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Case study

The primary diagnosis and the coexisting anxiety disorders have no impact on the additional surgical procedure after spinal cord stimulators implantation: An analysis of 11,029 patients

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ABSTRACT

Studies have demonstrated superior outcomes and cost effectiveness of the spinal cord stimulation (SCS) for the treatment of chronic pain syndromes such as failed back surgery syndrome (FBSS) or complex regional pain syndrome (CRPS). However, little is known about the impact of primary diagnosis or mental disorders on the revision rate. This is the Retrospective cohort study to analyze the reintervention rates based on the primary diagnosis or comorbid mental disorder. Data of the annual trends of SCS use, revision and removal rate of SCS and additional surgical rate after removal was collected and analyzed for patients undergoing SCS between 2007 and 2015, within a private insurance billing database. Trial cases were excluded from this study. The results showed 11,029 patients received SCS implantation with percutaneous electrodes (PE, n = 7418) or surgical electrode (SE, n = 3611). There was a trend of increasing use of SCS from 2007 to 2013, followed by a decrease in last two years. There was no significant difference in the neither removal nor revision rate regardless between the patients with FBSS or CRPS at each time point. Although the removal rates within 2 years were significantly higher in the patients with anxiety disorders compared to the patients without any mental disorders (PE: $p < .001$, SE: 0.003), the rate of additional surgery after the removal showed no significant difference (PE: $p = .532$, SE: $p = .262$). Therefore, we concluded that the primary diagnosis and the presence of anxiety disorders did not have an impact on the additional surgical rate following SCS implantation.

1. Introduction

Since the Food and Drug Administration approved spinal cord stimulators (SCS) in 1989, the treatment has been applied for intractable neuropathic pain. The candidates for SCS are usually patients who are diagnosed with failed back surgery syndrome (FBSS) or complex regional pain syndrome (CRPS). Patients who have completed a successful trial will receive surgical implantations of spinal cord stimulators with either percutaneous electrodes (PE) or paddle-type surgical electrodes (SE) placements. Studies including randomized control trials have demonstrated superior outcomes and cost effectiveness with the use of SCS compared to conservative medical management or repeated surgeries for the treatment of chronic pain syndromes [1–3].

SCS are considered safe and effective, however, high rates of revision or additional spinal surgery after removal have been reported; Babu et al. found the revision rate of SCS was up to 24% within four years follow up [4]. Furthermore, the SCS revision surgery reduces patient satisfaction and outcomes while increasing their risk and healthcare costs [5]. Some factors such as age, gender and postoperative pain score are reported as risk factors for revision surgery [6], however, little is known about the impact of primary diagnosis or mental disorders on the revision rate.

One-third of patients who were diagnosed with FBSS were accompanied with anxiety disorders [7]. The strong relationship between the presence of mental disorders and poor outcomes of spinal surgery are well described [8–10]. Therefore, we have analyzed the revision and removal rates based on the primary diagnosis (FBSS or CRPS) and mental disorders.

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2. Material and method

Data was collected and analyzed for patients undergoing spinal cord stimulator implantation between 2007 and 2015 using the commercially available PearlDiver software (PearlDiver, Inc., Colorado Springs, CO, USA) [11]. The orthopedic records were searched using International Classification of Disease, Ninth Revision (ICD-9) and Current Procedural Terminology (CPT) codes, from the Humana database patient population, a private insurance billing database. Our database was compliant with all regulations associated with the Health Insurance Portability and Accountability Act (HIPPA). The institutional review board (IRB) at our institution approved the study protocol with a full waiver of HIPAA Authorization and Informed Consent due to the retrospective nature of our study. This study was funded by departmental funds.

2.1. Data collection

Patients who underwent spinal cord stimulator implantation were identified. They were defined as patients having both neurostimulator and electrode insertion codes. Patients who had codes for electrodes without codes for neurostimulators were considered as trial cases, and omitted from the study. Patient data from 2007 to 2015 was incorporated for analysis of trend, and patient data from 2007 to 2013 was used for analysis of revision rates to ensure patients' follow up >2 years. In the analysis of trend, "incidence" was defined as the number of patients with SCS per 100,000 patients in a particular year. Revision and removal rate was defined as [(number of patients who underwent primary surgery in 2007–2013 and underwent revision or removal surgery within 3 months, 1 year or 2 years after primary surgery)/(the total number of the patients who underwent primary surgery in 2007–2013)]. The rates were subsequently analyzed based on the type of primary diagnosis (FBSS or CRPS), and the presence of mental disorders. The mental disorders included mood disorders (depression, manic and bipolar), anxiety disorders, somatoform disorders and personality disorders. Finally, patients who underwent additional spinal surgery after SCS removal within 2 years of primary implantation were collected to compare the additional surgical rate between the subgroups. Additional spine surgery included the code for lumbar fusion as well as decompression surgery. All codes are shown in Table 1. Due to the nature of PearlDiver software, we cannot detect subgroups with less than 10 patients. Those cohorts were annotated as "<10".

Table 1
Description of coding.

	Coding
CPT	
Implantation of stimulator	63685
Implantation of PE	63650
Implantation of SE	63655
Revision of SE or PE	63663, 63664
Removal of SE or PE	63661, 63662
Additional surgery	22558, 22612, 22630, 22633 63030, 63005, 63012, 63017 63047, 63056, 63087, 63102
ICD9	
FBSS	72281, 72282, 72283
CRPS	33721, 33722, 3544, 35571
Mood disorders	29606, 29646, 29656, 29666, 29626, 29636, 29616
Anxiety disorders	30000, 30001, 30002
Somatoform disorders	30081, 30082, 30089
Personality disorders	3010, 30110, 30113, 30120, 30122, 3013, 3014, 30150, 30159, 3016, 3017, 30181, 30189, 3019

2.2. Statistical analysis

The chi-square test and residual analysis (if required) were used for the statistical evaluation. Odds ratios (OR) and 95% confidential intervals (CI) were calculated using chi-square tests. The result of residual analysis was described as $p < .05$ when the variables were $2.58 \geq |r|$ according to the Haberman's method[12]. All analyses were performed using SPSS computer software (version 23; SPSS, Chicago, IL, USA). Two tailed *P* value <.05 was considered statistically significant.

3. Results

A total of 11,029 patients were enrolled in our study; 7418 patients had SCS with PE and 3611 patients had SCS with SE (Fig. 1). There was no significant difference in gender ($p = .608$) or age distribution ($p = .129$) between PE and SE (Table 2).

3.1. Trend of SCS use

There was a trend of increasing use of SCS from 2007 to 2013, followed by a decrease in last two years. From 2013 to 2015 the overall incidence dropped by 19.3% (from 20.3 to 16.4 patients/100,000 patients, Fig. 2). Annual trends of subgroups divided by patients' primary diagnosis showed that patients diagnosed with FBSS were more likely to receive SCS with PE than SE in 2015 compared to 2007 (OR = 1.29, $p = .029$, Fig. 3a). In contrast, there was no change in trends in stimulator use for CRPS (Fig. 3b).

3.2. Revision and removal rate

The revision rate within 3 months for SCS with SE was significantly higher than with PE ($p = .003$), however, the rate within 1 or 2 years showed no significant difference ($p = .268$, 0.649, Table 3). The removal rates of PE were significantly higher than of SE at each time point (3 month: $p > .001$, 1 year: $p = .010$, 2 years: $p = .045$, Table 3).

3.3. Comparison between primary diagnosis

There was no significant difference in the revision rate at each time point between the subgroup with FBSS and CRPS, regardless of the type of stimulator electrode (Table 4). Likewise, the removal rate also did not show any significant differences between FBSS and CRPS at every timepoint (Table 4).

3.4. Comparison between mental disorders subgroups

Among the patients who were treated with PE, 74 patients (1.5%) had mood disorders, and 2367 patients (49.1%) had anxiety disorders. Meanwhile, among the patients who were treated with SE, 42 (1.8%) patients had mood disorders, 1130 (48.5%) patients had anxiety disorders, 13 (0.6%) patients had somatoform disorders, and 41 (1.8%) patients had personality disorders. In the comparison of revision rate, there was no significant difference between the patients with anxiety and without any mental disorders (Table 5). In contrast, the removal rates within 2 years were significantly higher in patients with anxiety disorders compared to the patients without any mental disorders, regardless of the electrodes type (PE: $p < .001$, SE: $p = .003$, Table 5). However, the

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