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Cohort Study

Long-Term Outcomes After Spinal Cord Stimulator Placement in Patients with Pre-procedural Active Opioid Use Versus Patients Who Were Opioid-Naïve

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Background: Outcome optimization after the placement of a spinal cord stimulator (SCS) is critical. The objective of this study was to determine if an association existed between pre-procedural opioid use (compared to patients who were opioid-naïve) and postoperative long-term outcomes following SCS placement.

Objective: To examine the impact of preprocedural opioid use on long-term outcomes after SCS therapy.

Study Design: Cohort study utilizing a nationwide database.

Setting: Retrospective.

Methods: With the use of data from HCA Healthcare's national database, a retrospective cohort study was performed to analyze differences in outcomes between opioid-naïve patients and preoperative opioid users who underwent SCS placements. The primary outcome of interest was device explantation at 6 months and 12 months. Secondary outcome measurements included reoperations and readmissions at 6 months and 12 months, as well as operative complications. Multivariable logistic regression models were performed to analyze the association of preoperative opioid use with those outcomes. The odds ratio (OR), 95% confidence intervals (CI), and *P* values were reported for the independent variables.

Results: The final study population consisted of 13,893 patients who underwent SCS placements. In univariate analyses, patients who used opioids preoperatively had higher 6-month (3.6% vs. 2.6%) and one-year removal rates (3.6% vs. 2.8%) (all $P < 0.009$). On multivariable logistic regression, those using opioids preoperatively had higher odds of removal at 6 months (OR = 1.290, 95% CI 1.05-1.58, $P = 0.01$) and at one year (OR = 1.23, 95% CI 1.01-1.50, $P = 0.04$). There was no difference between patients requiring preoperative opioids and patients who were opioid-naive as far as the odds of 6- or 12-month readmissions were concerned. Compared to the opioid-naive group, patients requiring preoperative opioids had increased odds of reoperation at 6 months (OR = 1.2, 95% CI 1.02-1.40, $P = 0.03$). There were no differences in the odds of complications between both cohorts.

Limitations: Opioid use in this study was defined as using opioids preoperatively in the 30 days leading up to surgery.

Conclusion: Patients requiring preoperative opioids before SCS placements had increased odds of SCS explantation at 6 months and 12 months, as well as increased odds of reoperation at 6 months.

Key words: Spinal cord stimulation, opioid use, opioid use disorder, opioid tolerance, explant, readmission, outcomes

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Spinal cord stimulator (SCS) implantation is being increasingly utilized for managing chronic pain conditions that are minimally responsive to conservative management (1-2). Despite some studies calling the efficacy of spinal cord stimulation into question (3-4), economic studies have supported the use of the procedure for its demonstrated association with gains in quality-adjusted life years and relative cost-effectiveness compared to conventional medical management (5-6). Another potential benefit of SCS therapy is a potential reduction or discontinuation of opioid dependence (7). Opportunities to minimize the complications and improve the long-term success of SCS therapy have also been pursued, including psychiatric optimization (8), high-frequency paresthesia-free stimulation (9-10), and the use of new technologies to reduce equipment malfunctions and lead migration or fracture (2,11-12).

Studies have shown that large opioid requirements and opioid tolerance were associated with increased rates of SCS system failures and explantations (7,13-15). Sharan et al noted that consuming a daily dose of 90 mg or more of a morphine milligram equivalent (MME) was an independent predictor of explantation (7). Pope et al observed that SCS explantations occurred earlier in patients whose daily morphine equivalent doses exceeded 100 mg prior to SCS implantation (13). Adil et al indicated that SCS therapy patients who became weaned off opioids entirely ranged from 34.2% in the ≤ 20 MME group to 5.1% in the > 90 MME group (14-15). Therefore, patients dependent on high-dose opioids prior to SCS implantation would be more likely to fail the SCS procedure and continue long-term opioid therapy (7). Notably, studies also found that opioid dosages typically rose the year before SCS implantation (7). Few studies have examined the association of preoperative opioid use with other long-term outcomes (e.g., readmission, reoperation, etc.) after SCS implantation.

Accordingly, the purpose of this retrospective cohort study was to compare long-term outcomes following SCS implantation in patients who did not use opioids preoperatively to patients who did. Specifically, we aimed to examine SCS explant, reoperation, complications, and readmission rates at 6 months and 12 months after SCS therapy. We hypothesized that: (1) those requiring opioids preoperatively would have greater explantation rates than opioid-naive individuals at 6 months and 12 months (7,8,12,16); (2) preoperative opioid use would be associated with increased readmission rates; and (3) those requiring opioids preoperatively would be likelier to require device reoperation.

Methods

Data Registry

This study received approval and clearance from HCA's Graduate Medical Education (GME) institutional review board prior to initiation. Because of the study's retrospective design and the de-identified nature of data inquiry, the study was granted exempt status, and consent requirements were therefore waived. A multicenter national data source that compiles demographic, preoperative, perioperative, and postoperative data across all inpatient and outpatient centers within the HCA Healthcare network was used for the analysis. This dataset is national, with most of the included health centers concentrated in the South, West, and Midwest regions.

Participant Inclusion and Exclusion

The criterion for inclusion was the receipt of SCS therapy at an HCA Healthcare facility between January 1, 2014, and May 1, 2021. Study participants included patients aged 18+ years old. Two common procedure terminology (CPT) codes were to identify recipients of SCS implantation: 63655 (open laminectomy SCS implantation involving a laminectomy) and 63650 (percutaneous SCS implantation). Clinical indications for SCS

therapy included but were not limited to chronic pain, failed back surgery syndrome (FBSS) (e.g., post-laminectomy pain syndrome), neuritis, spondylosis, degenerative disc disease, complex regional pain syndrome, spinal stenosis, and lumbago, among others. Patients with incomplete encounter data were excluded (Fig. 1).

Study Population and Covariates

The 2 cohorts studied were those who used opioids preoperatively and those who did not, the latter labeled as opioid-naïve patients. Preoperative opioid use was defined as a patient having an active prescription for opioid medications within the 30 days leading up to surgery. The primary outcome of interest was device explantation at 6 months and 12 months. Secondary outcome measurements were reoperations and readmissions at 6 months and 12 months, as well as operative complications. Complications included all relevant mechanical, infectious, bleeding, battery, and surgical complications, such as lead displacement or fracture, hematoma and hemorrhage, battery failure, and surgical pain or seroma formation. Other outcome measures included hospital length of stay (LOS). The covariates included were demographic variables, types of SCS implantation (open approach vs. percutaneous approach), encounter type (inpatient, observation, outpatient), insurance type (Medicare, Medicaid, private, other), gender (male vs. female), race (White, Black, Hispanic, other).

Statistical Analysis

All statistical analyses were performed using SAS software version 9.4 for Windows (©2022 SAS Institute, Inc.). Univariate analyses were used to examine differences between both cohorts. For continuous variables, t tests were utilized, and for the comparison of categorical variables, chi-squared analysis was used. Multivariable logistic regression was performed for each outcome variable of interest, including operative complications, explantation, reoperation, and readmission rates. All covariates were included in the multivariable models and consisted of open approach, psychiatric comorbidities, age, gender, race, BMI, Elixhauser Comorbidity Index score, smoking status, and insurance. For logistic regression, we reported the odds ratio (OR) and 95% confidence intervals (CI).

Results

Study Population

There were 20,981 patients meeting inclusion criteria, of whom 13,893 remained after exclusion, with 8,414 (60.6%) reporting preoperative opioid use. The most common indications for SCS placement were

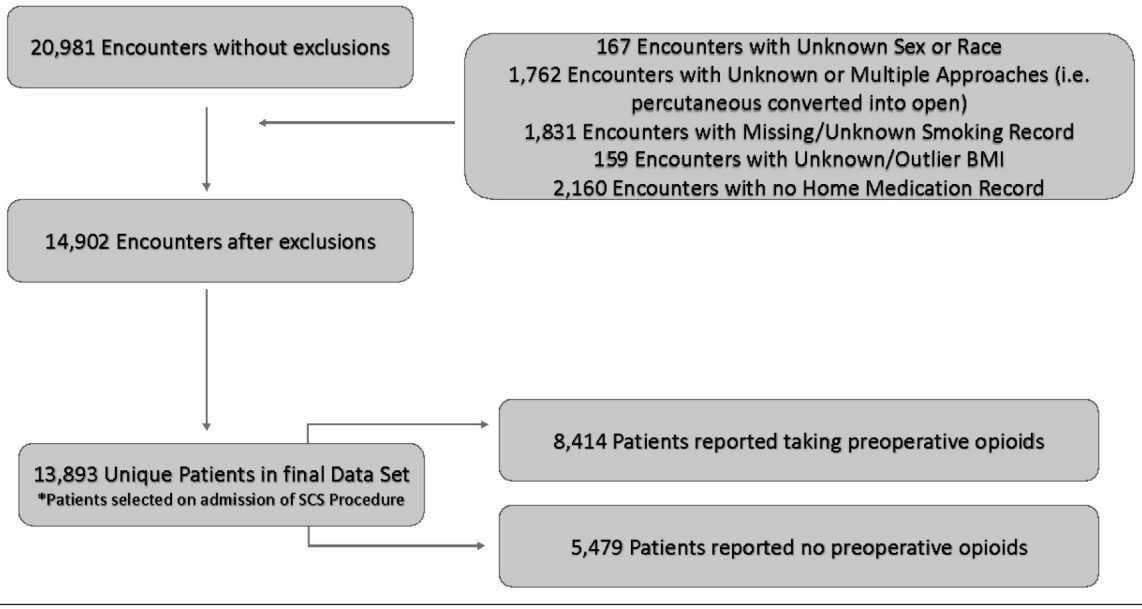

Fig. 1. *Summary of inclusions and exclusions.*

chronic pain (n = 8963, 64.5%), followed by FBSS (e.g. post-laminectomy pain syndrome) (n = 5,971, 43.0%), neuritis (n = 5,098, 36.7%), spondylosis (n = 1,870, 13.5%), and degenerative disc disease (n = 1,830, 13.2%). The most common insurance was Medicare (n = 8,355, 260.1%). Most patients were female (n = 8,083, 58.2%), with White being the most represented race (n = 11,643, 83.8%). The majority of SCS placement cases were performed on an outpatient basis (n = 12,074, 86.9%). A majority were also performed using an open approach (n = 8,465, 60.6%).

The most common complications in the cohort were infection (n = 402, 2.9%), followed by lead fracture (n = 343, 2.5%), battery failure (n = 282, 2.0%), mechanical complications (n = 271, 2.0%), lead displacement (n = 183, 1.3%) and reoperation (n = 120, 0.9%). The overall complication rate at one year was 12.5% (n = 1,742). With respect to the outcome variables of interest, the 6- and 12-month readmission rates were n = 1,610 (11.6%) and n = 1,834 (13.2%), respectively. As shown in Tables 1 and 2, explantation rates at 6 months were 3.21%, and at one year, they were n = 460 (3.3%), with no significant differences in explantation based on approach (i.e., percutaneous vs. open) but slight significant differences based on opioid use ($P < 0.008$).

Revision rates at one year were 311 (2.2%), respectively. The preoperative opioid group was found to have a higher proportion of female patients (59% vs. 57%, $P = 0.019$) and a greater proportion of current smokers (21.7% vs. 19.7%, $P = 0.012$). With respect to outcomes, the patients with preoperative opioid use demonstrated a greater rate of 6-month readmission (12.1% vs. 10.9%, $P = 0.03$), a greater rate of 6-month removal (3.6% vs. 2.6%, $P = 0.002$), a greater rate of one-year removal (3.6% vs. 2.8%, $P = 0.005$) and a greater rate of one-year reoperation (7.5% vs. 6.3%, $P = 0.006$) (Table 3).

In the multivariable analysis, patients with a history of preoperative opioid use were found to have increased odds of explantation at 6 months (OR = 1.29, 95% CI 1.05-1.58, $P = 0.014$), as did those with Medicaid insurance (OR = 1.89, 95% CI 1.26-2.82, $P = 0.002$) and high Elixhauser Comorbidity Index scores (OR = 1.10, 95% CI 1.01-1.20, $P = 0.02$) (Table 4).

According to the multivariable analysis, use of preoperative opioids was associated with increased odds of explantation at one year (OR = 1.23, 95% CI 1.01-1.50, $P = 0.04$), as were Medicaid insurance (OR = 1.09, 95% CI 1.22-2.72, $P = 0.003$) and a high Elixhauser Comorbidity Index score (OR = 1.09, 95% CI 1.01-1.19, $P = 0.003$). Meanwhile, increasing age was associated with decreased odds of explantation at one year (OR = 0.99, 95% CI 0.98-0.99, $P = 0.006$) (Table 5).

Secondary Outcomes

Multivariable regression showed that preoperative opioid use was associated with increased odds of reoperation at 6 months (OR = 1.19, 95% CI 1.02-1.40, $P = 0.031$), as was Medicaid insurance (OR = 1.61, 95% CI 1.14-2.28, $P = 0.006$). Hispanic race (OR = 0.69, 95% CI 0.50-0.95, $P = 0.023$) and older age (OR = 0.99, 95% CI 0.98-0.99, $P < 0.001$) were both associated with decreased odds of reoperation at 6 months (Table 6).

Our multivariable analysis demonstrated that preoperative opioid use trended toward increased odds of one-year reoperation (OR = 1.15, 95% CI 1.00-1.32, $P = 0.05$), whereas Medicaid insurance was significantly associated with one-year reoperation (OR = 1.79, 95% CI 1.34-2.41, $P < 0.001$). Categories associated with decreased odds of one-year reoperations include former smokers (OR = 0.85, 95% CI 0.73-0.99, $P = 0.04$), Hispanic ethnicity (OR = 0.76, 95% CI 0.58-0.99, $P = 0.04$), and advanced age (OR = 0.98, 95% CI 0.97-0.99, $P < 0.001$) (Table 7).

Table 1. *Univariate statistics for comparative explantation rates of percutaneous and open approaches.*

	Percutaneous		Open		Test Statistic	*P* value
	n	%	n	%		
6-Month Removal	279	3.3%	167	3.1%	$\chi^2 = 0.512$	0.474
One-Year Removal	289	3.4%	171	3.2%	$\chi^2 = 0.719$	0.397

Table 2. *Univariate statistics for comparative explantation rates of opioid and nonopioid groups.*

	Nonopioids		Opioids		Test Statistic	*P* value
	n	%	n	%		
6-Month Removal	145	2.7%	301	3.6%	$\chi^2 = 9.254$	0.002
One-Year Removal	154	2.8%	306	3.6%	$\chi^2 = 7.073$	0.008

Table 3. *Univariable statistics stratified by preoperative opioid use.*

		No Opioid	Preoperative Opioid	*P* value
Encounter Type	Inpatient	455 (8.3%)	801 (9.5%)	0.006
	Observation	247 (4.5%)	316 (3.8%)	
	Same-Day Discharge	4777 (87.2%)	7297 (86.7%)	
Insurance Type	Medicare	3425 (62.5%)	4930 (58.6%)	< 0.001
	Medicaid	184 (3.4%)	348 (4.1%)	
	Private	1194 (21.8%)	1992 (23.7%)	
	Other/ Uninsured	676 (12.3%)	1144 (13.6%)	
Gender	Female	3121 (57%)	4962 (59%)	0.019
	Male	2358 (43%)	3452 (41%)	
Race	Other	116 (2.1%)	134 (1.6%)	0.002
	Hispanic	433 (7.9%)	647 (7.7%)	
	Black	332 (6.1%)	588 (7%)	
	White	4598 (83.9%)	7045 (83.7%)	
Smoker	Never	4365 (45.3%)	1329 (42.6%)	0.012
	Former	3360 (35%)	1113 (35.7%)	
	Current	1898 (19.7%)	677 (21.7%)	
ICU Admission	0	5414 (98.8)	8316 (98.8%)	0.908
	1	65 (1.2%)	98 (1.2%)	
6-Month Readmission	0	4884 (89.1%)	7399 (87.9%)	0.030
	1	595 (10.9%)	1015 (12.1%)	
One-Year Readmission	0	4792 (87.5%)	7267 (86.4%)	0.063
	1	687 (12.5%)	1147 (13.6%)	
One-Year Interrogation	0	5422 (99%)	8313 (98.8%)	0.385
	1	57 (1%)	101 (1.2%)	
One-Year Removal	0	5325 (97.2%)	8108 (96.4%)	0.005
	1	154 (2.8%)	306 (3.6%)	
One-Year Revision	0	5361 (97.8%)	8221 (97.7%)	0.585
	1	118 (2.2%)	193 (2.3%)	
One-Year Reoperation	0	5135 (93.7%)	7783 (92.5%)	0.006
	1	344 (6.3%)	631 (7.5%)	
Any Complication	0	4817 (87.9%)	7334 (87.2%)	0.190
	1	662 (12.1%)	1080 (12.8%)	

Table 4. *Multivariable logistic regression for 6-month explantation.*

	Odds Ratio	95% CI for OR		*P* value
		Lower	Upper	
Preoperative Opioid Use	1.290	1.053	1.580	0.014
Open Approach	1.089	0.895	1.326	0.395
Psychiatric Comorbidities	0.949	0.812	1.109	0.511
Age	0.989	0.980	0.998	0.015
Gender	0.867	0.710	1.057	0.158
Race = Black	1.109	0.780	1.575	0.565
Race = Hispanic	0.701	0.467	1.052	0.086
Race = Other	0.813	0.380	1.741	0.594
BMI	0.986	0.971	1.001	0.067
Elixhauser	1.102	1.014	1.199	0.023
Smoker = Current	1.131	0.886	1.444	0.323
Smoker = Former	0.915	0.731	1.147	0.443
Ins = Medicaid	1.885	1.259	2.823	0.002
Ins = Medicare	0.977	0.748	1.277	0.865
Ins = Other/Charity	1.093	0.796	1.500	0.582

Table 5. *Multivariable logistic regression for explantation after one year.*

	Odds Ratio	95% CI for OR		*P* value
		Lower	Upper	
Preoperative Opioid Use	1.232	1.010	1.502	0.039
Open Approach	1.102	0.908	1.338	0.326
Psychiatric Comorbidities	0.974	0.837	1.132	0.728
Age	0.988	0.979	0.996	0.006
Sex	0.867	0.713	1.055	0.153
Race = Black	1.073	0.755	1.523	0.695
Race = Hispanic	0.728	0.492	1.077	0.112
Race = Other	0.786	0.367	1.683	0.536
BMI	0.987	0.973	1.002	0.088
Elixhauser	1.094	1.007	1.189	0.033
Smoker = Current	1.108	0.871	1.409	0.405
Smoker = Former	0.907	0.726	1.133	0.389
Ins = Medicaid	1.820	1.218	2.721	0.003
Ins = Medicare	0.995	0.765	1.294	0.971
Ins = Other/Charity	1.088	0.797	1.485	0.596

In the multivariable analysis, preoperative opioid use was not associated with 6-month readmission rates. Factors associated with decreased odds of 6-month re-admission included open-approach surgery (OR = 0.77, 95% CI 0.69-0.85, $P < 0.001$), older age (OR = 0.98, 95% CI 0.98-0.99, $P < 0.001$), Hispanic ethnicity (OR = 0.68, 95% CI 0.55-0.84, $P < 0.001$), as well as both current and

Table 6. *Multivariable logistic regression for reoperation after 6 months.*

	Odds Ratio	95% CI for OR		*P* value
		Lower	Upper	
Preoperative Opioid Use	1.190	1.016	1.394	0.031
Open Approach	1.004	0.860	1.172	0.958
Psychiatric Comorbidities	1.005	0.888	1.137	0.940
Age	0.985	0.979	0.992	< 0.001
Gender	1.051	0.900	1.227	0.530
Race = Black	1.022	0.763	1.367	0.886
Race = Hispanic	0.692	0.503	0.951	0.023
Race = Other	0.990	0.573	1.712	0.972
BMI	0.989	0.977	1.001	0.075
Elixhauser	1.021	0.953	1.094	0.554
Smoker = Current	0.970	0.796	1.180	0.758
Smoker = Former	0.840	0.704	1.003	0.054
Ins = Medicaid	1.614	1.144	2.275	0.006
Ins = Medicare	1.076	0.872	1.328	0.496
Ins = Other/Charity	1.103	0.861	1.413	0.436

Table 7. *Multivariable logistic regression for reoperation after one year.*

	Odds Ratio	95% CI for OR		*P* value
		Lower	Upper	
Preoperative Opioid Use	1.147	1.000	1.316	0.050
Open Approach	0.998	0.872	1.141	0.972
Psychiatric Comorbidities	1.032	0.928	1.148	0.557
Age	0.985	0.979	0.991	< 0.001
Gender	0.970	0.847	1.111	0.659
Race = Black	0.978	0.755	1.267	0.866
Race = Hispanic	0.761	0.584	0.993	0.044
Race = Other	0.946	0.581	1.541	0.824
BMI	0.992	0.982	1.003	0.150
Elixhauser	0.991	0.933	1.053	0.777
Smoker = Current	1.002	0.844	1.188	0.985
Smoker = Former	0.847	0.725	0.988	0.035
Ins = Medicaid	1.794	1.339	2.405	< 0.001
Ins = Medicare	1.093	0.910	1.314	0.343
Ins = Other/Charity	1.114	0.897	1.383	0.330

former smoking status (ORs = 0.82-0.86, *P* = 0.94-0.98) and greater BMI (OR = 0.99, 0.98-0.99, *P* = 0.007) (Table 8).

According to the multivariable analysis, preoperative opioid use was not associated with one-year admission rates. Numerous other variables were found to be associated with decreased odds of readmission at one year, including the open approach (OR = 0.78, 95% CI 0.71-0.86, *P* < 0.001), older age (OR = 0.98, 0.97-0.99, *P* < 0.001), Hispanic ethnicity (OR = 0.69, 95% CI 0.57-0.85, *P* < 0.001), and other factors, including BMI and smoking status (*P* < 0.001-0.009). Medicaid insurance was associated with greater odds of one-year readmissions (OR = 1.33, 95% CI 1.05-1.69, *P* = 0.02) (Table 9).

An additional regression was run for perioperative complications at both groups' initial visits. Preoperative opioid use was not associated with perioperative complications (OR = 1.09, 95% CI 0.91-1.31, *P* = 0.35). The open approach was associated with higher odds of operative complications (OR = 1.21, 95% CI 1.01-1.45, *P* = 0.04).

Discussion

This study's main finding was that preoperative opioid use was associated with increased odds of SCS explantation at 6 months and 12 months and increased odds of reoperation at 6 months. Numerous other factors were found in multivariable regression to be associated with explantation, including Medicaid insurance and a higher comorbidity burden via Elixhauser increasing the odds of explantation at both 6 and 12 months. The open approach was found to be associated with decreased odds of readmission at 6 months and 12 months, although it was also associated with higher odds of operative complications.

The main results of our study support the primary hypothesis that individuals requiring preoperative opioids had higher explantation and reoperation rates than those who were opioid naïve. Ashwini et al demonstrated that MME doses in the 5-90 mg/day range were independently associated with heightened explantation rates (7). Hwang et al (17) found that opioid status (naïve vs. tolerant) was not individually associated with explantation. However, their study was a retrospective review of 45 patients, while the current study included a sample size of over 18,000 patients from multiple institutions. The conclusions from these data are twofold: first, multiple previous studies have suggested that SCS therapy has the data-proven effect of decreasing opioid requirements after permanent IPG implantation (14,18,19), with other studies reporting no such decrease in postoperative opioid requirements (20). Future prospective powered studies are necessary not only to improve optimize selection criteria for SCS therapy and thus maximize benefits but also to study opioid outcomes in a pre-, peri- and postoperative fashion, which will better differentiate those who experience pain relief and reductions in opioid require-

Table 8. *Multivariable logistic regression for readmission after 6 months.*

	Odds Ratio	95% CI for OR		*P* value
		Lower	Upper	
Preoperative Opioid Use	1.070	0.960	1.193	0.222
Open Approach	0.765	0.688	0.851	< 0.001
Psychiatric Comorbidities	0.933	0.853	1.020	0.125
Age	0.982	0.977	0.987	< 0.001
Gender	0.952	0.854	1.061	0.376
Race = Black	0.974	0.791	1.200	0.807
Race = Hispanic	0.679	0.547	0.843	< 0.001
Race = Other	0.786	0.520	1.188	0.254
BMI	0.989	0.980	0.997	0.007
Elixhauser	1.035	0.987	1.086	0.159
Smoker = Current	0.817	0.708	0.942	0.005
Smoker = Former	0.863	0.765	0.975	0.018
Ins = Medicaid	1.263	0.980	1.628	0.071
Ins = Medicare	0.971	0.840	1.122	0.691
Ins = Other/Charity	0.967	0.814	1.150	0.708

Table 9. *Multivariable logistic regression for readmission after one years.*

	Odds Ratio	95% CI for OR		*P* value
		Lower	Upper	
Preoperative Opioid Use	1.042	0.940	1.155	0.432
Open Approach	0.780	0.706	0.863	< 0.001
Psychiatric Comorbidities	0.949	0.873	1.031	0.217
Age	0.980	0.976	0.985	< 0.001
Gender	0.920	0.830	1.020	0.112
Race = Black	1.043	0.859	1.265	0.672
Race = Hispanic	0.692	0.565	0.848	< 0.001
Race = Other	0.795	0.539	1.172	0.246
BMI	0.987	0.979	0.995	< 0.001
Elixhauser	1.028	0.982	1.076	0.240
Smoker = Current	0.807	0.705	0.924	0.002
Smoker = Former	0.858	0.765	0.962	0.009
Ins = Medicaid	1.327	1.045	1.686	0.020
Ins = Medicare	0.996	0.868	1.142	0.952
Ins = Other/Charity	0.977	0.829	1.151	0.779

ments from those who do not. Furthermore, other measurable outcomes are possible, including perceived pain relief or even specific percentage reductions in opioid consumption (21). Second, our data link preoperative opioid use to explantation, so they naturally raise the question of whether an MME can be titrated to meet the "sweet spot" of an individual's opioid requirements, which may minimize explantation risk preoperatively and perhaps even increase the patient's likelihood of postoperative freedom from opioids. This observation underlines the importance of studying the effects of pre- and postoperative opioid consumption on SCS placement outcomes (22). Limiting variability in opioid outcome studies can help restrict heterogeneity and facilitate further meta-analyses.

Our study also found that patients with Medicaid insurance were associated with worse overall SCS therapy outcomes. More specifically, patients with Medicaid insurance had heightened rates of explantation at both 6 and 12 months and of reoperation at one year. Previous studies have demonstrated an association of Medicaid patients with poor surgical outcomes (23-26). Recent work by Jones et al and Orhurhu et al also found that patients with Medicaid insurance were less likely to receive SCS therapy than those eligible for Medicare only (27-28). However, outcomes for Medicaid patients after SCS placement are poorly documented, outside of numerous studies demonstrating possible access issues for those with Medicaid, among other factors (e.g., race, comorbidities, etc.) (29). The association observed between Medicaid and heightened explantation and reoperation rates may be due to various confounding factors. Medicaid insurance is known to be associated with low socioeconomic status, which is a potential social determinant of health. These individuals not only have less access to quality health care but also less frequent access to care and, when they do, more often need emergency services (30). This group may have poorer follow-up care after SCS therapy and may present longer down the line, when a more significant care episode (e.g., revision, explantation) is required. Another possibility is that this group of individuals may have worse pain states to begin with and possibly higher levels of opioid therapy, which could translate to a higher initial baseline risk of explantation.

An additional important outcome of this study was that the open approach was associated with higher odds of operative complications than the percutaneous approach. This finding is in line with an earlier study by our group that, in multivariable analysis, found a trend toward heightened operative complications from the open approach (2). In that study, mechanical complications and surgical pain were the most frequent complications associated with the open approach, while device interrogation and battery complications were more common in the percutaneous group. All in all, this type of research can work to better define numerous outcomes after SCS placement (e.g., complica-

tions, readmission, reoperation, etc). We can then use data-driven strategies to optimize outcomes after SCS therapy irrespective of surgical approach.

This study has important limitations. The study's definition of preoperative opioid use was active use within the 30 days leading up to surgery. Due to the limitations of the dataset, we were not able to characterize opioid use in a more granular fashion (e.g., quantity, dosing, duration). In addition, these data come from a national registry comprising numerous hospitals and healthcare centers in the HCA Healthcare network. Because our source is a data registry, all the limitations associated with retrospective registry research apply, including but not limited to associations (i.e., noncausal limitations), residual confounding by uncoded variables, and human error associated with data entry. Furthermore, our study was devoid of data on patients' socioeconomic statuses or the type of stimulation used (high frequency, burst, etc). Finally, we were unable to control for hospital-level confounders (e.g., specific institution, hospital-specific patient populations) because we did not have access to specific institutional identifiers. With those data, we could use a mixed-effects regression model to control for hospital-level differences.

Conclusions

Preoperative opioid use was associated with increased odds of SCS explantation at both 6 and 12 months, as well as increased odds of reoperation at 6 months. Medicaid insurance and a higher comorbidity burden (Elixhauser) were associated with increased odds of explantation at 6 months and 12 months. The open approach was associated with decreased odds of readmission at 6 months and 12 months but increased odds of operative complications.

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