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384 Spinal Cord Stimulation for Chronic, Intractable Pain: Experience over Two Decades
Clinical Study

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ABSTRACT: OVER THE PAST two decades, spinal cord stimulation devices and techniques have evolved from single-channel systems, with electrodes requiring laminectomy, into programmable "multichannel" systems with electrodes that may be placed percutaneously. We have reviewed our experience in 320 consecutive patients treated with these devices at our institution between 1972 and 1990. Technical details of treatment as well as patient characteristics have been assessed as predictors of clinical outcome and of hardware reliability by univariate and multivariate statistical methods. Current follow-up has been obtained at intervals from 2 to 20 years (mean, 7.1 yr) postoperatively on 205 patients. All clinical outcome measures have been based on disinterested third-party interview data--standard analog pain ratings, employment status, activities of daily living, and use of analgesics. At 7-year mean follow-up, 52% of the 171 patients who received permanent implants reported at least 50% continued pain relief. A majority had maintained improvements in activities of daily living and analgesic use. Analysis of hardware reliability for 298 permanent implants revealed significantly fewer clinical failures ($P < 0.001$) and technical failures (in particular, electrode migration and malposition, $P = 0.025$) as single-channel implants have evolved into programmable, multichannel devices. Our analysis of technical and clinical prognostic factors may be useful to the clinician in selecting patients for this procedure.

KEY WORDS: Chronic pain; Electrical stimulation; Spinal cord stimulation

Spinal cord stimulation was introduced more than 20 years ago as a reversible, nondestructive technique for the management of chronic, intractable pain [69]. Percutaneous methods for electrode introduction, originally developed to screen patients for implantation of these devices [18,21,23,76] were adapted in the 1970s for use with permanently implanted systems [51,86]. Recent technical improvements in implanted hardware, in particular the development of arrays of multiple electrodes and supporting electronic devices, have led to improved clinical outcome [37,55].

We have reviewed our entire institutional experience with spinal cord stimulation over the past two decades and have obtained current follow-up, by disinterested third-party interview, on all available patients. This has permitted an analysis of clinical predictors of outcome, as well as technical and clinical comparisons of percutaneous and laminectomy electrodes, and of older single-channel and newer "multichannel" systems.

METHODS

Our study population was drawn from a consecutive series of 320 patients with chronic, intractable pain, who underwent implantation of temporary and/or permanent spinal cord stimulators (Medtronic, Inc., Minneapolis, MN; Neuromed, Inc., Ft. Lauderdale, FL) at the Johns Hopkins Hospital between 1971 and 1990. (Thirty-one of these patients, who received implants in the mid-1970s, and 66 who were implanted in the mid-1980s have been described previously, on the basis of prior follow-up interviews [41,51,55,57]. All patients were screened with a temporary electrode to establish satisfactory relief of pain before implantation of a permanent device. After screening, 249 (78%) of these patients proceeded to have a total of 298 permanent implants; the additional implants were performed because of wound infections, electromechanical failures, or system upgrades to improved devices.

Two hundred five patients (64%) were available for current follow-up interview. (Over the two decades that this series spans, 13 patients had died.) Of the 205, 34 had received only temporary electrodes; 171, after screening with a temporary electrode, had proceeded to have permanent implants. Permanently implanted electrodes were placed percutaneously in 134 of the 171 patients and by laminectomy in the remaining 37. Seventy-five were single-channel and 96 were multichannel programmable devices (technically, single-channel devices gated to multiple outputs). In our overall series of 298 permanently implanted devices in 249 patients, there were 226 percutaneous and 72 laminectomy electrodes; 131 were monopolar or bipolar, and 167 were arrays of four or eight contacts. The associated implanted electronics were single-channel, radiofrequency-coupled devices in 144 patients and multichannel, programmable radiofrequency-coupled devices in 154.

The 205 patients were grouped into three diagnostic categories: 153 with "failed back surgery syndrome" (postlaminectomy syndrome), with varying degrees of lumbar arachnoid fibrosis), 11 with spinal cord injury, and 41 with pain syndromes of "peripheral" origin. Within these groups, 87, 90, and 68%, respectively, had received permanent implants. The 41 "peripheral" pain syndromes included 24 discrete peripheral nerve injuries--6 upper and 9 lower extremity, 3 intercostal or abdominal, and 6 inguinal; 5 postamputation pain syndrome; and 3 cases of "reflex sympathetic dystrophy."

All patients were assessed and treated in an institution with a multidisciplinary pain treatment

program, which includes routine psychological evaluation before treatment. Patients with nonphysiological or "Waddell" signs at the time of examination, with serious drug-seeking or abnormal illness behavior, or with major unresolved issues of secondary gain were excluded or were treated in a behavioral program and then reconsidered. Spinal cord stimulation was restricted to those who had an objective basis for complaints of pain for whom conventional medical, surgical, and behavioral therapy had been unsuccessful. The topography of pain was an important selection criterion; because it has been difficult to achieve overlap of axial lower back pain by stimulation paresthesias and because this is an important determinant of pain relief [5,30,32,36,49,55,59,75,78], we have not selected patients in whom lower back pain was the sole complaint.

Patients were interviewed individually by telephone (and, in a small number of cases, in person) by a disinterested third party who was not involved in patient care and had never been involved in their treatment. Patients referred to a standardized questionnaire that had been mailed to them in advance and to which they returned after the interview (for validation and for measurement of visual analog rating scales). Patient ratings of pain and its relief were obtained by standard methods [16,25], including visual analog scales. In addition to these global ratings, our patients also rated pain intensity as a function of time by using a standard six-point verbal rating scale [47]. Standard measures of quality of life and functional capacity and an adjective checklist describing each patient's pain experience [47] also were incorporated into the questionnaire.

STATISTICAL METHODS

The statistical endpoints of this study included several dichotomous outcomes. For the 205 patients with current clinical follow-up, we considered: [1] The result of the initial trial of stimulation with a temporary electrode--specifically, whether implantation of a permanent device followed; [2] the result 6 months after implantation of a permanent device--a patient who no longer reported 50% pain relief was defined as an "early failure"; [3] the long-term result, at last (mean, 7 yr) follow-up, assessed by several measures: (a) continued relief of pain by at least 50%, combined with patient satisfaction with treatment. ("Considering the hospitalizations, discomfort, expense … would you go through it all again for the same result?") This endpoint was chosen by convention, for consistency with the literature on spinal cord stimulation and on failed back surgery syndrome [11,20,33,54-57,80]; (b) return to work; (c) functional gains and losses in activities of daily living, medication use, and neurological symptoms.

The following patient characteristics and technical factors were considered as independent variables in the statistical analysis: patient age; sex; diagnosis (grouping failed back surgery syndrome patients, spinal cord injury patients, and those with pain of peripheral origin); length of follow-up; physical findings (deep tendon reflexes, strength, sensation, straight leg raising, range of motion, and lumbosacral spine tenderness--each coded as normal, abnormal, or nonphysiologically abnormal [e.g., exaggerated, superficial lower back tenderness]); preoperative use of narcotics or benzodiazepines; preoperative work status; time elapsed since first operation; number of operations before stimulator implantation; degree and duration of relief by procedures before stimulator implantation; type of electrode; choice of evaluative, affective, and sensory adjectives from an abbreviated McGill checklist [47] (aching, burning, cramping, dull, exhausting, frightful, pounding, pressing, punishing, sharp, shooting, sickening, terrifying, wretched); patient rating of the percentage of pain perceived in the low back; laterality of pain (percentage on most severely involved side); and overlap of pain by stimulation paresthesias.

The reliability of implanted hardware was analyzed separately by standard survival statistical methods. Two endpoint categories were considered in the survival analyses: electromechanical device failure (device no longer functional) and clinical failure (device no longer used). Intervals to these endpoints were calculated from the dates of surgery. Event time distributions were estimated by the method of Kaplan and Meier [27] and were compared by the log-rank statistic [42]. Independent preoperative factors prognostic for survival were selected by use of the Cox proportional hazards model [8]. The sample size for device statistics was 298 systems implanted in 249 patients--the entire series of patients identified as having undergone permanent implants. Long-term clinical follow-up was available on 171 of these patients, as already noted; for the others; hospital and office chart data were used to establish the reliability of the hardware.

The associations between dichotomous outcomes (e.g., temporary versus permanent implant) and categorical independent variables (e.g., diagnosis) were tested by cross-tabulation techniques with χ^2 and Fisher's exact test. Associations with all variables, both continuous and categorical, were tested by univariate logistic regression. Time-to-event hardware reliability data were tested by Kaplan-Meier survival analysis, with Cox proportional hazards modeling. Covariates having some prognostic value (i.e., $P < 0.15$) were entered into a multivariate model, and nonsignificant effects were removed in a stepwise fashion. Hazards were expressed relative to a baseline reference category for individual prognostic factors. All P values reported are two sided [8,9,17].

RESULTS

The mean follow-up interval was 7.1 ± 4.5 years (range, 1.5-20.4 yr). Mean age at the time of the procedure was 47.3 ± 12.0 years (range, 20.3-84.2). Average duration of symptoms had been 11.8 ± 8.2 years (range, 4 mo-44.4 yr). The average patient had undergone 3.1 ± 2.1 prior surgical procedures for the relief of pain (range, 0-12). Fifty-four percent of the group were men.

At current (mean, 7 yr) follow-up, 52% of the 171 patients receiving permanent implants reported at least 50% continued relief of pain. Sixty percent

reported that they would go through the procedure again for the same result. Forty-three percent met both of these criteria; another 9% met the 50% pain relief criterion but were "unsure" whether they would go through the procedure again. Twenty-two percent of the 171 patients (n = 37) with permanent implants reported that they had never experienced as much as 50% relief of pain (our standard criterion for proceeding to a permanent implant). A subset of 7% (n = 12) claimed never to have experienced any relief at all (contrary to contemporaneous hospital records). Six months after permanent implant, the fraction of patients reporting less than 50% pain relief climbed to 40% (n = 69)--although the great majority continued to use the device (see below). An overlapping subset of 13% (n = 22) reported unexplained, complete loss of pain relief, after an initially successful result, at intervals ranging from 4 days to 11 years (median, 82 d) after implant. This occurred in the absence of any other physiologic change, such as change in location or quality of pain, or of stimulation paresthesias or evident technical problem such as electrode migration or mechanical failure.

In addition to global ratings of overall pain intensity and pain relief, our patients also rated pain intensity as a function of time using a standard six-point verbal rating scale [47]. Figure 1 presents a histogram of average ratings of the percentages of time spent at each intensity by patients receiving permanent implants. The fraction of time at the highest intensities was reduced by more than half, and the fraction of time with "no pain" or pain of low intensity increased severalfold.

At long-term follow-up, 54% of our patients with permanent implants and under age 65 were actively working, by comparison with 41% preoperatively. Sixteen patients who had not been working preoperatively had gone to work fulltime, and three had gone to school fulltime; five such patients had gone to work parttime. Fifteen patients had improved from parttime to fulltime. Nine who were already working fulltime and eight who were working parttime reduced their workload, quit, or retired. (Fourteen patients had been 65 or older at the time of their implantation; another 20 turned 65 during the follow-up interval.) Of the patients under 65 who received only temporary electrodes, 61% had been working; 37% of those who remained under 65 continued to work at the time of long-term follow-up. (No data on work status were provided by 4 of our patients with permanent implants or by 16 of those receiving only temporary electrodes.)

Other secondary outcome measures are summarized in Figure 2. Patients graded their abilities to perform various activities of daily living in terms of impairment due to pain, reported their ongoing medication use, and reported pertinent neurological symptoms (motor, sensory, and bladder/bowel function). Improvement was reported by a majority of patients in many activities of daily living. A majority of patients (58%) reported a reduction in or an elimination of analgesic intake. A small number reported progressive neurological symptoms, but none were associated with or attributed to the use of the implanted stimulator.

Patients reported using their implanted stimulators, on the average, 11.5 ± 8.1 hours daily (range, 0.5-24). (After the stimulator was turned on, average latency before pain relief was perceived was 8.3 ± 15.7 minutes [range, 0-60]). Relief reportedly persisted for an average of 2.0 ± 6.6 hours after the stimulator was turned off (range, 0-60; i.e., 0-2.5 d). The average frequency setting selected by patients was 62.7 ± 54.2 pulses per second (range, 8-200). As illustrated in Figure 3, only one patient selected a rate below 25 pulses per second, even though the range from 2 to 25 pulses per second represents over 50% of the total range of the rotary frequency control on our most commonly used radiofrequency transmitter. An analysis of clinical and technical prognostic factors revealed the following.

Only 68% of patients with pain syndromes of "peripheral" origin received permanent implants, by comparison with 87 and 90% of those with failed back surgery syndrome and spinal cord injury, respectively ($P < 0.015$). There were no other statistically significant differences, on any of the independent variables tested, between patients who had only temporary electrodes and those who proceeded to permanent implants.

Short-term relief of pain (by at least 50% 6 mo after permanent implant) was associated significantly ($P < 0.05$), by univariate analysis, with overlap of pain by paresthesias, with female sex, with a small number of prior operations, and (marginally) with choice of the adjective "sharp." Choice of the adjectives "pounding" and "sickening" was unfavorable. Choice of a large number of affective or descriptive adjectives was significantly associated with poor outcome. By multivariate analysis, overlap of pain by paresthesias and choice of the adjectives "pounding" and "sharp" remained significantly associated with outcome ($P < 0.05$), whereas the other variables were removed from the analysis in stepwise fashion.

Long-term "success" (at least 50% pain relief) and willingness to repeat the procedure, reported at 7-yr mean follow-up) tended ($P = 0.05$-0.10) to show associations with the following: having a few prior operations; having a small reported percentage of lower back pain; and not choosing the adjective "wretched" from the adjective checklist. None of the other independent variables was associated with this outcome.

None of the independent variables tested showed any significant association with long-term work status. These variables included patient age and preoperative work status.

At long-term follow-up, a cumulative score of gains and losses in everyday activities, medication use, and neurological symptoms was considered as an outcome measure (dependent variable) for the 171 patients received permanent implants. By univariate analysis, there were statistically significant associations ($P < 0.05$) between favorable outcome and overlap of pain by stimulation paresthesias and the absence of significant weakness at the time of

initial physical examination. The estimated percentage of lower back pain was marginally significant ($P = 0.06$) as a favorable factor, with a regression coefficient near zero. By multivariate analysis, an absence of weakness at the time of preoperative examination was the only significant determinant of outcome. Figure 2 is a histogram of the individual categories, showing the fraction of patients reporting gains and losses in everyday activities, medication use, and neurological symptoms.

Kaplan-Meier survival statistics were calculated for the various electrode configurations used over the past two decades. The statistical endpoint for electrode survival was loss of stimulation paresthesias overlapping a patient's usual distribution of pain--whether because of physical migration or malposition of the electrode. The lowermost curve in Figure 4, indicating the highest failure rate, represents dual, independently inserted percutaneous electrode, connected to a single-channel, nonprogrammable device. The curve immediately above that represents a fixed bipolar laminectomy electrode, implanted as a single-stage procedure with single-channel electronics. During the first year, these curves were superimposed, indicating that the rate of "migration" or malposition, as defined clinically, was similar for the two devices. After the first year, the dual percutaneous systems continued to fail at a slow rate, cumulatively amounting to about 22% over the ensuing 17 years. The uppermost curves all represent multicontact electrode arrays of both percutaneous and laminectomy configurations. There was no significant difference between these configurations; by comparison with them, however, the percutaneous single-channel leads were significantly more prone to migration failure compared with multichannel leads (n = 90; hazard ratio = 9.7; $P = 0.025$, by the Cox proportional hazard survival analysis). The single-channel, bipolar laminectomy electrode was also less reliable compared with the same group (n = 22; hazard ratio = 6.0; $P = 0.10$).

The implanted electrode/lead assembly failed electromechanically (fatigue fracture of conductors and/or insulation failure) in 22 instances, in 298 systems (a 7% failure rate by system). The second component of the implanted system, the radiofrequency receiver, failed in 16 instances, in 298 systems implanted in 249 patients (a 5% failure rate by system). Cox proportional hazard survival analyses showed no significant differences among these devices for these relatively infrequent events.

In calculating electrode and receiver reliability, if a patient stopped using a functioning device because of inadequate coverage and/or pain relief, the case was censored at that time. In a separate analysis, however, these events were considered as clinical failures, along with actual hardware failures in cases where replacement was not thought to be worthwhile. These data are plotted in Figure 5 as Kaplan-Meier survival curves. Overall, multichannel (quadripolar) systems had a significantly greater clinical reliability than do single-channel systems (hazard ratio = 0.45; $P < 0.001$). Percutaneously inserted electrode arrays with multichannel systems had the same high reliability as did systems with laminectomy electrodes. In addition to these technical factors, potential clinical prognostic factors (diagnosis, age, and sex) were assessed; none had a significant effect upon reliability.

SURGICAL COMPLICATIONS

No major morbidity (spinal cord compression or injury, bacterial meningitis, or life-threatening infection) has occurred in our experience with spinal cord stimulation over two decades. The overall incidence of surgical would infections, all superficial or extraspinal, was 5%. All cleared promptly after the removal of hardware and a short course of antibiotics, permitting a second implantation. Within this small subset of patients, there was no statistically significant difference between different hardware configurations; in particular, we observed no infections in a subset of 18 quadripolar laminectomy electrode arrays with temporary percutaneous extensions, which were used in the late 1970s and early 1980s.

DISCUSSION

Over the past two decades, techniques and devices for spinal cord stimulation have undergone considerable refinement. The earliest devices required a laminectomy for the placement of an intraspinal monopolar or bipolar electrode. With increasing appreciation of the importance of patient selection, with recognition that even the most careful clinical selection process was not completely successful, and with cognizance of the technical importance of proper electrode placement, percutaneous methods were developed for the insertion of temporary screening electrodes [18,21,23]. These quickly evolved into percutaneous methods for the implantation of permanent electrodes [51,86].

Although in some recent series [28,61] no percutaneous trial was reported, we have continued to use temporary percutaneous electrodes as a screening technique to demonstrate satisfactory relief of pain before a permanent system is implanted. In treating pain syndromes of "peripheral" origin, where the yield of permanent implants has been relatively low (68% of patients receiving temporary electrodes), the percutaneous test phase is of obvious importance in patient selection. Even in higher-yield situations (failed back syndrome and spinal cord injury, with 87 and 90% rates of permanent implants, respectively), this approach has technical advantages. Temporary electrodes may be placed in a fluoroscopy suite, away from the time constraints of the operating room, so that potential stimulation sites may be mapped more exhaustively. In the great majority of cases, only one percutaneous interlaminar needle is placed under local anesthesia; there is no need for sedation, which would compromise patient participation. The percutaneous test phase educates the patient as to the primary technical goal of the procedure--achieving optimal overlap of pain by stimulation paresthesias. Patient interaction during the permanent implant, which may require sedation, is thereby enhanced, and

the procedure is expedited [53].

A "temporary" electrode may be placed so as to allow its conversion to a permanent implant, in a two-stage procedure. This requires an incision, to be closed over an anchoring sleeve (secured to interspinous or supraspinous ligament for percutaneously placed electrodes) or over a laminectomy site, with subcutaneous tunneling to a percutaneous exit for temporary leads. This procedure is performed in an operating room, as opposed to a fluoroscopy suite. We used this configuration briefly, in patients already successfully screened with a temporary percutaneous electrode, when implanting arrays of multiple electrodes via laminectomy for use with single-channel implants. This allowed ambulatory testing to determine the optimal configuration of anodes and cathodes to be hard-wired to a single-channel implant, at a time when programmable, multichannel implants were not yet available. In our small sample of 18 patients, we did not observe an increased rate of infection, although this has been reported for larger series treated in this manner [28,35]. We have avoided this configuration for an additional reason: the decision by patient and staff for or against a permanent implant may be influenced unduly by a major investment of time, effort, and potential morbidity in a "temporary" electrode that requires return to the operating room for either pulse generator implantation or removal. No such commitment is associated with a percutaneous electrode designated from the outset as strictly temporary and destined for removal, regardless of the patient's decision.

The criteria for proceeding from a temporary to a permanent implant have varied widely; some authors have required a minimum of 70% reported pain relief [38,46], and some have required a test phase as long as 2 months [45]. As few as 40 [11] to 47% [72] of patients receiving temporary electrodes have proceeded to permanent implants. Our routine policy has been to offer a permanent implant to patients who, after a percutaneous test phase of at least 2 to 3 days, have reported at least 50% pain relief, while demonstrating improved activity and stable or improved use of analgesics. A minimum of 50% reported pain relief is also one of our criteria (and a standard in the literature) for long-term "success"; this leaves no margin for any decline in pain relief, as reported by many of our patients. Prolonging the percutaneous test phase and requiring a higher percentage of reported pain relief before proceeding to permanent implant would be expected to improve long-term "success" by this measure; however, this arbitrarily emphasizes one of many potential outcome measures. We have accordingly considered several outcome measures for this series and have studied prognostic factors for each.

The reported rates of success in the spinal cord stimulation literature typically are based upon the number of patients undergoing surgery for implantation of permanent devices and not upon the number screened (which may not be specified; see Table 1). In this series, the rate of permanent implants was 78% overall and 87 to 90% in patients with failed back surgery syndrome and spinal cord injury; adjustment for this would be minor by comparison with other series, with implantation rates as low as 40% [11]. Percutaneous electrode placement has very low morbidity, comparable to that of myelography and diagnostic nerve blocks, which are used widely in screening patients for other surgical pain-relieving procedures.

Disinterested third-party interview always has been central to our follow-up methods in clinical studies of pain management [41,51,52,54-57] and is reported increasingly [4,19,28,32,40,41,50,68,74] in the literature on spinal cord stimulation (summarized in Table 1). As noted previously [19,55], this reveals a different picture from hospital and surgeon's office records. In this series, it was noteworthy that 7% of our patients (n = 12) who had received permanent implants told the third-party interviewer that they had never experienced any relief of pain at any time, whereas according to hospital and office records, no patient had reported this. Overall, 22% (34 patients) reported to the interviewers that they had never experienced as much as 50% relief of pain; this in fact has been our standard requirement before proceeding to a permanent implant.

We observed a relatively high rate of return to work, by comparison with other published studies on spinal cord stimulation. Among our patients under the age of 65 receiving permanent implants, there was an improvement from 41% working preoperatively to 54% working at mean 7-year follow-up. Our patients who received only temporary electrodes, on the other hand, deteriorated from 61% working to 37% working. Our observations may in part reflect our follow-up, the longest in the literature, representing the longest window of opportunity for return to work by our patients; however, this should have yielded better results for patients receiving only temporary electrodes. It does not reflect any patient selection policy on the basis of employability; at the time of implantation, 14% of our patients had reached and another 20% were within 10 years of age 65.

Return to work is an important outcome measure, regarded by some authors as critical [77,85], whereas others temper this with the realistic perspective that a typical laborer with failed back surgery syndrome will have difficulty finding work after prolonged disability, even with satisfactory pain control [32,41]. We have not incorporated this into an arbitrary definition of "success"; there is no universally accepted definition. Rather, we have considered it as one of many outcome measures and have attempted to derive clinically meaningful prognostic factors for each.

Technical factors influencing outcome

Technical difficulties with implanted spinal cord stimulators have become significantly less frequent with contemporary multichannel devices. Outright hardware failures such as electronic malfunction of the implanted receiver, lead fatigue fracture, and insulation failure have always been infrequent. The "migration" of implanted electrodes, however, occurred frequently with early percutaneous electrode

systems before insertion and anchoring techniques were refined [35,51]. Independently inserted pairs of electrodes for bipolar stimulation were particularly problematic, because they were vulnerable to the movement of either with respect with the other [35,51]. This is physically impossible with arrays of multiple electrodes, which evolved into percutaneous designs in the 1980s. Arrays of electrodes remain subject to migration or malposition; however, a significant incidence has been reported when these have been used with single-channel implants [61]. It is difficult in practice to distinguish true migration (physical movement of the electrodes after implantation) from malposition of other causes, e.g., a change in the relationship of electrodes and spinal cord when the patient moves from the prone position, used for implantation, to the supine or erect position, in which the device is used therapeutically. An experienced patient or one whose pain relief is declining may develop a growing appreciation of the shortcomings of a particular configuration. Programmable implants permitting noninvasive selection of the contacts in an array address these problems; in this series, these systems have required further electrode positioning significantly less often than did single-channel systems. Our experience with both single-channel and multichannel devices has permitted direct comparison in a previously reported subset of this series [55], showing the clinical superiority of multichannel devices. In the 20-year experience reported here, this is demonstrated by our clinical device survival statistics.

Superposition of stimulation paresthesias upon the topography of a patient's pain has been described as necessary for obtaining pain relief [5,30,32,49,55,75,78]. Although this may be a necessary condition for pain relief, it is not sufficient. Some patients report no relief or declining relief of pain despite ongoing, technically adequate stimulator function. The mechanism for this is unclear; attributing it to the disappearance of a placebo response is simplistic and does not explain satisfactorily those failures that occur after extended periods. Fibrosis around implanted electrodes has been implicated in technical failures [29,32,60,63], but we found no instances of this; all of our documented technical failures were electromechanical. Electrode position is critical to achieving satisfactory overlap of pain by stimulation paresthesias [34], and therefore, arrays of multiple electrodes are technically advantageous [37,55]. We are developing a computer-controlled, patient-interactive system to facilitate the clinical use of these systems and psychophysical studies [58].

Our observations of patient preferences for particular stimulation parameters have implications for the underlying mechanisms of pain relief. The apparent requirement for a minimum pulse repetition rate is consistent with a mechanism involving the frequency-related conduction block, acting at branch points of primary afferents in the dorsal columns, with collaterals to the dorsal horn [6]. Alternative mechanisms--detailed in the animal literature and beyond the scope of this clinical paper--may also be frequency dependent. Psychophysical study of the effects of spinal cord stimulation on clinical and experimental pain and sensory function in humans [43] may help elucidate these mechanisms.

Our observations also have implications for the longevity of implants powered by primary cells; an average pulse repetition rate of 63 per second, average usage of 12 h/d, and a preference for complex electrode geometries with more than one anode and cathode [55] impose significant demands on an implanted power source. A majority of our patients continue to use their devices at the time of long-term follow-up, a mean of 7 years after implantation--longer than the projected shelf life, let alone the service lifetime, of typical systems powered by primary cells. Accordingly, we have continued our routine use of radiofrequency-coupled devices powered by externally worn batteries.

Clinical prognostic factors

In addition to the technical factors enumerated above, we observed several patient characteristics that were associated with treatment outcome. Short-term relief of pain (6 mo postoperatively) was significantly better in female than in male patients. We made the same observation in a subset of 66 of these patients reported earlier [55]. Women fared better than men in one other large spinal cord stimulation series [65]; however, others have found no significant difference between the sexes [28,32,46]. Women have been reported to adapt more readily to the use of implanted stimulation devices in another application--a functional device used in footdrop patients [83]. The observed difference between the sexes cannot be attributed to any difference in occupational demands--indeed, there was no difference in work status as an outcome.

Achieving stimulation overlap of the lower back is recognized as technically difficult and may require complex electrode geometries and extensive psychophysical testing [36,59]. Furthermore, axial pain is commonly mechanical nociceptive and may be less responsive to spinal cord stimulation than is pain associated with deafferentation or neural injury [67]. We have accordingly selected patients in whom lower back pain is not the predominant complaint; within this select group, we have observed minimal associations between the presence of lower back pain and the outcome of treatment. Another aspect of pain topography, reported to be important, is that unilateral pain syndromes are more easily treated [32, 46,62,65,76], but our analysis of patient analog ratings did not show this.

We noted a tendency to superior outcome in patients with a small number of prior operations, although other authors have not reported an association [46,76]. Long duration of symptoms has been associated with unfavorable [35] as well as favorable [28] outcomes. In our series, with an average duration of symptoms of over 12 years, there was no association with outcome. We did note an association between weakness on preoperative neurological examination and functional outcome score; this has not been reported previously. We are evaluating strength and functional capacity formally and

objectively in our ongoing studies of patients undergoing spinal cord stimulation and subsequent operation for failed back surgery syndrome.

We observed no association between outcome and preoperative use of opiates or benzodiazepenes, which have been reported previously as adverse prognostic factors [35]. We routinely exclude patients, however, for active problems with drug habituation or drug-seeking behavior. The importance of psychological issues in selecting patients for spinal cord stimulation, as for pain-relieving procedures in general, has been stressed by many authors [4,7,12,19,22,40,41,45,50,61,74,76,84]. We have routinely excluded patients with significant drug habituation problems, major issues of secondary gain, or obvious psychological problems; some have been reconsidered after completing a behavioral program. Standardized psychological testing has been reported to correlate significantly with the outcome of the implantation of stimulating electrodes for pain relief [2,10]; not all authors have found them useful, however [46,50], and some [21] consider that the judgment of the experienced surgeon is of primary importance. We have routinely and prospectively collected standardized psychological test data on our recent spinal cord stimulation patients for analysis when long-term follow-up data become available. This may allow further refinement of patient selection.

CONCLUSIONS

Technical improvements in implanted spinal cord stimulation devices over the past two decades have led not only to enhanced system reliability, but also to improved clinical results. An analysis of prognostic factors has revealed a number of significant determinants of outcome--notably, the importance of achieving close correspondence of stimulation paresthesias with the topography of each patient's pain, which has been enhanced by the development of multichannel devices. Associations between certain patient characteristics (e.g., axial lower back pain) and outcome are of some value in patient selection, but we found no significant predictors of the outcome of percutaneous stimulation trials, apart from diagnosis. A percutaneous trial, therefore, remains an important aspect of this procedure. Overall morbidity has been quite low. As most patients with implanted spinal cord stimulators continue to report at least 50% relief of pain at 7-year mean follow-up, this modality compares favorably with treatment alternatives for chronic, intractable pain.

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COMMENTS

Dr. North and his colleagues at Johns Hopkins have provided us with an exceptionally good study of the long-term outcome of spinal cord stimulation (SCS) for the control of chronic pain in 320 patients treated from 1972 to 1990. As the authors have pointed out, this report joins a large and growing number of investigations (48 cited in this article that attest to the safety and efficacy of this technique. At 7 year-mean follow-up, 52% of their available patient population maintained more than 50% pain reduction. In fact, a 50 to 60% long-term success rate is a repetitive theme in other carefully reported series of pain patients treated with SCS. Although this result may seem modest, to my knowledge, there is no other surgical procedure that produces comparable results for this difficult problem. This, taken together with the high degree of safety of the procedure, makes SCS the surgical procedure of choice for the failed back surgery syndrome, and possibly for selected cases of spinal cord and peripheral nerve injury with associated pain syndromes.

It has been known for some time that one of the principles of SCS is that *the patient must feel the stimulation in the area of perceived pain*. North et al. have now shown that there is a statistically significant direct relationship between the overlap of stimulation-induced paresthesias and pain relief from SCS. Furthermore, these results corroborate those of prior studies with regard to the superiority of programmable multichannel devices over the earlier monopolar systems and with regard to the observation that a small reported percentage of lower back pain is a favorable prognostic indicator for pain relief from SCS. More over, this series shows that effective pain control translates into objectively improved activities of daily living and decreased analgesic use. The data also indicate that, contrary to prior studies, bilateral leg pain is no more difficult to treat than unilateral. Interestingly, patient age and preoperative work status *did not* show a significant association with long-term success, findings that, to some extent, undermine traditional "clinical wisdom" regarding patient selection for invasive chronic pain management.

A notable result of this research was that there was also an improvement in the work status of patients receiving permanent implants from 41% employed preimplant to 54% at the time of follow-up postimplant. The job status of patients that were not implanted actually deteriorated from 61% employed to 37% at time of follow-up. Although there were possible selection factors in these two groups and although this is not a statistically significant result, these data indicate that return to work and job retention may be additional benefits of SCS. This finding is of obvious importance when we attempt to determine the cost effectiveness of the procedure.

In several ways, this report is a model for future outcome studies focusing on the surgical management of pain. First, the authors used a "disinterested" third party both to interview the patients at the time of follow-up and to report the data. This step helps to reduce (but not eliminate) the bias that inevitably creeps into surveys of patients performed by the principal surgeon, his associates, or trainees. Second, the authors report the results using appropriate statistical techniques, including the Kaplan-Meier method, which allows analysis of an evolving and incomplete data set. Third, the authors have attempted to correlate various aspects of the patients' clinical condition, demography, technical aspects of the prosthetic implant, activities of daily living, employment status, and drug usage with the long-term success of the SCS implant.

In conclusion, SCS is one of the safest and most effective procedures currently available for the surgical management of chronic pain. This thoughtful, well-executed, and important investigation has added to our understanding of the application of this surgical strategy.

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This report represents a most complete and useful summary of the neurosurgical group at Johns Hopkins with the use of spinal cord stimulation for treating chronic pain. Although I do not carry the procedure out in exactly the same technical manner as the authors, my results are very similar to theirs. Their long-term success rate of approximately 50% is very similar to my own long-term success rate over a similar interval of about 20 years. It has been my unfortunate recent experience that spinal cord

stimulation, because it is relatively technically easy, is being carried out by individuals without sufficient experience or knowledge of the chronic pain problem, leading to disappointing results and complications. These individuals include inexperienced neurosurgeons, anesthesiologists, and orthopedists.

Like the authors of this report, I believe that spinal cord stimulation has a definite role to play in treating chronic pain problems. As the authors so correctly stress, the selection of patients with attention to important prognostic factors is essential if one is to achieve even a 50% success rate. In addition, unfounded recommendations to the patient that spinal cord stimulation has an 80 to 90% or greater chance of relieving chronic pain is a disservice both to the patients and to the medical profession. Every individual involved with patient selection and implanting spinal cord stimulators should read this report carefully. I believe it will serve as the outstanding compilation of experience with this form of therapy for a long time to come.

Ronald F. Young
Orange, California

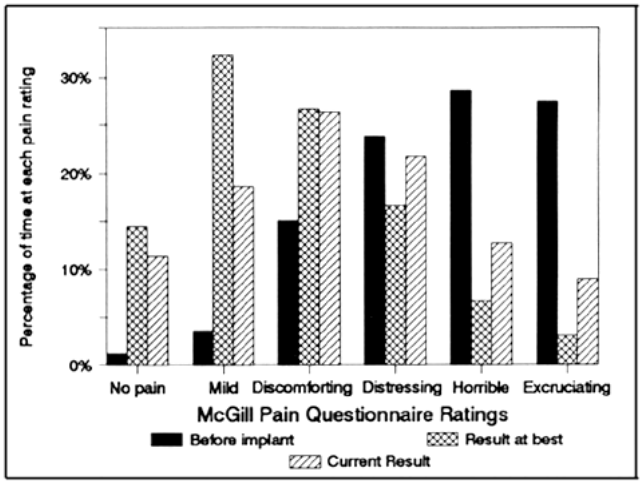

Figure 1. Histogram of the average ratings, by patients receiving permanent implants, of the percentage of time spent at each level on a standard six-point verbal pain rating scale (47). The fraction of time at the highest intensities was reduced by more than half, and the fraction of time with "no pain" or pain of low intensity increased severalfold.

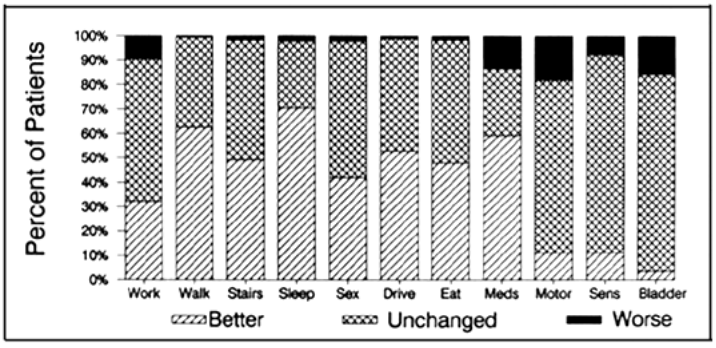

Figure 2. Histogram of changes in patients; ratings of their abilities to perform various activities of daily living in terms of impairment due to pain, of ongoing medication use, and of reported neurological symptoms. The percentages of patients reporting gains, losses, and no change are represented in a stacked bar format. Most patients reported improvement in a number of everyday activities and in medication use.

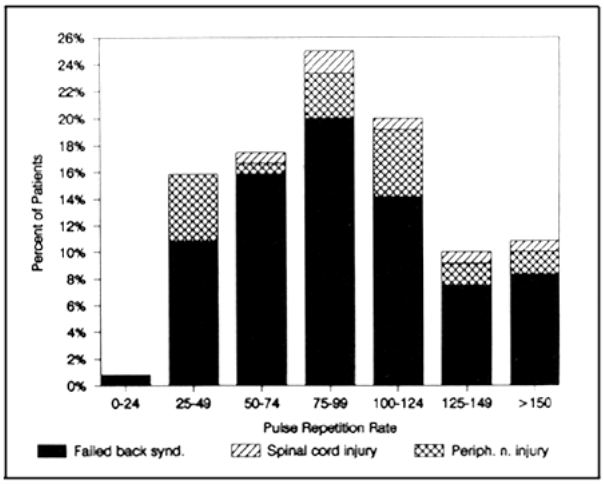

Figure 3. Histogram of pulse repetition rates selected by patients. Only one patient selected a rate below 25 pulses per second, although the range from 2 to 25 pulses per second represents over 50% of the total range of the rotary frequency control on our most commonly used radiofrequency transmitter. The average frequency setting was 62.7 ± 54.2 pulses per second (range, 8-200). This has implications for the mechanism of relief of pain by spinal cord stimulation. *synd*, syndrome.

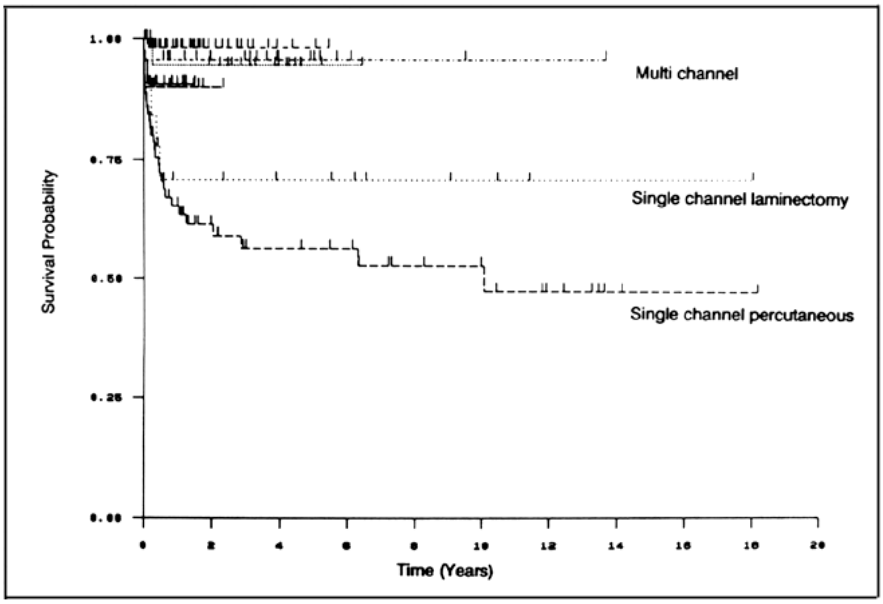

Figure 4. Kaplan-Meier survival curves for the various electrode configurations used over the past two decades. The statistical endpoint for electrode survival was loss of stimulation paresthesias overlapping a patient's usual distribution of pain--whether because of physical migration or malposition of the electrode. The lowermost curve, indicating the highest failure rate, represents dual, independently inserted percutaneous electrodes, connected to a single-channel, nonprogramnmable device. The curve immediately above represents a fixed, bipolar laminectomy electrode, implanted as a single-stage procedure with single-channel electronics. These were significantly less reliable than any percutaneous or laminectomy array used with programmable, multichannel electronics.

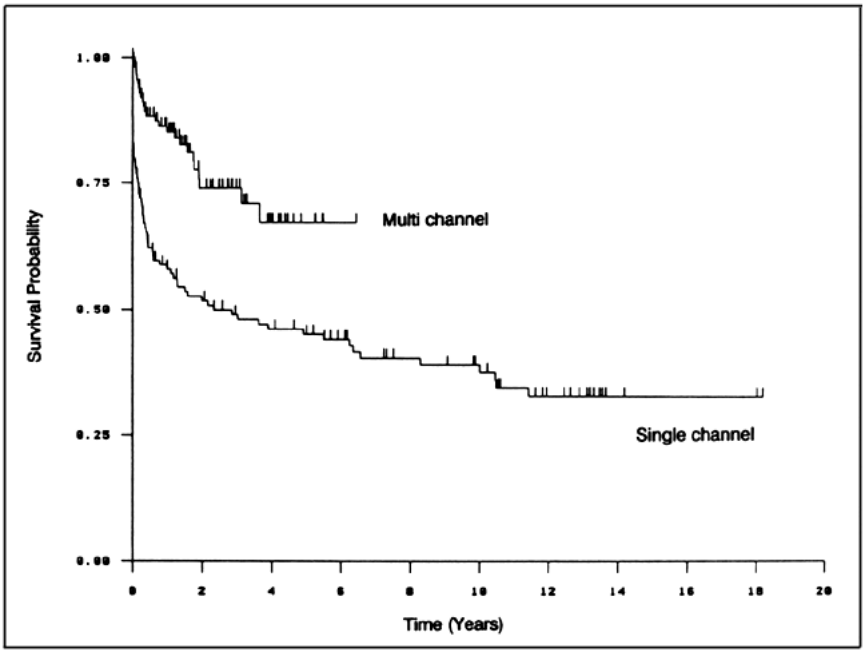

Figure 5. Kaplan-Meier survival curve showing the clinical failure rate of single-channel and multichannel spinal cord stimulation implants. The statistical endpoint is the time at which a patient permanently stopped using a device for any reason, including hardware failure without replacement. Programmable, multichannel (quadripolar) systems had a significantly greater clinical reliability than did single-channel systems (hazard ratio = 0.38; $P < 0.001$).

Series (Ref. No.)	Number Screened	Number Implanted	No. of Failed Backs	Follow-up, Mean	Follow-up, Range	Third Party Follow-up[b]	Excellent/good Results (≥50% relief) (%)	Excellent/good FBSS Results (%)[c]
Blume et al., 1982 (1)		20	20		Up to 3 yr		70	70
Broseta et al., 1982 (3)		11		13 mo	3–20 mo		64	
Burton, 1975 (4)	0	75	55	1 yr		Y (mfr.)	59	
Burton, 1977 (5)		198	186				43	
Clark, 1975 (7)		13	6				54	67
De la Porte and Siegfried, 1983 (11)	94	36	36	36 mo	3–96 mo		60	
de Vera et al., 1990 (12)	124	110	18				75	
Demirel et al., 1984 (13)	48	33	11		2–5 yr		18	
Devulder et al., 1990 (14)		45	23				78	
Devulder et al., 1991 (15)		69	43		Up to 8 yr		55	
Erickson and Long, 1983 (19)	10	70			Up to 10 yr	Y (60)	15–20	
Hoppenstein, 1975		27	12				58	64
Hunt et al., 1975 (24)		13	5		9 mo–4 yr		15–31	20–60
Kälin and Winkelmüller, 1990 (26)			77				88	88
Koeze et al., 1987 (28)	0	26	5	28 mo		Y	46–62	
Krainick and Thoden, 1989 (30)	126	91	5		Up to 5 yr		18	
Kumar et al., 1986 (31)		60	54		6–60 mo		62	
Kumar et al., 1991 (32)	121	94	56	40 mo	6 mo–10 yr	Y	66	
Law, 1983 (35)		81					36–80	
Leclercq and Russo, 1981 (37)		20	20		1–>24 mo		50	50
LeRoy, 1981 (39)		49	49	30.7 mo	1–63 mo	N	60	
Long and Erickson, 1975 (40)		69	54		12–35 mo	Y	18	
Long, 1981 (39)		31	24		4–7 yr	Y	73 at 3 yr	
McCarron and Racz, 1987 (44)		22			3–24 mo		68	
Meglio et al., 1989 (45)	109	64	19			N		23
Meilman et al., 1989 (46)	20	12	20		Up to 3.5 yr		60	60
Mittal et al., 1987 (48)	31	26	21				46	
Nielson et al., 1975 (50)	221	130	79		1–>35 mo	Y	49	46
Pineda, 1975 (60)		76	56				43	43
Racz et al., 1989 (61)	0	26	18		12–42.7 mo	N	65	
Ray et al., 1982 (62)		78	50	19.4 mo	3–64 mo		49	
Richardson et al., 1979 (64)	36	22	12		1–3 yr		56	
Richardson and Shatin, 1991 (65)		136	136	45 mo		Y (mfr.)	67	67
Robb and Robb, 1990 (66)	65	79	22		6 mo–5 yr		72	69
Sánchez-Ledesma et al., 1989 (67)	49	33	0	5.5 yr			57	
Shatin et al., 1986 (68)		116			0.9–13.3 mo	Y (mfr.)	74 at 6 mo	
Shealy et al., 1975 (70)	0	80			7 mo–?	N	25	15–45
Shelden et al., 1975 (71)		27	3					67
Siegfried and Lazorthes, 1982 (72)	191	89	75	~4 yr	1–8 yr		37	
Simpson, 1991 (73)	24	56	7	29 mo	2 wk–9 yr		47	
Spiegelmann and Freedman, 1991 (74)	43	30	18	13 mo	3–33 mo	Y	60	
Sweet and Wepsic, 1974 (76)	100	98	33				21–42	15–45
Urban and Nashold, 1978 (78)	20	7	9				86	
Vogel et al., 1986 (79)	50	27	29		>3 yr	N	18.6	
Waisbrod and Gerberskagen, 1985 (81)		16	16	16 mo	6–30 mo	N	75	
Winkelmüller, 1981 (82)	94	71	56		4 mo–7 yr			69
Young and Shende, 1976 (84)		27	17		16–51 mo		66 ≥ 50	
Young, 1978 (85)	14	51	25	38 mo	12–67 mo		65 ≥ 50	

[a] The clinical literature on spinal cord stimulation, summarized here, contains a wide variety of temporary electrode screening protocols, follow-up intervals and methods, and criteria for success; comparison or meta-analysis is difficult. In common usage, a "good" or "excellent" result indicates a minimum of 50% reported pain relief, but this is only one of many important outcome measures.

[b] Third-party follow-up: mfr., device manufacturer.

[c] FBSS, failed back surgery syndrome.

Table 1. Summary of Clinical Literature on Spinal Cord Stimulation[a]