Pain Physician 2024; 27:441-446 • ISSN 1533-3159

Cross-Sectional Survey

Single Institutional Cross-Sectional Phone Survey Study: Evaluation of Causes for Loss to Follow-up After Spinal Cord Stimulator Implantation

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Disclaimer: Kang, Glicksman, Ho, and Hoang contributed equally. Simopoulos and Robinson also contributed equally. There was no external funding in the preparation of this article.

Conflict of interest: Each author

Background: Spinal cord stimulation (SCS) is often an option of last resort for patients with post-laminectomy syndrome or an alternative option for patients with complex regional pain syndrome, chronic nonsurgical low back pain, or painful diabetic peripheral neuropathy when conservative management has failed. Although SCS is a helpful option, it is not without complications that can frequently lead to explantation of the SCS device and dissatisfaction with the treatment. Furthermore, as with any technology, SCS has potential issues that may lead to patient frustration and ultimately result in patient noncompliance and lack of follow-up visits.

Objectives: The goals of this study are to explore the magnitude of and reasons for patient loss to follow-up after SCS device implantation.

Study Design: A cross-sectional phone survey.

Setting: A tertiary-care academic hospital.

Methods: A cross-sectional phone survey was performed on 49 patients who were deemed lost to follow-up when they did not return to the clinic one month after being implanted with permanent SCS devices at Beth Israel Deaconess Medical Center. Patients were administered an institutional review board-approved questionnaire exploring their reasons for not returning to the clinic.

Results: Over a 5-year period, 257 patients underwent full implantation of an SCS device. Of the 49 patients lost to follow-up, 24 were able to be contacted, and they completed the questionnaire. Twenty of the patients continued to use the SCS device but were lost to follow-up for the following reasons: 58% (14/24) due to improvement of pain, 13% (3/24) due to minimal improvement in pain control, 4% (1/24) due to other urgent health conditions, and 8% (2/24) due to patient noncompliance and missing follow-up appointments (4/24). Four patients discontinued using the SCS device after an average of 1.5 years +/- one year, 12% (3/24) due to inadequate pain control and 4% (1/24) due to inability to recharge the device (1/24). Of these patients, 2 of the 4 contacted their SCS representatives for help with troubleshooting prior to discontinuation. None of the patients was explanted.

Limitations: The main limitation of this study was the incompletion rate, which was 51.0% (25 out of 49 patients).

Conclusions: This paper, the first cross-sectional study of loss to follow-up among patients who are implanted with SCS devices, identifies that up to 19% of patients are quickly lost to follow-up after implantation. Only half of the patients in this study could be reached, with most successfully using their device for meaningful pain control, but a substantial number of patients likely required additional device optimization for pain relief.

certifies that he or she, or a member of his or her immediate family, has no commercial association (i.e., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article.

Article received: 12-02-2023
Revised article received: 05-11-2024
Accepted for publication: 05-22-2024

Free full article: www.painphysicianjournal.com

Key words: Loss to follow-up, spinal cord stimulation, cross-sectional study, phone survey, pain relief, single center, chronic pain, neuromodulation

Pain Physician 2024: 27:441-446

Chronic pain afflicts 20.5% of the population of the United States, significantly encumbering a staggering 50.2 million adults' daily living activities and overall functionality (1). Of this population, an estimated 50,000 patients undergo spinal cord stimulator (SCS) implantation annually (2). The science of neuromodulation, first conceived in the 1960s, has advanced exponentially within the past decade (3,4). One type of neuromodulation, SCS, aims to alleviate chronic pain by targeting the dorsal column with electrically stimulating large-diameter Aβ neurons to disrupt neuronally derived dysregulated pain signals from smaller Aδ and C neurons (5). Since its inception, SCS has been found to be safe, reversible, and widely accepted, with well-established efficacy compared to conservative medical management and repeat lumbar surgery (6,7). Nonetheless, SCS therapy has its own drawbacks, which may result in dissatisfaction with the therapy, reoperation (including explantation), and loss to follow-up, although newer technologies and waveforms are reducing the frequency of these issues (8-11).

While numerous studies have documented the efficacy of SCS, detailing post-procedural follow-ups and degrees of improvement in patient-reported pain, function, and psychological sequelae, an ongoing problem has been seen with this type of treatment: the attrition of patients during follow-up (12-17). Previous studies have attempted to investigate the characteristics of patients who have the propensity to be lost to follow-up after the completion of pain treatments (18). However, to our knowledge, there has not been a study evaluating why patients are lost to follow-up shortly after the implantation of SCS devices specifically.

We hypothesized that patients may choose not to follow up for reasons including but not limited to the presence or absence of pain relief, various SCS-related complications (e.g., loss of efficacy or loss of stimulation coverage, dissatisfaction with the amount of pain relief), patient noncompliance, or patient relocation (19,20). As such, the goal of this study was to explore the causes of loss to follow-up for patients who were implanted with permanent SCS devices in a single large-center institution over a 5-year period.

Methods

Study Design and Setting

A retrospective chart review that had received institutional review board approval (Protocol #2018-P-000081) was performed on 257 patients who, between 2016 and 2021, were implanted with permanent SCS devices by 2 experienced interventional chronic pain specialists. Forty-nine of the 257 patients did not return to the clinic for further appointments after the one-month post-procedure follow-up visit, so those patients were eventually deemed lost to follow-up. Therefore, those patients had no contact with the pain center for a minimum of one year and a maximum of 5 years, depending on the time the implantation occurred. These 49 patients were then contacted via telephone calls that utilized a standardized verbal script. During the phone call, the following were explained: (1) the reason for conducting the clinical study, (2) protection of patient confidentiality, (3) that participation was voluntary and patients were free to withdraw from the study at any time, (4) absence of association between participation and future care, (5) our intent to evaluate and potentially publish the findings, and (6) contact information for the Beth Israel Deaconess Medical Center Human Subject Protection Office in case patients had any additional questions or concerns. If patients con-

sented to participate, they were then asked a series of questions relating to pain relief (or lack thereof) and use of the SCS device (Appendix). The number of phone calls and attempts were tabulated. If we made more than 3 attempts to contact a patient without receiving a response or a patient opted to withdraw during the conversation, the effort was considered incomplete and no further attempt was made.

Results

Between 2016 and 2021, a total of 257 patients underwent permanent SCS implantation by one of 2 experienced interventional chronic pain specialists at our institution. Of these 257 individuals, 49 (19.1%) were deemed lost to follow-up (Table 1). Their mean age was 60.1 +/- 11.9 years, with 29 women (59.2%) and 20 men (40.8%). Post-laminectomy syndrome (PLS) was the leading diagnosis (53.1%). The patients' demographics are detailed further in Table 1 and Appendix Tables A and B.

Of the 49 individuals who were lost to follow-up, 24 were able to be reached during this study, and they successfully completed the study questions and associated questionnaires (Table 1). Approximately 10% of patients originally implanted could not be reached. However, reaching the 24 patients who would later participate in the study required an average of fewer than 2 calls. These patients had a mean age of 62.7 +/- 11.8 years. Thirteen were women (54.2%), and 11 were men (45.8%) (Table 1). The leading diagnosis of these patients was PLS (50.0%), followed by chronic lumbosacral radiculopathy (29.2%). Three patients held more than one diagnosis (Appendix B).

Of the 24 patients who were able to be reached during the study, 14 (58.3%) reported that they did not follow up due to an improvement in pain, while 3 (12.5%) reported that they did not follow up due to little to no improvement in pain (Table 2). Four of the 24 patients did not follow up due to patient relocation (16.7%). Of the 3 remaining patients in the complete group, other pressing health conditions (4.2%) and noncompliance with scheduling and attending appointments (8.4%) were listed as reasons for not following up (Table 2).

In total, 4 patients (16.7%) reported that they were no longer using their SCS devices. These patients reported that they discontinued using the SCS device at a mean of 1.5 +/- one years after the implantation. Of these 4 patients, 3 (75%) reported a lack of pain control as their reason for discontinuing their use of the SCS device, while one patient (25%) reported difficulty charging the device due to electrical issues at home and ultimately underwent spinal surgery. Two of these patients reported that they contacted their representative prior to discontinuing their use of the SCS device (Table 2).

The other 25 patients (51.0%) were documented as incomplete after 3 unsuccessful phone call attempts or because the patients chose to withdraw during the conversation (Table 1). Twenty-two patients did not an-

Table 1. *Information on patient demographics.*

	Complete	Incomplete
Number of Patients	24 (49.0%)	25 (51.0%)
Age (mean +/- SD)	62.7 +/- 11.8 years	53.7 +/- 18.6 years
Gender (M:F)	11:13	9:16
Diagnosis*		
Chronic lumbosacral radiculopathy	7 (29.2%)	4 (16.0%)
CRPS 1	2 (8.3%)	3 (12.0%)
CRPS 2	5 (20.8%)	4 (16.0%)
Diabetic neuropathy	1 (4.2%)	0 (0.0%)
PLS (back)	12 (50.0%)	14 (56.0%)
PLS (neck)	0 (0.0%)	2 (8.0%)

*Three patients in the complete group and 2 patients in the incomplete group held more than one diagnosis, as shown in Appendix Table A. CRPS 1 = complex regional pain syndrome 1; CRPS 2 = complex regional pain syndrome 2; PLS (back) = post-laminectomy syndrome of low back; PLS (neck) = post-laminectomy syndrome of neck; SD = standard deviation.

Table 2. *Information on 24 patients who completed the survey and were lost to follow-up.*

Patients using SCS	
Reasons for Not Following Up	20/24 (83.3%)
Improvement of pain	14/24 (58.3%)
Little to no improvement of pain	3/24 (12.5%)
Patient relocation	4/24 (16.7%)
Other pressing health conditions	1/24 (4.2%)
Noncompliance with scheduling and attending appointments	2/24 (8.4%)
Patients No Longer Using SCS	4/24 (16.7%)
Reasons for Stopping SCS	
Not effective at controlling pain	3/4 (75%)
Difficulty charging device and subsequent spinal surgery	1/4 (25%)
Length of Time Before Stopping SCS (Mean + SD)	1.5 + one years
Percentage of Patients Who Stopped Using SCS and Who Contacted Representative	2/4 (50%)

swer any of the 3 attempts (88.0%), one patient repeatedly stated that the call did not arrive at a good time to talk (4.0%), and 2 patients (8.0%) opted out of the study during the last phone call. Due to incompletion, no information pertaining to those patients' initial failure to follow up could be obtained.

Discussion

In the US health care system, factors such as younger patient age, physician transitions, and markers of social vulnerability have been observed to have significantly associations with patient loss (21). We recognize that individuals struggling with chronic pain are often inundated by distressing symptoms that amplify their psychiatric burdens and elevate their overall medical complexity. In the realm of the health care system, it is imperative to gain a deeper comprehension of this phenomenon, with a focus on the overarching objective of enhancing patient care comprehensively and ultimately potentially alleviating the strain on the infrastructure of health care (21).

An extensive review of the medical literature reveals a paucity of data exploring the underlying factors that contribute to loss to follow-up after the permanent placement of SCS devices and among other health conditions (22–24). Of the 49.0% (24/4) of patients who completed the survey, 58.3% (14/24) chose not to follow up because they experienced improvements to their pain symptoms. For those patients who reported little to no improvement and had device-related issues, multiple actions would have been key to improving their overall outcomes: managing expectations, setting the patients up with the devices' representatives, and educating the patients on knowing when to reach out to the representatives, and the options for optimizing pain relief. These findings underscore areas in which improvements may be needed. Leveraging newer technologies may cause fewer patients to be lost to follow-up, and those who have dysfunctional devices can seek troubleshooting assistance, which may allow those patients some level of pain control or revision of the implant (25-28).

Newer technologies, such as the cloud-connected Prospera™ SCS System with Embrace One™, may allow SCS-related issues to be addressed more quickly (29). For example, SCS-related issues in cases involving the Prospera™ SCS System that were either triggered by that system or raised by the patient were resolved within 1.9 days, whereas issues in cases involving other SCS systems required 7.2 days to resolve (29). Although SCS is about using neuromodulation to address patients' pain, the ability to resolve issues and deliver expedited customer service by company representatives may also result in improvement of patients' overall states, clinician efficacy in providing patient care, and patients' perception of the outcomes of their treatments (30,31). Moreover, the chronic pain physician may also assess the status of the SCS device and its utilization through a central remote monitoring application and may bill, when appropriate, for remote therapeutic monitoring, adding another step in preventing patients from being lost to follow-up (10). Data gathered through evaluation of the patients lost to follow-up may further guide future studies in developing interventions that can potentially improve the understanding of solutions for targeting this population (32).

Limitations

The main limitation of this study was the high incompletion rate, i.e., a rate of 51.0% (25 out of 49 patients). We systematically reached out to these patients at various times throughout the day, acknowledging that, due to certain constraints, some individuals might have been inadvertently missed during typical waking hours and that other factors might have also prevented patients from answering. At least 3 outreach attempts were made, and those that did not result in replies from patients were documented as incomplete. Because this study was descriptive, there were no concerns regarding generalizability, since our aim was to provide some insight behind the reasons why loss to follow-up occurred in our specific patient population.

Conclusion

Our study demonstrates that a significant proportion of patients are lost to follow-up shortly after the implantation of SCS devices. While most surveyed patients elected not to follow up because of adequate pain control, an appreciable number remained suboptimally treated and made no attempt to establish return visits to the clinic. Contacting implanted patients proved to be a moderately successful approach to making other strategies available for optimizing treatment outcomes for SCS patients.

In recent years, the neuromodulation community has demonstrated a commitment to delivering innovative strategies that may potentially address the issue at hand. As the trend of remote monitoring for newer devices grows, expert recommendations pertaining to the remote management of SCS de-

vices have been published, exploring the prospect of promptly identifying and resolving SCS-related issues (10). This advancement offers not only the opportunity to rectify suboptimal pain relief proactively but also the ability to detect and address any anomalous data points associated with patients' device usage. As we endeavor to enhance our patients' daily quality of life through sustainable modalities, we should actively leverage this information as a foundation for further progress (10).

Acknowledgments

We would like to thank Valerie Goodspeed, Anna Fratello, Kelly Lee, Philip Zhang, Abeer Santarisi, MD, Nikita Moreira, Anna Hu, Megan Borrell, and Juan Pablo Espinosa Leon, MD for their assistance in this project.

Author Contributions

KK, MG, JH, and KH analyzed the data and wrote and edited the manuscript. AP, SM, JH, CY, AF, AK, MS, and JG assisted in writing, editing, and providing expert guidance. TS and CLR planned the project, analyzed the data, and wrote the manuscript.

Supplemental material is available at www.painphysicianjournal.com

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Appendix

Patient Questionnaire for Phone Call

1. Which of the following was your reason for not following up after your spinal cord stimulator was placed?
    a. Improvement of pain
        i. If yes, go to 2.
    b. Little to no improvement of pain
        i. If yes go to 6.
    c. Problem with the spinal cord stimulator
        i. If yes, go to 10.
    d. Other (please explain)
        i. Go to 9.
2. Are you still using the device?
    a. Yes
        i. If yes, go to 4.
    b. No
        i. If no, go to 5.
3. Are you still getting pain relief from the spinal cord stimulator?
    a. Yes
    b. No
4. What is the reason for no longer using it?
    a. Pain no longer exists
    b. Little to no improvement of pain
    c. Problem with the spinal cord stimulator
    d. Other (please explain)
5. Approximately how long did you try the spinal cord stimulator before stopping?
    a. One week
    b. One month
    c. One year
    d. Other
6. Did you reach out to your representative to troubleshoot your device?
    a. Yes
        i. What is your best estimate of how many times you have met your representative?
    b. No
        i. What was your reason for not reaching out?
7. Which of the following is your reason for not using the device?
    a. Battery life (includes frequent recharging)
    b. Not effective at controlling pain
    c. Other
8. If other, please explain.

Appendix Table B. *Additional demographic information, including race, education status, employment status, ease of use of the SCS device, whether patients were using opioids to treat their pain, and psychosocial factors. *All under treatment.*

	Completed	Did Not Complete
Race		
White	83.3% (20/24)	92.0% (23/25)
Black	8.3% (2/24)	4.0% (1/25)
Declined to Answer	8.3% (2/24)	4.0% (1/25)
Education Status		
High School Degree/General Educational Diploma	29.2% (7/24)	40.0% (10/25)
Vocational/Technical Degree	20.8% (5/24)	12.0% (3/25)
College/Graduate Degree	33.3% (8/24)	40.0%% (10/25)
Declined to Answer	16.7% (4/24)	8.0% (2/25)
Employment Status		
Employed	54.2% (13/24)	48.0% (12/25)
Unemployed	16.7% (4/24)	12.0% (3/25)
Retired	20.8% (5/24)	16.0% (4/25)
Disabled	0.0% (0/24)	20.0% (5/25)
Unknown	8.3% (2/24)	4.0% (1/25)
Ease of Use for the SCS?		
Yes	100.0% (25/24)	88% (22/25)
No	0.0% (0/24)	12% (3/25)
On Opioids for Pain		
Yes	75.0% (18/24)	72.0% (18/25)
No	25.0% (6/24)	28.0% (7/25)
Psychosocial Factors*		
Attention-deficit/hyperactivity disorder	0.0% (0/24)	4.0% (1/25)
Adjustment/post-traumatic stress disorder	4.2% (1/24)	4.0% (1/25)
Bipolar disorder	4.2% (1/24)	0.0% (0/25)
Major depression	33.3% (8/24)	20% (5/25)
None	58.3% (14/24)	72.0% (18/25)