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Abstract

Objective. The concept of neuromodulation via the use of spinal cord stimulators (SCS) was first established over forty years ago. Since then, its popularity has grown as numerous studies have demonstrated its utility to reduce chronic pain, improve patient function, and reduce long-term health care costs. The aim of this study was to update the pain medicine community on the evolution of SCS practice trends in academic centers.

Design. Ninety-three pain medicine fellowship programs in the United States were identified from the Accreditation Council for Graduate Medical Education Website and were contacted to participate in an internet survey. A 37-item questionnaire was inspired by a previous study performed by Fanciullo et al. Questions focused on three main themes regarding SCS clinical application, namely demographics, education, and technical matters.

Results. Completed surveys were received from 50 institutions, all of which reported performing SCS interventions. Annual implants ranged from 0 to 150. Fellowship training was cited as the most valuable modality for learning implantation. Nearly all programs reported manufacturer representative participation during SCS procedures, with a minority of program directors discouraging their involvement in fellow education. SCS trials were performed exclusively on an outpatient basis. The average length for trials was 4–7 days. The most common indication for SCS implantation was failed back surgery syndrome, which also had the highest 2-year success rate. Post procedure, patients generally were followed up every 2–4 weeks for device reprogramming, which was performed by company representatives 92% of the time.

Conclusion. Standardized SCS training is imperative as the implementation of neuromodulation therapy continues to increase.

Key Words. Spinal Cord Stimulation; Neuromodulation; Pain Fellowship; Survey

Introduction

In 1967, based upon the “gate theory” proposed by Melzack and Wall, Shealy et al. implanted the first spinal cord stimulator (SCS) device and demonstrated that pain signal transmission can be inhibited by electrical stimulation [1]. Since then, SCS technology and implementation have advanced a great deal, with more than 14,000 SCS implantations performed worldwide each year [2]. The most commonly reported indication for SCS use in the United States is failed back surgery syndrome (FBSS); however, it has been used successfully to treat complex regional pain syndrome (CRPS), diabetic neuropathy, radiculopathy, phantom limb pain, spinal cord injury related pain, arachnoiditis, peripheral vascular disease, intractable abdominal pain, and recurrent angina pectoris [3–15]. Contraindications to implantation include psychological unsuitability (significant depression, anxiety, or personality disorder), non-neuropathic pain, bleeding disorders, or anticoagulation therapy [16]. The ultimate objective of spinal cord stimulation is to decrease pain that
Survey of Academic SCS Practices

Methods

Once an institutional review board approval was obtained, a 37-item questionnaire was constructed, which was based upon a modified version of the 1999 survey distributed by Fanciullo et al. The 93 anesthesiology pain fellowship programs and their respective program directors were identified via the official ACGME Website. Each program director was e-mailed a cover letter describing the study, along with a hyperlink providing access to the secure survey Website. Two weeks after the initial e-mail was sent, a follow-up notification was e-mailed. At week four, in conjunction with a third e-mail, a telephone call was made to each program director’s secretary as a reminder for the study to be completed. At week six, non-responding institutions were contacted via a fourth e-mail and a second telephone call was made. Additionally, two responses were recorded via paper. Data collection spanned from October 2011 to March 2012. Responses that were unclear or incomplete were not interpreted or considered in the calculation of percentages. If answers were given as ranges, the averages were tallied and used in the final computations.

Each program’s reply was noted by their internet protocol address logged by the survey Website. Only the investigators had access to this information; however, no participant’s name could be directly identified. Programs that did not respond were noted and contacted according to the previously mentioned protocol. Anonymity was sacrificed, in a few cases, in an attempt to amass as many responses as possible.

The questionnaire was constructed in three sections (Appendix 1). It consisted of some of the same questions and expanded upon others originally posed by Fanciullo et al. The first portion focused on demographics, including the number of fellows at particular centers, the number of practicing anesthesiologists, whether or not they performed SCS procedures, and if so, how many. The second segment outlined specifics related to education and procedural matters, such as the number of SCS trials/implantations performed by the anesthesia department including who is deemed the most valuable trainers of SCS implantation, manufacturer presence during implantation, success rates based on indication, and the role of psychologists in screening and follow-up. The final inquiries related to technical issues, namely length of trial time, role of manufacturer presence at trials, how leads are secured, hospital length of stay for trial and permanent implantation, parameter settings, battery and lead types, the role of surgeons during implantation, instrument revision rates, and follow-up care.

Results

Completed questionnaires were received from 50/93 (54%) program directors. The number of faculty in the pain practices totaled 324 (range 1–25), with an average of 6.48 per program. Of these, 67% reported that they implant and/or trial SCS. Of note, every program had at
least one person on staff performing implantations and/or trials (range 1–20). The estimated number of annual SCS trials ranged from 5 to 200, with an average of 46.12 per program or 7.12 per attending. Permanent implantations ranged from 0 to 150, with an average of 32.44 per program or 5.01 per attending. Overall, 71.43% of SCS trials were deemed successful, with 87.28% of those progressing onto permanent implantation.

There were 193 available fellowship positions (range 1–8), with an average of 3.86 trainees per program. Program directors were asked to rank the first, second, and third most important resources for SCS implantation education. Pain fellowship training was cited most valuable by 89.1% of the respondents (Table 1). Manufacturer-sponsored workshops were felt to be the second most beneficial tool by 64.4% of directors. Lastly, nearly 70% of directors agreed that continuing medical education conferences were the least significant resource. Programs reported a nearly unanimous attendance by manufacturer representatives during the SCS trials and permanent implantations, with average rates of 97.96% and 97.92%, respectively. Generally, program directors were in favor of manufacturer’s involvement in the training of fellows, with only 29.2% reporting they were against this practice. Furthermore, 91.84% of directors listed representatives as the primary provider for device reprogramming when indicated.

SCS trials were exclusively performed as an outpatient procedure with a few programs admitting permanent implantations for overnight observation. Survey question 12 listed several medical conditions commonly treated with SCS implants, and respondents were asked to rank the frequency of utilization. Question 13 followed a similar format but focused on success rates for a given diagnosis. Both were rated on a 1–5 scale, where the lower average rating indicated more frequent use and higher success rate, respectively. The most common indication for an SCS trial was FBSS, with CRPS receiving the vast majority of second place votes (Table 2). FBSS was felt to have the highest 2-year success rate and received 52.08% of first place votes, followed again by CRPS, which had a large number of first place votes but had an overall higher average rating (Table 3).

Eighty-seven percent of respondents referred to a psychologist/psychiatrist before the SCS trial. Ninety-one percent of patients received a trial preimplant, with only 2.1% proceeding to implantation the same day. Nearly 85% of practitioners felt 4–7 days were required in order to deem an SCS trial successful. Trial leads were secured to the skin by a combination of methods, including suturing (61.7%), taping (51.1%), and/or tunneling (12.8%). Cylindrical octapolar dual leads were predominantly used. The most important factor listed in battery selection was patient preference, with 77.28% of people choosing a rechargeable model. Thirty-five percent of pain physicians performed implantations independently. When requiring the assistance of a surgeon, the most frequently cited reason was to perform a laminotomy. Only 6.5% of

<table>
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<tr>
<th>Table 1</th>
<th>Most valuable source of fellow spinal cord stimulator training</th>
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<tr>
<td></td>
<td>Most Valuable</td>
</tr>
<tr>
<td>Fellowship</td>
<td>89.1% (41)</td>
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<tr>
<td>Manufacturer-sponsored workshops</td>
<td>13.3% (6)</td>
</tr>
<tr>
<td>Conferences</td>
<td>4.7% (2)</td>
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Please rank the value of each category, from most to least valuable, in educating pain medicine fellows in trialing and implantation of spinal cord stimulators. The most common choice for each category is displayed in bold. (N = 49).

<table>
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<th>Table 2</th>
<th>Most common indication for SCS trials</th>
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<tr>
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<td>1</td>
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<tr>
<td>Failed back syndrome</td>
<td>87.5% (42)</td>
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<tr>
<td>CRPS I, II</td>
<td>2.13% (1)</td>
</tr>
<tr>
<td>Chronic radiculopathy (no past surgery)</td>
<td>5% (2)</td>
</tr>
<tr>
<td>Peripheral neuropathy</td>
<td>2.4% (1)</td>
</tr>
<tr>
<td>Ischemic pain</td>
<td>4.8% (1)</td>
</tr>
<tr>
<td>Phantom limb pain</td>
<td>0.0% (0)</td>
</tr>
<tr>
<td>Spinal cord injury</td>
<td>0.0% (0)</td>
</tr>
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</table>

Please rank the five most common indications for SCS trials in your Department? (“1” being the most common and “5” being the fifth most common). The most common choice for each category is displayed in bold. (N = 49). CRPS = complex regional pain syndrome; SCS = spinal cord stimulator.
patients fail intraoperative testing secondary to inadequate paresthesia coverage of the painful area (Table 4). This was also felt to be the most likely reason for SCS trial failure (Table 5). Personal experience gained from past programming based on specific patient factors, such as diagnosis, age, and involved region, was the most readily cited method to maximize paresthesia coverage.

In terms of post-procedure care, patients were generally observed every 2–4 weeks (64.44%) after implantation to calibrate settings. Once optimized, the majority (82.79%) are seen no more than four times per year. Over the patient’s lifetime, lead and pocket revisions are required and were performed by physicians at a rate of 6.23% and 3.27%, respectively, on an annual basis.

Discussion
Comparing the information gathered during this study with that of Fanciullo et al. in 1999 demonstrates a great

<table>
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<th>Table 3</th>
<th>Diagnoses with the highest 2-year implant success rates</th>
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<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Failed back syndrome</td>
<td>52.08% (25)</td>
</tr>
<tr>
<td>CRPS I, II</td>
<td>26.26% (13)</td>
</tr>
<tr>
<td>Chronic radiculopathy (no past surgery)</td>
<td>10.52% (4)</td>
</tr>
<tr>
<td>Peripheral neuropathy</td>
<td>6.06% (2)</td>
</tr>
<tr>
<td>Ischemic pain</td>
<td>10.5% (2)</td>
</tr>
<tr>
<td>Phantom limb pain</td>
<td>0.0% (0)</td>
</tr>
<tr>
<td>Spinal cord injury</td>
<td>0.0% (0)</td>
</tr>
</tbody>
</table>

Please rank the SCS indications with the highest 2-year success rates? (*1* being the highest success rate and *5* being the fifth highest success rate). The most common choice for each category is displayed in bold. (N = 48). CRPS = complex regional pain syndrome; SCS = spinal cord stimulator.

<table>
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<th>Table 4</th>
<th>Reasons for intraoperative spinal cord stimulator trial failure</th>
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<tr>
<td></td>
<td>1</td>
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<tr>
<td>Inability to place leads epidurally</td>
<td>40.74% (11)</td>
</tr>
<tr>
<td>Inadequate paresthesia coverage of painful region</td>
<td>57.9% (22)</td>
</tr>
<tr>
<td>Adequate paresthesia coverage, but excessive undesirable sensations</td>
<td>25.64% (10)</td>
</tr>
<tr>
<td>Psychological factors</td>
<td>0.0% (0)</td>
</tr>
<tr>
<td>Patient request to terminate the procedure</td>
<td>14.3% (1)</td>
</tr>
<tr>
<td>Opioid-induced hyperalgesia</td>
<td>0.0% (0)</td>
</tr>
</tbody>
</table>

Please rank the top three reasons that explain intraoperative testing failure during trial lead placement. The most common choice for each category is displayed in bold. (N = 48).

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<th>Table 5</th>
<th>Patient-centered reasons for spinal cord stimulator trial failure</th>
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<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Inadequate paresthesia coverage of painful region</td>
<td>52.5% (21)</td>
</tr>
<tr>
<td>Adequate paresthesia coverage, but excessive undesirable sensations</td>
<td>21.43% (9)</td>
</tr>
<tr>
<td>Patient dislikes the sensation</td>
<td>31.82% (14)</td>
</tr>
<tr>
<td>Psychological factors</td>
<td>20.0% (1)</td>
</tr>
<tr>
<td>Opioid-induced hyperalgesia</td>
<td>0.0% (0)</td>
</tr>
</tbody>
</table>

Please rank the top three reasons why patients fail SCS trials, although successful lead placement and coverage was achieved. The most common choice for each category is displayed in bold. (N = 48).
deal of change within the US academic pain practices over the last decade. The average number of attending and fellow positions has both increased by one full person in order to meet the demands of an expanding population and developing field. Fanciullo et al. concluded that 804 SCS implantations were performed by 76 institutions for an average of 10.6 per program. Currently, 1,330 SCS implantations were reported by 48 institutions, which equates to 27.7 per institution. This demonstrates that programs have become more interventional with a 262% rise in yearly implantations. Moreover, greater than 67% of staff now perform SCS procedures compared with 42% previously. This is likely the result of a continued familiarity with the technology, validation of its benefits, a broadened list of indications, and manufacturer marketing. Although 89% of directors felt that instruction during fellowship was the most important educational experience with regard to SCS implantation, a large discrepancy still exists with regard to experience garnered at particular institutions. For example, one program did not perform any permanent implantations on an annual basis, while another was completing 150. This indicates a lack of training uniformity across various sites relegating some graduates to seek training solely via workshops or conferences. It is doubtful that full mastery of these complicated devices can be accomplished in a short 2- or 3-day course. Considering the consistently increasing application of these therapies, pain fellowship programs must assume responsibility for providing proper training in order to ensure the development of competent pain management physicians in the clinical and technical aspects of SCS therapy.

A pervasive theme throughout the Fanciullo et al. study was the involvement of manufacturer representatives within the realm of SCS implementation. Engaging in relationships with these organizations raised concern for bias in selecting devices and evaluating treatment approaches for chronic pain states. These sentiments were shared by roughly 50% of the program directors, who affirmed that manufacturers should not be involved in the training of fellows. Our data support a shift in this paradigm. In general, company involvement through representatives has expanded with a majority of practitioners utilizing their services to educate the patients and fellows, set instrument parameters as directed during procedures, and provide patient follow-up care. Currently, only 29.2% of program directors view manufacturer involvement negatively. One respondent wrote: “their added resources enhances the experience of newly learning fellows and allows them to advance their skills.” Their presence within the operating room has escalated from 73% to nearly 98% for both trials and implantations. Furthermore, 91% of physicians instruct manufacturers to perform device reprogramming, a task that was normally relegated to pain center staff. Keeping up with technological advancements, device complexity and novel componentry is the responsibility of physicians practicing evidence-based medicine. Enlisting the aid of representatives to share their product expertise is one element of a multifaceted approach to accomplish this goal.

Our survey sought to further explore the clinical aspects of SCS application touched upon in the previous study. The three most cited indications for trials—FBSS, CRPS, and chronic radiculopathy (Table 2)—also had the corresponding most favorable 2-year success rates (Table 3). These results are consistent with those found in current literature [19] and data collected in an article detailing Canadian SCS practices [20]. This supports the fact that SCS use, with a proper indication, can be of significant benefit. Moreover, experience over the last decade has demonstrated that these procedures are safe. According to respondents, trials are now performed entirely on an outpatient basis, in comparison to a 49% admission rate in 1999. On the other hand, trial length is virtually unchanged, with 4–7 days being the standard of care. A recent prospective analysis of various chronic pain patients substantiates the use of these time frames [21]. Thirty out of 40 patients achieved a successful trial, which was judged by a 50% reduction in visual analog pain scale in 3–15 days, with a mean duration of 5.97 days.

With regard to treatment shortcomings, respondents stated that the most significant explanation for intraoperative stimulation (IOS) (Table 4) and long-term trial failure (Table 5) was inadequate paresthesia coverage of the painful region. A study by Gordon et al. noted a scarcity of publications providing guidance on IOS parameter settings. The absence of a standardized algorithm forces physicians to attempt multiple programming combinations relying solely on empirical adjustment or personal experience [22]. In fact, respondents quoted that they often rely on a combination of experience (67%) or random trial and error (23%). The second most significant reason given for trial failure was excessive undesirable sensations. This is a consequence of unwanted stimulation of dorsal nerve roots instead of selectively targeting the dorsal columns [23]. To combat this issue, Tiede et al. trialed a high-frequency SCS system with promising results. The system generates innovative waveforms and currents that produce pain relief without paresthesias, limiting unwanted stimulation. Twenty-one of 24 patients treated for chronic back pain preferred treatment with the novel system [24]. These findings are echoed by the work of De Ridder et al., who published data on burst SCS models, which utilize intermittent packets of closely spaced, high-frequency stimuli [25]. In contrast to current tonic stimulation programs, the larger pulse width and lower amplitudes of the burst design induce subthreshold stimulation of Aβ fibers, which are implicated in the generation of paresthesias. Further research will be required to validate these approaches as a viable treatment options.

Conclusions

This investigation provides insight into current SCS practice in US academic pain medicine programs. Over the last decade, the use of SCS therapies has gained further
acceptance. This is reflected in an increase in annual trials and implantations. Generally, manufacturers now play a more substantial role in patient care and fellow education. However, consistent SCS training and instruction among programs is still lacking. Data collected in this article demonstrate that continued analysis is needed in the areas of device programming to help develop disease-specific standardized algorithms. Research concentrated on improving pain coverage while limiting unwanted side effects will ultimately allow more individuals to receive effective SCS treatment.

References
Gharibo et al.


Appendix 1

1) Are spinal cord stimulators (SCS) utilized in your practice?
   a) Yes b) No
2) If you do not utilize SCS in your Department, the main reasons are?
   a) Lack of expertise b) Not convinced it helps patients c) Inadequate staffing d) Reimbursement e) Other
3) How many physicians are present in your pain practice?
4) How many of the physicians defined above trial or implant SCS?
5) How many ACGME accredited pain medicine fellowship positions does your program have?
6) Estimate the number of SCS trialed yearly at your institution by Department.
7) Estimate the number of SCS permanently implanted yearly at your institution by Department.
8) Please rank the value of each below in educating pain medicine fellows in trialing and implantation of spinal cord stimulators.
   a) Fellowship b) Manufacturer Workshops c) Conferences d) Other
9) In what % of SCS trials in your Department, are manufacturer representatives present?
10) In what % of SCS permanent implantations in your Department, are manufacturer representatives present?
11) What is your opinion on SCS manufacturers directly training fellows?
    a) Strongly Favor b) Favor c) Neutral d) Against e) Strongly Against
12) Please rank the 5 most common indications for SCS trials in your Department?
    a) FBSS b) CRPS c) Radiculopathy d) Neuropathy e) Ischemic Pain f) Phantom limb pain
    g) Spinal Cord Injury h) Other
13) Please rank the SCS indications with the highest 2 year success rates?
    a) FBSS b) CRPS c) Radiculopathy d) Neuropathy e) Ischemic Pain f) Phantom limb pain
    g) Spinal Cord Injury h) Other
14) How do you utilize a psychologist/psychiatrist in the decision making process for SCS treatment (select all that apply)?
    a) Not routinely b) Selectively c) Routinely, Pre-trial d) Routinely, Post-trial f) Other
15) What % of SCS trials are successful in the practice?
16) What % of the successful trials proceed to system implantation?
17) What % of your SCS patients in the practice have received a trial pre-implant?
18) What % of your SCS patients receive system implantation on the day of the successful trial lead placement and paresthesia coverage?
19) How many days are trial electrodes left in on the average before assessing whether a trial is successful?
    a) 0 b) 1 c) 2-3 d) 4-5 e) 6-7 f) 8-10 g) Depends upon trial progress
20) If manufacturer representatives are present during the intraoperative test stimulation what is their role (select all that apply)?
    a) Provide product information b) Provide verbal patient education c) Provide written patient education d) Set parameters they see fit e) Set parameters as instructed by physician f) Follow up with patient before discharge g) Follow up with patient after discharge h) Other
21) How do you routinely secure your trial SCS leads (select all that apply)?
    a) Taped b) Sutured c) Tunneled d) Anchor to fascia of other soft tissue e) Anchor to spinal ligaments f) Other
22) Do you admit SCS trial patients overnight?
    a) Yes b) No
23) How many days do the permanently implanted patients typically stay in the hospital?
24) To achieve optimal paresthesia coverage during intraoperative stimulation, I set parameters through:
    a) Random trial and error b) Personnel experience c) Standardized protocol d) Parameters published in literature e) Other
25) Please approximate what % of patients have the following types of leads placed for permanent system implantation
    a) Cylindrical Quadrupolar single lead b) Cylindrical Quadrapolar dual lead c) Cylindrical Octapolar single lead d) Cylindrical Octapolar dual lead e) Flat Quadrupolar f) Flat Octapolar g) Other
26) What % of the SCS patients in the Department have the following battery types?
    a) Non-rechargeable b) Rechargeable c) Radiofrequency System
27) What % of time is the implantation performed with the aid of a surgeon?
28) When a surgeon is present during the permanent implantation, what is their role (Select all that apply)?
   a) Never present  b) Laminotomy  c) Electrode placement  d) Anchoring  e) Pocket creation
   f) Tunneling  g) Other
29) Rate the following parameters in importance in selecting a battery (rechargeable, nonrechargeable, size, etc) for an individual patient ("1" most important to "5" least important):
   a) Patient preference  b) Cost  c) Size  d) Physician preference
   e) Time between charges  f) Longevity  g) Relationship with company
   h) IPG parameter specifications  i) Other
30) What % of patients fail intraoperative stimulation and do not proceed with the trial?
31) Please rank the top three reasons that explain intraoperative testing failure during trial lead placement.
   a) Inability to place leads  b) Inadequate paresthesia coverage
   c) Excessive undesirable sensations  d) Psychological factors  e) Patient request
   f) Opioid induced hyperalgesia  g) Other
32) Please rank the top three reasons why patients fail SCS trials, although successful lead placement and coverage was achieved.
   a) Inadequate paresthesia coverage  b) Excessive undesirable sensations
   c) Patient dislikes the sensation  d) Psychological factors
   e) Opioid induced hyperalgesia  f) Other
33) How frequently are patients evaluated after implantation to optimize their settings?
   a) Every week  b) Every 2-3 weeks  c) Every month  d) Every 2-3 months
34) How frequently are patients who have achieved satisfactory analgesia with SCS without opioids evaluated?
   a) Every 2 weeks  b) Every month  c) Every 2-3 months  d) Every 6 months  e) Greater than every 6 months
35) Who typically reprograms the SCS parameters when indicated (select all that apply)?
   a) Attending  b) Fellow/resident  c) NP/PA/RN  d) Company Representative  e) Other
36) What % of the SCS patients require a lead revision on an annual basis?
37) What % of the SCS patients require a pocket revision on an annual basis?