 15% of the patients went back to work after treatment. Improvement in quality of life was 27% in this group, as compared with 12% in the control group, in which no patient returned to work. Drug intake was also reduced in the SCS group, which is the most important finding of this study. It must be kept in mind that the results of this study reflect the skills of an experienced medical team; another, less experienced group would not necessarily achieve the same results.

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**K**umar et al. of the University of Saskatchewan present a study of the cost-effectiveness of SCS as compared with CPT. Sixty patients underwent SCS, and 44 patients in whom a trial of SCS had failed were the controls. These patients were followed for a 5-year period, and actual costs incurred for diagnostic imaging; professional fees paid to physicians; implantation costs, including hardware; nursing visits for the maintenance of the stimulators; physiotherapy; chiropractic; massage therapy, and hospitalization costs for breakthrough pain, were all calculated. In addition, the authors analyzed outcomes based on the Oswestry questionnaire (2) to estimate the effect of treatment on quality of life. On the basis of this analysis, Kumar et al. conclude that the cumulative mean cost of SCS therapy during a 5-year period was \$29,122 per patient, as compared with \$38,029 per patient for CPT. Extrapolating the cost savings for an additional 5 years on the basis of these data, the authors predict that the cost savings would be even greater.

A number of aspects of this study merit comment. First, the cost of Canadian health care in comparison with that of the United States is a relative bargain in that fees and profits are statutorily limited. Even taking into account the relative inflation of the Canadian dollar in comparison with the U.S. dollar, I think that the actual dollar savings in the United States might be even greater than the savings projected in this study. Nevertheless, the cost analysis is performed within a system that is quite scrupulous about cost accounting.

This type of study is difficult to conduct in any environment. One can certainly quibble about the nature of the "control group." The study was not performed in a group of patients who would otherwise have gone forward with SCS on the basis of a successful trial, which would constitute the authors' "ideal" study, in which patients would be randomized to either SCS or CPT. As the authors point out, this type of randomized study would present some ethical problems. Whether these difficulties can be surmounted in a future study remains to be seen. Nevertheless, the control group (Group B) in this study represents a group in whom an SCS trial had failed and, for that reason, may represent a more difficult category of patient. Potentially, Group B's treatment would seem more expensive than that of the patients who underwent SCS (Group A), regardless of the therapy implemented.

Perhaps most striking is the similarity of the results of this study to those reported by Bell et al. (1). That study also found that the financial breakeven point for SCS was approximately 2 years, as compared with more conservative management. It also found that at 5 years, SCS had a distinct cost-effectiveness advantage over nonsurgical management. The difference between these two studies is that the analysis of Bell et al. was based in part on cost projections, whereas Kumar et al.'s data represent actual costs. That the results of these two studies, which were performed in two different countries under different circumstances, are in such close agreement suggests to me that there is an important principle at work: namely, that SCS does result in health care system cost savings that are realized only after several years. It may well be that a more rigorous Class I outcome study of SCS in comparison with conservative management will be performed. Until that time, this study by Kumar et al. should be considered the benchmark work.

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