

Factors Affecting Outcome of Spinal Cord Stimulation in Pain Associated with Failed Back Surgery Syndrome

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Abstract

Background: Although Spinal Cord Stimulation (SCS) is selected for chronic intractable pain treatment in patients with Failed Back Surgery Syndrome (FBSS), the long-term outcome still remains controversial.

Objectives: To investigate factors which affect long-term effect of SCS in patients with lower back and leg pain due to FBSS.

Methods: All subjects were divided into ineffective and effective groups according to the duration of SCS (less than 2 years or more). The results were analyzed in relation to the site of pain, presence/absence of lower back pain, number of operations, number of intervertebral levels treated, duration of pain, time from the initial operation to SCS implantation and time from the first examination to SCS implantation.

Results: The study included 49 patients. 13 patients were classified into the Ineffective group and 36 patients into the Effective groups. Two factors including presence/absence of lower back pain and the time from first examination to SCS implantation contributed to significant difference to long term effectiveness.

Conclusion: The long-term outcome of SCS was poor in patients with FBSS who had lower back

Keywords: Spinal cord stimulation; Failed back surgery syndrome; Lower back pain

Introduction

Failed Back Surgery Syndrome (FBSS) is understood to be a disease in which Lower Back Pain (LBP), leg pain, or leg numbness remains or recurs after spinal cord surgery for degenerative disease of the spine. The cause of pain in FBSS is difficult to determine from physical examination and diagnostic imaging. This is because nociceptive, neuropathic or psychogenic factors may also be involved in the cause [1,2]. For FBSS, treatment of pain includes pharmacological therapy, physical therapy, nerve block and surgery. However, nerve block can sometimes be inadequate. This is due to an adhesion from surgery or from a reoperation which can cause additional or new pain. Therefore, it is crucial to select an appropriate treatment according to each patient.

Spinal Cord Stimulation (SCS) has been used as a treatment for various types of pain since the first trial by Sheal et al. [3] in 1967. Currently, this method is established as a mode of treatment for chronic intractable pain [4,5]. SCS is indicated as a treatment for FBSS as it can be performed on an area other than the site of surgery. Therefore, there have been many studies which have reported the use of SCS for FBSS. However, according to Kumar and Toth [6], the long-term effect of SCS varies among studies, ranging from 40% to 70%. This suggests the long-term effect of SCS is unstable.

In this study, we retrospectively examined patients who had undergone SCS therapy for LBP and/or pain of the lower extremities due to FBSS, to investigate factors that affect long-term outcomes of SCS.

Materials and Methods

Patients

This study was approved by the institutional ethics committee of Hyogo College of Medicine, and acknowledged with a written consent from all participating patients.

The participants of this study were patients who underwent SCS trial for FBSS in our institution between January 2001 and December

2012. The patients included in this study were those who had lower back or leg pain after lumbar spine surgery; those with high surgical risk that did not respond to pharmacological therapy or other conservative treatment; or those who declined further surgery. SCS implantation was indicated for two types of patients; for those who showed improvements against their symptoms; or those who requested a SCS implantation.

We classified the patients who underwent SCS implantation into two groups: Patients in whom the duration of SCS therapy was less than 2 years (Ineffective group) and patients in whom SCS therapy was continued for 2 years or more (Effective group). These patients were further classified into groups by the following criteria; Site of pain (unilateral/bilateral), presence/absence of LBP, number of surgical operations (twice or more), number of intervertebral levels treated (two or more), duration of pain (time from perception of pain to the first visit to our department), time from the initial surgery to SCS implantation and time from the first examination at our pain clinic to SCS implantation.

Methods of SCS trial, implantation and selection of the device

The SCS trial was conducted either using the puncture or surgical (buried) trial, involving insertion of the lead under local anesthesia in an angiographic laboratory. One or two 4-electrode leads (Medtronic, Inc., Minneapolis, MN, USA) were placed at a site where an appropriate paresthesia was induced to cover the site of pain.

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The SCS trial period was approximately one week and the efficacy of the trial was evaluated at the end. SCS implantation was decided according to changes in Activities of Daily Living (ADL) and by the degree of patient's satisfaction during the trial period.

For SCS implant, local anesthetic was administered to patients in prone position on an operating table and the locations of the leads were re-adjusted if required. SCS implantation was then performed under general anesthesia. The Implantable Pulse Generator (IPG), Synergy[®] or Itrrel[®] III (Medtronic, Inc, Minneapolis, MN, USA), was implanted in the left lower quadrant of the abdomen. After SCS implantation, the leads were revised if a fracture was suspected or the IPG required a battery change.

Statistical analysis

We analyzed the prognostic factors by χ^2 -test or un-paired t-test using IBM SPSS Statistics 19 (IBM., New York USA). ROC analysis was performed using UNISTAT 6.5 (UNISTAT Lt., London, UK) to analyze receiver operating characteristic curve. $P < 0.05$ was considered statistically significant.

Results

Overall, 49 patients had SCS implanted. 24 patients had primary diagnosis of lumbar spinal stenosis; 20 patients with lumbar disc herniation; 4 patients with lumbar spondylolisthesis; and 1 patient had a lumbar compression fracture. SCS implantation was ineffective against 26% (13/49) and effective against 74% (36/49). Although 2 groups showed no significant difference in the respective outcome measures (Table 1), 2 outcomes performed using ROC analysis with p-value less than 0.35 (presence/absence of LBP and intervals between first visit to the pain clinic and SCS implantation), revealed significant differences in these measures between the groups (AUC=0.75) (Figure 1).

Discussion

The results of this study showed that SCS treatment against FBSS resulted in a 74% long-term effectiveness, similar to previously reported rates [7,8]. These results support that SCS is an effective treatment for FBSS. However, SCS can be ineffective on a long-term basis if the

	Effective group (n=36)	Ineffective group (n=13)	p value
Gender (Male:Female)	19:17	5:08	0.387
Age (Average \pm SD)	61 (\pm 14.9)	58 (\pm 15.9)	0.492
Bilateral leg pain (%)	16 (45)	6(46)	0.918
Lower back pain (%)	14(39)	9(69)	0.062
Number of operation; more than twice (%)	13(36)	6(46)	0.656
More than two intervertebral levels operated (%)	21(58)	7(54)	0.785
Duration of pain (Average \pm SD)	46 (\pm 83.4)	61 (\pm 47.3)	0.539
0-3/3-6/>6 (Year)	27/5/4	5/4/4	
First operation~SCS (Average \pm SD)	89 (\pm 111.8)	95 (\pm 87.6)	0.872
0-3/3-6/>6 (Year)	14/9/13	5/3/5	
First examination ~SCS (Average \pm SD)	17 (\pm 45.6)	31 (\pm 48.7)	0.335
0-1/1-3/>3 (Year)	30/4/2	6/4/3	

Table 1: 2 Patient background.

patient has LBP and long standing pain prior to the implantation. To enhance the effectiveness of SCS, certain measures should be taken against these factors.

One of the reasons how LBP results in ineffective SCS outcome is that LBP involves various pain. The mechanisms underlying LBP are thought to involve neuropathic pain (spinal fibrosis, insufficient decompression, recurrent symptoms of spinal column stenosis, and recurrent disc herniation), nociceptive pain (degeneration of intervertebral discs, implantation problems, facet pain), and psychogenic pain [9]. SCS is considered to be effective for neuropathic pain. Hence, for patients with LBP, it is important to sufficiently evaluate the cause of pain to avoid SCS being ineffective.

To decide whether SCS is the appropriate treatment for the pain, pre-evaluation using nerve blocks (spinal or epidural block) and a Drug Challenge Test (DCT) should be carried out. This will determine types (neuropathic, nociceptive and psychogenic) and the location of pain (peripheral and central).

Although diagnosis using nerve block can be inaccurate, Moriyama [10], Yanamoto and Murakawa [11] reported that epidural administration of local anesthetics is useful to determine whether the pain mechanism is located central or peripheral to the spinal cord. SCS can be effective for peripheral pain, which can be diagnosed by nerve block. A DCT is used to evaluate the mechanisms of pain by intravenously administering small doses of analgesia. The mechanism of pain can be assessed by the effect of analgesia on pain [12]. Medication used for DCT is opioids (morphine for nociceptive pain), Na⁺ channel blockers (lidocaine for neuropathic pain) and benzodiazepines (benzodiazepine for psychogenic pain). If the Visual Analog Scale (VAS) score reduces to half after the administration of these drugs, we consider the pain to be responsive to these drugs. Thus, we determine the pain by DCT and decide whether SCS is indicated for the pain as follows:

(I) SCS is not indicated for pain that is responsive to benzodiazepines in the DCT. Therefore, pharmacological therapy should be performed first.

(II) SCS is not indicated for pain that is responsive to intravenous opioids or Na⁺ channel blockers and oral medication with the same efficacy. Therefore, pharmacological therapy should be performed first.

(III) When pain is responsive to intravenous opioids or Na⁺ channel blockers and is unresponsive to oral medication with same

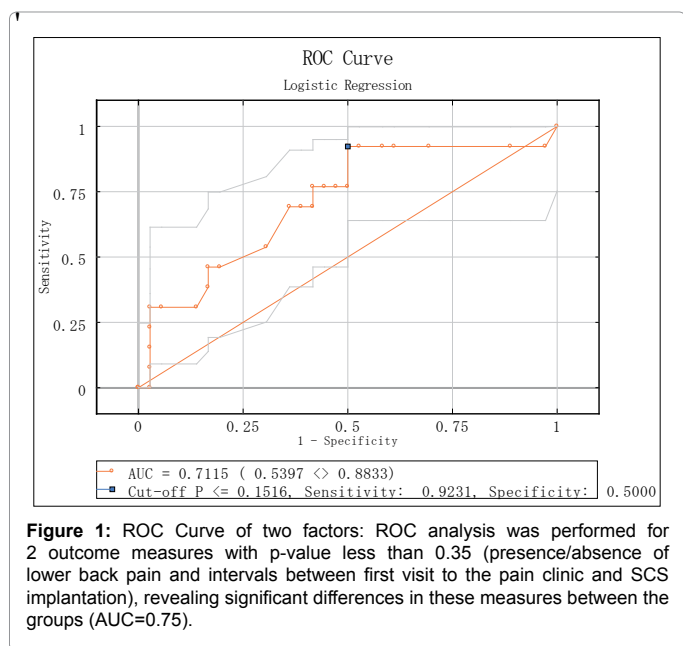


Figure 1: ROC Curve of two factors: ROC analysis was performed for 2 outcome measures with p-value less than 0.35 (presence/absence of lower back pain and intervals between first visit to the pain clinic and SCS implantation), revealing significant differences in these measures between the groups (AUC=0.75).

efficacy, nerve block should be performed.

The indications for SCS can also be determined on the basis of responsiveness to nerve block;

1. No analgesic effects are noted: Central pain is suspected thus, it is not an indication for SCS.
2. Temporary analgesic effects are noted: If patient satisfaction is minimal with the pain relief, central pain is suspected, thus it is not an indication for SCS. If the patient is satisfied with the pain relief, SCS should be considered.
3. Continuous analgesic effects are noted: The pain is considered to be peripheral neuropathic pain. SCS should be considered.

The results of this study showed satisfactory outcomes of SCS for pain of the lower extremities, suggesting that patients with neuropathic pain were able to be selected with DCT and nerve blocks. Although patients with LBP involving neuropathic factors were selected, the long-term outcome of SCS was poor. Taylor, et al. [5] considers SCS to be effective against Chronic Back and Leg Pain (CBLP), however, from an anatomical point of view, the effect of SCS can be limited towards LBP [13-15].

Recent development of 8-electrode leads, 3- and 5-column paddle leads and dual-lead stimulation systems have allowed delivering 16-electrode pulses from one IPG using novel stimulation patterns. These can be beneficial for treatment of LBP. Rigoard et al. [16]. Who used 3-column paddle leads for patients with FBSS with severe LBP, reported that they achieved stable stimulation in the lumbar region. Son, et al. [17] also mentions that for FBSS, the use of paddle leads are a factor for successful SCS trial.

In this study, all patients with LBP also had pain of the lower extremities. SCS leads were placed at the Th8-Th11 and Th11-L1 (target areas for lead placement for the pain of lumbar region and the lower extremities) [18]. Since the leads used in this study were 4-electrode leads, stimulation could only be provided to limited areas. Thus a stable stimulation could not be delivered to both the lumbar region and the lower extremities. For many patients, SCS programming parameters were adjusted to induce paresthesia at the region of pain in the lower extremities. This is possibly the reason for a poor long-term outcome seen in our patients after SCS. The new 8-electrode lead and new devices which allows for a variety of programming options enable extensive coverage of pain areas. Thus, patients with LBP can expect to receive the effects of a constant stimulation.

Chronic pain is a condition in which pain stimulation is continuously delivered from the peripheral to the central nervous system. This cause plastic changes in the nerves and alters the response to the stimuli or transmission of pain. In addition, chronic pain affects the mechanisms of pain perception and results in complex pathology that deeply involves mental/psychological factors. Therefore, pain is thought to become chronic and complex with time. This study showed that patients with long intervals between the first visit to the pain clinic and SCS implantation have a tendency of poor long-term outcome with SCS. Kumar et al. [6] reported that one of the prognostic factors was the interval between the first surgery and SCS implantation. The longer duration of pain affects long-term outcome of SCS. Thus, it is necessary to initiate an active treatment for pain at an early stage. It is essential to evaluate the mechanism of pain and determine whether the pain is indicated for SCS.

The present study was a retrospective study that focused on the review of medical records. Therefore, it was difficult to obtain information in regards to nature of pain, changes in the VAS score

and medication dosage before and after SCS implantation. Prospective investigation in a greater number of patients is required in the future.

Conclusion

Our study confirmed that SCS is a mode of effective treatment for pain in patients with FBSS. However, patients with long durations of pain prior to SCS implantation had poor long-term outcomes. Evaluation of LBP mechanisms, new approaches to LBP with latest SCS devices and leads with a variety of programming patterns are the keys to improve the long-term outcomes. Therefore, it is essential to shorten the duration of pain and determine whether SCS is indicated for the pain at an early stage.

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