

SPINAL CORD STIMULATION IN TREATMENT OF CHRONIC BENIGN PAIN: CHALLENGES IN TREATMENT PLANNING AND PRESENT STATUS, A 22-YEAR EXPERIENCE

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OBJECTIVE: To present an in-depth analysis of clinical predictors of outcome including age, sex, etiology of pain, type of electrodes used, duration of pain, duration of treatment, development of tolerance, employment status, activities of daily living, psychological status, and quality of life. Suggestions for treatment of low back pain with a predominant axial component are addressed. We analyzed the complications and proposed remedial measures to improve the effectiveness of this modality.

METHODS: Study group consists of 410 patients (252 men, 58 women) with a mean age of 54 years and a mean follow-up period of 97.6 months. All patients were gated through a multidisciplinary pain clinic. The study was conducted over 22 years.

RESULTS: The early success rate was 80% (328 patients), whereas the long-term success rate of internalized patients was 74.1% (243 patients) after the mean follow-up period of 97.6 months. Hardware-related complications included displaced or fractured electrodes, infection, and hardware malfunction. Etiologies demonstrating efficacy included failed back syndrome, peripheral vascular disease, angina pain, complex regional pain syndrome I and II, peripheral neuropathy, lower limb pain caused by multiple sclerosis. Age, sex, laterality of pain or number of surgeries before implant did not play a role in predicting outcome. The percentage of pain relief was inversely related to the time interval between pain onset and time of implantation. Radicular pain with axial component responded better to dual Pisces electrode or Specify-Lead implantation.

CONCLUSION: Spinal cord stimulation can provide significant long-term pain relief with improved quality of life and employment. Results of this study will be effective in better defining prognostic factors and reducing complications leading to higher success rates with spinal cord stimulation.

KEY WORDS: Benign pain, Present status, Spinal cord stimulation, Treatment planning

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Pain is the major driving force for a patient to seek medical attention. It is a complex behavior process whose anatomy and physiology is not yet fully understood and is subject to continuing exploration and research. Melzack and Wall (54), by propagating the gate theory, stimulated new interest in pain research and therapy. Since 1967, spinal cord stimulation (SCS) has been steadily gaining support as a reversible and nondestructive method of effectively controlling chronic intractable pain (75). In recent years, SCS has been applied with increasing effectiveness because of improved patient selection criteria (40, 48, 49), improved accuracy in electrode placement (40, 62, 70, 71, 72), and improvements made to the multipolar and multichannel devices (40, 59, 62).

Despite this evidence, the indications and especially the long-term efficacy of SCS continue to be debated because of highly variable reports of long-term success rates (18, 19). The commonly used methods of monitoring the effectiveness of SCS are pain relief measurement scales, self-rating questionnaires of pain assessment and function, and quality of life assessments (78). However, it must be kept in mind that because pain is the product of various factors that vary from patient to patient, the success rate by SCS cannot be predicted with certainty without trial stimulation, even for the same underlying pathology in two different subjects.

The global treatment of failed back syndrome (FBSS) by SCS remains unresolved (18, 19, 77). Even though SCS has been

shown to effectively control radicular pain using single lead systems with multiple contacts, the challenge to treat predominantly axial low back pain persists. Most attempts to achieve stimulation-induced paraesthesias in the entire lumbar region to control axial pain results in simultaneous stimulation of nerve roots supplying the lower abdominal wall, which is poorly tolerated by patients. To overcome this problem, various investigators have advocated the use of multiple lead systems (4, 79) or transverse tripolar lead configurations (29).

We present a retrospective analysis of our experience with SCS over the past 22 years, with a mean follow-up time of 97.6 months. We have undertaken an in-depth analysis of our series for clinical predictors of outcome including age, sex, etiology of pain, type of electrode used, duration of treatment, and employment status. Outcome measures included pain relief, psychological factors, activities of daily living, and quality of life.

We also considered causes of long-term failures and have identified a group in whom, after initial pain relief, pain control eventually fades despite a fully functional stimulating system. We have labeled this phenomenon “tolerance,” for lack of a better descriptive term.

We have also analyzed the complications as they influence the long-term effectiveness of this modality and included suggestions of how to avoid them. In addition, we have analyzed the possible advantages of the dual-Pisces and Specify Lead systems (Medtronic, Inc., Minneapolis, MN) in treating low back pain with a predominant axial component. Results of this study will be effective in better defining prognostic factors, leading to improved patient selection and higher success rates with the use of SCS.

METHODS

Patient Selection

Our database consists of 452 patients over a 22-year period. Forty-two of these implant recipients were excluded who had less than 1 year of follow-up available, either because of loss of contact or death not related to their implant. This leaves an eligible study group of 410 patients for whom we have continuous data available. This includes data from 46 patients who died at various points during the 22-year study period, but who had a minimum of 1 year of follow-up available.

Our study group of 410 patients consisted of 252 men and 158 women, with a mean age of 54 years (range, 21–87 yr). Before implant, all patients in our series had used narcotic medications for pain control and were gated through a multidisciplinary pain clinic where they received conventional pain management that eventually failed to provide adequate pain control. They were then referred for consideration of SCS therapy. These patients were categorized according to etiology of pain, as shown in Table 1. The following criteria were met by all patients who underwent a trial of SCS: 1) a defined, non-malignant, organic cause of pain; 2) failure of medical management for at least 6 months; 3) remedial surgical procedure not feasible or advisable; 4) absence of a major psychiatric disorder as determined by psychiatric screening; patients who were found to have significant somatization complaints were excluded; 5) elimination of inappropriate drug use before implantation; 6) absence of unresolved issues of secondary gain or litigation that could potentially be central to the propagation of the pain complaint; and 7) capacity to give informed consent for the procedure.

TABLE 1. Etiology of pain and internalization rates^a

Etiology	No. of patients	Initial pain relief		Long-term pain relief	
		Success (%)	Failure (not internalized)	Long-term successes (%)	Late failures
FBSS	220	184 (83.6)	36	132 (60)	52
Peripheral vascular disease	52	42 (80.7)	10	31 (60)	11
CRPS I and II	32	28 (87.5)	4	23 (72)	5
Peripheral neuropathy	17	14 (82.4)	3	12 (71)	2
Phantom limb pain/stump pain	5	1 (20)	4	1 (20)	0
Multiple sclerosis	19	17 (89.5)	2	15 (79)	2
Angina	9	9 (100)	0	9 (100)	0
Bone and joint pain syndromes	8	8 (100)	0	4 (50)	4
Spinal cord injury/lesion/cauda equina syndrome	15	7 (46.7)	8	5 (33)	2
Perirectal pain	6	4 (66.7)	2	3 (50)	1
Postherpetic/intercostal neuralgia	19	10 (52.6)	9	4 (21)	6
Upper limb pain secondary to disc surgery and miscellaneous pain syndromes	8	4 (50)	4	4 (50)	0
Total	410	328 (80)	82	243 (59.3)	85

^a FBSS, failed back syndrome; CRPS, complex regional pain syndrome.

All patients who were considered suitable candidates for SCS initially underwent a trial period of stimulation for 4 to 7 days to ascertain their response to stimulation. Only those patients who achieved 50% or greater pain relief on trial stimulation had their systems internalized.

Clinical Evaluation

Patients were followed at 6-month intervals for the first 3 years and annually thereafter. The mean average follow-up period was 97.6 months. All follow-up was performed by a disinterested third party reviewer, a physician with a special interest in pain management who was not involved in patient care or preparation of this manuscript. Pain relief was scored at each follow-up examination by use of a modified visual analog scale (VAS) (20, 31), with a numerical scale of descriptors ranging from 0 to 10. This allowed patients to quantify their pain objectively both before and after implantation of the SCS electrodes. The degree of successful pain relief was classified as excellent (> 75%), good (> 50%), or poor (< 50%). Patients falling in the categories of excellent and good pain relief were considered to be successful responders to therapy.

Functional Evaluation

The patients' functional status and affective responses to pain were evaluated using the Oswestry Disability Index (ODI) (26), the McGill Pain Questionnaire short-form (MPQ) (53), the Beck Depression Inventory (BDI) (12, 13), and the Roland Morris Questionnaire (RMQ) (74). These questionnaires were implemented in the latter part of the study, with 56 patients completing the assigned questionnaires over the past 3 years. These evaluations were performed before the implant and postoperatively at 6 months and at yearly intervals afterward. The results were then averaged for purposes of reporting.

Etiologies of Pain

FBSS was the most common indication for SCS in this series, with a total of 220 (53.6%) patients composed of 141 men and 79 women. This group of patients had previously undergone lumbar disc excisions, laminectomies with or without foraminotomies, or spinal fusions as indicated for various surgical pathologies. The authors recognize that this group represents three specific underlying pathologies, namely, epidural fibrosis, arachnoiditis, and radiculopathy. However, every patient included in this group after surgery complained of radicular pain, and their magnetic resonance imaging showed varying degrees of epidural fibrosis. Patients with arachnoiditis also show concomitant evidence of epidural fibrosis and have had radiculopathy as these patients have undergone previous surgeries. Therefore, it is very difficult to assign one specific cause of continued pain and produce comparative analyses. We have therefore decided to maintain the broad nomenclature of FBSS for this group as has been generally accepted in the literature.

The average number of preimplant operations in this group was 2.9 ± 1.3 . Before implantation, each patient in this group was clinically evaluated and investigated with either computed tomography or magnetic resonance imaging scans to confirm the presence of varying degrees of epidural or perineural fibrosis, or arachnoiditis, considered to be responsible for their continued symptoms. These evaluations demonstrated that there were no surgically correctable lesions present.

The second most common indication for SCS in our series was peripheral vascular disease (PVD) causing rest and claudication pain. This accounted for 52 (12.7%; 35 men, 17 women) patients. All patients in this group were found to have diffuse vascular disease involving both large and small vessels, as confirmed by Doppler ultrasound and confirmed by angiography, such that revascularization procedures were no longer deemed a feasible option. These findings were also affirmed by consulting a vascular surgeon.

Complex regional pain syndrome (CRPS) Types I (26 patients) and II (6 patients) accounted for 32 (7.8%; 16 men and 16 women) patients in our series. Currently, the diagnosis of CRPS is based upon the clinical presentation because there is no objective diagnostic test and no gold standard for comparison. The criteria for diagnosing CRPS I have been adopted by the International Association for the Study of Pain in their consensus statement, which was published in 1994 (55). In our series, we have used guidelines proposed by Stanton-Hicks et al. (76), which incorporate the International Association for the Study of Pain taxonomy and consists of 1) history of limb trauma; 2) pain in the limb outside the distribution of a single peripheral nerve; and 3) objective physical findings such as edema, diminished function of the affected area, stiffness of the involved joints, characteristic skin and soft tissue changes; vasomotor instability, and bony demineralization in late stages. The major criterion differentiating CRPS I from CRPS II is the presence of partial injury to a major peripheral nerve.

Table 1 summarizes the distribution of all patients according to their etiologies, including the remaining 106 patients, which represent a diverse group of etiologies such as diabetic peripheral neuropathies, phantom limb pain, multiple sclerosis, intractable angina, bone and joint pain syndromes, pain secondary to spinal cord injury or lesions (including cauda equina lesions), perirectal pain, postherpetic or intercostal neuralgia, spinal cord tumor, and peripheral nerve tumor.

Electrode Implantation

All electrode systems used were manufactured by Medtronic Inc. (Minneapolis, MN). The electrodes used in our series consisted of Pisces-Sigma (66 devices [this electrode was used in the early portion of the study; however, it is no longer available]), Pisces-Quadripolar (326), Resume I/II (122), and Specify lead (11), giving a total of 525 devices used in this series. The Pisces-Sigma lead was a unipolar electrode with a 3 mm stimulating tip. The Quadripolar Pisces electrodes have four cylindrical contact points, each 3 mm in length and

spaced 6 mm apart. The Resume electrodes have four circular contact points, each with a stimulating area of 12 mm². The Specify leads contain two, four-electrode vertical arrays spaced 2 mm apart. The contact points are 2 × 3 mm and are spaced 6 mm apart vertically. Pisces Quadripolar leads were implanted percutaneously, whereas Resume or Specify leads were placed through a small laminotomy. Implantation procedures were performed under sterile conditions, under local anesthesia supplemented by conscious sedation. Techniques of implantation have been discussed previously (41). For upper limb pain, the stimulating tips of the electrodes were positioned most frequently between C5 and T1, and for lower limb pain between T9 and T11. For angina pain, electrode tips were placed between C7 and T1. All patients in our series underwent a trial stimulation of 4 to 7 days before permanent implantation of the system.

The implantation of paddle electrodes (Resume or Specify) requires a laminotomy, which is usually performed under local anesthesia, augmented by conscious sedation. In spite of this, the procedure remains quite discomforting to the patient. Since last year, we have switched to performing this implantation under spinal anesthesia, after the report by Lind et al. (47), and would like to confirm that the stimulation-induced paresthesiae are still reproducible with only a slightly higher amplitude required when compared with the cases performed under conscious sedation.

To address the historically poor response of predominantly axial pain in addition to radicular pain in the lower limbs, we are now using either a dual Pisces spinal electrode or the Specify lead system. The overlap of stimulation induced paresthesias is also facilitated by increasing the number of contacts. For example, four contact points result in 50 possible combinations, eight contacts result in 6050 possible combinations, and a 16 contact system escalates the number of combinations several fold. In such cases, the use of computer programming becomes more efficient than manual trial.

Pulse Generators

The pulse generators used were fully programmable and implantable battery powered systems. Single channel systems include Itrel I, II, and III (Selectra) and a dual channel system (Synergy; Medtronic, Inc.). The Synergy system is used in patients with Specify leads or in those with dual Pisces or dual Resume leads. The Synergy system has the advantage that it can be used with single lead system or as a dual channel system. It also has the flexibility that when using dual channel, transverse stimulation across the physiological midline is feasible, which allows for more precise paraesthesia coverage and increased longevity of battery life.

The X-trel system (Medtronic, Inc., Minneapolis, MN), which has been used in this series, is a radio frequency system that consists of a receiver and an external power transmitter. This system was selected when power demand during trial stimulation was of a magnitude that forecasted a much shorter life span of the Itrel system or for patients who lived in remote

areas, making visits to neuromodulation nurses for adjustments of settings inconvenient. The production of the X-trel system has now been discontinued by the manufacturers in the last 2 years.

Programming

To improve the effectiveness of stimulation, various combinations of unipolar, bipolar, or multipolar electrode contact configurations were used. Guarded cathode (central cathode with two lateral anodes: + - +) or tripolar configurations (Cathode on one lead, staggered by 2 anodes on an adjacent lead on the other side of the midline: [-||+]) have also been used to improve efficacy by producing stimulation-induced paresthesia that totally overlaps the area of pain that was not otherwise achievable. The tripolar configuration was achieved by using dual Quadripolar Pisces electrodes or Specify leads, which permits the use of the tripoles on either side or across the physiological midline. Thus, the selection of cathodes and anodes is possible in either the longitudinal or in the transverse directions.

Various cycling modes were introduced to prolong the life of the pulse generator battery. Parameter settings were variable and consisted of frequencies which ranged between 55 and 60 Hz, pulse widths of 210 to 300 ms, and amplitudes between 1.5 and 6.0 V. Initially, most stimulation units were cycled on for 1 to 2 minutes and off for 5 to 7 minutes. For people who could not tolerate longer periods of off cycles, we used a cycle of 1 to 2 seconds on and 1 to 2 seconds off. The Synergy system now allows a much wider range of settings, including cycling on/off in fractions of 1 second. We evaluated the effect of rapid cycling on VAS scores in patients who could not tolerate the longer "off" cycles.

Statistical Analysis

For comparisons between two groups, a two-tailed Student's *t* test was used to evaluate significance, with a cutoff of less than 0.05. Nonparametric Kaplan-Meier survival curves were used to demonstrate differences in electrode effectiveness, with four primary endpoints: 1) failure of trial stimulation; 2) loss of satisfactory pain relief despite corrective procedures; 3) refusal of the patient to undergo corrective procedures; and 4) gradual loss of satisfactory pain relief in the presence of a technically functioning electrode. For reporting functional and affective outcomes (ODI, MPQ, BDI, RMQ), each individual set of guidelines was applied. Fisher's exact test was used when appropriate to compare small sample sizes and dichotomous variables. Hazard ratios for various electrode types have been previously described (40).

RESULTS

Pain Relief

With trial stimulation, 328 (80%) of 410 patients experienced greater than 50% pain relief according to VAS and subsequently had their systems internalized. Eighty-two (20%) pa-

tients who failed trial stimulation were classified as early failures. At the mean follow-up period of 97.6 months (range 6–258 mo), 243 (74.1%) patients of the internalized group continued to receive satisfactory pain relief. Eighty-five patients were thus considered late failures (postinternalization) because of progressive loss of effective pain relief on follow-up. Among the 243 patients receiving long-term satisfactory pain relief, 62 (25.5%) reported excellent results (>75% pain relief), whereas the remaining 181 (74.5%) patients reported good pain relief (>50% relief). Therefore, of the 410 patients who received trial stimulation, effective long-term pain control was achieved in 59.3% of the patients enrolled. Figure 1 shows a Kaplan-Meier survival curve demonstrating a progressive decline in efficacy of SCS with time. With advancing technology and improved patient selection, the survival time of the systems has increased. Likewise, the percentage of patients with long-term successful pain relief has increased in the past decade (39) from 51% to 59.3%.

Status of Patients Who Failed Trial Stimulation

Eighty-two patients who failed to meet the minimum requirements of 50% pain relief relative to pre-implant levels did not have their systems internalized. Fifteen of these patients proceeded to receive deep-brain implants, and eight others underwent intrathecal morphine/other drug delivery system implantation. Eighteen patients died of unrelated causes during the 22 years study period, and 10 were lost to follow-up. Of the remaining 31 patients who continue to be managed on conservative medical therapy, only 2 are currently able to work on a part time basis. These patients continue to require regular visits to their family physicians and occasional hospital admissions for disabling breakthrough pain and continue to depend on narcotics for pain relief.

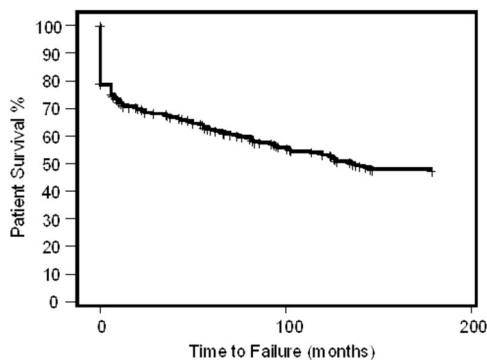


FIGURE 1. Kaplan-Meier survival curve for all patients receiving spinal cord stimulation. Statistical endpoint for patient survival was 1) failure of trial stimulation, 2) loss of satisfactory pain relief despite corrective procedures, 3) refusal of patient to undergo corrective procedures, and 4) gradual loss of satisfactory pain relief in presence of a technically functioning electrode. Curve illustrates initial loss in survival because of failed trial stimulation and a subsequently gradual loss of pain control during period of study (from, Kumar K, Toth C, Nath RK, Laing P: Epidural spinal cord stimulation for treatment of chronic pain—some predictors of success. A fifteen-year experience. *Surg Neurol* 50:110–121, 1998).

Clinical Prognostic Factors

Etiology of pain

Table 1 demonstrates the efficacy of SCS with respect to different pain etiologies. FBSS patients formed the largest group in this series (220 patients) and had a long-term success rate of 60%. PVD was another etiology that responded well to SCS, with 60% in this group experiencing good pain relief. The decline in efficacy may be a reflection of natural progression of the disease in relation to a long follow-up period. In 32 patients with CRPS I and II, 23 (71.8%) continued to receive successful long-term pain relief, although no patients were able to return to gainful employment in spite of good control of pain and paresthesias. All nine patients treated for angina achieved long-term success. Peripheral neuropathy secondary to diabetes mellitus was an indication for SCS for 17 patients, with a 71% long-term success rate. Of 19 patients with multiple sclerosis causing lower extremity pain, 15 (78.9%) continue to enjoy good pain relief. They also reported improvements in gait and sphincter control as added benefits.

Age

Of our total group of 410 patients, 213 patients were greater than 50 years of age, whereas 197 were less than 50 years of age. The mean age of patients at implantation is 54 years (range 21–87 yr). An analysis of internalization rates based on patient age showed that among those older than 50 years of age, 174 patients of 213 (81.7%) received adequate pain relief and had their systems internalized. For patients younger than 50 years of age, 154 of 197 (78.2%) had their systems internalized. No significant difference was found between these age groups with respect to success of trial stimulation and internalization (Fisher's exact test, $P = 0.389$).

Sex

Of 252 males who were screened with trial stimulation, 197 (78.2%) had their systems internalized. Similarly, 131 of the 158 (82.9%) females had their systems internalized. Thus, sex did not show a statistically significant difference in terms of successful implantation based on the Fisher's exact test ($P = 0.256$).

In the first year of treatment, women experienced better pain relief than men: 107 of 131 (81.6%) versus 151 of 197 (76.6%), respectively. Females with internalized systems had good pain relief for a mean of 24.1 month, as compared with male patients with internalized systems, for an average of 34.1 months. Therefore, females had a slightly higher rate of internalization and better pain relief in the first year; however, in the long-term, males seem to have higher success rates.

Laterality of pain in FBSS

Of the 220 patients with FBSS, 145 reported unilateral pain, of which 121 (83.4%) had their systems internalized. Another 75 patients with bilateral limb pain underwent trial stimulation, after which 63 (84%) had their systems internalized. There was no significant difference in internalization rate

based on laterality of symptoms. Long-term data indicates that 86 of 145 (59.3%) patients with unilateral pain continue to enjoy good pain relief at last follow-up, whereas 46 of 75 (61.3%) patients with bilateral pain are experiencing good pain relief. Thus, laterality of pain does not appear to influence the long-term success rate of SCS based on Fisher's exact test.

Pre-implant surgeries

Other variables, such as number of pre-implant operations and the time from first operation to implant, have shown significant prognostic value in the past (40). In this series, 331 patients had one or more surgeries before consideration for SCS therapy, either for evaluation or treatment of pain (2.9 ± 1.3 average procedures [mean $\pm$ standard deviation], with a maximum of 19 surgeries in one case). The majority of these patients represented FBSS, which may be a confounding factor. Among 79 patients who had three or more surgeries, 51% had long-term success, compared with a success rate of 54% among 252 patients who had less than three surgeries before implant, thus giving the group as a whole a long-term success rate of 53%. The difference between the two groups did not reach statistical significance based on Fisher's exact test ($P = 0.69$).

Among the 36 patients who had no previous surgery, such as those with peripheral neuropathies or pain caused by multiple sclerosis, the long-term success rate was higher at 75%, although these represent entirely different disease processes as compared with patients who require surgical treatment for their underlying pathology.

Duration of pain before implantation

Our previous experience (40) has shown that the success rate of SCS is inversely related to the time interval between the onset of chronic pain syndrome to the time of implantation. This may be related to adaptation of the nervous system to pain, learned behavior, or worsening/natural history of the disease process over time. Figure 2 shows that the success rate decreases from approximately 85% for a delay less than 2 years to approximately 9% if the delay is 15 years or longer. Student's *t* test analysis proved significant at $P < 0.001$, with the majority of these cases diagnosed as FBSS, which may be a possible confounding factor. Where possible, therefore, implantation should be performed within 5 years of the onset of symptoms.

Effects of Rapid Cycling

In the past 2 years, we have tried rapid cycling in 53 patients who could not tolerate longer "off" periods. The rapid cycles consisted of on/off periods of 1 second or fractions of a second. Twenty-eight of 53 patients experienced improvement in VAS scores, with an average improvement of 14 ± 6 points. However, patients who required more than 4 V, when switched to rapid cycling, especially split second cycles, tended to develop increased tone in the lower limbs and thus did not tolerate these settings. Battery life was generally pro-

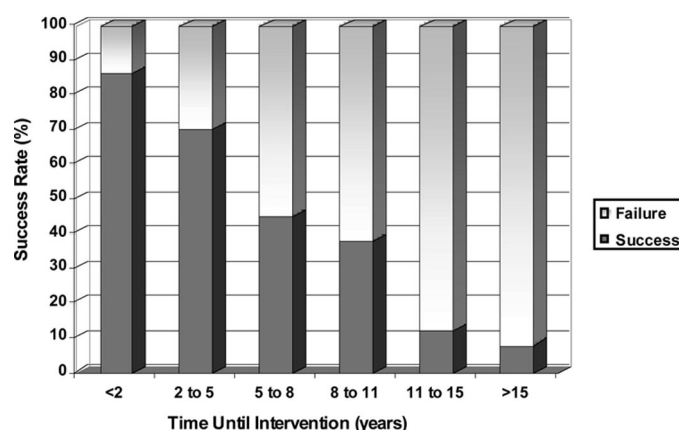


FIGURE 2. The rate of success of SCS is inversely related to time interval between beginning of chronic pain syndrome and time of implantation. Success rate decreases from 85% with a delay of less than 2 years to approximately 9% if the delay is 15 years or longer.

longed in patients using rapid cycles but was confounded by other parameters such as pulse width and amplitude.

Functional Outcomes and Patient Satisfaction

Figure 3 shows changes in functional outcome on the basis of four standard measures of disability, including the ODI, MPQ, RMQ, and BDI. Results of the ODI showed that patients experienced an average improvement in disability of 27% after SCS at last follow-up. This is a significant improvement according to ODI guidelines. The RMQ showed that patients experienced an improvement of 47%. The BDI results indicate that the average patient qualifying for this study was experiencing moderate depression, with an average pre-intervention score of 22.8. After SCS, the average score decreased to 8.8, which falls within the normal range. Results of the MPQ (short form) were also favorable, primarily in that the affective component of the questionnaire revealed that emotional contributions to pain were minimal in our study group. Average pre- and post-SCS scores were 4.7 and 2.7, respectively. Scores greater than 8 reflect a strong emotional content. The sensory

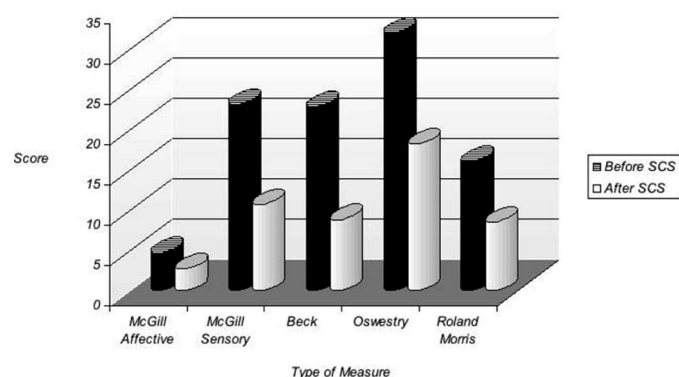


FIGURE 3. Bar graph showing the effect of SCS on various functional and psychological parameters.

component of the MPQ revealed an average pre-SCS score of 23.1, which falls into the moderate category (range, 15–25). After SCS, the average score fell to 10.7, which is categorized as mild, indicating an improvement (range, 5–15).

Of the 410 patients in this series, only 19 were able to work before SCS therapy. After SCS therapy, this number increased to a total of 58 employed patients in the study group. Fifteen patients who were employed on a part-time basis before the procedure reported significant increases in their time at work and activity level at work after SCS therapy. No patient who was previously employed became unemployed as a result of SCS therapy. None of the patients who failed trial stimulation were able to return to work during the study period.

In the past 3 years, we decided to assess patient satisfaction to SCS therapy. For this purpose, 56 consecutive patients were given a questionnaire after at least 1 year after implant surgery asking, "Knowing what you know about this therapy's (SCS) benefits, associated risk, complication and side effects, would you undergo the surgery again if necessary, and would you recommend the procedure to friends and relatives with similar problems with pain?" The responses were sorted into three groups (i.e., very satisfied, satisfied, and unsure). Thirty-six (64%) patients reported being very satisfied, 14 (25%) patients reported being satisfied, and the remaining 6 (11%) patients were unsure. Because SCS is the only modality that has given them comfort and has reduced their drug intake, the majority

of patients concluded they would have little hesitation recommending this procedure to their friends or relatives with similar pain problems.

Complications

The incidence and types of complications are presented in Table 2. Most of these are hardware-related. Electrode displacement, in either the axial or transverse planes, was the most frequently encountered complication, and occurred in 88 (21.5%, 9.5% if sigma systems are excluded) patients. Sixty-four displacements were in the axial plane, and 24 were in the transverse plane. This displacement results in altered stimulation-induced paresthesia and loss of pain control. Displacement was common with the Sigma systems (49 of 66 electrodes), which was the primary electrode available during the early phases of the study. This susceptibility to displacement and fracture was caused by defective metallurgy, a single contact point so that slight displacement resulted in loss of pain control, and undulations in the stem of the lead that easily led to displacement after any jarring or twisting motions of the back. The incidence of displacement decreased substantially after introduction of the newly designed Quadripolar-Piscis systems. In the dorsolumbar area, if the patient has torsion scoliosis, the lateral displacement increases by twofold because of this underlying anatomical change. The displace-

TABLE 2. Incidence and types of complications^a

Complication	Incidence (%)	Comment
Displaced electrode	88 (21.5)	Forty were repositioned, 48 were replaced (49 of these displacements occurred in sigma electrodes)
Fractured electrode	24 (5.9)	All replaced satisfactorily; usual site was distal to the fixation point to the deep fascia where the lead enters the spinal canal
Infection	14 (3.4)	Four resolved with antibiotics, 10 required removal and subsequent re-implantation
Hardware malfunction	20 (4.9)	Because of increased impedance, electrodes were replaced
Electrical leak	4 (1)	All were replaced; usual site was junction of connector cord to distal electrode or pulse generator
Subcutaneous hematoma	18 (4.4)	At the site of the pulse generator; one required surgical evacuation, 6 required aspiration, and 10 resolved spontaneously
CSF leak	2 (0.5)	Resolved spontaneously
90 degree rotation of pulse generator	3 (0.7)	Resulted from faulty anchoring of pulse generator to fascia, required repositioning
Discomfort over pulse generator	5 (1.2)	In 2 cases, pulse generator was placed too low in the anterior abdominal wall and caused irritation of the ilioinguinal node, requiring repositioning In 2 cases, it was placed over the lower ribcage in the earlier part of the study and needed to be repositioned over the anterior abdominal wall In 1 case, when placed over the gluteal region, the pulse generator caused pain on lying down, requiring repositioning
Insulation damage	9 (2.2)	Occurred in cases where rigid twist lock anchor was used requiring replacement of the lead

^a CSF, cerebrospinal fluid.

ment rate is twice in the cervical region as compared with lower dorsal placements because of mobility of cervical spine. In lower dorsal areas, displacement is rare with the Resume or Specify leads because of the paddle configuration of the electrode. In 24 (5.9%) patients in whom the cause of stimulation failure was recognized to be a fractured electrode, all electrodes were replaced. Twenty (4.9%) patients encountered malfunction of the electrode because of high electrical impedance possibly related to fibrosis at the stimulating contact points or leakage of body fluids at the junction of the lead to the extension cord. In nine patients, damage to the insulation of the lead was caused by the use of a hard plastic twist lock anchoring device. In these two subgroups, because of decreased pain control, electrode replacement was required. Fourteen (3.4%) patients experienced infection, 4 of which resolved with antibiotics, whereas the other 10 required removal of the hardware and subsequent reinstallation. Four cases of electrical leakage required replacement of the systems. This was more common in the early years of the study when radiofrequency systems were commonly used and occurred predominately at the site of the receiver. Two cases of cerebrospinal fluid leak resolved spontaneously. Eighteen patients developed a postoperative subcutaneous hematoma at the site of the pulse generator. One patient required re-exploration and evacuation of the hematoma, whereas 6 resolved with aspiration, and 11 resolved spontaneously. There have been three cases in which the pulse generator was found to have rotated itself 90 degrees (standing on edge) because of faulty anchoring. These cases were discovered in the recovery room when the patient woke up soon after internalization and complained of severe pain at the site of pulse generator. All cases required reopening and repositioning of the generator. There were five cases of pain over intracorporeal pulse generator (IPG) requiring repositioning. In our experience over 2 decades with SCS, we have not encountered any injury to the nerve root or spinal cord, epidural abscess, meningitis, or epidural hematoma. In our series, there has been no mortality attributable to SCS.

Tolerance

When trying to analyze the cause of failure of satisfactory pain relief at long-term follow-up, we found that a certain number of patients start to require increasing amplitude of current to maintain satisfactory pain control. Over time, these patients lose satisfactory pain control, even when the system is fully functional and stimulation continues to produce overlapping paresthesias in the territory of pain. For lack of any better terminology, we have labeled this phenomenon as "tolerance." This has been reported by other investigators: North et al. (62) and Pineda (65, 66). Tolerance has no specific time of onset, and its development has been seen scattered throughout the follow-up period (Fig. 4). In our opinion, tolerance has been the single most important causative factor in the 85 long-term failures in our series. The etiology of this phenomenon is still not well understood and may be related to plasticity of central pain processing systems (25, 28, 36).

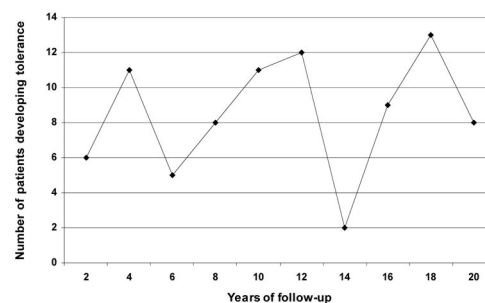


FIGURE 4. Graph showing the development of tolerance over time. Values indicate number of patients developing new onset of tolerance during each 2-year period. Incidence of tolerance is scattered throughout follow-up period.

The Influence of Third-Party Coverage

Any patient who was involved in active litigation or was found to have unresolved issues of secondary gain were excluded from this study. Coverage by the Worker's Compensation Board (WCB) is not subject to litigation in Canada by law but acts as a health insurance and disability benefit. Therefore, we have considered the influence of coverage by WCB in the propagation of long-term disability in patients with FBSS undergoing SCS. One hundred six patients with FBSS had WCB coverage at the time of trial stimulation; 89 (83.9%) reported good pain relief and had their systems internalized. The results at the last follow-up show that 54 (50.9%) patients with WCB coverage continued to have successful pain relief. Among the 114 patients with FBSS without WCB coverage, 89 (78.6%) had their systems internalized, and 80 (70.1%) had good pain relief at last follow-up. This difference was significant using Fisher's exact test ($P < 0.0038$). Thirteen patients (14.6% of internalized patients) without WCB coverage returned to gainful employment. Only 4 of 89 patients (4.5% of internalized patients) with WCB coverage returned to gainful employment after SCS. This difference was also significant using Fisher's exact test with $P = 0.0387$. Thus, it seems that third-party coverage negatively affects the outcome and impairs the return to gainful employment.

Although we have attempted to avoid cases that are currently involved in active litigation, a recent study by van Buyten (79) reveals no difference in VAS scores in patients involved in active litigation when compared with the total study population undergoing SCS.

Predominant Axial Pain

Lower extremity pain secondary to radiculopathy consistently responds well to SCS. However, when axial pain is present and predominates over the radicular lower extremity pain, it becomes difficult to treat. In the past 2 years, we have evaluated the benefits of dual Quadripolar-Pisces and Specify lead electrodes in sciatic pain with a preponderance of axial pain. Preliminary results for 32 patients with predominant axial pain were analyzed at the end of a 1 year follow-up. Twenty-four patients had a dual Quadripolar-Pisces, and

eight patients had Specify spinal electrodes implanted in the lower dorsal area. In all of these 32 patients, an average reduction in the axial pain on VAS scoring was 58%, and the reduction in the radicular pain was 60%. The remaining 152 patients with FBSS and predominantly leg pain and minor axial pain, who were implanted with single lead systems, had an average reduction in VAS scoring of axial pain of only 15% and a radicular pain reduction of 64%. Alo et al. (4) have also found that dual lead systems are more beneficial for predominantly axial pain.

The effect on pain relief was correlated with use of staggered or parallel Quadripolar-Pisces electrode configurations. Our data suggests, although not statistically significantly using Fisher's exact test, that pain relief is superior when the Quadripolar-Pisces electrodes were placed in a staggered position; 11 of 18 patients with this configuration had good pain relief, whereas only three out of six with a parallel arrangement had good pain relief. Moreover, in six of eight patients where Specify leads were used, excellent pain relief was achieved. Although the Specify leads have a parallel arrangement, superior results were only achieved when staggered configurations were used through programming. At the time of writing, there is no known documentation in the literature regarding the benefits of the Specify lead for predominant axial pain, except our small series of patients.

Effects of Electrode Type on Outcome

Our present and previous data (40), as well as previous publications (58, 62), clearly demonstrate that multipolar and multichannel electrode systems are superior with respect to successful pain relief over a longer period of time. The plate electrodes have a longer survival time than the Pisces electrodes (Figure 5). Although the difference is marginal, the

benefit has been demonstrated consistently and is confirmed by other researchers (56, 59, 60).

DISCUSSION

SCS has become an established treatment option for controlling chronic, benign pain because of its reversibility, minimal invasiveness, low complication rate, and its effectiveness. Recent publications have also shown that SCS is technically superior and cost effective, as compared with conventional medical management, especially in the treatment of FBSS (14, 15, 17, 38). This has provided further impetus in the use of this technology.

There is now an extensive body of literature describing experiences with SCS over the past 30 years (19, 22, 40, 62, 63). This article is based on analysis of the second largest published database of patients currently available to study the long-term effectiveness of SCS for chronic pain. The only other larger series was published by Lazorthes et al. (46). A recent literature review of 49 studies, with a total population of 2520 patients, by Cameron (19) shows an average success rate of 67%, when followed for at least 6 months. A subanalysis demonstrated a strong positive correlation between the etiology of pain and the success rate.

Our results show that effective long-term pain control, with a mean follow-up of 97.6 months, was achieved in 59.3% of all patients screened and 74.1% of the 328 patients who had their systems internalized. This demonstrates that effective long-term pain control is now a predictable and reproducible outcome in the hands of experienced physicians.

Demographics and Prognosis

We have found no significant influence of age, sex, number of previous operations, or laterality of pain with respect to long-term success. We found that females in this series had a slightly higher rate of internalization and better pain relief in the first year; however, in long-term follow-up, males experienced higher success rates. Analysis of surgical influence revealed that patients who had no prior surgery had a higher long-term success rate as compared with those who had at least one prior procedure (68% versus 53%, respectively), although these may simply represent entirely different disease processes.

Our previous experience (40) has shown that the success rate of SCS is inversely related to the time interval between the first operation performed on the affected region of the body and time of implantation. This may be, in part, because of reinforcement of pain pathways over time and subsequent learned behavior, making changes in these pathways more resistant to treatment with SCS with passage of time.

Role of Trial Stimulation

In this study, we have tried to achieve a total overlap of stimulation induced paresthesia in the territory of pain because, in our experience, failure to achieve this has led to less

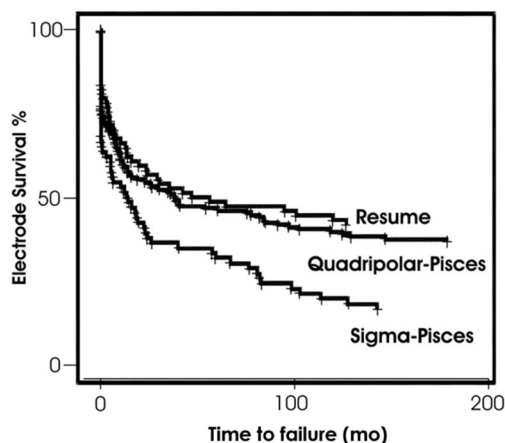


FIGURE 5. Kaplan-Meier survival curve for electrode types used in spinal cord stimulation. Graph shows that plate type of electrodes have a longer survival time than electrodes (from, Kumar K, Toth C, Nath RK, Laing P: Epidural spinal cord stimulation for treatment of chronic pain—some predictors of success. A fifteen-year experience. *Surg Neurol* 50:110–121, 1998).

than optimal results. However, a recent prospective study by Allegri et al. (1) has shown that complete coverage is not necessary to achieve a good outcome.

We have shown that approximately 20% of patients fail trial stimulation in spite of the best efforts in selecting candidates for SCS therapy. This emphasizes the importance of screening with percutaneous electrodes before permanent implantation, which is currently not a standard protocol in some centers, despite a very low morbidity rate. This approach reduces the rate of failed permanent implants, and improves cost effectiveness. The trial stimulation also allows for a period of patient adjustment to stimulation-induced paraesthesia and counseling by the neurosurgical team. The main disadvantages to this process are that it is an added procedure with associated costs and minimal risks such as root irritation, hematoma, or infection, which may add to the hospital stay.

Reasons for failure of trial stimulation in patients who are otherwise considered to be good candidates for SCS are poorly understood. It is hypothesized that these patients may be an example of a population whose primary pain mechanisms or pathology are unsuitable to SCS or whose anatomy or physiology in some way may prevent accurate electrode placement. Recently developed computer models that mimic the effects of SCS on spinal nerve fibers and the use of somatosensory evoked potentials will likely lead to better results (6, 29). Computer assistance in generating optimal configurations during trial stimulation may also add to success rates (57).

Role of Spinal Anesthesia in Implanting Paddle Electrodes

Implantation of paddle electrodes under conscious sedation is quite discomforting, which has persuaded us to use spinal anesthesia for this purpose. We have found that spinal anesthesia does not abolish the stimulation-induced paresthesia or prevent proper placement. This is contrary with the belief of anesthesiologists that spinal anesthesia will produce complete motor block and anesthesia, but, in fact, it does not block all sensory transmission in the superficial layers of the spinal dorsal columns, thus permitting intraoperative testing and proper lead positioning. Lind et al. (47) concluded that the subarachnoid anesthetic agent acts predominantly on the spinal rootlets and perhaps the ganglia, rather than on the spinal afferent pathways. The authors acknowledge that the type of anesthesia used has no effect on success rates.

Role of Rapid Cycling in Pain Relief and Prolongation of Battery Life

In our experience, the benefits of rapid cycling are improved pain relief and prolongation of battery life of the fully implantable systems. Patients who required greater than 4 V and were switched to rapid cycling, especially split-second settings, tended to tolerate it poorly as they developed increased tone in the lower limbs, and therefore this should be avoided for these patients. The physiology of this phenomenon is not understood. This observation of the benefits of

rapid cycling has not yet been reported elsewhere in the literature.

Successful Etiologies

Our experience (Table 1) parallels others in demonstrating that etiology of pain is a crucial prognostic factor in predicting outcome. Although statistical analysis is difficult because of large variations in sample size, our numbers demonstrate that success rates vary with etiology of pain, which is consistent with the literature (16, 27, 30, 34, 40, 41, 50, 62, 63, 65). The most satisfying pain relief is achieved in patients with FBSS, angina, CRPS, and PVD that was not amenable to revascularization surgery.

Failed Back Syndrome

Improvements in patient screening and the use of multipolar and multichannel electrode configurations have improved long-term success rates, quality of life, and reduced requirements for pain medication. This is reflected by greater incidence of long-term successes of 60% when compared with our previous publication of 47% (40).

The patients in our series who had a predominance of axial pain combined with either unilateral or bilateral leg pain responded well to either a dual Quadripolar-Pisces or a Specify lead system, powered through a Synergy pulse generator. In these patients, a staggered dual electrode configuration (Quadripolar Pisces electrodes) or specify leads appeared to be more effective than a single ray of electrodes placed in the midline, although this difference did not reach statistical significance. This difference may also be confounded by comparing recent patients to earlier patients in that during this period, there has been a progressive evolution of equipment and technique. The staggered configuration is intended to allow for increased axial paraesthesia coverage. In situations where there is a preponderance of axial pain, even in conjunction with a unilateral leg pain, a single lead electrode needs to be placed at a higher vertebral level to produce paraesthesias in the mid to upper lumbar regions. In our experience, this produces dorsal root fiber stimulation more than dorsal column stimulation, causing annoying paraesthesias in the lower abdominal wall much earlier than paraesthesias in the lumbar region. This limits its application in predominant lower back or axial pain. Holsheimer (29) has shown that, by using a transverse tripole electrode, it is possible to steer stimulation away from the dorsal root fibers and improve paresthesia coverage and pain management.

Our work does not support earlier findings (63) that the single electrode system is superior in treating unilateral or bilateral pain with a major axial component. Previous work by Law (44) and Aló and Holsheimer (3) have shown that the small differences in stimulation amplitudes between a patient's perception threshold and discomfort threshold often prohibits effective paraesthesia coverage of the painful area. Results from computer models using a single lead electrode configuration show that contact separation distance and the

distance between the electrode and the spinal cord (governed by the depth of the cerebrospinal fluid at that segment) are the two most critical factors that may explain this phenomenon (10). In contrast, dual lead electrode systems permit bipolar and tripolar configurations, using horizontal combinations that cross the physiological midline, yielding superior results as indicated by our series. Staggered, parallel, multicontact electrodes seem to be more efficacious than parallel, nonstaggered configurations. At present, it is difficult to be clear about the electrophysiological explanation for the higher success rate achieved with staggered configuration. A possible explanation is that by staggering the electrodes, the contact separation distance is reduced, providing more extensive paraesthesia coverage (3). The superiority of the Specify lead may be related to its paddle configuration, which prevents displacement, large contact surface area, which can be placed on either side of the physiological midline, and the ability to use both axial and tripolar (guarded cathode) configuration.

Peripheral Vascular Disease

The benefits of SCS in PVD have been shown previously by Kumar et al. (41). This work demonstrated beneficial effects of SCS on PVD in successful cases as shown by increased transcutaneous partial pressure of oxygen measurements (average increase of 45.5 ± 17 mm Hg), peak flow velocity (average increase, 40.4 ± 40.2 cm/s), pulse volume recording (average increase, 5.4 ± 1.0 mm³), reduced rest pain, and improved probability of ulcer healing. The additional benefit of increased perfusion results in increased rates of limb survival and more distal amputation in cases where amputation was necessary (8, 32, 42). Other studies in the literature have shown similar benefits (16, 24, 27, 32).

Complex Regional Pain Syndrome

CRPS has been shown to respond well to SCS, which is consistent with the literature (19, 34). We also found that SCS will control pain of CRPS when it spreads to a second limb by implanting additional electrodes (45). In spite of good pain control, we have not been able to show a functional improvement in the affected limb. Recent prospective, randomized controlled trials (34, 35) have shown similar improvements in pain without improvements in functional outcome. This may be related to the delays in diagnosis and initiation of treatment, which permits permanent changes to set in soft tissues and joints of the affected limb.

Angina

In our short series of nine patients with angina secondary to end-stage coronary artery disease (New York Heart Association Class III/IV), in whom further revascularization was not possible, all showed marked reduction in number of attacks, improved exercise tolerance, and reduction in nitrate consumption. Although decreasing the severity and frequency of episodes of angina, SCS does not suppress the cardiac pain that signals impending further damage of the myocardium

(11, 23, 25, 50). This group has proven to be one of the most gratifying to treat. Prospective, randomized, controlled trials that have compared SCS with coronary artery bypass graft have found that the mortality rates were higher in the coronary artery bypass graft group and that both groups had significant reduction in number of attacks and nitrate use (43, 50). SCS has been shown to decrease myocardial oxygen consumption and improved myocardial microcirculatory blood flow (43).

Pain Caused by Other Etiologies

Pain originating from partial spinal cord injury or lesion, postherpetic or intercostal neuralgias, or perirectal pain showed a moderate response to SCS. Pain caused by cauda equina lesions, paraplegic pain, bone and joint pain, and phantom limb pain responded poorly in our series and continue to be a challenge to this form of therapy.

Complications

Most complications in this series were hardware-related (Table 2), the most common being fracture or displacement of electrodes. The most common fracture site was distal to the point of anchor where the lead exits from the deep fascia. This is related to the bend or kink at this point, which seems to be the site of the greatest stress caused by repeated bending motion of the spine. Another interesting observation during the revision of the implants was that the rate of fracture increases when the anchor is 1 cm or more beyond the point of exit; this may be related to the increased bend/kink in such cases. The vertical displacement in a Pisces type of electrode also seems to have a relationship to where the IPG is implanted in the abdominal wall versus gluteal area. The incidence seems to be higher when the IPG is implanted in the gluteal region (2 of 14 cases). This may be related to the increased excursion of the cable in flexion-extension of the lumbar dorsal region causing a pull on the lead through the anchor, resulting in downward displacement of the electrode. Further bench tests are needed to evaluate the degree of excursion in various areas to evaluate this observation.

According to a study by North et al. (58), in a case of displacement, to recapture paresthesia coverage, surgical revision was needed in 23% of cases when simple bipolar leads were used, but the revision rate dropped to 16% when multichannel devices were used by reprogramming. According to Alo et al. (6), only 3.8% cases required surgical revision with the use of eight-electrode lead and complex programming. We found an increased incidence in the development of high impedance when plastic twist lock anchors (9 cases in this series) were used to stabilize the lead. The twist lock anchor causes a break in the insulation/coil of a lead and ultimate failure. This damage to the lead is related to two factors: 1) pressure exerted by the twist lock mechanism on the insulation and 2) stress caused by repeated flexion and extension of the spine at this fixed point. In our experience, the best anchor to use is the three-wing plastic one, but it must be placed immediately at the point of exit of the lead

from the spine (to minimize the bend/kink at the exit thus reducing the incidence of fracture) and secured well to the deep fascia by a 0 silk suture. Some surgeons prefer to further reinforce this area by silicon adhesive (E Buchser B, Linderoth, personal communication, 2004). This helps to lower the incidence of axial displacement of the electrodes because of a tug caused by movements of the dorsal lumbar spine during regular body movement. Use of prophylactic antibiotics has been helpful in our series by keeping the infection rate down to 3.4% as compared with the literature where infection rate ranges from 5 to 9% (33, 68), no occurrence of meningitis, and requiring a fewer number of systems to be explanted.

Exhaustion of the batteries of the IPG is not a real complication and as such has not been included in the compilation of the complications. It is, however, a cost factor and an added hazard to the patient because of the need of surgery to replace it. The battery life is governed by the amplitude, pulse rate and width, and duration of stimulation per day. In our series, on average, IPG needed to be replaced in the fourth year postimplantation (38). With the availability of rechargeable systems, this problem will be partially alleviated. However, the authors understand that rechargeable systems will have a lifespan between 7 to 10 years depending on the manufacturer because of limitations imposed by changes of chemical degradation of the battery.

Tolerance

Tolerance remains a challenge to the maintenance of high rates of long-term success, regardless of early successful results. It is believed that tolerance may be caused by plasticity of pain pathways either in the spinal cord (24), thalamus (36), or cortex (28). Fibrosis around the stimulating tip has also been implicated (37, 40, 69, 73), but has not been proven by autopsy or surgical exploration. Gradual loss of pain control after a successful period is a multifactorial problem involving physiological, pathological, and psychological factors.

A review of the literature fails to provide an adequate explanation or guidance in its treatment. Stimulation "holidays" of up to 6 weeks have met with minimal success, with only two patients in our cohort resuming successful pain control. Addition of adjuvant medications, such as amitriptyline or L-tryptophan, has been met by equally poor results in our experience.

Role of Psychological Factors

The four tests (ODI, MPQ, RMQ, and BDI) used in our study that measure both the functional and psychological state of the patient before and after SCS all demonstrate an improvement in degree of disability, symptoms of depression, improvement in pain scores, and generalized well-being. Furthermore, 15.4% more patients returned to gainful employment after successful implantation. Studies by Pincus et al. (64) and Mannion et al. (51) suggest that psychological factors play an important role in patients' perception of pain, as well as their level of disability and response to therapy. In patients with chronic low back pain, studies have shown that aside

from pain itself, the only other negative predictors of response to therapy are fear avoidance behavior (21, 80) and psychological distress (9, 64). These three traits were consistently associated with a reduction in disability scores. However, objective measures such as electromyography of the paravertebral muscles and range of motion assessments did not show a significant correlation with level of disability. North et al. (61) found that although some statistically significant associations exist between psychological test scores and results of screening with temporary percutaneous electrodes, a multivariate analysis failed to demonstrate any significant association between psychological test scores and long-term implant results.

Patient controlled stimulation programs, when integrated in SCS therapy, have shown an 80% satisfaction rate in a cohort of 79 patients followed over a 3-year period (3). This increased success rate may be partly caused by perceived self-efficacy in controlling pain (51), which is especially significant in addressing fear avoidance and psychological distress as predictors of postintervention outcome (61).

CONCLUSIONS

Our data indicate that SCS can provide significant long-term pain relief and improve quality of life in a variety of benign intractable pain generating etiologies. The most beneficial effects are noted in cases of FBS, CRPS I and II, pain secondary to PVD, angina, multiple sclerosis, and peripheral neuropathy. In addition to improvements in pain intensity, patients also reported increases in social interactions, mood elevation, and various factors in daily living. SCS using multipolar and multichannel stimulation programs have improved long-term success rates significantly in comparison with the previous decade. The use of multiple leads allowing multiple electrode combinations and sophisticated programming appears to hold much promise in the treatment of patients with predominantly axial back pain, which in the past has been resistant to SCS therapy. The complication rate is low, which makes SCS a relatively safe and effective approach in management of long-term pain. In the literature, SCS has also been shown to be cost effective when compared with conventional medical treatment for similar etiologies (35, 38, 52, 77). The concept of tolerance continues to be the most significant challenge to long-term efficacy of SCS therapy, and further work is required to elucidate its pathophysiology. Prospective, randomized controlled studies that are currently in progress will further confirm the above conclusions.

Treatment of chronic benign pain by spinal cord stimulation has been applied with increasing effectiveness in recent years. Despite this evidence, the indications and especially long-term efficacy continues to be debated. We provide an depth analysis of clinical predictors of outcome including age, sex, etiology of pain, type of electrode used in low back pain with a predominant axial component, duration of treatment, complications with suggestion of how to reduce their incidence, development of tolerance, employment status, activities of

daily living, psychological status, and quality of life. Our study group of 410 patients (252 men, 58 women) had a mean age of 54 years. Patient data was collected over 22 years, with a mean follow-up period of 97.6 months. Results of this study will be effective in better defining prognostic factors and reduced complications leading to higher success rates.

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COMMENTS

This is a most ambitious study based on the authors' exceptionally extensive and long-term experience of spinal cord stimulation (SCS) applied for a variety of pain conditions. However, in recent years, the usefulness of SCS has been questioned because of the poor level of evidence supplied in support of its efficacy considering that there are just a few prospective, randomized trials (1) as compared with the large number of retrospective case studies. It is true that these studies report surprisingly concordant outcomes, similar to that documented in the present study, but that, unfortunately, does not help to convince those who argue that only good, evidence-based medical care can be justified. With regard to SCS, which is not suitable for placebo-controlled studies, I personally do not agree with this somewhat rigid attitude but this is the situation that we have to live with. Therefore, I regret to say, the present report does not add much to what has been previously published and does not supply further evidence supporting its efficacy.

This is a very long article covering almost all aspects of SCS. However, I find it problematic that all types of diagnoses have been lumped together. Thus, it is misleading to give an overall result such as 74% of the internalized patients experiencing good pain relief when this figure refers to totally different diagnoses such as angina, that is highly likely to respond, and spinal cord injury pain where the outcome generally is poor. A small series of not more than nine patients with angina is of very limited interest considering the many publications of large numbers of cases with this diagnosis. “Bone and joint pain syndromes” is included, but is mostly ambiguous and can hardly be considered as a disease or pain diagnosis.

I am very surprised that the first inclusion criterion is just “organic pain.” To a reader lacking experience and knowledge about SCS, these criteria might imply that this is a treatment for virtually any type of chronic pain. It is presently universally realized that SCS is preferentially, or perhaps exclusively, effective for certain forms of neuropathic pain. It is most likely that the effect in ischemic pain is secondary to stimulation induced changes in circulation, oxygen demand, etc. This is presumably the reason why the mostly nociceptive pain components represented by

axial pain in the lumbar back generally responds poorly. The authors state that radiating pain in a leg was present in all their patients who were treated for pain following back surgery. In fact, they experienced what we generally refer to as lumbosacral rhizopathy.

Although the exceptionally long mean follow-up period (almost 8 years) is impressive, the ongoing changes in selection criteria and device improvements have, for obvious reasons, influenced the outcomes over the years and the results of the past decade should, therefore, have been given separately; in fact, these most recent experiences are the only ones being of interest and serving as guidelines for those who intend to start this form of treatment.

An interesting part of the article is that discussing "failed back syndrome." It has been much disputed whether it is possible to produce paresthesias that cover the axial back region and whether pain confined to that region, conceivably being of a nociceptive type, may be suppressed by SCS. The authors' experience with staggered dual electrodes suggests that perhaps this is possible. A thorough study of this particular topic is indeed needed, and I anticipate that it would be much more relevant and interesting than the present study.

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1. Turner JA, Loeser JD, Deyo RA, Sanders SB: Spinal cord stimulation for patients with failed back surgery syndrome or complex regional pain syndrome: A systematic review of effectiveness and complications. *Pain* 108:137-147, 2004.

In this study, Kumar et al. have described their considerable experience with SCS. Their analysis of 22 years' follow-up in 410 patients is among the largest series and longest follow-up periods in the literature, and they should be congratulated for having kept detailed records of their patients over such a long period of time. And, although the authors' conclusions on factors influencing outcomes in SCS are not surprising or novel, they do serve to substantiate the observations of previous investigators in other series.

The applicability of the type of data collected in this study has to be taken with a grain of salt, however. Like most of the literature on SCS, this study is classified as Class III data. Retrospectively collected information is heavily influenced by confounding variables and the tendency to drill for data. In this particular study, the patient population is too diverse, with too many disease processes, too many techniques, and too many examined variables. Data collection is not rigorously controlled, and there is a tendency of loss to follow-up which is difficult to control. Moreover, with such a long-term study, one of the difficulties we have to contend with is the evolution of technique and technology (which have been considerable over this time period). It is, therefore, impossible to make any definitive conclusions based upon the data presented.

Given the limitations of a long-term, diverse and retrospective trial, the data should be interpreted with caution. Perhaps the greatest value of a series such as this is to make hypotheses based on the authors' observations that may be tested in a more controlled fashion. In this vein, the following observations made by the authors are interesting and should spur further study:

1) The duration of pain prior to SCS correlates inversely with long-term success of the therapy. This is an observation that has been made anecdotally by many practitioners. The data presented in this study are, therefore, compelling in this regard, although the basis for this phenomenon is purely speculative. It would probably be unethical to study this in a randomized fashion, a prospective study of patients with a single,

well-defined diagnosis, and matching important confounding variables would go a long way in deciphering this correlation.

2) Rapid cycling of stimulation is poorly tolerated by patients. The ability to rapidly change or alternate stimulation parameters is a relatively recent development, due to improvements in microprocessors and the engineering of the stimulation generator. However, the physiological effects of rapid cycling or stimulation parameter changes are not well studied. This area is ripe for study, since device manufacturers continue to tout the advantages of such cycling and program changes, without any evidence that this is beneficial for patients.

3) Staggered contact arrays provide superior axial paresthesia coverage. Axial coverage has been the "holy grail" of SCS, and perhaps the single greatest point of contention between implanters on techniques, lead types and contact configurations. Excellent studies using finite element modeling have suggested a theoretical advantage for transverse stimulation. However, the precise contact polarity configuration needed to maximize coverage of low back pain should be studied in detail.

4) Hardware failures are due to lead strain over the fascia proximal to the anchor, and seem to be greatest in cases where the generator is located in a gluteal position. Every implanter has a ritualized method of placing the lead, anchor, extension and generator - mostly to reduce the risk of hardware movement or failure. The fact that these methods differ between implanters indicates a lack of understanding of the forces that affect SCS systems in the long term. A study looking at failure modes of SCS systems, based upon different lead configurations, spine regions, and generator locations would go a long way to sorting out these troublesome issues.

5) The development of a delayed analgesic failure to SCS (tolerance) occurs at a steady clip throughout the post-implantation follow-up period. Tolerance is a poorly understood phenomenon which deserves detailed study in a prospective fashion. Retrospective studies such as the present one are too confounded by the natural histories of multiple underlying diseases, age, and sex issues, as well as differing implantation techniques and system types.

The observations made by Kumar et al. over the past 22 years give a glimpse into the utility of SCS in the treatment of pain of multiple etiologies, as well as the limitations and pitfalls of this technique. This information should stimulate well-controlled, focused studies performed in a prospective fashion that could add to the ranks of Class I and II data vital to the advancement of the field.

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This is the latest report, and an important addition to the literature, from a center with one of the largest experiences with SCS. It is among the very largest case series, adding to a large body of similar evidence of clinical efficacy of SCS, and it offers valuable observations. Successful treatment of axial low back pain with increasingly complex electrode arrays, in particular dual columns of contacts on either side of the midline, has been reported, and is corroborated here. Case series observations do not allow any conclusions as to their efficacy by comparison with single columns in the midline. We have recently reported a controlled trial in patients with axial pain, comparing these configurations directly, and using quantitative, computerized measurements (2). Although we observed worthwhile long-term clinical results with dual columns, as in the present series, we found that (in the acute setting, in which we made direct comparisons) dual columns are in many respects technically inferior, as predicted by the modeling work of Holsheimer (1). We anticipate that SCS manufacturers will develop electrodes combining the best features of both designs, and that clinical series like this one will report continued improvement in outcomes.

Favorable experience is reported here with laminectomy electrode placement under spinal anesthesia. This is said to offer improved overall patient comfort, while still allowing some stimulation paresthesias to guide placement. It remains to be shown, however, that it does not increase the risk of complications, not only suboptimal electrode position, but also inadvertent (fortunately rare) operative injury. Pain is, after all, sometimes a biologically useful sensation.

The “dual channel” devices described here do not allow simultaneous (rather, they allow alternate) delivery of different signals to different electrode contacts, and so in fact they are single channel. True multichannel systems have been used in SCS; the transverse tripole system described by Holsheimer (1) is an example. “Tolerance” is most commonly used to describe an increasing dose requirement (of a drug) to achieve the same effect. It is used here to describe loss of pain relief (therapeutic effect) in the presence of adequate paresthesia coverage (a consistent and necessary side effect), which can occur in patients whose amplitude requirements (dose) are constant, as well as those in whom there is an increase. Indeed, many patients whose amplitude requirements increase maintain a good therapeutic result. The relationships between these

phenomena remain to be shown, apart from the obvious circumstance in which amplitude requirements exceed system capacity. The authors correctly qualify their use of the word “tolerance,” which does not adequately describe the situation.

Kumar et al. are to be commended for adding this large experience to the SCS literature. We look forward not only to continued technical advances, but also to following up on case series observations from this center and others, with randomized, controlled trials.

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Spinal dysraphism with detailed cross-section of dysmorphic spinal cord. (From, von Recklinghausen FD: Untersuchungen über die Spina bifida. Berlin, G. Reimer, 1886.)

