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The Incidence of Spinal Cord Injury in Implantation of Percutaneous and Paddle Electrodes for Spinal Cord Stimulation

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Abstract

Objective—Spinal cord stimulation (SCS) has been proven effective for multiple chronic pain syndromes. Over the past 40 years of use, the complication rates of SCS have been well defined in the literature; however, the incidence of one of the most devastating complications, spinal cord injury (SCI), remains largely unknown. The goal of the study was to quantify the incidence of SCI in both percutaneous and paddle electrode implantation.

Methods—We conducted a retrospective review of the Thomson Reuter's MarketScan database of all patients that underwent percutaneous or paddle SCS implantation from 2000 to 2009. The main outcome measures of the study were the incidence of SCI and spinal hematoma within 30 days following operation.

Results—Overall 8,326 patients met inclusion criteria for the study (percutaneous 5,458 vs. paddle: 2,868). The overall incidence of SCI was 177 (2.13%) (percutaneous: 128 (2.35%) vs. paddle: 49 (1.71%), p=0.0556). The overall incidence of spinal hematoma was 59 (0.71%) (percutaneous: 41 (0.75%) vs. paddle: 18 (0.63%), p = 0.5230).

Conclusion—Our study shows the overall incidence of SCI in SCS is low (2.13%) supporting that SCS is a safe procedure. No significant difference was found in the rates of SCI or spinal hematoma between the percutaneous and paddle groups. Further studies are needed to characterize the mechanisms of SCI in SCS and long-term outcomes in these patients.

Keywords

spinal cord stimulation; spinal cord injury; complications; spinal hematoma; SCS

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Introduction

Spinal cord stimulation (SCS) is an adjustable, reversible, and non-destructive treatment for a variety of chronic pain syndromes. Its efficacy has been proven in multiple randomized controlled trials for failed back surgery syndrome (FBSS)[1-7], complex regional pain syndrome (CRPS)[3, 6, 8, 9], refractory angina pectoralis[10-12], painful diabetic neuropathy[13], and peripheral vascular disease[14]. SCS has also been shown to be cost-effective for FBSS, complex regional pain syndrome (CRPS), and refractory angina pectoralis when compared to conventional medical therapy alone[5, 7, 9, 14-16].

Despite its efficacy and cost-effectiveness for a wide variety of indications, SCS is an invasive procedure with inherent associated risks. SCS systems utilize either percutaneous leads implanted by an intervetionalist, or paddle leads implanted surgically through a laminectomy. In a systematic review, Turner et al. found the mean rate of postoperative complications for SCS across studies to be 34.3%. The most common complications were equipment failure, superficial infection, and pain in the region of stimulator components[17]. Likewise, in a 20 year review of the literature, Cameron concluded that the most common complications of SCS included lead migration (13.2%), lead breakage (9.2%), infection (3.4%), hardware malfunction (2.9%), and unwanted stimulation (2.4%)[18]. Although there is a wealth of literature characterizing the complication rates of SCS, almost all previous studies fail to quantify a rare but devastating complication of SCS implantation, spinal cord injury (SCI). Unlike the many common complications, such as superficial infection, that are easily remedied in modern practice, SCI can lead to permanent neurologic sequelae including paralysis, hypesthesia, and incontinence. Despite the devastating consequences, the incidence of SCI in SCS remains largely unknown. In one of the only studies on this topic, Levy et al. estimate the incidence of SCI to be less than 0.6% with surgical implantation of paddle electrodes[19].

In this study, we retrospectively examined a large, nationwide cohort of patients that underwent either percutaneous or paddle electrode SCS between the years 2000 and 2009 using the Thomson Reuter's MarketScan database. The goal of the study was to quantify the incidence of SCI in both percutaneous and surgical placement of electrodes for SCS to further characterize this trend in current practice.

Methods

Data Source

Data for this study was obtained using the Thomson Reuter's MarketScan database that contains claims records from employers, health plans, government, and public organizations for over 158 million patients in the United States since 1996. The database includes claims information from Commercial Claims and Encounters, the Medicare Supplemental and Coordination of Benefits (COB), and Medicaid. In this study, we examined all patient healthcare utilization between 2000 and 2009 including clinical utilization (inpatient and outpatient), pharmaceutical claims, insurance enrollment and costs representing all subsections of the MarketScan database. In MarketScan each patient is assigned a unique,

encrypted enrollee ID that is used to link patient information between tables while allowing all patient information to be deidentified. Because the MarketScan database is deidentified, the Institutional Review Board deemed the study exempt from review.

Study Sample

International Classification of Diseases 9 (ICD-9) and Current Procedural Terminology 4 (CPT-4) codes were used to select patients for this study. To be included in the study patients needed to undergo implantation of SCS (CPT-4: 63650 and 63685 or 63655 and 63685; ICD-9: 03.93 and 86.94-86.98), have at least 90 days of follow up after SCS, and be 18 or older at the time of SCS implantation. Patients with SCS or SCI within 1 year prior to lead implant were excluded from the sample. Patients with procedures that could not be clearly identified as percutaneous (CPT-4: 63650) or paddle (CPT-4: 63655) implantation were also excluded.

Main Outcome Measures

The main outcome measures for this study were rate of SCI (ICD-9: 952.00-952.09, 952.10-952.19, 952.2, 952.8, 952.9, 950-957, 998.1) and spinal hematoma (ICD-9: 998.1) within 30 days of SCS. Odds ratio for SCI was calculated for taking any drug classified as an anticoagulant in MarketScan within 30 days of SCS procedure. More specifically, odds ratios were calculated for aspirin, clopidigrel, enoxaparin, and heparin individually.

Statistical Analysis

All continuous variables including age and number of days of follow up were summarized using means and standard deviations. Categorical variables including gender, Charlson Comorbidity Index (CCI), insurance type, SCI, and year of procedure were summarized using counts and percentages. CCI is a predictor of 1-year mortality in patients and is based off a score including 19 conditions. CCI has been validated in numerous patient populations and diagnoses[20]. Comparisons of categorical variables were conducted using chi-square analysis or Fisher's exact test when the incidence of events was low. All multivariate models including the odds ratios were adjusted for age, sex, Charlson Comorbidity Index, and insurance type. Statistical significance was defined by $p < 0.05$. All analyses were conducted using SAS 9.3 (SAS Institute, Cary, NC).

Results

Patient Cohort

The demographics of the patient sample are outlined in Table 1. Between 2000 and 2009, 8,326 patients that underwent SCS met inclusion criteria for the study with 5,458 patients undergoing percutaneous lead placement and 2,868 patients undergoing paddle lead placement. In the overall patient sample, the mean ± SD age was 54.4 ± 13.19 years (percutaneous: 54.5 ± 13.33 years vs. paddle: 54.2 ± 12.92 years) and 5,142 (61.76%) patients were female (percutaneous: 3,417 (66.45%) vs. paddle 1,725 (60.15%)). Overall, 491 (5.90%) patients had a CCI equal to 1 (percutaneous: 250 (4.58%) vs. 241 (8.40%)) and 126 (1.51%) patients had a CCI greater than or equal to 2 (percutaneous: 83 (1.52 vs. paddle 43 (1.50)).

The breakdown for diagnosis at time of SCS for both percutaneous and paddle lead procedures is outlined in Table 2. The most common pain diagnosis at time of SCS was postlaminectomy syndrome totaling 3,198 (38.41%) patients. The next most common diagnoses included neuritis or radiculitis with 3,067 (36.84%), back pain with1,722 (20.68%), chronic pain syndrome with 1,646 (19.77%), degenerative spine disease with 1,517 (18.22%), CRPS with 595 (7.15%), and pain in limbwith 483 (5.80%) patients, respectively.

Spinal Cord Injury

The rates of SCI and spinal hematoma in both patient cohorts are outlined in Table 3. In our overall patient sample the total incidence of SCI within 30 days after SCS implant was 177 (2.13%) patients. The difference in incidence between the two groups bordered on significance with 128 (2.35%) patients in the percutaneous group and 49 (1.71%) patients in the paddle group experiencing SCI ($p = 0.0556$). The incidence of spinal hematoma within 30 days following the procedure was 59 (0.71%) patients overall. There was no statistically significant difference between the groups with 41 (0.75%) patients in the percutaneous group and 18 (0.63%) in the paddle group experiencing a spinal hematoma ($p = 0.5230$).

Table 4 outlines the odds ratios for using antiplatelet or anticoagulant medications within 30 days prior to SCS procedure. We found the odds of SCI increased by 2.428 (95% CI 1.406 to 4.193) if the patient took any type of anticoagulant medication within 30 days prior to the procedure. Similarly, the odds of SCI increase by 2.994 (95% CI 1.267-6.840) if the patient took warfarin within 30 days before the procedure. We found no statistically significant increase in odds of SCI for patients taking aspirin, clopidigrel, or enoxaparin alone.

Discussion

Spinal Cord Stimulation has been in use for more than 30 years to treat various chronic pain syndromes[18]. Over the decades improvements in electrode design and surgical techniques have led to increased efficacy and reduced complication rates in SCS. Many of the common complications including superficial infection, lead migration, and lead breakage can usually be remedied with conventional medical management, revision, or removal of the SCS system with the patient rarely experiencing long-term sequlae[17, 18, 21, 22]. Given the low incidence and straightforward treatment of these complications, SCS has emerged as a safe, efficacious, and reversible treatment for various chronic pain syndromes.

The most feared complication of SCS is SCI, which can result in irreversible neurologic deficits including paralysis, hypesthesia, and incontinence. Despite the extensive literature characterizing the complications of SCS, very few studies report the incidence of SCI. Levy *et al*. report that the incidence of SCI in paddle electrodes implanted via laminectomy is 0.6%[19]; however to our knowledge, there has been no study that directly reports the rate of SCI in percutaneous implantation. In our study we found the overall incidence of SCI to be 2.13% with 2.35%in the percutaneous group and 1.71% in the paddle group. The p-value was 0.0556, and thus bordering on significance. Future studies are needed to further characterize the rate of SCI in percutaneous and paddle electrodes. Of note, we found a higher rate of SCI in paddle electrode implantation than previously reported by Levy et al[19].

This difference in SCI incidence is most likely explained by the methods in which the data were collected in each study. In the current analysis we reviewed the MarketScan database and defined SCI using ICD-9 and CPT-4 codes, whereas Levy *et al*. used self-reported rates from medical device companies' (Medtronic, St Jude Medical, and Boston Scientific) Medical Device Report databases. Additionally, our study included a decade of patient data from 2000 to 2009; however, Levy *et al*. examined patients between 2007 and 2010, and these different rates may reflect improvements in clinical practice in more recent years. The lower incidence of SCI reported by Levy and colleagues is likely due to these methodological differences including different data sources, different time scales, and alternative definitions of SCI.

We examined the relationship between various anti-platelet and anticoagulant medications and risk of SCI. Our analysis showed that taking any anticoagulant within 30 days prior to procedure resulted in a 2.428 increased odds of SCI (95% CI 1.406-4.193). Taking warfarin alone was associated with a 2.944 increase in odds of SCI (95% CI 1.267-6.840). Our analysis did not show a statistically significant increase in odds of SCI with aspirin, clopidigrel, and enoxaparin (Table 4). Our expectations were that all of these medications would increase the odds of SCI. Limitations in the analysis could have affected the ability to detect statistically significant effects. Using the MarketScan database, we were only able to tell if the patient had taken the medications 30 days prior to procedure. We were unable to determine the dosages of medications or how long before the procedure each medication was discontinued. Future studies analyzing specific risk factors for SCI in SCS are warranted as we have shown that approximately 2% of patients experience some degree of SCI.

The risk of neurologic injury has been proposed to be related to the volume and stiffness of the implanted electrode[19]. The theoretical risk of injury increases with electrode size, as large electrodes are more likely to compress the spinal cord and lead to ischemia; especially if edema occurs following electrode insertion. Our study shows that the rate of SCI is higher in percutaneous electrodes than paddle electrodes with the difference bordering on statistical significance. Thus, there must be factors that contribute to risk of SCI in SCS other than electrode volume.

One possible mechanism for our finding that rates of SCI are higher in percutaneous vs. paddle lead placement is that percutaneous lead placement is a blind procedure and thus more likely to result in injury. Multiple mechanisms of SCI in SCS have been reported including epidural hematoma[23, 24], cord compression[19], cord contusion[23], traumatic cord injury[25], and epidural abscess[26, 27]. As percutaneous electrodes are inserted through a Tuohy needle without direct visualization, there is an increased risk of causing injury to the local anatomy including blood vessels and the spinal cord itself. The blind nature of percutaneous electrode insertion poses risks of traumatic injury to the spinal cord by either direct penetration with a Tuohy needle or blunt trauma to the cord during electrode insertion. In fact, a case of quadraparesis following percutaneous electrode implantation into the spinal cord itself has been reported[25]. The patient emerged from general anesthesia with weakness in all 4 extremities and intramedullary electrode placement was noted on a post-operative Computed Tomography (CT) scan. Although an extreme case, this description demonstrates

the dangers of performing a blind procedure in the spinal canal[25]. Smith *et al*. describe a case of paraparesis following the implantation of percutaneous electrodes. The patient recovered well postoperatively until he developed bilateral lower extremity weakness 5 days following the procedure due to development of a spinal hematoma. Despite prompt surgical evacuation of the hematoma, the patient's neurologic deficits did not resolve[23]. Spinal hematoma is one of the major mechanisms of SCI in both percutaneous and paddle electrode implantation as demonstrated by the rates found in our study (33% of all SCI patients). The risk of hematoma development is greater during blind percutaneous lead placement as there is a chance that a small bleed, such as a torn bridging vein, may go undetected during the procedure. The uncorrected bleed can then evolve into a spinal hematoma resulting in SCI. This phenomenon is illustrated in the case described by Smith *et al*., as the patient's symptoms did not develop until 5 days following the procedure[23]. Surgical placement of paddle leads allows for direct visualization of the surgical site affording the surgeon the ability to avoid damage to nearby anatomic structures and to insure proper coagulation of hemorrhages. Further studies are warranted to investigate the risks associated with the blind nature of percutaneous implantation and its associated peri- and post-operative complications.

Several precautions can be taken to minimize the aforementioned peri- and post-operative complications. First, the appropriate use of anesthesia and intraoperative monitoring is crucial. Multiple options exist including local anesthesia in the awake patient and general anesthesia with electromyography (EMG), motor evoked potentials (MEP), and somatic sensory evoked potentials (SSEP). Traditionally, SCS implantation has been done under local anesthesia in the awake patient allowing the patient to directly report the location of paresthesias or any new onset of neurologic symptoms such as weakness that may represent impending SCI. However, awake surgery can be both anxiety-provoking and uncomfortable for many patients, especially if paddle electrodes are implanted though a laminectomy. Prior studies have demonstrated general anesthesia with intraoperative neuromonitoring is a safe and effective alternative to awake surgery that allows for a higher degree of patient comfort[28, 29]. It is also useful in patients with comorbidities that may preclude conscious sedation such as obstructive sleep apnea or obesity[28]. EMG and SSEP allow for proper electrode position and paresthesia coverage to be determined while the patient is under general anesthesia[28, 29]. MEP and SSEP are used to monitor for any potential injury to the spinal cord during the procedure and are used in all other spinal surgeries performed under general anesthesia[28]. Anesthesia and monitoring options for each patient are determined at the discretion of the surgeon and are vital to minimize the risk of an irreversible deficit.

Close observation of neurologic function following SCS is crucial in minimizing neurologic injury. In the days to weeks following surgery, patients are at risk for developing SCI due to a spinal hematoma[23, 24] or epidural abscess[26, 27]. Implanting physicians must maintain a high level of suspicion following SCS that any newly developing neurologic deficits may represent signs of hematoma or abscess formation. These sequelae may also present with severe back or lower extremity pain[30]. Prompt evaluation with a CT scan and surgical intervention are critical to minimize any further neurologic injury and to give the patient any chance of recovering the lost neurologic function.

Our study sampled a large nationwide cohort using the Thompson Reuters MarketScan database. The large cohort allows our study to overcome biases due to differences in practice in different regions and at different institutions. Despite its strengths, we do recognize its associated limitations. First, the study is retrospective and nonrandomized and therefore cannot control for confounding variables. It is important to note that our observed rate of SCI is based upon ICD-9 codes for SCI. Using the MarketScan database, we have no way to evaluate the severity and duration of neurologic deficits sustained by patient. Also, the exact mechanism of spinal cord injury (with the exception of SCI due to spinal hematoma) was unable to be determined. Using the MarketScan Database, we were unable to determine what percentage of implants were cervical versus thoracolumbar. Were also unable to determine what percentage of implants were trials versus permanent procedures. Because patients were selected using diagnosis and procedure codes, miscoding could have resulted in inappropriate inclusion or exclusion of patients from the study. Both ICD-9 and CPT-4 codes were used in an effort to reduce miscoding.

Conclusion

Despite these limitations, the current study offers a valuable addition to the SCS literature. Although there are many previous reports investigating the complications associated with SCS, ours is the first to our knowledge to investigate and compare the incidence of SCI in both percutaneous and paddle electrode implantation. Furthermore, with thousands of patients in each cohort, this study is highly powered to address our question. We found that the overall incidence of SCI in SCS was low (2.13%), and that there was no significant difference in rates of SCI between percutaneous and paddle implantation. Given that our study found approximately 2% of patients experience some degree of SCI, future studies investigating the risk factor of SCI are critical. Our findings suggest that while reversible complications may be more common, SCI as a result of SCS is uncommon. More studies are needed to further characterize the mechanisms of injury and outcomes in these patients.

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Table 1

Patient Demographics

	All	Percutaneous SCS	Paddle SCS
Overall - no. (%)	8,326 (100.0)	5,458 (65.55)	2,868 (34.45)
Female - no.(%)	5,142 (61.76)	3,417 (62.61)	1,725 (60.15)
Age - mean (SD)	54.4 (13.19)	54.5 (13.33)	54.2 (12.92)
Insurance - no. (%)			
COMMERCIAL	5,577 (66.98)	3,713 (68.03)	1,864 (64.99)
MEDICAID	1,125 (13.51)	655 (12.00)	470 (16.39)
MEDICARE	1,624 (19.51)	1,090 (19.97)	534 (18.62)
Follow Up Days - mean (SD)	703.4 (584.06)	724.6 (592.23)	663.0 (566.10)
Charlson Comorbidity Index - no. (%)			
0	7,709 (92.59)	5,125 (93.90)	2,584 (90.10)
1	491 (5.90)	250 (4.58)	241 (8.40)
2	121 (1.45)	80 (1.47)	41 (1.43)
3 or higher	5 (0.06)	3 (0.05)	2 (0.07)

Table 2

Diagnosis at time of SCS

	All	Percutaneous SCS	Paddle SCS
Back Pain - no. (%)	1,722 (20.68)	790 (14.47)	932 (32.50)
Chronic Pain Syndrome - no. (%)	1,646 (19.77)	968 (17.74)	678 (23.64)
Complex Regional Pain Syndrome - no. (%)	595 (7.15)	399 (7.31)	196 (6.83)
Degenerative Spine Disease - no. (%)	1,517 (18.22)	1,017 (18.63)	500 (17.43)
Neuritis or Radiculitis - no. (%)	3,067 (36.84)	2,108 (38.62)	959 (33.44)
Limb Pain - no. (%)	483 (5.80)	231 (4.23)	252 (8.79)
Postlaminectomy Syndrome - no. (%)	3,198 (38.41)	2,127 (38.97)	1,071 (37.34)

Table 3

Rate of SCI and Spinal Hematoma in 30 Days

	All	Percutaneous SCS	Paddle SCS	p-value
Spinal Cord Injury - no. (%)	177 (2.13	128 (2.35)	49 (1.71)	0.0556
Spinal Hematoma - no. (%)	50 (0.71)	41 (0.75)	18 (0.63)	0.5230

Table 4

Odds of SCI when using anticoagulant or antiplatelet drug with in 30 days of procedure

	Odds Ratio	95% CI for Odds Ratio	
Aspirin	3.522	0.812	15.269
Enoxaparin	1.86	0.395	8.764
Clopidigrel	1.639	0.744	3.613
Warfarin	2.944	1.267	6.84
Anticoagulant Drug Class	2.428	1.406	4.193