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Review Article

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The Association of Pre-Procedural Psychological Evaluations on Post-Procedural Pain Control in VA Patients Who Received Spinal Cord Stimulator Therapy

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Abstract

Introduction: *Spinal cord stimulators (SCSs) are intended to treat chronic pain and are marketed as an opioid alternative. Patients require psychological screening prior to device placement to ensure the patient has an ideal profile that would lead to the device's being effective. There is variation in the quality of pre-procedure psychological evaluations (PPPE), which may be associated with post-procedure pain (PPP) control. This fact is significant given that psychological evaluations are not currently regulated. Varying implementation of PPPE subsequently leads to variation in clinical practice and outcomes where patients may not achieve the desired outcome.*

Aim: *This research is a retrospective, longitudinal, cohort study using secondary data collected from the electronic medical record (EMR) in an ambulatory pain clinic of patients who received SCS implants. The purpose of this study is to examine the association between the quality scores of PPPE and PPP control. We hypothesize that patients who had a poor-quality score of PPPE also had less PPP control, possibly due to being misclassified as an appropriate candidate for the device. The following aims are proposed to achieve the purpose:*
1. Examine the association between the quality score of PPPE and PPP (average pain score 2 to 6 weeks post SCS placement).
2. Determine the association between the quality score of PPPE and PPP improvement (comparing pre SCS and post SCS pain scores).

Methods and analysis design: *For aim 1, a bivariate correlation will be utilized to determine if PPPE quality scores and PPP scores are related. For aim 2, a logistic regression will be utilized to analyze the quality scores of PPPE and PPP improvement, since the outcome variable will be dichotomous (improved or not improved). If necessary, an adjusted model, or interaction model, will be considered to look for interaction among covariates, such as age. This study would need a sample size of 123 to be powered at 80% with a .05 significance level.*

Ethics and dissemination: The novel information gathered through this research intends to assist clinicians in identifying optimal candidates for SCS devices and may reveal common factors in patients who are successful in achieving improved pain control after spinal cord stimulator placement.

Keywords: *Spinal Cord Stimulator, Psychological Screening, Opioid Use, Veterans, Retrospective Chart Review*

Background

Chronic pain is defined as pain that persists after healing is expected, or pain that occurs without any obvious tissue damage when it lasts or recurs for more than 3 to 6 months [1]. Chronic pain is one of the most frequent conditions, affecting an estimated 20% of people worldwide and accounting for 15% to 20% of office visits [1]. Spinal Cord Stimulator (SCS) implantation is a non-opioid treatment option for chronic pain patients who have failed previous measures targeting pain control. For patients with intractable chronic pain, a permanently implanted SCS device presents a treatment option for providing long term pain relief and minimizing the need for pharmacologic modalities. An SCS device is effective by producing changes in cortical activity experienced by the brain, causing down-regulation of some components of pain, ultimately

leading to modifications in pain thresholds [2]. However, literature reports sporadic and inconsistent degrees of success in patients with an implanted SCS, where post-procedure pain (PPP) control remains suboptimal in about 40% of cases one year postoperatively [3]. The elimination of chronic pain following SCS therapy is highly variable due to the patients' characteristics and pre-existing conditions. The psychological conditions are predictive of SCS outcome [4, 5]. Chronic pain patients have many psychosocial comorbidities (e.g., depression and anxiety) that can limit the benefit of SCS therapy. Thus, most implantations in the United States require a pre-procedure psychological evaluation (PPPE) to assist in determining appropriate patients for the correct procedure. However, there is a lack of guidelines for PPPE [6]. There are no validated psychological assessments that are optimized specifically for SCS implantation. The current PPPE have not been standardized, leading to variations among clinicians in appropriately classifying patients for SCS eligibility. To fill the gap of knowledge, the purpose of this study is to examine the association between the quality scores of PPPE and PPP control after considering the influence of sociodemographic and clinical characteristics in chronic pain patients who had SCS implants. We hypothesize that patients who had a poor-quality score of PPPE also had less PPP control possibly due to being misclassified as an appropriate candidate for the device. The following aims are proposed to achieve the purpose:

1. Examine the association between the quality score of PPPE (assessed by a PPPE quality checklist) and PPP (assessed by the Numeric Rating Score [NRS]).
2. Determine the association between the quality score of PPPE and PPP improvement.

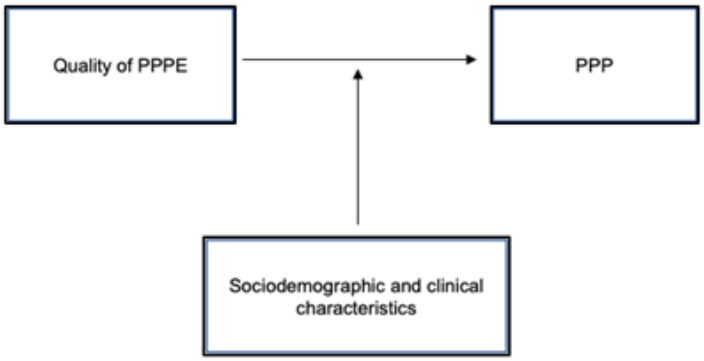
Methods

Study Design

This study is a retrospective, longitudinal, cohort study using secondary data collected from the electronic medical record (EMR) in an ambulatory pain clinic of patients who received SCS implants. Subjects were selected from the outpatient pain clinic affiliated with a comprehensive health system located in the southeast region of the United States. This study was submitted to the Institutional Review Board and has received approval

Conceptual Framework

The conceptual framework upon which this study is based is the theory of unpleasant symptoms (TUS). The TUS can be used to predict and explain the causational process of social and health behaviors based on psychological determinants [7]. The behavioral process begins with (a) beliefs and attitudes, (b) social norms, and (c) perceived control; ending in the actual performance of a behavior [7]. Strengths of the TUS include the effects of symptom experience, where the patient expects SCS implantation to lead to a particular experience (PPP control). With an increased understanding on the relationship of the PPPE, providers may be better able to theorize about the positive or negative outlook towards SCS placement, helping to better identify optimal candidates for the procedure. Figure 1 explains the conceptual model for this research. This conceptual framework demonstrates the impact of the quality of PPPE on PPP. We believe PPPE plays a vital role in determining which chronic pain patients are appropriate for SCS, leading to optimized pain control after SCS implants. To examine the association between PPPE quality and PPP control, investigators will need to control potential confounding and/or covariates that are identified from patients' sociodemographic and clinical characteristics. For application to this research, a PPPE is expected to capture the psychological factors that can influence the patient's PPP control after SCS placement.



Note. PPPE = pre-procedure psychological evaluation; PPP = post-procedure pain.

Figure 1: *Conceptual Model to Explain the Influence of PPPE on PPP*

Study Setting

Data were collected from an outpatient chronic pain clinic affiliated with an academic health system located in the Southeastern United States. The clinical operations of this system include a 478-bed level 1 trauma hospital and more than 80 wide range ambulatory services. The health system provides care in Georgia, South Carolina, and North Carolina. Additionally, the health system hosts a chronic pain medicine rotation for medical students, explicitly focusing on: (a) trigger point injections, (b) lumbar and caudal epidural steroid injections, (c) medial bundle branch nerve blocks, (d) sacroiliac joint injections, and (e) SCS implants. The section chief of anesthesiology and pain medicine was a part of this research committee and provided significant assistance in making this research possible. Patients are typically seen at the pain clinic as a referral from a primary care provider, or as a referral from another pain clinic that cannot provide additional treatments, such as SCS implantation.

Study Participants

The data for this study come from the EMR of the outpatient chronic pain clinic. The medical records were abstracted from patient data collected during routine care that these patients were receiving during treatment for SCS devices, including demographic data and PPP control. The selected study variables are records that are based on details provided by the patient during the patient visit and reviewed by the clinical team. PPPE data is completed either within the health system, where the evaluation is readily available as a clinical note, or it is completed outside of the health system, where the evaluation is scanned into the EMR as a PDF attach-

ment. Both sources of PPPE data were utilized for this research. The records of non-VA patients were noted to have more missing data, missing psychological evaluations, and did not create a study sample where data could consistently be retrieved.

Inclusion and Exclusion Criteria

Inclusion and exclusion criteria for subjects to be eligible/ineligible for study inclusion are detailed in Table 1. To be included the patient must have: (a) history of chronic pain, (b) prior initial placement of a SCS device, (c) chronic opioid use prior to placement of the SCS device, and (d) age 18 or older. Subjects will be excluded if they have any of the following: (a) did not have a personal history of military service, (b) was not the first time an SCS device was implanted, or (c) missing psychological assessment data (subjects with incomplete but not entirely missing psychological screening data was included). The sample was determined based on a convenience sample of EMRs that were available that met the inclusion criteria.

Sample Characteristics

The preliminary sample size of this study was 50 subjects. The distribution of age was 30 thru 90, with a mean age of 59, and median age of 60. Gender was fairly distributed with 54% male (27 subjects) and 46% female (23 subjects). Race was distributed as follows: 58% White, 30% Black, and 12% other. Body mass index (BMI) was a mean of 31.6, a median of 40, with a range of 19.1 thru 44.1. Comorbidities of interest included diabetes and smoking status. 28% or 14 subjects had diabetes, and 20% or 10 subjects admitted to cigarette smoking.

Study Procedures

Data Access

Initial access to the EMR involved training about utilizing the EMR for research projects. This training outlined the requirements for access to the EMR and was conducted by the institution's research system administrator. After training, login-in credentials were granted for the principal investigator to access the EMR.

Data Extraction and Transfer

After access was granted to the EMR, records were reviewed to determine what parts of the EMR would need to be collected to support the research aims. Each selected variable or data point of the EMR was then discussed with a clinical data support analyst employed by the institution. Weekly meetings were held during this period with the analyst, principal investigator, and major advisor, to discuss the feasibility of extracting the data. All data except the PPPE data were professionally extracted from the EMR to an Excel data spreadsheet. These included all sociodemographic and clinical characteristics, and numeric pain scores. PPPE were PDF documents which required manual review and data extraction by the research team.

Data Storage

Data were collected using a spreadsheet, which allowed for additional data points to easily be added, and stored on the password protected Box cloud platform. At the conclusion of the data collection period, all data were de-identified and data analysis was completed. De-identifying data prior to analysis helped to maintain subject confidentiality.

Data Management

Data management of data collected by the data analyst in Microsoft Excel was difficult to manipulate, sort, and review because of the large volume of data contained in the file. The clinical support data analyst was able to extract 14 data points including: (a) age, (b) gender, (c) smoking status, (d) history of diabetes, (e) history of hypertension, (f) medical diagnoses codes and (g) pain score prior to SCS implant, (h) pain score post SCS implant, (i) race, (j) ethnicity, (k) zip code, (l) weight, (m) height, (n) BMI, and (o) for 73 subjects. The resulting Excel file had 5 sheets of data, each with several thousand rows of data ranging from 4,000 to 8,000, across 15 columns for the aforementioned variables. This data included redundant information. For example, a subject's demographic data was collected multiple times in the resulting dataset. The EMR (Cerner) does not allow for data extraction that allows for redundant information to be removed easily.

Microsoft Access was chosen as software to trial, as the program was easily available to the research team. The Microsoft webpage explicitly refers to Access as, "a more convenient interface than Excel for working with your data" [8]. Access allows for several different databases to be created where paths can be created between the databases to customize and utilize information across the databases [9]. Figure 2 provides a visual of this process in a simplified three step process.

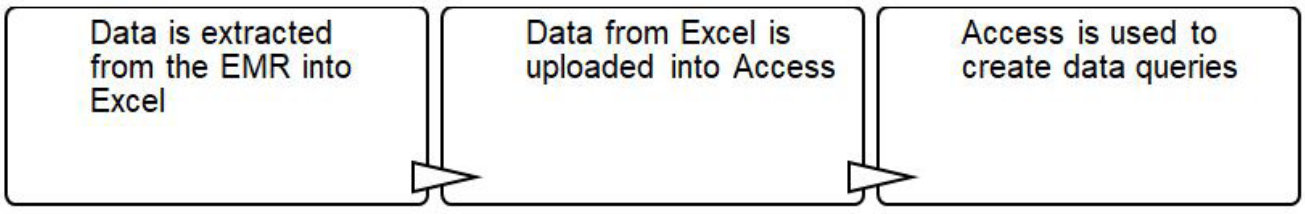


Figure 2: *Using Microsoft Access for Large File Data Management*

Variables and Measures

Post Procedural Pain (PPP)

PPP is conceptually defined as pain experienced by a patient after the placement of a SCS device. Its operational definition is the average NRS score within two to six weeks after SCS placement (dependent variable for Aim 1). Improvement in the PPP (dependent variable for Aim 2) will be dichotomized into improved versus unimproved categories. Improvement is determined by the difference in NRS scores between pre and post SCS placement (average pain score 1 to 14 days before SCS placement minus average pain score 2 to 6 weeks after SCS placement). For example, if a patient's PPP average score was 3, and their average NRS score was 8 prior to SCS placement, 3 minus 8 indicates a decrease of NRS score by 5, or improvement.

Quality of Pre-Procedural Psychological Evaluation (PPPE)

The conceptual definition of the quality of PPPE is an evaluation or assessment completed by a healthcare professional to determine if a patient meets the criteria to be a potential recipient of a SCS. The PPPE operational definition is the score of the PPPE checklist. The 49 selected components of the checklist attempt to capture a comprehensive clinical picture of the patient, including details about the clinician completing the assessment, knowledge, and expectations about the SCS device, social and functional history, and the actual psychological assessment utilized in the interview process (if applicable). PPPE quality scores will be treated as a continuous variable.

Demographic and Clinical Variables

All demographic data available from the EMR will be collected and considered for classification as a confounding variable. As previously mentioned, these can include: (a) age, (b) gender, (c) smoking status, (d) race, and (g) geographic location. Clinical variables will include: (a) history of hypertension, (b) history of diabetes, and (c) types of psychological clearance assessments utilized.

Participation and Sample Size Determination

Given that this study is a retrospective chart review of patients who have previously undergone SCS placement, no participants will need to be contacted or recruited to participate. There is no direct benefit to patients participating in the study; there will not be any study interventions, and no direct contact with any patients.

Approximate power estimation was calculated with R Console software. Based upon a two tailed test with an approximate correlation (r value) of .25 (moderate to small correlation), a significance level (p value) of .05, and a power of 80%, the study would need a sample size of 123.

Statistical Analysis

Data were summarized using simple measures of summary statistics, such as means, medians, mode, and ranges. Descriptive statistics are useful for continuous variables, such as age. Statistical significance is visually illustrated with the use of bell curves and explained by describing the standard deviations of the data. The use of standard deviations allows investigators to understand how spread out the data is from the mean. Testing for normal distribution of the data assists investigators in determining how the data should be presented. Central tendency and dispersion are utilized for normally distributed data, where median and interquartile ranges will be utilized for non-normal distributions. Spreadsheet programs, such as Microsoft Access and Microsoft Excel, allow for categorical variables to be coded and presented in the form of frequency charts. The investigators are familiar with SAS Studio statistical analysis software and will perform additional analysis through this platform.

For aim 1, a bivariate correlation will be utilized to determine if PPPE quality scores and PPP scores are related. For aim 2, a logistic regression will be utilized to analyze the quality scores of PPPE and PPP improvement, since the outcome variable will be dichotomous (improved or not improved). If necessary, an adjusted model, or interaction model, will be considered to look for interaction among covariates, such as age. A sensitivity analysis in multiple imputation will be utilized to determine if any missing data is of clinical significance. Multiple imputation relies on the assumption of missing data being at random. All data analysis will be completed in consultation with a biostatistics expert, who is also a member of the principal investigator's dissertation advisory committee.

Discussion

As with all other retrospective studies, our work cannot determine a causative relationship between any independent variable and SCS outcome. The findings from this study will provide additional evidence about psychological factors related to pain control after the placement of an SCS. Clinicians can then develop a sensitive screening tool to determine and identify patients who would be more likely to respond to SCC treatment, further limiting treatment failure and financial expenses. Alternatively, the results of this research could identify educational interventions to promote patients' awareness and knowledge in managing their pain and opioid use prior to SCS placement. Other pre-operative strategies could also be implemented to increase appropriate patient selection and improve the treatment's success rate [10-21].

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References

1. Hylands-White, N., Duarte, R. V., & Raphael, J. H. (2017). An overview of treatment approaches for chronic pain management. Rheumatology international, 37(1), 29-42.
2. Abd-Elsayed, A., Schiavoni, N., & Sachdeva, H. (2016). Efficacy of spinal cord stimulators in treating peripheral neuropathy: a case series. Journal of clinical anesthesia, 28, 74-77.
3. Gee, L., Smith, H. C., Ghulam-Jelani, Z., Khan, H., Prusik, J., Feustel, P. J., ... & Pilitsis, J. G. (2019). Spinal cord stimulation for the treatment of chronic pain reduces opioid use and results in superior clinical outcomes when used without opioids. Neurosurgery, 84(1), 217-226.
4. Simopoulos, T., Sharma, S., Wootton, R. J., Orhurhu, V., Aner, M., & Gill, J. S. (2019). Discontinuation of chronic opiate therapy after successful spinal cord stimulation is highly dependent upon the daily opioid dose. Pain Practice, 19(8), 794-799.
5. Fama, C. A., Chen, N., Prusik, J., Kumar, V., Wilock, M., Roth, S., & Pilitsis, J. G. (2016). The use of preoperative psychological evaluations to predict spinal cord stimulation success: our experience and a review of the literature. Neuromodulation: technology at the Neural Interface, 19(4), 429-436.
6. Block, A. R., & Marek, R. J. (2020). Presurgical psychological evaluation: Risk factor identification and mitigation. Journal of Clinical Psychology in Medical Settings, 27(2), 396-405.
7. Godin, G., & Kok, G. (1996). The theory of planned behavior: a review of its applications to health-related behaviors. American journal of health promotion, 11(2), 87-98.
8. Microsoft. Using Access or Excel to manage your data. Support n.d.;
9. Micrrosoft. Basic tasks for an Access desktop database. Support n.d.
10. Mekhail, N., Mehanny, D., Armanyous, S., Saweris, Y., & Costandi, S. (2019). The impact of obesity on the effectiveness of spinal cord stimulation in chronic spine-related pain patients. The Spine Journal, 19(3), 476-486.
11. Pak, D. J., Gruber, J., Deer, T., Provenzano, D., Gulati, A., Xu, Y., ... & Mehta, N. (2019). Spinal cord stimulator education during pain fellowship: unmet training needs and factors that impact future practice. Regional Anesthesia & Pain Medicine, 44(3), 407-414.
12. Nelson, D. V., Kennington, M., Novy, D. M., & Squitieri, P. (1996, June). Psychological selection criteria for implantable spinal cord stimulators. In Pain Forum (Vol. 5, No. 2, pp. 93-103). Churchill Livingstone.
13. Campos, N., Wandner, L., Kurihara, C., Bushey, D., Griffith, S., Liu, R., & Spevak, C. (2017). (418) Psychological comorbidities as a predictor of success of Spinal Cord Stimulator (SCS) implants based on 3-month outcome measures in the Military Health System (MHS). The Journal of Pain, 18(4), S78-S79.
14. Strauss, I., Taha, K., Krishna, V., & Hodaie, M. (2016). Younger age predicts greater effectiveness of spinal cord stimulation for chronic pain. Acta neurochirurgica, 158(5), 999-1003.
15. Bir, S. C., Konar, S., Maiti, T., Nanda, A., & Guthikonda, B. (2016). Neuromodulation in intractable pain management: outcomes and predictors of revisions of spinal cord stimulators. Neurosurgical focus, 40(5), E4.
16. Marola, O., Cherala, R., Prusik, J., Kumar, V., Fama, C., Wilock, M., ... & Pilitsis, J. G. (2017). BMI as a predictor of spinal cord stimulation success in chronic pain patients. Neuromodulation: Technology at the Neural Interface, 20(3), 269-273.
17. De La Cruz P, Fama C, Roth S, et al. Predictors of spinal cord stimulation success. Neuromodulation. 2015;18(7):599-602. doi:10.1111/ner.12325
18. Slangen, R., Schaper, N. C., Faber, C. G., Joosten, E. A., Dirksen, C. D., van Dongen, R. T., ... & van Kleef, M. (2014). Spinal cord stimulation and pain relief in painful diabetic peripheral neuropathy: a prospective two-center randomized controlled trial. Diabetes Care, 37(11), 3016-3024.
19. Simpson BA. Spinal cord stimulation. Br J Neurosurg. 1997;11(1):5-11. doi:10.1080/02688699746627
20. Davis III, C. E., Kyle, B. N., Thorp, J., Wu, Q., & Firnhaber, J. (2015). Comparison of pain, functioning, coping, and psychological distress in patients with chronic low back pain evaluated for spinal cord stimulator implant or behavioral pain management. Pain Medicine, 16(4), 753-760.
21. Malige, A., & Sokunbi, G. (2019). Spinal Cord Stimulators: A Comparison of the Trial Period: Versus: Permanent Outcomes. Spine, 44(11), E687-E692.

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