

Use of Accelerometry as an Educational Tool for Spinal Cord Stimulation: A Pilot Study

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Background: Spinal cord stimulation (SCS) is an important option for patients with chronic neuropathic pain. In the United States, a successful SCS trial determines eligibility for SCS implant. Metrics to determine success are often self-reported and subjective, which may limit achievement of patient goals. This study aimed to assess whether patients undergoing SCS implant after successful trial felt that use of external accelerometry prior to implant was a useful educational tool to objectively appraise function and achievement of treatment goals.

Methods: This was a single center, prospective, pilot study. Sixteen subjects with persistent spinal pain syndrome type 2 underwent a percutaneous SCS trial. Five subjects did not have a successful trial, one expired after the SCS trial, before implant, and one dropped out prior to completion of post-implant follow-up visits. Nine subjects underwent SCS implant and completed the required follow-up visits. All subjects were provided an Actigraph GT3X external accelerometer, worn 7 days prior to the trial to determine baseline physical activity and during the 7-day trial to assess for change in activity from baseline. Results were shared with subjects to individualize goals for therapy. Goal attainment was assessed at 1, 3, and 6 months after implant. Subjects wore the accelerometer again 24 hours before visits to update progress in meeting treatment goals. The primary outcome was satisfaction with using accelerometry as an educational tool to appraise function and guide treatment goals for SCS therapy. Secondary outcomes included physical activity, as captured via accelerometry, as well as validated patient-reported measures of pain severity, physical functioning, and quality-of-life.

Results: Eight of nine subjects were satisfied with accelerometry as an educational tool. Secondary outcomes were not reliably assessed due to poor stewardship and study execution.

Conclusion: External accelerometry may assist patients in developing individualized functional treatment goals for SCS therapy.

Keywords: low back pain, accelerometer, physical activity, spinal cord stimulator, patient

Introduction

It has been estimated that up to 50.2 million adults (20.5%) report pain on most days or every day. Of those, it has been estimated that as many as 15.7% of patients with chronic pain have a syndrome with a neuropathic component. Chronic neuropathic pain is associated with dysfunction, disability, depression, disturbed sleep, and reduced quality-of-life.¹⁻³ SCS, which is thought to modulate nociceptive input and processing in the spinal cord, may be an important therapeutic option for carefully selected patients with chronic, intractable neuropathic pain of the trunk and/or limbs.

In the United States, clinical guidance necessitates a successful SCS screening trial prior to SCS implant^{4,5} and carefully selected patients typically undergo a 3–7-day percutaneous SCS trial before permanent surgical placement.² An expert panel defined a successful trial as the patient reporting $\geq 50\%$ pain relief with stable or reduced pain medication.⁵ Pain relief is subjective and usually evaluated in clinical settings by self-reported scales such as the Numeric Rating

Scale⁶ and Visual Analog Scale.⁷ Although these subjective methods have been “golden standards” for pain measurement,⁸ the accuracy and utility of self-reporting are limited under certain circumstances.

Unfortunately, SCS therapy is not effective in all surgically implanted SCS patients, despite seemingly successful percutaneous SCS trials. Loss of therapy and subsequent surgical explant rates continue to rise. To promote longitudinal maintenance of therapy, it is critical for patients and clinicians to be able to accurately appraise results of SCS trials before SCS implant to verify candidacy of therapy. Surgical explant of SCS systems not only increases medical and surgical risk to the patient, but also has important negative implications for healthcare resource utilization (HCRU) and the practice of pain management.³

While self-reported measurement tools, such as pain severity and physical function scales, constitute the principal means of quantifying treatment effects, novel objective measurement tools have emerged to supplement patient-reported information. Objective measures of physical activity are thought to be less vulnerable to limitations of patient-reported outcomes, including recall bias and social desirability bias.⁴ In addition, use of objective measures of physical activity during a percutaneous SCS trial may help patients to decide on whether to pursue surgical implantation.

Accelerometers have been widely used in the medical literature as objective proxy measurements of physical activity.⁵ Manufacturers of SCS systems continue to advance the field of neuromodulation by applying new technologies, including the evolution of adaptive stimulation systems as a potential means of adjusting stimulation output based on patient positioning.^{6,7} The presence of an internal accelerometer provides an opportunity to individualize stimulation patterns according to the patient’s own dynamic positional changes to avoid unpleasant over-stimulation or under-stimulation in traditional SCS systems and to decrease the need for frequent compensatory manual programming.⁸ In addition, the existence of internal accelerometers provides feedback on post-implant physical activity.

Previous studies have examined use of pedometers, which quantify physical activity via traditional step-counts, to appraise objective physical activity as a treatment outcome after SCS implantation.^{9,10} There is little data on use of external accelerometers, which use triaxial data including speed, tilting motion, and orientation of a body or an object to quantify a variety of physical activities beyond step-counts alone.¹¹ Accelerometry may provide information on activity levels, sleep, and body movements. If used before SCS therapy to establish a baseline and then during SCS trial, information provided may assist in assessing, developing, and individualizing treatment goals for SCS therapy prior to implant.

Thereby, the primary purpose of this study was to assess whether patients felt satisfied using accelerometry prior to and during the SCS trial as an educational tool to objectively appraise function and develop individualized treatment goals for SCS therapy.

Secondary outcomes included investigator goal achievement, assessment of physical activity via Physical Activity Recall Questionnaire (PARQ) as captured via accelerometry, and validated patient-reported measures of pain severity, physical functioning, and quality-of-life measured after SCS trial and implant. Parenthetically, it was theorized that use of objective physical activity metrics to supplement patient-perceived outcomes before and during a SCS trial would serve to educate both the patient and the provider as to the potential for therapeutic success with SCS implantation. As education is one of the social determinants of health,⁸ an appreciation of potential functional gains with SCS may potentially reduce patient stress, enhance coping mechanisms, and improve satisfaction longitudinally. This knowledge may eventually lead to enhanced provider–patient communication among this patient population.¹²

Methods

Study Design and Participants

This study was a single-center, prospective, non-randomized observational pilot study of adult patients with chronic intractable neuropathic pain of the back and limbs refractory to medical and/or surgical intervention. All recruited study subjects underwent rigorous screening for appropriateness of SCS therapy per standard clinical protocol. All participants were recruited from a single-center, metropolitan, academic spine clinic. All recruited subjects were caucasian females with a mean age of 50, median pain duration of 6.61 years, suffering from chronic back and leg pain secondary to persistent spinal pain syndrome type 2. Data were collected at baseline, after SCS trial, and at 1, 3, and 6 months after

implant. This study was approved by the Lifespan – Rhode Island Hospital IRB 1 # 00000396 and IRB 2 #00004624, as meeting the standards for the protection of humans per 45CFR46/21CFR56 in compliance with the ICH GCP corresponding to the FDA/DHHS regulations.

Ethical Approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional review board and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. The Rhode Island Hospital Institutional Review Board reviewed and initially approved this study on 8/19/2014, Reference # 409014. Study participation was not required to receive SCS implantation.

Informed Consent

Informed consent was obtained from all individual participants included in the study. All subjects read and signed an informed consent form approved by the Rhode Island Hospital Institutional Review Board.

Inclusion Criteria Included

1. Patients were appropriate candidates for SCS therapy for chronic intractable neuropathic pain of the back and/or leg.
2. Patients were willing to participate in the study and able to sign a Research Informed Consent form.
3. Patients with a baseline Numeric Pain-Related Score (NPRS) of six or higher within the previous 2 weeks of assessment.
4. Patients willing to potentially undergo permanent SCS implant surgery (assuming $\geq 50\%$ pain relief and functional improvement from a 7-day percutaneous SCS trial).

Exclusion Criteria Included

1. Patient's chronological age <18 and >80 years.
2. Patient's not found to be suitable candidates for SCS trial for any reason including a pretrial psychological assessment.
3. Patients with co-morbid conditions that limited ambulation to walking ≤ 100 ft (ie, COPD, severe hip, or knee arthritis).
4. Patients with systemic infection.
5. Patients with an anatomical abnormality that would preclude safe and appropriate lead placement.
6. Patients with chronic pain secondary to malignant disease.
7. Patients with a life expectancy of less than 6 months.
8. Female candidates who were pregnant or those who were of child-bearing potential and not using adequate contraception as determined by the investigator.
9. Patients currently implanted with a stimulation system including, but not limited to spinal cord stimulators, cardiac pacemakers, deep brain stimulators, vagal nerve stimulators, or an implantable infusion pump.
10. Patients with severe emotional or psychiatric conditions with the potential for interfering with regimen compliance.
11. Patients with a spinal cord stimulation system or targeted drug delivery system already implanted.
12. Patients not found to be candidates for permanent implantation.
13. Patients who decided not to undergo permanent implantation despite a successful trial.

Measures

Upon enrollment in the study, subjects were asked to identify one primary functional goal for participation in spinal cord stimulation therapy. The primary outcome was whether patients undergoing SCS implant after a successful trial were satisfied in using an external accelerometer as an educational tool to objectively appraise function and achievement of their pre-determined treatment goals at 1, 3, and 6 months after implant.

Patients were asked whether baseline and SCS trial accelerometry data were useful in appraising achievement of their longitudinal treatment goals, recorded as a binary outcome of satisfied vs unsatisfied, at 1, 3, and 6 months after implant. The pre-operative goal achievement was intended to record whether patients subjectively felt their treatment goals were met by the spinal cord stimulator. This was recorded as a binary outcome: met vs not met. This was completed at post-operative months 1, 3, and 6.

Secondary outcomes included the following:

1. “Investigator Goal Achievement”, which was intended to record whether the investigator subjectively felt the patient’s treatment goals were met by the spinal cord stimulator. This was recorded as a binary outcome: met vs not met, and was completed at post-operative months 1, 3, and 6.
2. “Physical Activity Recall Questionnaire (PARQ)”, which is a valid self-reported instrument of moderate to vigorous physical activity over a 7-day period.¹³ Total physical activity was documented in hours over a 7-day period. This was completed at baseline, end of SCS trial, and at 1, 3, and 6 months after implant.
3. “NPRS”, which is a widely used, valid, and reliable 11-point (0–10) self-reported measurement of pain severity.¹⁴ Higher scores indicate greater pain severity. Patients were informed that a score of 0 indicated no pain, while a score of 10 would represent the worst possible pain that can be experienced. The NPRS is a valid, reliable, and appropriate tool to assess pain in clinical practice. NPRS scores were collected at baseline, end of SCS trial, and 1 month (± 7 days), 3 months (± 21 days), and 6 months (± 21 days) after SCS implant.
4. “ODI”, which is a commonly used, valid, and reliable self-reported measurement of low back pain-related disability.¹⁵ It consists of 10-items (each item using a 6-point ordinal scale) that correspond to the effects of pain on daily function (including pain intensity, personal hygiene, lifting, walking, sitting, standing, sleeping, sexual activity, social activity, and traveling), and yields an overall continuous score ranging from 0–100. Higher scores indicate greater low-back pain-related disability. ODI scores were collected at baseline, end of SCS trial, and 1 month (± 7 days), 3 months (± 21 days), and 6 months (± 21 days) after SCS implant.

Subjects wore the Actigraph GT3X external accelerometer on their waist, fastened by an adjustable belt. This model uses a rechargeable lithium-ion polymer battery, which is compact and lightweight (19 grams). It is capable of lasting up to 31 days in between charges, has 512 MB of memory, and can capture step counts, body position, acceleration, activity intensity, amount of sleep, and ambient light. Cumulative physical activity over a 7-day period is recorded in total hours.

The Actigraph GT3X measures physical activity in four ways: 1) total activity counts per day (TAC/d); 2) steps per day (steps/d); 3) physical activity energy expenditure (PAEE, kcal/kg/day); and 4) minutes per day (min/d) were spent in moderate- to vigorous-intensity physical activity (MVPA). Data based on both vertical axis counts only and triaxial counts are utilized. Total activity counts are the accelerations captured by the device that were filtered, full wave rectified, and integrated over time, representing the intensity of ambulatory activity. Vertical axis counts are activity counts measured in the vertical plane, whereas triaxial counts are a composite vector magnitude from three individual orthogonal planes (vertical, antero-posterior, and medio-lateral). TAC/d based on vertical axis and triaxial counts is determined by averaging the total activity counts per day across valid wear days. ActiGraph uses a proprietary algorithm to count steps and no information about the specifics of this process is publicly available. Step counts are based only on accelerometer data collected on the vertical axis. Steps/d are determined by averaging the steps taken per day across valid wear days.

Spinal Cord Stimulator Trial

All study subjects underwent a 7-day SCS trial using two 8-contact Medtronic subcompact electrodes inserted percutaneously under fluoroscopy. The leads were secured at the skin margin and connected to an external pulse generator. Patients received a system programmer, were educated on its use, and given access to adjust the system as needed to treat their pain.

Post-Trial SCS Placement Determination and Placement

At the end of the trial, the subject followed up with the provider to assess the success of the trial. All subjects needed at least 50% subjective pain relief during the trial SCS treatment to justify SCS implant. SCS implant was performed by the same provider who performed a previous SCS trial.

Post-Operative Assessments

As part of the standard practice, patients who underwent SCS implant were followed up at 7 days for a wound check, and at 1 month (± 7 days), 3 months (± 21 days), and 6 months (± 21 days) for re-programming. Subjects were asked to wear the external accelerometer for 24 hours prior to each of the 1, 3, and 6 month follow-up visits.

Data Analysis

All data were presented as means \pm SD unless otherwise stated. Significance level was set at $p \leq 0.05$. Descriptive statistics were calculated, and paired t-tests were used to test for within-group mean change mean between baseline, end of SCS trial, and at 1, 3, and 6 months.

Results

In total, 16 subjects met the study criteria and underwent the SCS trial. Five of the 16 subjects did not meet criteria for SCS implant due to lack of adequate pain reduction from the SCS trial. Additionally, one patient died after a successful SCS trial and prior to SCS implant. This internal adverse event was immediately reported to the IRB. It was determined that this death did not meet criteria for an unanticipated problem and was thereby not related to participation in the study. Finally, one patient dropped out of the study after a successful SCS trial and prior to completion of the 6-month follow-up visit due to unplanned cross-country relocation and inability to attend additional follow-up visits. Therefore, only nine of the original 16 subjects underwent SCS implant. All nine subjects were assessed at 1, 3, and 6 months after implant. Of note, due to damage of data storage equipment, a significant amount of the PAR survey and accelerometry data were lost.

At time of lead-pull upon completion of the SCS trial, subjects met with the provider to assess reduction of pain from the trial and to discuss the appropriateness of moving to SCS implant. At that time, baseline and trial accelerometry data was shared with each subject and explained in detail by the study personnel. Data from the external accelerometer was used as a proxy measurement of baseline physical activity, which allowed comparison to data from the SCS trial.

Upon presentation of this data, the patient was given the opportunity to ask questions to assist in interpreting the data. Subjects' pre-determined functional goals for participation in spinal cord stimulation therapy were again reviewed. Based upon interpretation of physical activity from accelerometry data, the patient was given an opportunity to revise their treatment goal to make goal attainment as realistic as possible. The subject was reminded that their goal would be reviewed at 1, 3, and 6 months after implant. For the nine subjects who had successful SCS trials, the Actigraph GT3X accelerometry data revealed a greater than 50% improvement in moderate- to vigorous-intensity physical activity (MVPA) as measured by each of the following: 1) total activity counts per day (TAC/d); 2) steps per day (steps/d); 3) physical activity energy expenditure (PAEE, kcal/kg/day); and 4) minutes per day (min/d). For the five subjects who did not achieve 50% pain relief from the SCS trial, these same measurements of physical activity revealed less than a 25% change from baseline.

Study Outcomes

Patients were asked whether baseline and SCS trial accelerometry data were useful in appraising achievement of their longitudinal treatment goals, recorded as a binary outcome of satisfied vs unsatisfied, at 1, 3, and 6 months after implant. The pre-operative goal achievement was intended to record whether patients subjectively felt their treatment goals were met by the spinal cord stimulator. This was recorded as a binary outcome: met vs not met. This was completed at post-operative months 1, 3, and 6. At the first post-operative visit, all subjects reported satisfaction with accelerometry use. At the 3-month postoperative visit, seven of nine subjects reported satisfaction with accelerometry use. At the 6-month

postoperative visit, eight of nine subjects reported satisfaction with accelerometry use. In aggregate, eight of nine subjects who underwent SCS implant were overall satisfied with using accelerometry as an educational tool to objectively appraise function and achievement of their treatment goals at 1, 3, and 6 months after implant. Very unfortunately, secondary outcomes could not be reliably assessed due to poor stewardship of records and technical deficiencies of study execution.

Discussion

To our knowledge, this is the first study to assess whether patients undergoing SCS implant after a successful trial were satisfied in using an external accelerometer as an educational tool to objectively appraise function and achievement of their treatment goals after SCS implant. This knowledge has important implications for design of appropriately powered clinical trials in the future.

The utility of accelerometry as a metric of physical activity is consistent with and expands upon work from Lange et al, who utilized an external pedometer as an external measure of spinal cord stimulation outcomes.⁹ While both pedometers and accelerometers have been used as externally worn devices to generate surrogate metrics of objective physical activity, accelerometers have been empirically superior in capturing physical activity among older adults.¹⁶ Furthermore, by demonstrating feasibility of incorporating accelerometry as an educational tool during the pre-operative SCS trial process, our results expand upon the findings from Schade et al, who demonstrated the feasibility of accelerometry in the post-implantation period alone.¹⁷

Thirty percent (5 of 16) of interested participants who were screened before the SCS trial were ultimately excluded from participation due to lack of adequate pain reduction from the SCS trial. This proportion is concordant with those reported from prior studies^{18,19} and underscores the importance of this element of the study design to appropriately power related clinical trials.

Limitations

Any study interpretation should acknowledge its unique strengths and weaknesses. There were major weaknesses of this study given large amounts of missing data and poor trial governance. This study was conducted as part of an effort to engage undergraduate students interested in pursuing an academic career in medicine. This was established to benefit students by fostering independent critical thought given earlier exposure to the hypothesis-driven scientific method. Additionally, it was felt that early participation and mentorship would not only build an academic foundation but would also enhance communication and collaboration skills to enrich their overall education. Unfortunately, this endeavor fell flat as there was inconsistent direction from faculty and unreliable commitment from both faculty and students. In short, this led to poor stewardship of records and technical deficiencies of study execution. Although it was initially felt that this would make any interpretation of this study unpublishable, the writers felt that presentation of existing data in an honest and unfiltered way would be worthy of pursuit. Outside of these obvious deficiencies, other weaknesses include a seemingly skewed subject cohort, which might make any interpretation of findings poorly generalizable to a more diverse patient population. All subjects were female, the overall sample size was small, and subjects were recruited from a single center, urban, academic institution in the Northeast Corridor of the United States.

Given the limited sample size, there was no opportunity for higher-order preliminary analyses of incorporating accelerometers into the trial process, nor more comprehensive and meaningful assessment of patient satisfaction, which includes baseline predictors, mediators, and moderators of response. However, similar sample sizes have been reported on comparable prior studies, and as a pilot study, statistical power is inherently less important. The writers fully acknowledge that assessment of patient satisfaction using a binary outcome of “met” vs “not met” is rudimentary at best.

Additionally, since physical activity data from the accelerometers and PAR surveys were limited from storage-related equipment issues, analysis of statistical significance was precluded, emphasizing the importance of meticulous data monitoring in further studies.

Lack of a control group did not allow randomization of participants who would receive an accelerometer during the SCS trial. Additionally, there was no comparison of data from patients who passed vs failed the SCS trial. Additionally,

as this study was unable to collect data on domains of psychological health (eg, depression, anxiety, self-efficacy, etc.), all of which are nearly universally accepted as potential confounding factors in the field of chronic pain.^{20–22}

Finally, as it was theorized that use of an accelerometer before and during a SCS trial might provide an educational opportunity for both patient and provider to assess change in physical activity to validate the decision to move forward with a SCS implant or not. However, no sophisticated tools for assessing educational needs, such as “KnowPain-50”, nor acknowledgement of different learning styles were implemented.^{23,24}

Given the numerous weaknesses of this study, we concede the difficulty in justifying publication of the limited results presented here. However, by sharing the significant deficiencies of the study design and execution, we hope to encourage other scientists interested in further study of objective measurement of pain to adjust their research plans, avoiding the pitfalls well illustrated in this study. Further research is needed to validate use of accelerometry as a clinically meaningful tool for assessment of physical activity among SCS candidates and whether it can serve as an educational tool to guide progression in therapy to SCS implant. Further studies might also assess algorithms to optimize processing and interpretation of raw triaxial accelerometry output, clinically meaningful important differences in these metrics, as well as patient acceptable symptom states. In addition to treatment satisfaction, pre-implantation data could assess other pertinent and clinically meaningful post-operative patient domains, including pain severity, physical functioning, opioid use, and return-to-work.

This pilot feasibility study will ideally provide the foundation to power a larger multicenter, prospective, randomized, blinded study to investigate use of accelerometry prior to SCS implant more thoroughly.

Conclusion

In conclusion, we found an initial indication that incorporating accelerometry was feasible and well-tolerated among patients who underwent SCS trial. This knowledge may educate patients and ultimately enhance appraisal of treatment efficacy by both patients and clinicians.

Disclosure

Dr Alexios G. Carayannopoulos reports grants from Medtronic Inc, during the conduct of the study. Dr Alaa Abd-Elseyed is a consultant for Medtronic. The authors report no other conflicts of interest in this work.

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