

General

A Survey on the Choice of Spinal Cord Stimulation Parameters and Implantable Pulse Generators and on Reasons for Explantation

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Objective

Spinal Cord Stimulation (SCS) is a vital treatment for chronic intractable pain. In the last few years, the field has undergone dramatic changes in new waveform and frequency introduction as well as device miniaturization. It is important to understand contemporary practice patterns regarding these parameters.

Methods

We surveyed the active membership of Spine Intervention Society (SIS), and American Society of Regional Anesthesia (ASRA) on their practices regarding various aspects of Spinal Cord Stimulation therapy. Here we report on SCS waveform usage, battery types, and causes of explant in this cohort of providers.

Results

There was similar degree of usage of tonic, burst, and 10 kHz usage at 71.5%, 74.1% and 61.7% respectively. Dorsal root ganglion stimulation was used by 32.6% and other modes of stimulation by 13.5%. Rechargeable systems were often or always used by 67.2% whereas 10% never used a rechargeable system. Most common cause of explant was loss of effectiveness, reported by 53.7%.

Conclusion

There has been significant adoption of new waveforms in daily practice of spinal cord stimulation therapy and there is robust mixed usage of new waveforms and frequencies. Rechargeable systems are the most commonly used but primary cell is also used in significant numbers. Loss of efficacy remains the most common cause of explant for the majority of practitioners. This survey establishes practice patterns of SCS usage regarding these important variables against which future changes can be gauged.

INTRODUCTION

Spinal Cord Stimulation (SCS) is an important therapy for chronic intractable pain. Multiple studies have demonstrated efficacy even after exhaustion of all conventional therapies.^{1,2} SCS is particularly effective for the management of neuropathic pain, with primary indications of post-laminectomy syndrome and complex regional pain syndrome.

Recently, technological breakthroughs have expanded the analgesic effectiveness of SCS and have provided superior outcomes compared to traditional tonic spinal cord

stimulation.³⁻⁵ Sub perception SCS in the forms of 10 kHz and burst have been evaluated in multicenter trials; demonstrating superior outcomes compared to tonic SCS. In addition to new waveforms, other device improvements have occurred including advances in primary cell technology. Primary cells are smaller and can last longer, thus becoming suitable especially for systems with low energy needs. This is exemplified well in the dorsal root ganglion stimulation.

The development of new approaches to electrical neuromodulation grew in part out of the recognition that traditional SCS device failure was due to loss of efficacy, pares-

thesia complications such as unwanted stimulation or poor somatotopic overlap, and hardware and biological complications.^{6,7} Explant rates have ranged from 7.6% to 30%.⁷⁻⁹ Loss of analgesic efficacy has been cited in the past as the most common reason for explantation. Thus, overcoming the limitations of paresthesia with the adoption of newer waveforms may shift the reasons for explantation of SCS devices.

We conducted a survey evaluating the practice patterns of physicians performing SCS therapy. There is a dearth of recent reports on the delivery of SCS therapy—specifically the choice of stimulation parameters and the choice of implanted pulse generator. We sought to provide quantitative information on these practice decisions and the perceived reasons for explant as exit from SCS therapy. These are very important aspects of SCS therapy and understanding how our peers practice creates opportunity for evaluation and improvement on one's own practice. We chose these as a separate topic to allow focused analysis and discussion.

METHODS

We created a survey with questions related to various aspects of spinal cord stimulation practice based upon topics of interest to the SCS community. It was submitted and approved by the Institutional Review Board and, subsequently, approved by the Boards of American Society of Regional Anesthesia (ASRA) and Spine Intervention Society (SIS). We could not send the survey to a dedicated neuromodulation society because of logistical reasons. The recipients (the active members of these societies) were invited for the survey through an email requesting their anonymous participation in a survey by clicking on a Survey Monkey link. They were informed that the survey was regarding the practice parameters of interventional pain physicians who perform spinal cord stimulator trials or implants. Since a significant number of physicians who received the email may be members of both societies, the recipients were asked to only complete the survey one time. In this review, we present the findings covering waveform usage, battery types, and the most common cause of explant in practice. The other important aspects of SCS therapy will be presented separately. We included dorsal root ganglion stimulation under SCS because of the overlap in diagnoses treated by this modality. The three questions were:

1. What type of stimulation do you utilize in your practice? (you may select more than one answer).
 - Choices included: tonic, burst, 10 kHz, dorsal root ganglion or other wave forms
2. Do you ever implant rechargeable batteries?
 - Choices included: always, often, sometimes, never.
3. What is the most common cause of explant in your practice?
 - Choices included: paresthesia intolerance/disconcordant, loss of effectiveness/tolerance, need for magnetic resonance imaging (MRI), biological complications such as IPG pain, device

complications such as lead migrations or lead fracture.

RESULTS

The survey was sent to 2967 members of SIS with 1259 opening the email and 3169 members of ASRA with 1477 opening the email resulting in 6136 emails sent and 2736 emails opened. The true response rate is unknown since the overlap in the membership of the societies is not known. Additionally, since these are not dedicated neuromodulation societies, the proportion of membership practicing neuromodulation is also not defined.

The survey responses were received between March, 20, 2020 and June 26, 2020 with 193 responding to question 1, 180 responding to question 2, 188 responding to question 3.

[Table 1](#) presents the proportion, percent, and 95% confidence interval (CI) of clinicians using different waveforms demonstrating similar usage of tonic, burst and high frequency between 60-75%. DRG stimulation was used by 32.6% of the recipients.

[Table 2](#) shows the type of battery used with 67.2 using rechargeable systems often or always and 10% using non rechargeable exclusively.

[Table 3](#) shows the most common cause of explant. Physicians continue to identify loss of efficacy as the primary reason for explantation of SCS devices (53.72%). There were still significant reports of biological (12.2 %) and device complications (20.7%) that necessitated removal.

DISCUSSION

Practice patterns of physicians who utilize spinal cord stimulation reveals robust mixed usage of contemporary waveforms and frequencies. There may now be more adoption or return to primary non-rechargeable IPGs but the primary driver of explantation remains loss of analgesic efficacy. Taking these survey findings into consideration, we will briefly review the literature in this regard for each aspect and attempt to provide a rationale for the observations as well as a brief review of therapies.

CLINICAL ADOPTION OF MODES OF SPINAL CORD STIMULATION

SCS waveforms and frequencies have recently undergone a dramatic transformation. SCS was initially introduced as a tonic and paresthesia-based technique. The gate control theory suggested that by stimulating the large myelinated A-beta fibers in the dorsal column and creating non-painful paresthesia in the area of pain, the entry of painful impulses was inhibited. There are other mechanisms proposed for the effect of SCS on pain, however paresthesia overlap remains essential to pain relief during tonic stimulation. The central focus on optimization of paresthesia as the core driver necessary for pain relief did not lend itself to consider alternative SCS waveforms as a potential therapeutic alternative for 40 years following its inception. Dur-

Table 1. Modes of Spinal Cord Stimulation Reported by Implanting Physicians: 193 responses

Type of Stimulation	Tonic	Burst	10 kHz	DRG	Other
Responses	138	143	119	63	26
%	71.5	74.1	61.7	32.6	13.5
95% CI	(65.1-77.8)	(67.9-80.2)	(54.8-68.5)	(26-39.3)	(8.6-18.3)

Note: Practitioners could select as many types of stimulation methods used in their practice.

Burst: May refer to different types used by manufacturers.

DRG: Dorsal root ganglion

Other: Other modes of stimulation

Table 2. Reported Use of Rechargeable Implantable Pulse Generators by Implanting Physicians Survey Data :180 responses

	Never	Sometimes	Often	Always
Responses	18	41	77	44
%	10	22.8	42.8	24.4
95% CI	(5.6-14.3)	(16.7-29)	(35.6-50)	(18.2-30.7)

Table 3. The Most Common Reason for Spinal Cord Stimulator Device Removal as Reported by Implanting Physicians from Survey Data

Cause of Explant	N 188
Paresthesia side effects: intolerance/ disconcordance % 95% CI	8 4.3% (1.9-8.2)
Loss of effectiveness % 95% CI	101 53.7% (46.3-61)
Need for magnetic resonance imaging (MRI) % 95% CI	10 5.3% (2.1-8.5)
Biological Complications % 95% CI	23 12.2% (7.9-17.8)
Device Complications % 95% CI	39 20.7% (15.2-27.3)
Other % 95% CI	7 3.7% (1.5-7.5)

IPG: Implantable Pulse Generator

ing these 4 decades, there were significant limitations to tonic SCS that were recognized as unlikely to be overcome by additional stimulating contacts or by combining SCS with peripheral nerve stimulation. Such limitations included:

- Poor paresthesia topographical pain coverage
- Unwanted paresthesia overlap of non-painful regions
- Unpleasant paresthesia sensations
- Positional variation with active paresthesia stimulation
- Paresthesia interferes with ability to physically function or sleep

- Paresthesia ceases to offer relief on temporary trial or long-term

Both burst modes and high frequency 10 kHz were introduced with the hopes of eliminating or significantly reducing all of these shortcomings of the classic tonic mode of SCS. Burst stimulation was introduced potentially to emulate neuronal firing modes and as another sub-paresthesia modality to control pain. Burst stimulation which has been best studied at five pulses with internal frequency of 500 Hz delivered at 40Hz with an intervening passive recharge phase has demonstrated superiority to tonic for mean pain intensity reduction and was preferred by the majority of the patients.⁵ Additionally, it may modulate the affective component of pain. The leads are usually placed in a similar manner for tonic stimulation and both modes may be used. The interchangeability between tonic and burst programming together with procedure similarity may account for the current high use of this mode reported in the current survey.

The field of spinal cord stimulation was dramatically changed by the introduction of paresthesia independent 10 kHz spinal cord stimulation. The system was approved for use in the European Union in 2010. Initial studies were done in Europe.^{10,11} The first pragmatic Randomized Controlled Trial (RCT) in the USA appeared in 2015, showing superiority of high frequency 10 kHz stimulation over tonic stimulation both for axial low back as well as leg pain.³ In addition to superior outcomes the axial back pain responder rate was 80% in the paresthesia free group. 10 kHz stimulation utilizes anatomical lead placement and paresthesia is neither obtained nor needed. Some physicians are utilizing deeper levels of sedation during 10 kHz stimulation placement as there is no need for paresthesia overlap for these cases.¹² Typically, the algorithm for programming for low back and leg pain starts at a bipole overlying the T9-10 disc space and then moving further away based upon the response. Other sites are used for other locations of pain such as abdominal pain, neck, and arm pain.^{13,14} The waveform has a pulse width of 30 microseconds delivered at 10

kHz with clinically used maximum amplitude of 3.5mA. The proposed mechanism of action of 10 kHz is still being investigated. It has been shown that paresthesia overlap does not affect outcomes with the system.¹⁵ The advantage of this system includes easier placement, avoidance of paresthesia side effects such as mismatch or unwanted stimulation as well as possibility of superior pain relief. However, the system, when used continuously at 10 kHz, needs to be charged daily. High clinical evidence has led to a quick adoption of this paradigm changing SCS delivery as is evident in this study.

Dorsal root ganglion stimulation was also developed to treat focal pain in the lower extremities that was frequently challenging to manage with tonic SCS. DRG stimulation was introduced to modulate the DRG and chronic pain. The lead or leads are placed proximate to the target DRG. In a prospective randomized trial DRG stimulation was compared to tonic stimulation in complex regional pain syndrome (CRPS) and shown to provide greater efficacy, patient satisfaction, and many subjects could attain pain relief at a sub threshold level.⁴ Despite some of the additional training and experience necessary to perform the DRG procedure, there has been significant adoption into clinical practice.

Other newer approaches to interlacing tonic with other waveforms such as burst and high frequency are in their infancy. In addition to new modes, tonic stimulation has also undergone significant evolution. A neural targeting study using electronic models to target an anatomic “sweet spot” demonstrated a responder rate of 71% for axial back pain. This was superior to a retrospective cohort using older tonic stimulation mode.¹⁶ Other modes of tonic stimulation include high dose stimulation. Differential target multiplexed stimulation targeting the interaction of the neuroglia appears to be another promising SCS mode.¹⁷ Another improvement in SCS technology is the development of closed loop SCS where the evoked spinal cord compound action potential is continuously measured and current adjusted to maintain stimulation in the therapeutic window. A prospective study demonstrated closed loop SCS as superior to open loop SCS.¹⁸ Finally, SCS systems that are capable of delivering multiple modes including tonic, burst, and high frequency sub-paresthesia simultaneously have also been approved and may be of further benefit.¹⁹ The proportion of physicians utilizing other modes in this survey was only 13%, it will be interesting to see how this changes as evidence of effectiveness evolves.

RECHARGEABLE VERSUS PRIMARY CELL

Historically the SCS impulse generator was implanted and powered by an external power source. With advances in technology, and miniaturization of size, the battery could be internalized and combined with the internal pulse generator. This obviated the need for carrying an external battery. The rechargeable systems were then introduced with potential to deliver more energy and use more bipoles. The battery can be charged by induction with frequency of charging based upon the power needs of the patient. With high energy settings such as 10 kHz system, high amplitude

tonic stimulation, and high-density stimulation, rechargeable systems with frequent charging are needed.

Consistent with new waveform and high frequency use patterns, 67.2% of the respondents always or often use rechargeable batteries. It is interesting that 10% of the respondents never use rechargeable batteries and 22.8% use rechargeable batteries only occasionally. It is possible that this 10% cohort is using burst or dorsal root ganglia stimulation or low energy tonic stimulation or other sub-paresthesia modes that would make a primary cell acceptable. Conversely, 24.4% use exclusively rechargeable IPGs suggesting high frequency use or multi-modal programming. Other factors also influence choice of IPGs so we cannot firmly conclude that IPG preferences are based on modes of SCS.

In addition to high energy delivery capability, other factors supporting use of rechargeable systems may be the fact that these are smaller than primary cells and have the potential to last more than 10 years when functioning ideally. This can be dependent upon the vendor and the robustness of the system. Longer cell life may mean lower reoperation rates which exposes the patient to further risks such as infection. A recent survey of 1177 implants retrospectively analyzed over a decade found favorable effect of rechargeable SCS systems on explantation rates.²⁰ Cost benefit analysis would favor a rechargeable system, but another study has shown that rechargeable systems are explanted earlier undermining the cost benefit analysis.⁶ It was postulated that this may represent device maintenance burden of daily charging with a system that may not be very effective. This could also relate to different indications in which a primary cell was placed as a majority of the systems in this retrospective cohort were rechargeable.⁶ The major inconvenience of rechargeable systems is the dependence upon charging. When considering low energy modes such as pulse dosing, burst stimulation, and DRG stimulation there is the option for using a primary cell. The option of not charging is very attractive to the patient and provides a great deal of independence, but benefit must be balanced with likely earlier reoperation for battery replacement and additional risk of infection, complication as well as increased cost. Thus, it is no surprise that physicians are with significant variation on type of IPG used in clinical practice.

CAUSES OF EXPLANT

The rate of spinal cord stimulator device explant in US is reported to be from 24% over an eight-year period to 30% over a thirteen-year period.⁷⁻⁹ Most explants occur in the first few years of the therapy initiation. Studies point to loss of efficacy as the primary cause of explant. Other major causes include biological complications such as infection, pocket pain or hardware related problems such as device malfunction, lead migration or lead fracture. The need to obtain an MRI and remission of pain are less frequent causes of explant.^{6,7}

Consistent with this data, most practitioners reported loss of efficacy as the most common cause of explant (53.72%) in their practice. Recent data supports loss of ef-

ficacy as the most common long-term cause of explantation, accounting for upwards of 65% of device removal.²⁰ Device complications and biological complications were reported as a major cause by 20.7% and 12.2% practitioners respectively. It is interesting that device complications as well as biological complications were the major cause of explant for a significant minority, this may just pertain to recall bias, or this may point to an opportunity for practice improvement for these practitioners.

To deal with loss of SCS analgesic efficacy, physicians are adopting novel frequencies, waveforms, multi-wave platforms, and the ability to use multiple programs. One recent retrospective study lends support to this approach suggesting that usage of 10 kHz and multiple wave forms may decrease the risk of device removal.²⁰ However, the addition of new pain conditions that can be treated with SCS novel modes of stimulation could lead to a higher rate of explant as the efficacy of SCS for these novel conditions remains poorly studied.

Moreover, device complications represented a significant reason for removal. Hardware failures have led to the development of more robust systems such that this problem can be mitigated e.g., multi-lumen leads have been shown to be fracture resistant and anchor design can also mitigate fracture rate.²¹ In addition, following good infection control protocols in addition to reduction in device size may further minimize wound infection and/or pocket pain.²²⁻²⁴ With most devices now MRI conditional, the need to explant a device to obtain an MRI should also be resolved.

This study has several limitations including variable response rates given overlap between society membership and incomplete responses to questions. Logistical reasons prevented this survey from being administered to dedicated neuromodulation societies that may have improved the accuracy of the response rate of recipients who perform neuromodulation procedures. Additional limitations inherent to surveys of this nature is dependence on clinical perception and recall rather than objective data. However, the study does give a real-world insight on the evolving use of SCS stimulation modes, IPG use, and the causes of explantation.

CONCLUSION

The responses from nearly 200 unique practitioners who perform SCS and are active members of national societies reveals that new frequencies and waveforms have already been adopted in day to day clinical practice. Consistent with the diversity of modes, rechargeable systems remain the most common systems used and the majority of SCS practitioners reveal that loss of effectiveness remains the most common cause of device explant and is consistent with the published literature in this regard. This survey establishes practice patterns of SCS usage in regard to these important variables against which future changes can be gauged.

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