Surgical Implants for Pain Management

A follow-up study of patients who have undergone implant of a pain management device.
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Pain patients who are candidates for surgical implants—whether a spinal cord stimulator or intrathecal pump—suffer chronic moderate to severe pain and have not benefitted from conservative or less-invasive treatment methods which include, but are not limited to, oral medications including opioids, physical therapy, injections, psychological therapy, holistic treatments (acupuncture, massage, cranial sacral), etc. In such instances, the use of such implants may be helpful to the management and reduction of pain and is often a last resort in the spectrum of treatment options.

It is common practice for patients to have a psychological pre-implant evaluation by a qualified licensed psychologist in their home state before implantation. It is important to fully understand the significance of this psycho-educational-evaluative role as it relates to patient satisfaction and aiding in the selection of optimum preventative treatments. These assessments are not considered forensic evaluations, but ones that are both evaluative and educational in nature. The patient’s response to these interactions is important in determining their readiness for being active participants in the aspects of both pain management self-care skills and for the management of issues that may arise from their implant.

This article is a summary of the results of a follow-up study of those patients who completed a pre-implant psychological evaluation and subsequently had an implant of a pain management device.

Psychologists and Pre-implant Evaluations

Psychologists have a long history of involvement in the scientific research, assessment and treatment of various types of health care interventions. These range from assessing and improving the effectiveness of working with diabetic patients to the more present-day concern of the obesity epidemic.1 Psychology also has a history of providing scientific research within the health care arena of biological, neurological, and behavioral medicine. Additionally, psychology has focused on issues faced by medical professionals and third-party payers who are concerned with utilization and over-utilization of health care. Physicians and surgeons are commonly coordinating care with psychologists to offer a unique perspective to complex health care concerns and work with pain patients issues in chronic pain clinics. Psychology has a central leading role as an adjunct to medical care.2

Behavioral medicine/health psychologists who work with chronic pain patients seeking surgical implants have an obligation to assess and understand the impact of these interventions on patients to improve pre- and post-surgery outcomes. Therefore, Behavioral Health Psychologists have an obligation to understand the bio-psycho-social issues that impact the medical environment. They help to facilitate communication and education between all parties,3 in addition to providing cognitive behavioral pain management therapy to improve the patient’s ability to become active participants in active self-care techniques. Real pain management is a great deal more than just administering a particular type of medical intervention ranging from medications to surgical interventions.

Due to the gravity of surgical implantation, it is expected that the psychologist conducting a pre-implant evaluation have a Doctorate in Psychology, is licensed in his or her state, and has a background working with chronic pain patients. They would also do well to have professional affiliations with pain organizations and have a background working with neurosurgery, neurology, or other pain related specialties.4
The Goal of Pre-implant Evaluations

When a surgical implant of a pain management device—such as a spinal cord stimulator or intrathecal pump—is indicated, important questions need to be answered. Besides looking to see if alternative approaches have first been tried, it is also important to select those patients who have the best chance of successfully responding to the surgical implant. We are all aware that some patients may not have the best results from surgery, even when all the physical findings are present to suggest the need for it.

The goal of a pre-implant evaluation is to determine which patients will have the best chance of a successful outcome and follow-up rehabilitation. Some patients will be poor responders to surgical intervention regardless of how successful the procedure may be. Others may have a better outcome if they have first received appropriate behavioral medicine treatments which make them more proactive in their recovery and subsequent rehabilitation. Some patients may first need help in identifying and eliminating issues in their lives that will interfere with their recovery.

It is important to note that the pre-implant psychological evaluation is not necessarily designed to eliminate candidates from surgical implantation. Rather it is designed to assist the surgeon, the patient, and the family in making appropriate decisions and treatment choices, depending on the particular needs of the patient. It focuses on the patient, personality style response patterns, personal life issues, issues that might result in setbacks, and other factors that are important to improved outcomes. Many medical patients are exhausted, confused, over-whelmed, not coping well, and need help in emotional stabilization prior to having any chance of using the medical interventions in an appropriate cost-effective manner.

At times the evaluation may recommend surgical implantation, but with very specific recommendations for post-surgical rehabilitation and recovery interventions that will enhance the chance of the patient responding in a positive manner and quickly returning to a functional capacity. As such, the pre-implant psychological evaluation is a bio-psycho-social-educational approach to helping patients make better use of the variety of treatment choices/options available. Many patients do not feel that they have more than a brief overview of what the entire process is all about. Therefore, education and information are a key focus of these evaluations.

Implant Evaluation Issues

Implant evaluation is part of a behavioral pain management approach to care. Evaluating patients for implants considers a number of factors including the patient’s:

- degree of understanding of the procedure
- degree of understanding the need to be active in self-care
- degree of understanding the need to make changes in usual methods of approaching life that may exacerbate pain problems
- degree of understanding life-style changes that are required as part of participating in this procedure
- the ability to respond to this behavioral pain management evaluation in a manner that improves knowledge, skills, and active-skills

Those individuals who have been involved in any type of behavioral pain management treatment have the advantage of knowing many of the active self-care management techniques that must be employed on a regular daily basis in their lives. Their response to behavioral medicine treatment provides a great deal of information on how they can respond to long-term rehabilitation and management issues subsequent to an implant procedure for which they are being considered. Observed behavioral actions are always more reliable in any evaluation procedure. In this sense, part of the evaluation relies on the patient’s response to pre-implant treatment interventions.
Objectives

In health care, the final determination of whether or not a surgical procedure will be of help should be decided by the patient. The patient may sometimes be the neglected aspect in the provision of health care services and treated as secondary to the physician in the health care paradigm. The health care model being proposed through this research study is based more on quality of care as measured by the patient. In psychological services, patients establish goals and then later report their level of attainment. Within the health psychology arena, the patient’s involvement should also be paramount.

The primary objective of this study was to correlate patient satisfaction of a spinal implant for pain control with pre-surgery depression, age, gender, and an exaggerated emotional component to the pain as evident on the McGill Pain Questionnaire (MPQ). These variables were noted in the participant's pre-surgical psychological evaluation and followed up with mailed questionnaires. This information contributes to the discussion on pre-implant psychological interventions to increase the chance of patient satisfaction. Implicit in this paradigm is increased communication between professionals and patients and ultimately a reduction in long-term health care costs.

Given that patients are an integral part of the health care paradigm, we need to understand their interaction and tailor approaches that increase patient satisfaction after implants and ultimately decrease overall medical utilization. Some questions that need to be explored include:

- What contributes to patient satisfaction?
- Why do some patients report miscommunication and unhappy interactions with providers?
- Why do some patients suffer from emotional turmoil—either caused by or aggravated by their medical issues?
- What aspect of patient satisfaction is important to a patient’s perceived success of a surgical procedure?
- Why do some patients with the same physical condition improve while others did not? This understanding is an important step towards incorporating the proper treatments to encourage a positive surgical outcome.

Methods

This study utilized a quantitative approach to allow for an analysis of how depression, emotionality, age, and gender related to patient satisfaction after a surgery for a spinal implant. Out of the 120 potential participants randomly provided by a Pacific Northwest medical facility, sixty-two individuals participated in the survey; 26 (41.9%) participants were Male and 36 (58.1%) participants were Female. Sixty-two (100.0%) participants were Caucasian. Quantitative assessments of the pre-surgical evaluations and a follow-up mailed questionnaire derived a statistical analysis of these variables.

This was a retrospective study that tried to determine if any suspected risks affected the outcome of patient satisfaction. Due to the still-emerging literature on this relatively new procedure, retrospective studies have been widely used. For example, Horsch, Schulte, and Cologne conducted a retrospective study that demonstrated a Spinal Cord Stimulator (SCS) was extremely beneficial in limb preservation in peripheral vascular disease. Retrospective continuous non-randomized studies have their limitations and cannot be generalized beyond this population. However, they can serve as a preliminary analysis of the factors under study and help to guide future research projects.

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Demographics

Descriptive analysis used frequency (number of occurrences out of total participants) and percentages
for the nominal (categorical/dichotomous) data. In the study, 26 (41.9%) participants were male and 36 (58.1%) participants were female. All of the sixty-two (100.0%) participants were Caucasian. The target population was male and female adults (ages 36-83) who had a pre-implant psychological evaluation for a pain management device—spinal cord stimulator or an intrathecal pump—and were being treated at an Oregon medical clinic. The demographic data analyzed came from the post-surgery mailed questionnaire. The questions were designed to give insight to any extraneous variables that may have an impact on patient satisfaction.

The demographic variables are as follows: Thirty-one (50.0%) participants had a Spinal Cord Stimulator (SCS) Implant, 12 (19.4%) had an Intrathecal Pump Implant (IP), 12 (19.4%) had an Implant trial but did not proceed to full implantation, and seven (11.3%) decided not to get an implant after the pre-surgical psychological evaluation. Three (4.8%) participants were in pain for three to four years; four (6.5%) were in pain for five to six years; four (6.5%) were in pain for seven to eight years; and 51 (82.3%) were in pain for nine or more years.

Results

The results indicated that no significant relationship existed when comparing depression and patient satisfaction and also that depression did not significantly predict post-implant patient satisfaction. There was no significant relationship when comparing age group and patient satisfaction; gender and patient satisfaction; and McGill Pain Questionnaire results and patient satisfaction.

The results did show a positive correlation coefficient between a diagnosis of depression on the (pre-implant) and age at the time of surgery and the McGill Pain Questionnaire, number of years spent in pain prior to surgery, and number of previous surgeries. The findings showed that the older the patient was, the better coping mechanisms and less depression they had—perhaps because the older generation was raised in a time when pain was not dwelled upon as it is nowadays. Younger participants reported more depression, intense pain, and less effective coping skills than older participants of the same race. Miaskowski points out the same inferences made by Erikson, namely, that the age at which chronic pain occurs impacts the individual as a function of interrupted life challenges and normal aging/life goals.

Thirty-one (50.0%) participants had fewer medical appointments after implantation, 19 (30.6%) had the same amount, and 12 (19.4%) endorsed not applicable due to not choosing to get the implant.

Eight (12.9%) participants worked prior to their implant; eleven participants (17.7%) did not work prior to implant; twenty-nine (46.8%) participants were retired; and 14 (22.6%) participants were on Social Security Disability. Six (9.7%) participants returned to work after implant, 11 (17.7%) did not, and 45 (72.6%) participants endorsed not applicable. Forty-two (67.7%) participants still have the implant, 10 (16.2%) do not, and 10 (16.2%) endorsed not applicable because they had decided against having the implant after their participation in the pre-implant psychological evaluation.

Post-surgical pain patients who had experienced a reduction in their pain tended to be participants who were satisfied with the spinal implant for pain control. Overall, thirty-nine (62.9%) participants were satisfied with their implant and 16 (25.8%) were not satisfied. The latter group included some of those who decided not to proceed with the implant or decided after the first external trial of the device to not proceed to the full implant.

In this study, 50.9% of the participants reported 50% or more of pain relief, and 62.9% of participants expressed satisfaction of the spinal device. Overall, forty-two (68.9%) participants thought that the pre-surgical psychological evaluation was beneficial, and 19 (31.1%) did not.

Discussion
This study was implemented with the intention of understanding what contributes and correlates with patient satisfaction of a spinal implant for pain control. This study helped refine an emergent theory of the role of patient satisfaction in spinal implants and offers a contribution to current empirical knowledge. This study is meant to be a foundation for future studies, which must continue to refine the development of standard protocols for conducting psychological pre-implant evaluations and correlating variables to patient satisfaction. This author believes that the results of this study may lay a foundation upon which to begin building and testing additional theories on patient satisfaction of spinal implants for pain control.

Spinal cord stimulator vs. intrathecal pump. Participants who had a spinal cord stimulator or an intrathecal pump were put into the same category in this current study. Subsequent studies will need to decipher the differences between these two types of implants and contributing factors.

Ethnicity. It must be recognized that there is great ethnic variability in the chronic pain population. The majority of chronic pain sufferers in the Northwest are of Caucasian descent with the sample in this study being entirely Caucasian, but this is not true for all areas of the country. Each geographic location has its own distinct ethnic identity and future research needs to take this into account. Pain is impacted by a variety of bio-psycho-social and cultural dimensions. One must not downplay the role of culture and ethnicity to the pain experience. In today’s social climate, there is an increasing need for research sensitivity and responsibility to address the ethnicity correlates to the chronic pain experience. Within other geographical regions, it is important to develop culturally-appropriate assessments for patient satisfaction after spinal surgery for pain control—particularly when there may be significant differences in outcomes among those with differing ethnicities.

Sample size. Ideally, this small introductory non-randomized follow-up study will be replicated and expanded in the future with a greater number of participants. The results of this study cannot be generalized beyond this small patient population. This was just an initial follow-up study of the impact of a spinal cord stimulator for pain control relative to several variables as previously noted.

**Summary**

These results can be used to build pre-surgery protocols to enhance patient satisfaction and to eliminate unneeded biases for depression, age, gender, and emotional correlates to the pain experience. It is acknowledged by many professionals in the chronic pain research field that additional empirical evidence is needed to fully develop an understanding of the correlations between pre- and post-surgical psycho-social variables lending to patient satisfaction. These results can help demonstrate the critical need for a multi-disciplinary language and understanding of this complex interplay of the bio-psycho-social aspects of chronic pain management. Physicians and psychologists will then be better able to implement an appropriate prevention and intervention programs that have been proven successful with chronic pain patients as well as gain additional insight when developing one of their own. Although the psychological evaluation is indicated prior to a trial of an implant, few studies have examined the relationship between psychological assessments and successful pain relief following a trial, and this should be an expanded focus of future research.

**Acknowledgement**

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**References:**

**Resources**

- 1. Blackburn G and Kanders B. Obesity Pathophysiology Psychology and Treatment. Chapman
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