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40 Spinal Cord Stimulation and Intractable Pain: Patient Selection

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HISTORICAL PERSPECTIVES

The use of electricity in the treatment of pain dates back to the pre-Christian era. The use of electric eels and torpedo fish to produce electrical stimulation when applied to the painful area was documented as early as 600 BC. Through the ages, repeated attempts to use electricity to treat pain have been recorded. In colonial America, Benjamin Franklin experimented with a wide variety of electrical treatments for pain. During the 1920s, electricity was touted as a treatment for everything from cancer to cocaine addiction.

In the late 1960s, Shealy and associates[1] again brought electricity to the forefront in the treatment of pain when they introduced dorsal column stimulation. Initial enthusiasm for the modality gave way to skepticism as technical failures secondary to device failure, lead fracture, and poor patient selection yielded limited long-term success. During the 1970s and early 1980s, most studies evaluating the long-term efficacy of dorsal column stimulation quoted success rates of approximately 40%. Technical advances leading to improved hardware, coupled with better patient selection, have improved the rate of long-term efficacy to approximately 70%. Higher success rates may be expected if the patient selection criteria as described in this chapter are adhered to.

MECHANISM OF ACTION OF SPINAL CORD STIMULATION

Shealy and associates[1] postulated an antidromic activation of A-beta afferents as the mechanism of pain relief observed with electrical stimulation of the dorsal columns of the spinal cord. The early clinical successess of this modality were seen as a clinical validation of the gate control therapy advanced by Melzack and Wall.[2]

Further studies have not elucidated a simple mechanism for the efficacy of spinal cord stimulation (SCS). Naloxone does not reverse SCS-induced pain relief, and spinal cord stimulation has not been shown to increase spinal fluid endorphins. Other postulated mechanisms include inhibition at supraspinal levels and activation of central inhibitory mechanisms that influence sympathetic efferent neurones.

WHERE SPINAL CORD STIMULATION FITS ON THE CONTINUUM OF PAIN TREATMENT MODALITIES

The management of chronic pain is most successful when the treatment plan includes a multidisciplinary approach to assess and direct appropriate treatment.[3] Spinal cord stimulation should be considered in carefully selected patients when conservative therapy has failed to provide adequate pain relief. Factors to be considered in the selection of patients for SCS are as follows:

- Competency and motivation of the health care professionals involved
- Diagnosis
- Failure of previous appropriate treatment modalities
- Results of psychological evaluation
- Presence of drug misuse or abuse
- Presence of alcohol abuse
- Unresolved compensation issues
- Results of trial stimulation
- Cost

COMPETENCY AND MOTIVATION OF HEALTH CARE PROFESSIONALS INVOLVED IN SPINAL CORD STIMULATION

As mentioned previously, the treatment of the patient with chronic pain is best accomplished utilizing a multidisciplinary approach. Physicians who are considering offering SCS as an additional treatment option to their patients with chronic pain must be thoroughly versed in the application of the less invasive treatment options commonly used to treat chronic pain. Not only must physicians have the technical expertise to perform the surgical component of SCS therapy, but more important, they must possess the expertise to diagnose and treat chronic pain. The use of a modality such as SCS requires a high level of commitment to the treatment of the patient with chronic pain. Physicians must have the necessary resources to assess, treat, and follow patients who have implanted SCS systems. Training of physicians and their nurses or implant coordinators is an essential but often overlooked aspect of providing SCS services. Minimum competencies and training standards have been developed by a Dannemiller Educational Foundation–sponsored panel

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of pain management physicians. These recommendations are presented in the final section of this chapter.

DIAGNOSIS

As experience has been gained with SCS, it has become apparent that certain types of pain respond well to this treatment modality. Treatment of other diagnostic categories have met with only limited success. As of this writing, the following types of pain are amenable to treatment with SCS:

1. Sympathetically mediated pain.
   a. Causalgia.
   b. Reflex sympathetic dystrophy.
2. Arachnoiditis.
3. Perineural fibrosis/failed back surgery.
4. Radicular pain.
5. Peripheral vascular insufficiency.
6. Phantom limb pain.
7. Deafferentation pain.
   a. Postherpetic neuralgia.
   b. Peripheral neuropathies.
   c. Nerve root avulsions.
   d. Spinal cord injury.
8. Angina.

There is no doubt that as further experience is gained with spinal cord stimulation and as hardware improves, this list will undergo changes.

SPECIFIC DIAGNOSTIC CATEGORIES AMENABLE TO SPINAL CORD STIMULATION

Lumbosacral Fibrosis/Arachnoiditis

De La Porte and Siegfried[4] reported on 38 patients suffering from low back pain after multiple myelographies and several surgical procedures on the lumbar spine. They used *lumbosacral spinal fibrosis* to represent the pathologic tissue proliferation seen following disc surgery. The term *arachnoiditis* has been used to describe the back that has undergone multiple operations, which is clinically often represented by *failed back surgery syndrome* (FBSS). An often-quoted review by McCracken from the worker's compensation board of Ontario, Canada, reported to the Ohio Industrial Commission that no patient was cured by a second operation. He advised that 20% are improved, 20% are made worse, and 60% are unchanged. With additional operations, the outcome worsens, and after four operations, 5% are improved and 50% are made worse. De La Porte and Siegfried's[4] early study is significant in that (1) they identify the prototypical group of patients with lumbosacral spinal fibrosis patients, (2) all their patients showed objective neurologic deficits, and (3) trial stimulation was increasingly utilized. Their results with SCS for lumbosacral fibrosis showed a decrease in medication intake in 40% of patients, a clear increase in working capacity in 26%, and a 60% success rate after a 4-year follow-up.

North and associates[5] reported on 5-year follow-up after SCS implantation in patients with failed back surgery syndrome. All of their patients were treated in the context of a multidisciplinary pain treatment center with psychological screening before surgical intervention. Selection for treatment with SCS was contingent upon objective evidence for the pain complaint, as determined by both clinical and radiographic examinations. All patients underwent a trial of SCS with a temporary percutaneous electrode positioned to overlap the patient's usual pain distribution. Follow-up in these patients was performed by disinterested third-party interviews at intervals of 2.2 years and 5.0 years. Successful outcome, defined as at least 50% sustained relief of pain and patient satisfaction with the result, was obtained in 53% of patients at 2.2 years and in 47% of patients at 5.0 years postoperatively. Ten of 40 patients who had been disabled preoperatively returned to work. Improvements in activities of daily living were recorded in most patients.

SCS patients, in this series, were compared retrospectively with groups undergoing repeated operation and dorsal root ganglionectomy.[5] Superior outcome was seen in the SCS group in average estimated pain relief, the percentage of patients reporting pain relief in excess of 50% at intervals up to 5 years postoperatively, and the percentage of patients who would go through the procedure again for the same result. This and many other studies squarely place FBSS as one of the best diagnostic criteria for the application of SCS.

Radicular Pain

Clinical experience suggests that radicular pain is treated more effectively than axial (low back) pain with SCS. Unilateral lower-limb pain responded best in all cases in a 10-year review by Kumar and colleagues.[6] Patients with low back pain and radicular pain responded well to SCS treatment during a follow-up of up to 42.5 months.[7] The previously mentioned study by North and associates,[5] however, failed to show a statistical difference in efficacy between radicular and the axial pain patients. The patients who had SCS, in fact, reported identical relief of axial pain and radicular pain.

Neuropathic, Deafferentation, and Sympathetically Maintained Pain

Other indications for SCS are neuropathic and deafferentation pain syndromes. Deafferentation pain occurs in susceptible individuals following lesions of the somatosensory system, often resulting in clinically detectable somatosensory loss.[8] The incidence of pain following a lesion is highly variable and differs with the site of injury. Deafferentation pain may have a delayed onset and has been reported to be rare in children. The pain is described as dysesthetic or causalgic and is usually associated with areas of partial sensory loss to at least one modality. Allodynia, hyperpathia, or hyperesthesia may be clinically evident.

In an extensive review of SCS, Meyerson[9] catalogued neurogenic, neuropathic, deafferentation, and other pain syndromes likely to respond to SCS. This review emphasizes three distinct categories; (1) peripheral nerve and root lesions, (2) spinal cord lesions, and (3) peripheral vascular disease. Subcategories with literature support for efficacy are as follows:

1. Peripheral nerve and root lesions.
   a. Posttraumatic neuropathy.
      i. Peripheral lesions.
      ii. Reflex sympathetic dystrophy syndromes.
         a. Now subsumed under the diagnosis of chronic regional pain syndrome, or SMP.
      iii. Postamputation pain (stump and phantom limb).
         a. Plexus injuries secondary to trauma, radiation, and malignancy.
   b. Rhizopathy.
      i. Postherpetic neuralgia.
      ii. Low back pain associated with radicular pain due to arachnoiditis and epidural fibrosis.
2. Spinal cord lesions.
   a. Pain associated with spinal cord injury.
   b. Postcordotomy dysesthesia.
   c. Multiple sclerosis.
3. Peripheral vascular disease.

Important follow-up work by Meyerson and associates[10] reinforces the efficacy and importance of SCS for neuropathic pain syndromes. This retrospective study looked at 84 patients followed for up to 16 years. The majority suffered from peripheral neuralgia due to trauma or surgery. All patients underwent trial stimulation via a temporary extension lead for 4 to 5 days. These researchers found that 56 of the 84 patients (67%) were still using their stimulators and reported pain relief. The conclusion of this study echoes results of the other studies looking at SCS for pain control, especially those utilizing trial stimulation prior to implantation. Spinal cord stimulation is an indispensable tool for treating chronic neuropathic pain and is an underutilized option in the pain management armamentarium.

PSYCHOLOGICAL FACTORS IN PATIENT SELECTION

It has become an accepted standard of pain management practice to have patients evaluated by a psychologist with a background or training in pain management prior to implantation of a SCS system. Psychological assessment has become an integral part of the total multidisciplinary evaluation and treatment process in chronic pain programs, for the following reasons. Experienced practitioners who work with patients with chronic pain on a regular basis recognize that chronic pain involves and influences the patient's entire social and emotional environment. Chronic pain cannot be treated in a narrow, simple manner without careful consideration of how that patient perceives and reacts to a constant state of discomfort. It is the exception when a patient does not present with measureable "functional overlay." Evidence now indicates that such a patient's emotional state directly influences the reporting of the current pain state and memory for recall of the pain rating. The patient's rating of the pain state is a dynamic estimation and not a constant predictable factor; therefore, it is necessary to evaluate the patient's emotional status at the time of the evaluation, because feedback on the visual or verbal analog scale directly influences decision-making.

Melzak and Wall[2] proposed the physiologically based gate theory of pain, which reinforces the importance of including a comprehensive psychological evaluation in the work-up all patients with chronic pain being considered for treatment. Subsequent research accumulated over the past 25 years indicates that higher neocortical processes influence the "gate" directly.[11]

The importance of integrating the psychological evaluation as part of the patient selection process is emphasized by Long and associates[12] in a 1981 article presenting the results of SCS collected by the John Hopkins group over the previous 10 years. By 1975, this group had developed a comprehensive pain evaluation that included a psychological component. Their test battery consisted of the California Personality Inventory, Adjective Check List, McGill Pain Questionnaire, Intelligence and Memory Testing, and the classification of the patient's pain response with the Hendler Pain Perception Test. They concluded that psychological factors were the most important reason for failure of SCS to provide pain relief.

Brandwin and colleagues[13] concluded, from their results with 11 patients with chronic pain, that higher elevations on the Minnesota Multiphasic Personality Inventory (MMPI) depression scale were associated with failure of SCS treatment. They further stated that the MMPI had predictive value, but that need for refinement of outcome measures and further clarification of psychological variables was evident. Daniel and coworkers,[14] found in 19 patients with chronic pain implanted with a spinal cord stimulator, that predictions of outcome based on psychological data were accurate for 76.5% of the patients. They suggested that psychological factors be made part of the preimplantation screening process. Contrary evidence was presented by Meilman and associates[15] from a series of 20 patients with chronic back pain who received spinal cord stimulation. They pointed out that their study had a number of limitations but concluded that outcome was not related to psychological evaluation, age, sex, or number of previous surgical procedures.

In a well-controlled study by Turner and coworkers,[16] psychological factors were found to predict overall surgical outcome for 83% of the patients. Their study was limited to lumbar laminectomy and discectomy procedures and included 106 patients with chronic low back pain. North and associates,[11] in a 1990 follow-up of 63 patients, described psychological screening as part of the preimplantation process but deferred further comment until their experience accumulates.

THE OREGON HEALTH SCIENCES UNIVERSITY (OHSU) EXPERIENCE

My colleagues and I at OHSU[17] undertook a study of psychological variables affecting outcome in spinal cord stimulation trials based on our experience. We utilized the psychological test battery developed by Kern Olson, PhD, which is based on Melzack's model of chronic pain, which comprises multiple measures assessing sensory, affective, and cognitive influences.[18] Factors associated with a high risk for developing stress-related disorders were also included. In particular, locus of control and absorption are part of the battery used in predicting outcome.[19] The full high-risk battery consists of the following tests:

- Minnesota Multiphasic Personality Inventory (MMPI)
- Symptom Checklist-90-R (SCL-90-R)

- Behavioral Analysis of Pain (BAP)
- Chronic Illness Problem Inventory (CIPI)
- Spielberger State-Trait Anxiety Scale
- Beck Depression Inventory (BDI)
- Locus of Control Scale
- Absorption Scale
- McGill Pain Questionnaire
- Social Support Questionnaire

All patients referred for spinal cord stimulation underwent a comprehensive evaluation and examination by an anesthesiologist specializing in pain management. Additional evaluations were conducted by a physical therapist with a special interest in chronic pain. Every patient with chronic pain completed the high-risk pain profile battery. If further diagnostic information was indicated, or if the case presented equivocal findings, other tests, such as a diagnostic epidural examination, were performed before a trial of SCS was recommended.

If the patients were considered appropriate by the multidisciplinary team, they were recommended for an inpatient, 3-day, percutaneous trial of SCS. Before the patients were admitted, they were also evaluated by the neurosurgeon who would be performing the final implant. Any patient who did not receive at least a 50% reduction in pain with the trial stimulation, as measured by a Verbal and Visual Analog Scale, did not receive the implantable device. In addition, patients who were actively abusing alcohol or drugs were excluded from the 3-day trial.

It was predicted that patients for whom the 3-day inpatient trial failed—i.e., who did not receive at least 50% pain reduction—would exhibit more psychological overlay as measured by the high-risk pain profile battery. Work by Costello and associates[20] with cluster-anaiytic typologies of subgroups with chronic pain provided the initial reference group for exclusion. Four groups—P, A, I, and N—were empirically derived from an MMPI meta-analysis, confirming the results of ten investigative teams. The *P* profile is the most elevated for psychopathology. Patients who demonstrated the P profile were recommended for conservative treatment and did not proceed to a 3-day trial. The *A* and *I* profile patients were considered for the trial on an individual basis, depending on T score elevations on the MMPI. All of the *N*, or normal psychological profile, patients proceeded to the 3-day trial.[20]

Forty-six patients referred to the OHSU Pain Service for spinal cord stimulation between 1989 and 1991 were included in the study. The average age of the patients was 49 years, with a range of 21 to 77 years. Twenty-five of the patients were female, and 21 were male. The patients were divided into two comparison groups, those who passed a spinal cord stimulator trial (N = 25) and those who failed it (N = 21).

Any subject who did not meet physical criteria indicated for spinal cord stimulation did not proceed to a 3-day inpatient trial. In addition, any patient who exhibited significant psychological problems was also excluded from the trial. Therefore, patients who eventually experienced the 3-day inpatient trial represent a relatively psychologically homogeneous sample of patients with chronic pain, thereby increasing the clinical importance if differences were revealed between the two comparison groups. *Failure* was defined as a visual analog report of less than 50% pain relief during the trial.

TABLE 40–1. MMPI Mean *t* Score Comparison

MMPI Scale	Passed $\bar{x}$	Failed $\bar{x}$	*t*	Significance
L	54	54	.05	
F	53	55	−.59	
K	58	58	.12	
Hs	70	72	−.35	
D	64	75	−2.53	$P < .02$
Hy	68	73	−1.45	
Pd	60	63	−1.15	
Mf	55	51	1.2	
Pa	58	59	−.68	
Pt	59	64	−1.22	
Sc	61	63	−.51	
Ma	56	51	1.5	
Si	52	57	−1.62	
	N = 24	N = 19	*df* = 41	

A chi-square analysis did not reveal significant differences based on age or gender. In addition, *t* tests did not reveal significant differences based on age ($df = 44$, $t = -.80$, $P = .43$ n.s.). Forty-three subjects completed an MMPI or an MMPI-2. Given that the items for the MMPI-2 are virtually identical to those for the MMPI, MMPI-2 raw scores were derived and converted into linear standard scores according to MMPI norm.

The various MMPI scales were compared, again using multiple *t* tests, to determine which might assist in differentiating the two groups. Out of these scales, only the depression subscale of the MMPI reached statistical significance ($P < .02$). The MA scale approached significance, with those who failed having less energy, consistent with a higher D score (Table 40–1). A further comparison of the remaining battery was completed utilizing multiple *t* tests. Only the Absorption Scale reached significance ($P < .05$) (Table 40–2).

To analyze the role that depression plays throughout this protocol, and because of its frequent use, the Beck Depression Inventory (BDI) was selected for further analysis. The BDI correlates significantly with the MMPI scales F, K, F-K, D, SC, and SI; the McGill Sensory and Affective

TABLE 40–2. Mean Score Comparisons for the High-Risk Battery*

Tests	Passed $\bar{x}$	Failed $\bar{x}$	*t*	*df*	Significance
McGill Pain Questionnaire					
Sensory	17	19	−.66	34	
Affective	3	4	−1.60	34	
Evaluative	3	4	−.59	34	
PRI	28	32	−.84	34	
I-E	9	8	.87	18	
Absorption Scale	7	12	−2.4	14	$P < .04$
Chronic Illness Problem Inventory	90	107	−1.02	12.7	
Total score					
CIPI Symptom focus score	3	5	−1.02	23	
Beck Depression Inventory	12	16	−1.6	32	
State Anxiety	24	25	−.62	26	
Trait Anxiety	19	21	−1.03	26	
State Anger	13	13	−.29	26	
Trait Anger	16	17	−.29	26	
Temperament	6	6	−.14	26	
Reaction	8	8	−.10	26	

*Rounded to nearest whole number.

scores, the McGill PRI, the total score on the CIPI, the illness focus score on the CIPI, the State Anxiety Scale, the Trait Anxiety Scale, and the State Anger Scale (Table 40–3). Several points must be made concerning these correlations. For one, there appears to be a very strong correlation between depression and the report of pain. For example, there is a correlation (r = .42) between the BDI and the McGill Sensory scores. The Sensory score also shares a great deal of variance with the total score on the McGill (r = .50). In terms of how this pain affects an individual's daily life, the BDI shares a high correlation (r = .80) with the total score on the CIPI. Further, the CIPI illness focus score indicated a significant association (r = .71).

In order to help determine which sets of variables predict a successful versus an unsuccessful trial, a stepwise logistic procedure was performed. Because of limited numbers on many of the variables, only the variables age, sex, and MMPI scales were utilized. Significance was set at $P < .05$ for entry into the stepwise model. The stepwise procedure resulted in a selection of two of the subsets, the depression scale and the hypomania scale of the MMPI. As noted before, in the t test analysis, a higher depression scale and a lower hypomania scale score were associated with SCS trial failure. According to the logistic procedure analysis, these two factors alone correctly predict a successful or unsuccessful trial approximately 70% of the time.

Two tests in the battery, the Absorption Scale[21] and the Locus of Control Scale, were included as research scales.[19] Wichramasekera[19] found that locus of control and absorption were predictive for stress-related disorders, suggesting that these scales would add important meaning for predicting chronic pain. The results of our study[17] indicate that greater impressionability or suggestibility, as measured by the Absorption Scale, are associated negatively with SCS trial outcome. Tellegen and Atkinson,[21] in their description of the Absorption Scale, state that it correlates well with other accepted measures of hypnotizability. It is the opinion of the senior author of our study, Dr. K.A. Olson, that the Absorption Scale may be one way to assess pain sensitivity.[17] Wichramasekera[19] concludes from his research that the highly suggestible patient is at risk for chronic pain because the pain stimulus tends to incubate psychologically over time.

TABLE 40–3. Correlations Between the Beck Depression Inventory (BDI), Minnesota Multiphasic Personality Inventory (MMPI) D Scale, and Other Measures

Measure	Correlation (r)*
With Beck Depression Inventory Scale (BDI)	($P < .05$)
McGill sensory score	(.42)
McGill affective score	(.66)
McGill total score	(.50)
Chronic Illness Problem Inventory (CIPI)	
Total score	(.80)
Symptom focus	(.71)
State Anxiety	(.42)
Trait Anxiety	(.53)
State Anger	(.52)
MMPI D	(.45)
With MMPI D Scale:	
McGill evaluative score	(.38)
CIPI total score	(.47)
Trait Anxiety	(.51)
BDI	(.45)

*$P < .05$.

Locus of control has been examined carefully by a variety of authors as it applies to chronic illness and health.[22] Although locus of control does appear to discriminate between a successful SCS trial and a failed one, locus of control can be considered important treatment information, especially from a cognitive behavioral perspective.

The major predictive variable derived from our study[17] appears to be mood or the evidence of depression. The high-risk pain profile battery assesses depression from a variety of sources, including the MMPI-2 D scale, the Beck Depression Inventory, the affective scale from the McGill Pain Questionnaire, and the SCL-90-R depression scale. Further, it is important to note that depression contributes significant variance to other aspects of chronic pain, including sensory components and an overall increased illness focus. Our experience with this series of patients suggests that positive findings for mood or depressive disorder in a majority of cases are a postmorbid finding. It is sometimes difficult to differentiate premorbid from post-morbid depression in patients with chronic pain. The patient's premorbid history, obtained through an interview and comprising school, health, marital, and work history, can be useful in delineating the existence of a premorbid mood disorder.

Fields[23] reaffirmed Melzack and Wall's[2] model of chronic pain when he proposed that mood disorders alter the evaluative aspect of the pain experience. Our results strongly suggest that depression adds significantly to the sensory or nociceptive components of chronic pain. This finding adds credence to the importance of psychological screening, because a mood disorder would inflate the patient's response to verbal and visual analog scales. The patient's preimplantation and postimplantation pain ratings during an SCS trial greatly contribute to the pain management team's decision-making. Appreciating the patient's state of mood enhances accurate prediction of pain relief and minimizes trial failure.

OTHER FACTORS TO CONSIDER IN THE PATIENT SELECTION PROCESS

As previously mentioned, patients suffering from chronic pain must undergo a comprehensive evaluation to ascertain an accurate diagnosis on which to base a treatment plan. This diagnosis helps ensure that the patient with chronic pain has had an adequate trial of appropriate, less invasive therapies prior to consideration of SCS. It is our strong belief that patients who exhibit inappropriate drug-seeking behavior or continue to misuse or overuse alcohol, prescription, or illicit drugs are poor candidates for SCS. Furthermore, patients for whom there are unresolved issues pertaining to workers' compensation or litigation or who exhibit "compensation neurosis" should also be excluded from SCS until these issues are clarified or resolved.

TRIAL STIMULATION

Trial stimulation is the final selection criterion before a patient proceeds to surgical implantation of an internalized

SCS system. There can be no doubt that trial stimulation has resulted in better patient selection and improved long-term efficacy, as seen in the long-term follow-up studies reviewed previously. The role of the anesthesiologist in developing and performing percutaneous trials is well described and continues to undergo refinement.[24] The important outcomes of percutaneous SCS trials are as follows:

- Patient selection
- Patient satisfaction
- Cost-effectiveness
- Determination of the permanent implantation site.

PATIENT SELECTION

Trial stimulation must result in the patient's report of reduction in pain. An objective increase in the patient's activities of daily living, a decrease in analgesic intake, or a combination of the two is required prior to SCS implantation.

Although Meilman and colleagues'[15] study used 70% reduction in pain as a criteria for success, most centers would accept a 50% reduction in pain as significant. Patients who present for SCS have experienced failure of all manner of conservative therapies, so achieving a 50% reduction in pain for these patients is not inconsequential.

A current controversy centers on how long a trial should be run before the decision is made to implant an SCS system. There are no prospective trials resolving this issue, each group of investigators fully believing their approach to be correct.

I currently utilize a 24-hour inpatient trial with a one-week outpatient extension. Having the patient in hospital allows our team to reassess lead configurations, encourage greater activity levels, and monitor progress with guidance from physical therapy services, if indicated. A further favorable prognostic factor, promoted by Linderoth (B. Linderoth, personal communication, 1993) is the presence of prolonged analgesia during the trial when the trial external generator has been turned off.

PATIENT SATISFACTION

Patient satisfaction issues may be totally separate from pain relief. Although the hallmark of a successful SCS trial is decreased pain, one has to affirm that the patient will be truly satisfied over the long term with the implanted system. My colleagues and I find the trial period an important time to re-address the issues of permanent implantation. Misconceptions about limitations on activity levels need to be addressed proactively. The cosmetic aspects of permanent implantation are commonly a concern in younger patients that surfaces during the trial period. Many of these issues are covered in the preimplantation period, during educational video and teaching sessions. It is well known that patients do not assimilate all presented information easily or totally and may require reinforcement.

COST-EFFECTIVENESS

Implantation of a SCS system without a trial is medically irresponsible and economically wasteful. There are two general approaches to SCS trials. The first is a totally percutaneous trial performed in a fluoroscopy unit under aseptic conditions, much as an invasive radiologist would perform catheterizations. The trial electrode is removed after the trial period whether or not it is a success. Subsequent implantation is performed through sterile surgical fields. This approach is utilized by both neurosurgeons and anesthesiologists. The second trial approach is to place an epidural trial electrode percutaneously in the operating room, at which time it is sutured to the posterior ligaments for anchoring, and the lead extension is tunneled to a lateral flank exit site. Subsequently, this lead is connected to an internal pulse generator (IPG) if the trial has been successful or is removed if not.

Reported series documenting efficacy of SCS trials show 50% of patients proceeding to full system implantation. Having to return a patient to an operating room 50% of the time to remove tunneled leads after an unsucessful trial does not appear to be cost-effective. A third approach to trial stimulation is mentioned for the sake of completeness but is to be condemned in its practice. Placement of platelike leads (Resume lead, Medtronic) through a laminotomy incision is sometimes utilized as a trial stimulation. These leads permit very little maneuverability in a cervico/caudal direction and do not allow for adequate screening of patients. The cost, discomfort to the patient, and limitation in screening ability should make it obvious that a Resume lead trial is inappropriate. The implantation of a Resume lead as a permanent lead, once a percutaneous trial has been deemed successful, is, however, a well-established option.

DETERMINATION OF THE PERMANENT IMPLANTATION SITE

The fourth important piece of information gleaned from the trial spinal cord stimulation is determination where the permanent electrode should be positioned. For the most part, positioning of the permanent electrode is based on the final position of the temporary electrode arrived at during trial stimulation. The maneuverability of the temporary electrode allows identification of the area of spinal cord in which stimulation results in the greatest reduction in pain symptomatology and the greatest improvement in the patient's functional capacity.

SUMMARY

The rationale utilized for SCS patient screening has evolved over the past three decades and continues to be refined as experience accumulates. The necessity of a well-thought-out, systematic process of patient selection, based on both physical and psychological factors, is imperative. Multidisciplinary evaluations and effective preimplantation trials contribute to the use of SCS as a viable option for certain patients with chronic pain.

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