Psychological factors in spinal cord stimulation therapy: brief review and discussion

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“...The most common reason for failure of stimulation techniques to relieve pain is the psychological status of the patient.” (Donlin Long, 1985)

More than 40 years ago, Shealy and colleagues introduced the concept of SCS based on Melzack and Wall’s gate-control theory of pain. This theory and its subsequent iterations allow for the role of psychological factors, including affective and cognitive components, in the modulation of pain. According to a report by North and Wetzel, this may have been the impetus for Shealy et al. to recommend the following selection criteria for patients to receive SCS: 1) emotional stability; 2) elevation of the depression scale score only (Scale 2 [D]) on the MMPI; and 3) cooperation with a rehabilitation program. Since its introduction, there has been an explosion in available SCS hardware and device options, computer modeling of stimulation parameters, theories of mechanism(s) of action, and the variety of disorders treated. Scores of studies involving thousands of patients have been published. However, reviews of the literature have indicated a reported loss of pain relief in up to 50% of patients at 1 to 2 years postimplantation, despite a successful trial period of stimulation. In one study, 100% of patients reported success at 16 months, but only 59% still had these results at 58 months. Psychological factors may play an important role in understanding this apparent loss of efficacy, particularly in the case of a technically adequate implant.

Nevertheless, any consideration of the role, meaning, and importance of psychological factors in SCS therapy is predicated on one’s satisfaction with current outcome measures and success rates. If a failure rate of 25 to 50% following a successful trial and subsequent implantation is acceptable, then an examination of psychological variables is required. If one adheres to a multidimensional model of pain, which specifies sensory–discriminative (somatosensory cortex), affective–motivational (limbic system), and cognitive–evaluative (prefrontal cortex) as key factors in the processing of pain, the potential significance of psychological variables becomes obvious. In this context, a preoccupation with the hardware at the expense of consideration of psychological variables may betray sound sense in trying to explain and/or enhance clinically meaningful outcomes.
has often been said that a good arrow will not reach its mark without a good archer. That is, no matter how good the device, success can only be assured if it is applied at the right time, to the right person, and in the right way.

Role of Psychological Variables

Examination of psychological variables can take several forms. One approach, and perhaps the most common, has been to obtain data from interviews and psychological testing. These data are then correlated to outcomes in an effort to identify predictors of success. A second approach considers the role of psychological factors, including the patient’s perception of pain, in outcomes assessment. It recognizes that numerous variables determine a patient’s perception of the efficacy of therapy and that such efficacy can be evaluated from a variety of perspectives, including the subjective and/or objective. Exploring the benefits of combining psychological and behavioral therapies with SCS therapy is yet another approach, and one that to date has been relatively ignored. Once again, a preoccupation with variables associated with the device may have inadvertently preempted this consideration. Finally, one can examine the psychological milieu involved in SCS therapy, including the patient’s and practitioner’s expectations and philosophical approach to chronic pain management.

In this article I suggest that the entire process surrounding SCS therapy can influence patient selection, trial stimulation procedures, and outcomes, including patient satisfaction. For example, the presence of a high-profile personality such as Mr. Jerry Lewis reporting successful results and, to some, an almost unprecedented degree of success has heightened the public awareness of SCS therapy. Consequently, in some cases a level of expectation exists on the part of the prospective patient that cannot be supported by existing data. Thus, the previously uninformed and reticent patient presents now with boundless enthusiasm for the therapy. Indeed, some present with a sense of entitlement and are resistant to and question the need for any type of extensive or psychological evaluation.

The impact of such an expectation was highlighted in a study by Kemler et al., in which they examined the effects of SCS plus physical therapy compared with physical therapy alone in the treatment of reflex sympathetic dystrophy (currently referred to as CRPS). Patients were randomly assigned to one group or the other following a trial period of stimulation. Patients assigned to the SCS plus physical therapy group showed a significant reduction in pain, even prior to implantation of the spinal cord stimulator.

This heightened level of patient expectation (or in some cases desperation), in combination with the reversibility of SCS, poses a very seductive scenario and may influence the practitioner’s threshold for performing SCS trials and/or implantation of the device. The economic considerations and the reinforcement of being known as a surgeon with experience in these types of implantations cannot be overlooked. In this regard, it is interesting to take note of the discrepancy often found between a given practitioner’s reported outcomes and the evidenced-based literature. Indeed, it appears that the more experienced, published, and outcome-oriented practitioners, although enthusiastic about SCS therapy, are more conservative in their predictions.

Assessing the role of psychological factors can be somewhat complicated. First there is the need to identify the presence or absence of these factors. Most patients show a mixture of depression, somatic focus (that is, hypochondriasis), anxiety, and/or emotional reactivity (that is, hysteria). The degree of sensitivity and specificity among various psychological tests in detecting these and other psychological states varies. Second, the magnitude of psychological factors appears to vary with the complexity of the disorder. Dworkin et al. noted increased psychological distress in patients with multiple areas compared with a single area of pain. Third, psychological factors may be mediators, modulators, or maintainers of pain, and Wallis et al. found that psychological distress as measured using the Symptom Checklist 90 resolved along with the pain in patients with a highly specific pain generator. This finding suggested that the psychological factors were secondary to the pain. Others, assessing patients with more generalized pain, did not find such a clear correlation. Patients with histories of physical and/or sexual abuse were found to be more likely to develop chronic pain following injury and their condition was more recalcitrant to treatment, implying some type of predisposition to pain. Such patients may have a different response to an acute procedure (that is, a brief stimulation trial) compared with long-term treatment (that is, prolonged SCS therapy), thus perhaps explaining the loss of efficacy postimplantation.

The role of psychological variables should be viewed from a longitudinal instead of a cross-sectional perspective. Depression is a good example. In the trial setting, depressed patients demonstrate increased tolerance to a variety of painful stimuli. However, when receiving long-term stimulation, depressed patients seem to have a lower threshold and tolerance for pain. This could be the basis for a false-positive trial, wherein the depressed patient responds in one fashion to a brief period of trial stimulation and in another to prolonged stimulation. Indeed, North et al. noted that certain psychological traits predicted pain relief during trial stimulation and immediately postimplantation, but not at the 3-month follow-up evaluation.

Psychological Screening and Assessment

Over the years a number of psychological tests have been used for screening patients. The MMPI has been used with regularity, although a review of the literature failed to reveal the superiority of any particular test or MMPI profile configuration as predictive of or associated with positive or negative outcomes. This is to be expected in part because patients with profiles consistent with severe affective, personality, or psychotic disorders would have been rejected. Some have found that the presence of a “conversion V” (wherein the scores on Scales 1 [hypochondriasis] and 3 [hysteria] are elevated relative to Scale 2 [depression]) is associated with a negative outcome. However, this finding is not consistent. Brandwin and Kewman noted lower hysteria and hypochondriasis scores and higher depression scores in treatment-resistant compared with successfully treated patients.
Interestingly, in a recent study hundreds of patients with various pain diagnoses were examined, and the modal profile was found to mimic the conversion V. The different diagnostic groupings were separated by the degree of elevation of the MMPI profile rather than the profile configuration. Given the state of the literature, it seems prudent to use psychological testing, in particular the MMPI, as one source of information. Indeed, Doleys and Brown found that patients with slightly elevated MMPI scores reported greater relief 4 years after implantation of a drug administration system than those with normal MMPI profiles. On reflection, this should not be surprising. Why would a patient whose emotional and physical life was so altered by pain that they would consider implantation of such a device manifest a normal MMPI? In this instance, a certain level of abnormality would be expected and appropriate. The authors, therefore, recommended a search for consistency across multiple sources of data, including complaints of physical and psychological symptoms, behavioral observations, and interview data from the patient and his or her significant others, in addition to psychological testing. Tests assessing readiness for change, coping skills, acceptance, and perceived disability should also be considered. These data would allow the use of clinical judgment rather than an overreliance on a specific score or profile.

Psychological assessment can fulfill several functions. Traditionally, psychological testing has been conducted in an effort to identify predictors of success. Dumoulin et al., for example, reported a correlation of greater than 0.8 on scores from a 24-item questionnaire. Daniel et al. calculated an 80% accuracy rate using the MMPI and BDI, among other tests. Long et al. reported a 33% success rate in unscreened patients compared with 70% in screened patients. Kupers et al. found that patients deemed appropriate for SCS therapy based on results of psychological screening had better outcomes than those deemed inappropriate. However, North et al. failed to find their tests to be predictive of long-term outcomes. In a study by Burchiel et al., the investigators found that the BDI score and Scale 9 (mania scale) on the MMPI emerged as predictors. In a subsequent study, however, the mean BDI score was 13, barely into the mildly depressed range, and a posttreatment reduction from 13 to 11, although statistically significant, is hardly impressive clinically. Other chronic pain populations demonstrated much higher scores. It may therefore be important to segregate patients into groups with low, moderate, or high scores based on these variables. Indeed, Porter-Moffitt noted very similar MMPI profiles among a large group of patients with chronic pain, but the degree of elevation varied for different diagnosis groups (that is, CRPS, failed–back surgery syndrome, and fibromyalgia).

Test and interview data can also be used to provide a description of the patient’s psychological makeup and status, suggesting deficits that may be ameliorated by psychological therapy, thus rendering the patient a more appropriate candidate. In addition, testing can be used to establish a baseline against which to measure improvement. I have enumerated various ways in which psychological evaluation and therapies can be useful in pretrial screening, during the period of trial stimulation, and after implantation.

The approach to screening and trial stimulation may also differ based on the goal. One goal may be to avoid a false positive (that is, long-term failure), another to avoid a false negative (that is, rejecting a potential long-term success). It seems somewhat short-sighted, given the dynamic nature of pain and its consequences, to evaluate the usefulness of psychological assessment based solely on its ability to predict pain reduction.

Patient Selection and Psychological Screening

In some arenas, patient selection is seen as the sine qua non of SCS therapy. The emphasis has often been on the type of pain (nociceptive compared with neuropathic); location of the pain (extremity compared with axial); and the ability to obtain concordant paresthesias. The need for a psychological evaluation has been driven largely by Medicare insurance requirements. The ability of a psychological assessment to predict outcomes, as noted earlier, has been questioned. However, the fact that one set of psychological tests was administered in a situation in which a preselection process was already in place and wherein an estimated 20% of patients were suspected of misrepresenting their response to trial stimulation should not necessarily be an indictment against psychological evaluations in general. Indeed, North et al. generally support psychological screening.

Such presurgical psychological screenings have been conducted with great success in other areas, including spine surgery. In this regard, it is noteworthy that, based on results of a recent survey of members of the European Federation of Chapters of the International Association for the Study of Pain, an attempt was made to develop a consensus statement representing the standard of care for SCS therapy. This survey noted that only 61% of respondents agreed that each patient should have a psychological evaluation. Severe depression, active psychosis, and untreated drug and/or alcohol abuse were not considered absolute contraindications by 74, 23, and 61% of respondents, respectively. The document published by the European Federation of Chapters of the International Association for the Study of Pain did stress that SCS should be combined with behavioral and psychological approaches to pain management, thus requiring a multidisciplinary setting, rather than being applied as an isolated treatment. This sentiment was echoed by Daniel et al. on page 776 of their article, when they stated “electrode implantation can serve as the initial step in a treatment plan followed by psychotherapy (to address psychological factors influencing pain).”

There have been some attempts to enumerate patient characteristics thought to be associated with outcomes. Daniel et al. considered the following to be red flags: 1) personality disorders (Axis II diagnosis; Diagnostic and Statistical Manual of Mental Disorders, ed. IV); 2) drug dependence; 3) unstable family and personal relationships; 4) poor vocational adjustment; and 5) involvement in litigation/compensation. Nelson et al. listed the following as contraindicators: 1) the presence of suicidality; 2) homicidality; 3) severe depression or other mood disorders; 4) somatization/somatoform disorder; 5) alcohol or drug dependency; 6) unresolved compensation/ litigation issues; 7) lack of social support; and 8) neurobehavioral cognitive deficits. In my study I used a somewhat
different tactic, outlining a number of characteristics thought to be positive indicators, including 1) general psychological stability; 2) effective defensiveness; 3) moderate levels of self-confidence and self-efficacy; 4) realistic concern regarding illness and proposed therapy; 5) mild depression appropriate to the situation; 6) general optimism regarding outcome; 7) ability to cope with flare-ups, complications, and side effects appropriately; 8) appropriately educated regarding the procedure and device; 9) supportive and educated family; 10) history of compliance/cooperation; 11) behavior and symptoms consistent with identifiable pathological condition; 12) behavioral/psychological evaluation consistent with symptoms and reported psychosocial status; 13) comprehension of instruction; 14) appropriate expectation by patient and significant other; and 15) ability and willingness to tolerate paresthesias. In each of these three instances the characteristics emerge as generalizations from other areas of research, clinical experience, and/or logical deduction. There is little experimentally or clinically based evidence to support one set of characteristics over another, although this should not be taken to mean that the characteristics lack relevance. One cannot avoid a certain amount of blatant assertion.

Psychological Variables and Outcomes

The significance of a single variable or a group of variables to a particular therapy is determined in part by the outcome measures emphasized. Concordant paresthesia and surgical complications are likely to be associated with surgeon and device variables; pain relief is associated with physiological and psychological issues; patient satisfaction depends on fulfillment of expectations and perceived effort by medical professionals; and QOL is measured by improved functional and psychological status. To date, most studies have focused on pain reduction as measured by a decrease in the visual analog scale or numerical rating scale scores. The role of psychological factors may be obscured depending on the relative contributions of sensory compared with affective components to these ratings, both of which are categories of the McGill Pain Questionnaire, or the importance of pain intensity compared with pain unpleasantness (see Doleys and Doherty for a more detailed discussion).

The outcome measure used would also influence the approach to trial stimulation. Concordant stimulation, and to some degree pain relief, can be established intraoperatively. A longer and more functional trial may be required to evaluate changes in mood, function, medications, and other QOL parameters. The historical emphasis on pain reduction and the apparent acceptance of a 50% success rate may be key factors in the debate over the necessity of preimplant trial stimulation and what constitutes an appropriate trial.

One advantage of SCS, particularly in comparison with intrathecal therapy, is that it frees the patient from the medical system. With the exception of a complication or periodic reprogramming, patients are rarely seen again until the device’s battery is depleted and requires replacement. By contrast, intrathecal therapy requires regular office visits for refills and possible adjustments of the medication. The reduced contact with the patient receiving SCS therapy places the emphasis on the device as the sole approach to pain management. Unless regular follow-up visits are requested, the opportunity to evaluate deficits in pain management and to introduce adjunctive therapies is missed. Admittedly, in a cost-conscious environment, one might find it difficult to justify other therapies such as physical rehabilitation or behavioral therapies. Such treatment, however, may increase the success rate. This is especially true in patients with neuropathic pain or CRPS, in whom improved functioning is emphasized over pain reduction. Pain relief (even in the presence of patient satisfaction and a willingness to repeat the procedure) in the absence of functional improvement and enhanced QOL, especially in the 20- to 60-year-old population, is a dubious outcome indeed.

Conclusions

Patient selection and therapeutic protocols oftentimes reflect the practitioner’s philosophical bias. Those physicians who believe in the multidimensional aspects of pain will usually insist on the application of a biopsychosocial compared with biomedical model in the treatment of chronic pain. These individuals are generally not deterred by issues of insurance coverage and are aware that some things are worth the price.

There are several variables that confer special status to SCS therapy, and/or issues of patient acceptance, compared with other therapies for chronic pain. These include the following: 1) the relative noninvasiveness of SCS therapy; 2) preimplant trial stimulation; 3) ongoing paresthesias; 4) unique side effects, such as positional sensitivity and electrode migration; 5) replaceable parts, that is, the battery; and 6) potential limitations, that is, use of magnetic resonance imaging and ability of the patient to drive with the device activated. Therefore, pretrial screening should take these into account. To the extent that reduction in pain as measured according to the visual analog scale or the numerical rating scale is a primary end point, psychological factors can be expected to exert a similar influence in SCS outcomes, as they do in other therapies. The customary factors would include depression, anxiety, secondary gain, personality structure, support system, reinforcement patterns, and so on.

When examining the psychological evaluations in various SCS studies, the following warrant consideration: 1) were well-known and validated tests used; 2) did the test have validity scales or some mechanism for detecting dissimulation (that is, fake good or fake bad); 3) were tests used in the context of an overall evaluation or was a clinical interview the only tool used; 4) was the evaluation done by an appropriately trained, knowledgeable, and experienced mental health practitioner; 5) did the evaluator have contact with the patient, or at least the outcome data, from the trial and follow-up visit; 6) were the screening tests readministered at follow-up evaluation; and finally 7) were both generic and disease-specific measures used to determine success?

The consideration of psychological factors and associated tests in SCS therapy incorporates several principles: 1) that chronic pain is multidimensional, involving sensory, affective, and evaluative components; 2) the relationship and influence of psychological factors on the experi-
The efficacy of a therapy and variables that most accurately predict this will be significantly influenced by the selection of device-specific, disease-specific, and/or generic outcomes. Therefore the absence of improvement in psychological variables or lack of predictive validity following a somatic treatment does not discount their role but may highlight the need for a targeted therapy to improve these factors. This may in turn enhance the overall efficacy of the somatic treatment. For example, the addition of eight sessions of cognitive behavioral therapy emphasizing coping skills, chronic pain management, acceptance, and so on may work synergistically with SCS therapy. In this case the focus is on taking what works and making it work better rather than improving predictability.

References


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