SPINAL CORD STIMULATION VERSUS REPEATED LUMBOSACRAL SPINE SURGERY FOR CHRONIC PAIN: A RANDOMIZED, CONTROLLED TRIAL

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OBJECTIVE: Persistent or recurrent radicular pain after lumbosacral spine surgery is often associated with nerve root compression and is treated by repeated operation or, as a last resort, by spinal cord stimulation (SCS). We conducted a prospective, randomized, controlled trial to test our hypothesis that SCS is more likely than reoperation to result in a successful outcome by standard measures of pain relief and treatment outcome, including subsequent use of health care resources.

METHODS: 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 could cross over to the alternative. Success was based on self-reported pain relief and patient satisfaction. Crossover to the alternative procedure was an outcome measure. Use of analgesics, activities of daily living, and work status were self-reported.

RESULTS: Among 45 patients (90%) available for follow-up, SCS was more successful than reoperation (9 of 19 patients versus 3 of 26 patients, $P < 0.01$). 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 ($P < 0.025$). Other measures of activities of daily living and work status did not differ significantly.

CONCLUSION: 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.

KEY WORDS: Chronic pain, Electrical stimulation, Failed back surgery syndrome, Low back pain, Lumbar radiculopathy, Randomized controlled trial, Spinal cord stimulation

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Between 10 and 40% of patients who have undergone lumbosacral spine surgery in the United States experience persistent or recurrent pain (14, 23, 24, 39, 49). This condition, sometimes referred to as "failed back surgery syndrome" (FBSS), is a challenge to multidisciplinary pain management strategies, including medical, surgical, rehabilitative, and behavioral therapy. FBSS patients, by definition, have failed to obtain lasting relief despite receiving a variety of therapies, including repeated operations, oral medications, nerve blocks, corticosteroid injections, physical therapy, and chiropractic care. FBSS is often complicated by depression, financial and personal stress, loss of employment or productivity, and diminished self-esteem (3, 25).

For more than 30 years, however, clinicians have successfully used spinal cord stimulation (SCS), a minimally invasive procedure, to treat selected patients with chronic pain, especially FBSS patients. Retrospective studies conducted at our institution indicate that, compared with neurosurgical FBSS treatment alternatives, such as repeated operation (34% success in 102 patients at mean 5-yr follow-up) (35), dorsal root ganglionectomy (success in 2 of 13 patients at 2 yr and 0 of 13 patients at mean 5.5-yr follow-up) (39), and radiofre-

quency facet denervation (45% success in 42 patients at mean follow-up of 3.2 yr) (38), SCS results in lower morbidity and a substantially higher rate of success measured in terms of pain rating, neurological function, quality of life, and ability to engage in activities of daily living (47% of 50 patients at mean 5-yr follow-up [36] and 52% success in 171 patients at mean 7-yr follow-up [41]). SCS also compares favorably with reoperation in the literature on the treatment of FBSS, although the reported reoperation success rates vary greatly (47). Clinicians, however, have generally reserved SCS to be used as a last resort in the treatment of FBSS.

To explore the relative merits of reoperation and SCS in the treatment of FBSS and to determine whether it would be more appropriate to offer SCS as a late, rather than a last, treatment strategy, we conducted the first prospective, randomized trial comparing reoperation and SCS for FBSS.

PATIENTS AND METHODS

To identify study candidates, eight spine surgeons at Johns Hopkins Hospital nominated patients with surgically remediable nerve root compression and concordant complaints of persistent or recurrent radicular pain, with or without low back pain, after one or more lumbosacral spine surgeries. All candidates met the criteria for surgical intervention: pain refractory to conservative care, with concordant neurological, tension, and/or mechanical signs and imaging findings of neural compression (2, 28). A neurosurgeon or orthopedic spine surgeon provided a confirming second opinion in every case.

Because current standards of practice indicate immediate reoperation in certain cases, we excluded patients from the study if they had any of the following: 1) a disabling neurological deficit (e.g., foot drop, neurogenic bladder) in the distribution of a nerve root or roots caused by surgically remediable compression; 2) radiographically demonstrated (by myelographic block or its magnetic resonance imaging equivalent) critical cauda equina compression (1); or 3) radiographic evidence of gross instability (spondylolisthesis or abnormal subluxation) necessitating fusion. We also excluded patients who had 1) significant untreated dependency on prescription narcotic analgesics or benzodiazepines; 2) major untreated psychiatric comorbidity (40); 3) unresolved issues of secondary gain; 4) a concurrent clinically significant or disabling chronic pain problem; or 5) a chief complaint of axial (low back) pain exceeding radicular (hip, buttock, and leg) pain. We accepted patients with axial low back pain if the intensity of this pain was equal to or less than that of their radicular pain. (Treatment of predominantly axial low back pain by SCS, although technically feasible, involves issues beyond the scope of this study [22] and is being investigated separately.) The study was presented to candidates as a comparison of two standard, nonexperimental procedures, SCS and reoperation, to determine whether SCS should be offered as an FBSS treatment before or after exhausting all reoperation treatment options.

To detect a statistically significant difference in outcomes at the $\alpha = 0.05$ level, with power $(1 - \beta)$ at the 0.8 level, and assuming that we would match our reported success rate for each procedure (35, 36, 41), we determined that we would need a sample size of 50. We randomized patients who consented to receive treatment by reoperation or by SCS and collected all baseline and follow-up data for these groups and for the group of eligible participants who refused randomization. The baseline evaluation included a psychological assessment using standardized tests and a quantitative evaluation of functional capacity conducted by a physical therapist. We administered validated instruments that have been in use at our institution for more than 20 years (35–39, 41) to capture disease-specific and general health outcome measures, including ratings of pain intensity measured on a visual analog scale and with an abbreviated checklist of adjectives (8, 12, 15, 23, 29, 48). Medication intake and ability to perform daily activities (29) were also assessed.

Randomization was determined by consecutively opening a series of numbered, sealed, opaque envelopes containing computer-generated random assignments provided by an outside biostatistician. Procedures were scheduled at the earliest possible date, subject to clearance from third-party insurers when required.

Reoperation involved laminectomy and/or foraminotomy and/or discectomy in all patients with or without fusion, with or without instrumentation. SCS treatment (33) began with percutaneous placement of a temporary electrode (3487A Pisces-Quad; Medtronic, Inc., Minneapolis, MN) for a therapeutic trial lasting at least 3 days. (Such a trial is routine before SCS implantation.) The SCS patients could receive a permanent implant (3487A-56 or 3587A Resume electrode, X-trel or Itrel pulse generator; Medtronic, Inc.) if they reported at least 50% estimated relief of pain (32) by standard pain rating methods and demonstrated stable or improved analgesic medication intake, with improved physical activity commensurate with neurological status and age. Any patient randomized to SCS who did not meet these criteria could immediately cross over to reoperation. Patients randomized to reoperation could cross over to SCS after a 6-month postoperative period.

The patients in all three groups were managed in accordance with the post-spinal surgery physical therapy protocol that is routine at our institution (17, 43). All received standard postoperative analgesics, which, along with any preoperative analgesics, we tapered as rapidly as possible.

Six months after the initial study procedure, a disinterested third party who was aware of which patient had which procedure but was not involved in the treatment contacted the patients for assessment of outcome using the same test instruments employed at baseline plus the routine scales used in studies of SCS and reoperation for FBSS to rate pain relief and patient satisfaction with treatment (8, 12, 15, 23, 29, 48). Attempts to obtain long-term follow-up data using the same questionnaires occurred for all patients annually for at least 2 years. The 2-year period would be extended, when necessary, to ensure collection of data at least 6 months after any crossover procedure that might have occurred during the 2-year period. For reoperation patients, at least one follow-up eval-

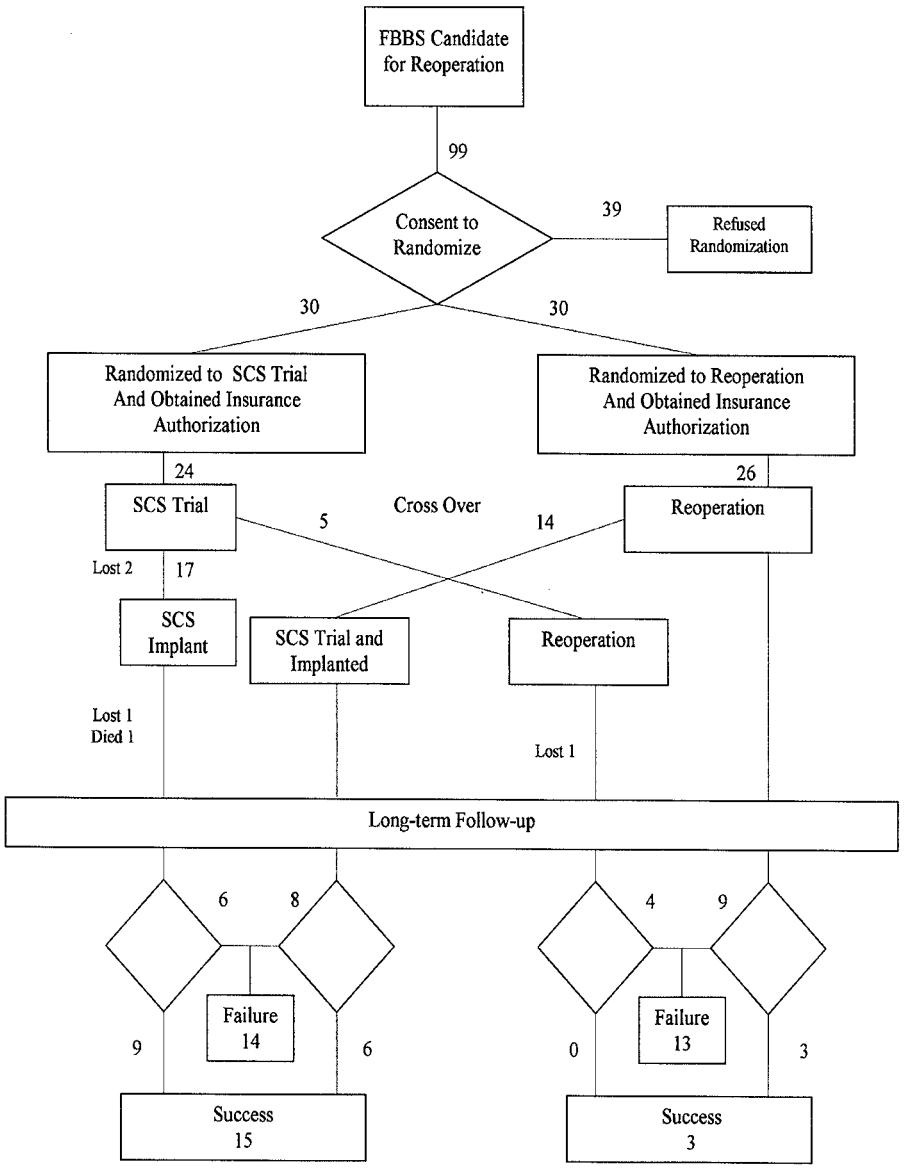

FIGURE 1. *Flow chart showing study design and outcomes for a randomized trial of SCS versus reoperation; patients could elect crossover from one procedure to the other if the results of the randomized procedure were unsatisfactory.*

uation included diagnostic imaging studies to determine whether the goals of surgery had been met.

At the onset of the study, we informed randomized patients of their option to cross over to the other treatment arm. While collecting follow-up data, the third-party interviewer reminded each randomized patient who had not crossed over of this option. Other than offering immediate crossover to patients for whom the SCS trial was not successful, the study protocol dictated that the treating physicians and nurses could address the crossover possibility only in response to a patient's specific request or complaint.

Statistical Analysis

The definition of "success" for this study combined two criteria commonly used in reported studies of FBSS (8, 12, 23, 48): at least 50% pain relief and patient satisfaction with treatment ("Considering the overall pain relief you have received from this procedure and considering the operation[s], hospitalization[s], discomfort, and expense involved, would you go through it all again for the result you have obtained?"). The study end points were 1) crossover from the randomized to the alternative procedure; 2) success at last follow-up; and 3) improvement in daily activities, neurological status, and medication use.

Our independent variables were randomized treatment assignment, age, sex, diagnosis, Workmen's Compensation status, physical findings (deep tendon reflexes, strength, sensation, straight leg raising seated and supine, range of motion, trunk rotation, axial compression, and superficial lumbosacral spine tenderness), number of previous operations, preoperative drug use (specifically benzodiazepines and narcotics), and choice of pain descriptors from an abbreviated McGill Pain Questionnaire checklist (30).

The associations between outcomes and independent variables were tested by cross-tabulation with χ^2 and Fisher's exact tests. Associations with all variables, both continuous and categorical, were tested by univariate logistic regression. Covariates having some prognostic value ($P < 0.15$) were entered into a multivariate model, with the effects that were not significant removed in a stepwise manner. All P values are two-sided.

RESULTS

As shown in *Figure 1*, 60 candidates for repeated operation (30 men and 30 women, ranging in age from 26 to 76 yr) from a consecutive series of 99 patients invited to participate in the study consented to randomization, and 50 proceeded to treatment. The 39 who refused randomization chose to undergo reoperation. Those accepting randomization were significantly older ($P = 0.004$, Student's t test) and those randomized and treated were significantly less often on Workmen's Compensation than those refusing randomization, but the groups did not differ in sex, number of previous operations, or percentage of axial low back pain (*Table 1*).

Patients on Workmen's Compensation consented to randomization as often as other patients but were randomized and treated significantly less often ($P < 0.01$, χ^2) because of failure to obtain third-party authorization. Thus, of the patients randomized but not treated, Workmen's Compensation insurance would not authorize study participation for 9, and a stroke precluded treatment in the 10th.

All 50 participants remained available for follow-up during the 6-month reoperation crossover period, and 49 (98%) provided full 6-month outcome data sets. One SCS patient, otherwise doing well, died suddenly of a cardiac event near the end of his 6-month follow-up interval.

As *Table 2* illustrates, 45 (90%) of 49 remaining randomized patients and 38 of 39 nonrandomized reoperation patients were available for a mean of 2.9 ± 1.1 years (range, 1.8–5.7 yr). We followed up the entire population eligible for the study to allow assessment of the external validity of the study results. We were unable to contact 4 patients randomized to SCS: 1 had an implant, 1 had crossed over to repeated operation, and 2 declined follow-up after failing the SCS trial.

We performed repeated lumbosacral spine operations in 31 participants (as randomized in 26 and as crossover in 5). The types of repeated operations proposed and performed were uniformly distributed across patient subpopulations. No significant difference in operations proposed was observed between the patients accepting randomization and those refusing it, between those randomized to reoperation and those randomized to SCS, or between those crossing over and those not crossing over from one procedure to the other (*Table 3*).

Frequency of Crossover to the Alternative Procedure

As illustrated in *Table 4*, the rate of crossover from reoperation to SCS was consistently higher than the rate of crossover from SCS to reoperation. Patients randomized to reoperation were significantly more likely ($P = 0.02$) than those randomized to SCS to cross over. Patients who refused randomization and underwent reoperation were also more likely to cross over than those randomized to SCS. No statistical test is applicable to this nonrandomized group.

For the overall population of 50, 14 (54%) of 26 reoperation patients crossed over to SCS, whereas 5 (21%) of 24 patients randomized to SCS crossed over to reoperation. This represents a statistically significant difference ($P = 0.02$) in favor of SCS over reoperation by Fisher's exact test. One additional patient chose to cross over from reoperation to SCS but was unable to obtain third-party authorization during the study period.

Analysis of prognostic factors by multivariate logistic regression revealed that patients randomized to reoperation ($P = 0.02$) and patients who were using narcotic analgesics before surgery ($P = 0.02$) were significantly more likely to "fail" their randomized treatment by this outcome measure, that is, they were significantly more likely to cross over to the alternative treatment.

Pain Control and Patient Satisfaction

Among patients available for long-term follow-up, SCS was significantly more successful than reoperation: 9 (47%) of 19 patients randomized to SCS and 3 (12%) of 26 patients randomized to reoperation achieved at least 50% pain relief and were satisfied with treatment ($P < 0.01$, Fisher's exact test). In a worst-case analysis, assuming that the patients not available for long-term follow-up were all SCS failures, the success rate for reoperation would remain 3 of 26, but the rate for SCS would become 9 of 23 instead of 9 of 19 ($P = 0.04$ as opposed to $P = 0.01$ by Fisher's exact test). SCS would remain significantly more successful.

Among the 39 patients who were offered but declined participation in the randomized study, 38 (97%) were available for follow-up. Of these, 10 (26%) were reoperation successes, 14 (37%) failed reoperation but did not elect SCS, and 14 (37%) failed reoperation and elected SCS, with 6 (43%) becoming successes. No statistical test is applicable to this nonrandomized group.

TABLE 1. Characteristics of the population eligible for the trial[a]

	Refused randomization (mean ± SD)	Randomized (mean ± SD)	Treated (mean ± SD)
No.	39	60	50
Age (yr)	43.9 ± 11.9	50.2 ± 13.3	52.0 ± 13.5
Female	15	30	26
Male	24	30	24
Prior operations	2.7 ± 1.1	2.5 ± 1.1	2.5 ± 1.1
Workmen's compensation	20	24	15
Low back pain (%)	41.2 ± 23.0	34.8 ± 20.7	32.6 ± 20.0

[a] SD, standard deviation.

TABLE 2. Follow-up yield of the population eligible for the trial[a]

	Assigned	Treated	Followed short-term	Followed long-term
Randomized to spinal cord stimulation	30	24	23	19
Randomized to reoperation	30	26	26	26
Nonrandomized reoperation	39	38	38	38
Total	99	88	87	83

[a] Values are numbers of patients.

TABLE 3. Types of repeated operations proposed and performed[a]

Operation proposed	Randomized		Treated	Repeated operation		Spinal cord stimulation	
	Refused	Accepted		Operations performed	Crossover operations performed	Operations deferred	Operations failed
Discectomy	9	15	11	6	0	5	4
Laminectomy	28	47	42	23	5	19	11
Foraminotomy	24	40	36	21	5	15	10
Fusion	10	11	7	3	1	4	1
Instrumentation	9	12	10	6	2	4	2
Total	39	60	50	26	5	24	14

[a] Values are numbers of patients. Types of repeated operations were distributed uniformly across patient subpopulations.

TABLE 4. Crossover rates[a]

	Assigned	Crossed over
Randomized to reoperation	26	14 (54%)
Randomized to spinal cord stimulation	24	5 (21%)
Nonrandomized reoperation	38	14 (37%)

[a] Values are numbers of patients and percentages.

Of the 15 patients randomized to SCS who received an implant, did not cross over, and were available for long-term follow-up, 9 (60%) were long-term successes by our pain relief/patient satisfaction criteria. Of the 12 patients randomized to reoperation who did not cross over, only 3 (25%) were long-term successes.

If the outcome assessment is based on latest treatment (including crossover), 52% of patients receiving an implanted spinal cord stimulator and followed long-term were successes (15 of 29 [15 as randomized and 14 as crossover]). The rate of success for all patients whose final study treatment was reoperation was 19% (3 of 16 [12 as randomized and 4 as crossover]). These success rates (which, of course, include effects beyond randomization) differ significantly by Fisher's exact test ($P < 0.05$).

The ultimate rates of success were lowest for SCS and reoperation among patients who crossed over. The patients who crossed over to SCS, however, reported a success rate of 43% (6 of 14 patients), whereas none of the 4 patients who crossed over to reoperation had a successful outcome. *Table 5* summarizes these results and illustrates that, at long-term follow-up, SCS was significantly more successful than reoperation ($P < 0.01$), whether performed as randomized or as

TABLE 5. Long-term outcomes of reoperation and spinal cord stimulation as randomized and as treated[a]

	Randomized	Crossover
Reoperation	12% (3/26)	0% (0/4)
Spinal cord stimulation	47% (9/19)	43% (6/14)

[a] Values are percentages and numbers of patients in each group.

crossover. Secondary reoperation was never successful, but secondary SCS was successful in 43% of cases.

Improvement in Activities of Daily Living, Neurological Status, and Medication Use

All patients rated impairment by pain in performing everyday activities (work, walk, climb stairs, sleep, engage in sex, drive a car, sit at a table to eat) and medication use and self-reported neurological function (lower extremity strength and coordination, sensation, bladder/bowel function). As shown in *Figure 2A*, at long-term follow-up, patients randomized to reoperation reported loss of function more often than improvement in several categories; this was not observed in any category for patients randomized to SCS (*Fig. 2B*). None of these differences was statistically significant except that patients randomized to repeated operation required an increase in opiate analgesic medications significantly more often ($P = 0.025$, Fisher's exact test) than those randomized to SCS at long-term follow-up. *Table 6* presents the details. Analyses of functional capacities and psychological test scores (as outcome measures, not just selection criteria or prognostic factors) are the subject of separate investigations.

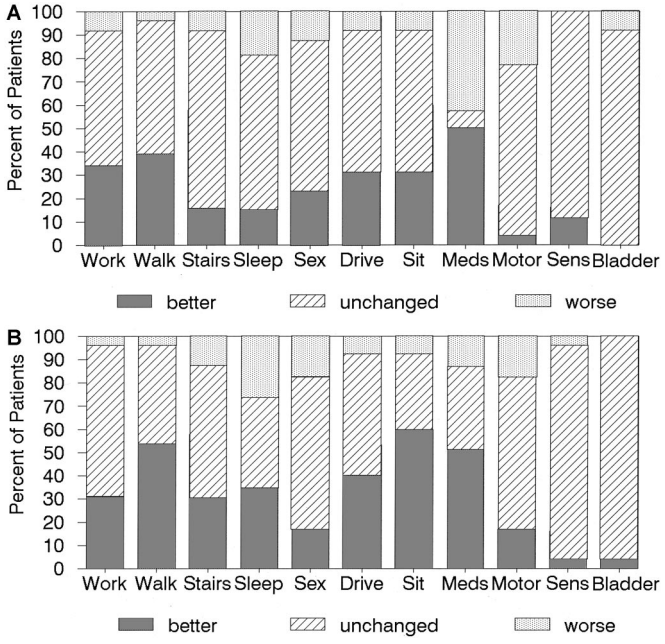

FIGURE 2. *Bar graphs. All patients rated impairment by pain in performing everyday activities (work, walk, climb stairs, sleep, engage in sex, drive a car, sit at a table to eat, medication use* [Meds]*, and self-reported neurological function: lower extremity strength and coordination, sensation* [Sens]*, bladder/bowel function). Patients randomized to reoperation* (A) *reported loss of function more often than improvement in several categories; this was not observed in any category for SCS patients* (B)*. The only statistically significant difference between patients randomized to reoperation and those randomized to SCS was an increased use of opioids by reoperation patients* (P = *0.025).*

TABLE 6. Opioid use as randomized at long-term follow-up[a]

	Opioid use stable or decreased	Opioid use increased
Reoperation	15/26 (58%)	11/26 (42%)
Spinal cord stimulation	20/23 (87%)	3/23 (13%)

[a] Values are numbers of patients in each group and percentages.

No significant treatment differences were detected in patients' ability to return to work. Most of the study population (52%) was retired or permanently disabled at the time of entry into the study. Of those employed at the time of study entry, all but one remained employed, and one increased from part-time to full-time employment. No other independent variable (age, sex, number of previous operations, etc.) showed a significant association with outcome.

Complications

One SCS patient developed an infection at the receiver site, which was treated by removal of the system followed by specific antibiotic therapy. The system was replaced without further complication. Three SCS patients (9% of permanent implants) underwent hardware revisions because of technical problems (electrode migration or malposition). One patient in the group that refused randomization developed a wound infection following instrumented fusion. After an extended hospitalization and additional surgery, she had a full recovery.

DISCUSSION

This prospective, randomized trial confirms the inference from previous studies that SCS is superior to reoperation in patients with persistent radicular pain after lumbosacral spine surgery. The study population was selected conservatively, with multiple confirmatory surgical opinions, for clear-cut persistent root compression and concordant radicular pain.

SCS has several advantages over reoperation. As a minimally invasive procedure, SCS has a very low morbidity rate, which continues to decline with technical improvements (41). The procedure is completely reversible, and before implantation of a permanent system, candidates are screened for response with temporary percutaneous electrodes that emulate the pain-ameliorating effects of the implanted system. In contrast, patient selection for reoperation is not so straightforward, because we can only infer the presence of a surgically remediable pain generator from imaging and other diagnostic studies.

Not only have SCS techniques improved since their introduction 30 years ago, patient selection criteria are also more specifically defined in several ways. First, we require that a specific diagnosis point to an objective basis for the pain

complaint. Thus, in our study population, all patients had an anatomic explanation for their pain complaint, but this is not necessarily the case in the general FBSS population. In fact, a review of available original imaging studies and clinical records of FBSS patients found that many did not meet accepted indications for their initial low back operation (28).

Second, patients must be assessed and treated in an institution with a multidisciplinary pain treatment program, which includes routine psychological evaluation before treatment. Thus, in patients with serious drug-seeking behavior, abnormal illness behavior, or major unresolved issues of secondary gain, SCS treatment is denied or deferred until after successful treatment or other resolution of these issues. In our clinical practice, SCS candidates receive a psychological evaluation to address possible depression or other comorbidities (19, 20, 40, 45). We followed this convention in this study but can provide no conclusion as to its validity.

The third SCS selection criterion was exhaustion of all reasonable alternative therapies, including reoperation and noninvasive medical, physical, and behavioral therapy. By indicating that reoperation should be deferred in favor of an SCS trial, the present study redefines this criterion.

A meta-analysis of the literature on SCS for FBSS revealed an overall reported rate of success (defined as at least 50% pain relief) of 59% (47). Reported rates of success vary from 12 to 88% at follow-ups ranging from 6 months to 8 years in multiple case series and a single prospective study (5, 11, 16). A review and meta-analysis of the literature on reoperation (35), including fusion, revealed that reported rates of success (defined in various ways) range from 12% (12) to 100%; no prospective studies have been conducted (4, 12, 46, 48, 49).

In the only direct comparison reported from the same institution using the same outcome assessment methods, we previously reported 5-year FBSS treatment success rates of 47% for SCS (36) and 34% (35) for reoperation. Over the past 20 years, we have observed substantially higher rates of success for SCS than for all neurosurgical treatment alternatives for FBSS, including dorsal root ganglionectomy (39) and radiofrequency facet denervation (38). The validity of retrospective comparisons, however, is open to question, even when the data are collected at the same institution, over the same period of time, using the same third-party interview methodology (with questionnaires differing only in treatment-specific items, such as SCS usage). Our reoperation success rate of 12% ties the all-time record low, in part because we added the requirement that a sine qua non for the success of Procedure A (in this case, reoperation) was that the patient not cross over to Procedure B (SCS). No previous study has included this criterion. In fact, several of the 14 reoperation patients who crossed over to SCS in an attempt to achieve even more pain relief actually had achieved reoperation success as we defined it in 1991 (when the patients did not have the option of an alternative therapy) (35). In contrast, none of the six patients who received stimulators as randomized and ultimately "failed" SCS therapy sought crossover to reoperation.

Calculation of a success rate, of course, involves the number treated. In the literature on SCS for FBSS (41), this is conventionally considered the number undergoing implantation of a permanent system. Conducting an analysis that includes all patients screened with temporary, percutaneous electrodes would reduce the success rate, particularly in studies with stringent criteria for the definition of a successful percutaneous trial. In this study, we included the patients screened in our outcome calculations; excluding them would improve our apparent success rate. Because 31 (17 as randomized and 14 crossover) of 38 (24 as randomized and 14 as crossover) patients (84%) who had an SCS trial received implants, however, this change would be minor.

As an outcome measure, self-selected crossover is a useful definition of treatment failure, and it mimics real-life healthcare-seeking behavior. One might expect that an SCS trial would be easier for an FBSS patient to accept than another invasive back operation and that this might affect patient enrollment, compliance, or crossover decisions. Of the 39 patients who refused randomization, however, all insisted on repeated operation even though the average number of previous operations for this group was slightly higher than that for study participants.

The fact that older patients accepted randomization significantly more often than younger patients might indicate that they have less enthusiasm for another operation, as opposed to symptomatic treatment for their chronic pain problem. The average age of the patients who were randomized and treated was 2 years higher (an insignificant difference) than the average age of all patients who were offered or who accepted randomization, perhaps reflecting the fact that Medicare did not require preauthorization for treatment.

Another statistically significant factor was the refusal of Workmen's Compensation insurance to approve study participation. In general, insurance authorization refusals and delays impeded performance of randomized procedures in the study, as occurs in everyday clinical practice. This situation, however, had no effect on the study population with respect to other patient characteristics that had prognostic significance. In no case of which we are aware was authorization withheld because of concerns specific to the study.

The source of follow-up information is of fundamental importance in interpreting reported outcome. As in our previous reports (27, 34, 37), a disinterested third party uninvolved in patient care conducted the interviews. Only a few other published studies have used this strategy (10, 18, 31); in some reports, follow-up data were obtained by the device manufacturer (6, 44) or from the surgeon's records. Data collected from these sources are substantially more favorable than those reported to an impartial third party (10, 26). In obtaining follow-up of pain therapies, we thus favor third-party interview as the most conservative approach (7). Although the use of a third-party interviewer is a reasonable strategy to reduce bias, however, we cannot consider bias eliminated because patients might yet infer that a connection, of necessity, exists

between the third-party interviewer and the treating physician.

The topography of pain remains an important selection criterion for SCS. In most patients, it is difficult to achieve overlap and associated relief of axial low back pain by stimulation paresthesia (22, 36, 41, 42). Consequently, in this study, we excluded patients in whom low back pain was the sole or chief (>50%) complaint. In the past, we limited patient selection for SCS to patients whose chief complaint was radicular, as opposed to axial, pain. We have learned, however, that SCS treatment can be effective in patients with a significant amount of axial pain (36). Predominantly axial as opposed to radicular pain has also been reported as an unfavorable prognostic factor (21, 42) for reoperation (13, 48). Within our select population, screened for predominance of radicular pain, we observed no association of treatment outcome with the reported proportions of axial and radicular pain. We have not studied patients with a chief complaint of axial low back pain and can reach no conclusions about this subpopulation; this will require further study.

Even though our study has demonstrated that treating FBSS with SCS instead of reoperation, as a late rather than a last resort, is more effective in terms of a variety of outcomes, clinicians should not overlook other treatments for FBSS. Indeed, we included some in this study as part of routine postoperative care (9). Thus, all of our patients followed a standard rehabilitation and physical therapy program and received analgesics under institutional protocols. This study offers no conclusions as to the value of these treatments, and none has been compared with SCS or reoperation in a prospective, randomized manner. In addition, we drew our patient population from a tertiary referral base. Notably absent were cases of extremely large, free-fragment disc herniations, which, we assume, are treated surgically in the community. We would not infer that our results apply to this group.

CONCLUSIONS

We have observed that SCS is significantly more successful than repeated operation, by multiple outcome measures, in selected patients with FBSS. In most cases, SCS eliminated the need for further spine surgery in patients identified as reoperation candidates by standard criteria. In contrast to reoperation, SCS provides the opportunity for patients to undergo a minimally invasive therapeutic trial before the definitive procedure and results in lower morbidity.

We also observed that patients randomized to SCS achieved success more often than those who crossed over to SCS after yet another low back operation. In patients with persistent radicular pain after lumbosacral spine surgery, therefore, our findings indicate that clinicians should offer SCS as an alternative to repeated operation before exhausting all surgical alternatives.

DISCLOSURE

Medtronic, Inc., provided funding for this study. RBN recently sold the assets of Stimsoft, Inc., a company developing pain stimulator technology, to Medtronic; Johns Hopkins University received a share of the proceeds.

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COMMENTS

The authors prospectively studied patients who were diagnosed with failed back surgery syndrome. Eligible patients had surgically remediable nerve root compression and complaints of persistent or recurrent radicular pain with or without lower back pain after one or more lumbosacral spine surgeries. The authors started with 99 patients: 39 refused randomization, 30 patients were randomized to the spinal cord stimulator branch, and another 30 were randomized to reoperation. There was a significant crossover from the reoperation group to the spinal cord stimulator group, but less in the other direction. Success was defined by the criterion that pain was relieved by at least 50%. Using this criterion, the authors concluded that 52% of the patients who had spinal cord stimulation had a successful outcome. The success rate for the reoperation group was only 19%.

The main problem with the study is that the authors compared heterogeneous groups on the basis of the different types of abnormalities that both groups had. However, the type of abnormalities seemed to be equal across groups, as was the type of operation (*Table 3* of the article). Unfortunately, the patient groups are quite small. The follow-up period, which seems to be either 2 or 3 years, is also short. Many of these patients could have recurrent problems beyond this period. It is well known that this is an extremely difficult population of patients to treat successfully. I agree with the authors' conclusion that clinicians should consider spinal cord stimulation as an alternative to repeated operations in patients with persistent radicular pain after lumbosacral spine surgery.

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The authors of this article report their experience with a group of patients who have failed surgery for low-back disorders. They conclude from their data in this randomized prospective study that spinal cord stimulation resulted in superior pain relief compared with reoperation. The fact that this was true even though all patients in their series had "an anatomic explanation for their pain complaint" is unexpected and counterintuitive and should force us to reconsider our management of this difficult group of patients if the authors' results can be repeated at other centers. The authors excluded from their study any patients whose initial preoperative studies showed no indication for their original surgery. This is not an insignificant number of patients in clinical practice, and its presence serves as a condemnation of the state of spinal surgical care in this country. In addition, the reader should be aware of the other patients whom the authors excluded from consideration for admission to their protocol: those whose back pain (as opposed to leg pain) was the predominant symptom were excluded, as were those who were untreated

narcotics addicts, those with secondary gain, and those with significant psychiatric problems.

The patients who are the most problematic to the spinal surgeon are those who have had neural compression from spondylotic changes or herniated discs, whose pain fails to resolve after operation, and who have no evidence of neural compression on postoperative imaging studies. Unfortunately, this meticulous and well-performed study provides us with no information on the management of this group of individuals.

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Cover of the first number of the first volume of Heber Robarts' American X-ray Journal, *1897. An allegorical figure of Science illuminates the Earth with light produced by a Crookes tube and a Knott high-frequency coil.*