# Impact of Spinal Cord Stimulation on Opioid Dose Reduction: A Nationwide Analysis

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**BACKGROUND:** Opioid misuse in the USA is an epidemic. Utilization of neuromodulation for refractory chronic pain may reduce opioid-related morbidity and mortality, and associated economic costs.

**OBJECTIVE:** To assess the impact of spinal cord stimulation (SCS) on opioid dose reduction.

**METHODS:** The IBM MarketScan® database was retrospectively queried for all US patients with a chronic pain diagnosis undergoing SCS between 2010 and 2015. Opioid usage before and after the procedure was quantified as morphine milligram equivalents (MME).

**RESULTS:** A total of 8497 adult patients undergoing SCS were included. Within 1 yr of the procedure, 60.4% had some reduction in their opioid use, 34.2% moved to a clinically important lower dosage group, and 17.0% weaned off opioids entirely. The proportion of patients who completely weaned off opioids increased with decreasing preprocedure dose, ranging from 5.1% in the >90 MME group to 34.2% in the ≤20 MME group. The following variables were associated with reduced odds of weaning off opioids post procedure: long-term opioid use (odds ratio [OR]: 0.26; 95% CI: 0.21-0.30; $P < .001$), use of other pain medications (OR: 0.75; 95% CI: 0.65-0.87; $P < .001$), and obesity (OR: 0.75; 95% CI: 0.60-0.94; $P = .01$).

**CONCLUSION:** Patients undergoing SCS were able to reduce opioid usage. Given the potential to reduce the risks of long-term opioid therapy, this study lays the groundwork for efforts that may ultimately push stakeholders to reduce payment and policy barriers to SCS as part of an evidence-based, patient-centered approach to nonopioid solutions for chronic pain.

**KEY WORDS:** Chronic pain, Morphine milligram equivalent, Opioid epidemic, Opioid misuse, Spinal cord stimulation

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Opioid misuse in the USA has become an epidemic, with fatal overdoses numbering 47 600 in 2017.[1] Notably, long-term opioid therapy has not been proven effective and is associated with dose-dependent risks, including misuse, development of opioid use disorder, and overdose.[2] Despite this, prescription opioid volume steadily increased between 1999 and 2010, and remained 3 times as high in 2015 as in 1999.[3] Among individuals who misused prescription pain relievers, the most commonly reported reason (62.6%) for their last misuse was to relieve physical pain.[4] There is also a tremendous economic burden imposed by the US opioid problem. For back pain in particular – the most common pain diagnosis associated with ambulatory care opioid prescriptions[5] – health expenditures increased by more than 80% over the past decade. The total economic burden of prescription opioid abuse, dependence, and fatal overdose was estimated at $78.5 billion in 2013.[4,6] Taken together, this demonstrates a need to create better nonopioid alternatives to treat pain.

**ABBREVIATIONS: CDC,** Centers for Disease Control and Prevention; **CI,** confidence interval; **CPT,** Current Procedural Terminology; **HCPCS,** Healthcare Common Procedure Coding System; **ICD,** International Classification of Diseases; **IPG,** implantable pulse generator; **MME,** morphine milligram equivalents; **OR,** odds ratio; **SCS,** spinal cord stimulator/stimulation

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Policies have recently been implemented to reduce opioid prescribing practices associated with increased overdose risks (eg, daily dosages >100 morphine milligram equivalents [MME], extended-release formulations, and co-prescription with benzodiazepines).[7-9] However, strategies to address the supply of prescription opioids must be enacted in tandem with system-wide efforts to provide access to alternative methods for management of pain. Neuromodulation, with its increasingly important role in treating chronic, neuropathic pain that is refractory to other therapies,[10] is a potential key solution to our overreliance on long-term opioid therapy. Spinal cord stimulation (SCS), a neuromodulation treatment that is less invasive than traditional spine surgery, has been shown to effectively treat chronic neuropathic pain in multiple randomized controlled trials but has not been studied on a wide scale for its ability to reduce opioid usage.

The objectives of this study were to analyze the impact of SCS on opioid dose reduction in a large cohort of US patients, along with the impact of modifiable and nonmodifiable variables on the likelihood of opioid weaning postoperatively.

## METHODS

### Data Source

The IBM MarketScan® database was utilized to retrospectively analyze opioid usage before and after SCS procedures. The database is comprised of administrative claims data from more than 100 million patients. Because the claims data are linked to encounter data across sites and types of practitioners, the database reflects actual treatment patterns accurately. Commercial Claims and Encounters and Medicare Supplemental and Coordination of Benefits, and Medicaid databases within MarketScan® were queried for patients 18 yr and older who underwent trial SCS lead implant after January 1, 2010, and permanent implantable pulse generator (IPG) implant before December 31, 2015, to allow for 1-yr pre- and postprocedure continuous enrollment data availability. Notably, SCS is a 2-part procedure; a patient first has SCS leads placed in the epidural space with wires connected to an external battery, and after a trial period confirming some pain relief, they proceed to permanent placement of an internal battery via the IPG. Writing herein reflects this temporal relationship between SCS lead and IPG placement.

Because this study used only de-identified data, it was not considered human subjects research and received Institutional Review Board approval exemption. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology reporting guidelines.

### Procedure Identification

Procedures were identified using a combination of International Classification of Diseases (ICD), ninth (ICD-9) and tenth revisions (ICD-10), Current Procedural Terminology (CPT®), and Healthcare Common Procedure Coding System (HCPCS) procedural codes (**Tables 1 and 2**, **Supplemental Digital Content**).

### Inclusion and Exclusion Criteria

The index IPG implant was defined as the first IPG implant received by the patient between January 1, 2010 and December 31, 2015. The index dates for SCS trial were particularly selected (Figure 1) because patients may have had multiple SCS trial leads placed prior to the IPG and initiation of the treatment. Patients were chosen if they had at least 1 SCS trial lead implant and 1 IPG implant. Patients from this initial cohort were excluded if they did not have an IPG implantation within 90 d of SCS trial date. For some patients, IPG billing may have been reported prior to SCS trial billing. In such situations, patients were included if SCS trial lead implant date was within 7 d of IPG implant date or SCS trial lead implant date was indexed as the same as IPG implant date. Additional inclusion criteria included a concurrent chronic pain diagnosis at implant (ICD-9 and ICD-10 codes given in **Table 3**, **Supplemental Digital Content**) and continuous enrollment data for 1 yr pre-SCS trial implant and post-IPG implant with completely captured pharmacy data (**Table 4**, **Supplemental Digital Content**). More detailed methods to exclude patients with invalid prescriptions or opioid records, or insufficient duration of SCS, can be found in **Methods**, **Supplemental Digital Content**.

### Variables of Interest

Demographics and baseline characteristics were collected at IPG-implant index date. Demographics included age at implant, sex, insurance type, geographic region, and employment status. Medications and comorbidities, including pain medication usage (**Table 4**, **Supplemental Digital Content**), chronic pain history, spine surgery history in the 1 yr preceding SCS (codes given in **Table 2**, **Supplemental Digital Content**), tobacco use, long-term opioid usage (defined as using opioids for >90 d within the 1-yr preindex period), concurrent benzodiazepine use (defined as at least 1 d overlap between opioids and benzodiazepine prescriptions during the 3-mo period before SCS trial), polypharmacy status (defined as using more than 5 types of medications during the 3-mo period prior to SCS trial), and Elixhauser Comorbidity Index[11] were derived from claims within a year prior to index SCS trial lead implant date. Postprocedure medications were identified using pharmacy claims within 1 yr after IPG implant index date.

Opioid usage was quantified with MME per day. For each opioid prescription, average daily (mg/day) and monthly (mg/month) MMEs were calculated. Monthly cumulative MME is the sum of monthly MME for all opioids taken concurrently. Opioid usage during the last 3 mo before SCS trial was set as the baseline for comparison. Opioid usage during the 4th quarter (the 10th, 11th, and 12th mo) after IPG implant was chosen to represent a stabilized level of opioid usage 1 yr after the implantation. Finally, for all patients, the absolute changes in average daily MME before and after SCS were calculated. According to the Centers for Disease Control and Prevention (CDC) guidelines,[12] patients were classified into dose groups based on pre-SCS trial and post-IPG average daily MME: no use, ≤20 MME, 20 to 50 MME, 50 to 90 MME, and >90 MME. Detailed explanations of the calculations to achieve each of the above values are offered in **Methods**, **Supplemental Digital Content**, and morphine equivalence conversion factors are given in **Table 5**, **Supplemental Digital Content**.

### Outcomes

The main outcomes were whether patients could benefit from SCS by completely weaning off opioids, achieve a clinically significant reduction in opioid use (moving from 1 dose category to another), or experience any level of opioid reduction in the 1 yr following the procedure and

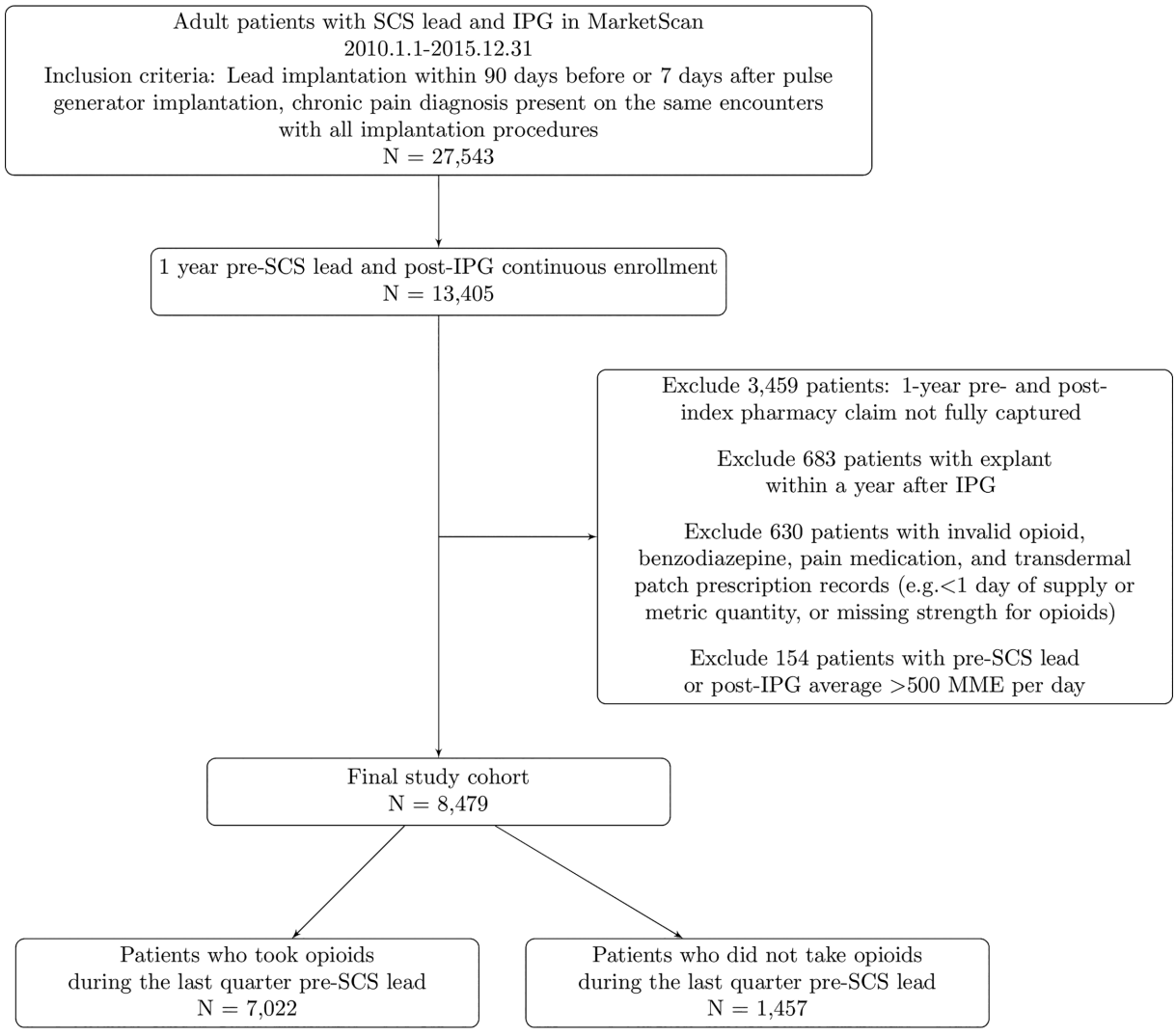


**FIGURE 1.** *Flow diagram indicating data retrieval steps, study outcomes, inclusion/exclusion criteria, and patient numbers using the IBM MarketScan® databases. IPG: internal pulse generator; MME: morphine milligram equivalent; and SCS: spinal cord stimulation.*

were defined by MME during the fourth quarter after IPG implant. The absolute change in average daily MME before and after SCS for all patients and the percentage change for pre-SCS opioid users were calculated. Multivariable logistic regression was used to determine modifiable and nonmodifiable risk factors associated with completely weaning off opioids postprocedure.

### Statistical Analysis

Continuous variables were summarized with means/medians, standard deviations/interquartile ranges, and ranges and compared between pre-SCS dose groups using Kruskal-Wallis tests. Categorical variables were summarized with frequency counts and percentages and compared with chi-square tests. Cross-tabulations were used to summarize opioid dose group changes before and after SCS.

A multivariate regression model was fit to assess the factors associated with completely weaning off opioids. Variables of interest included pre-SCS dose group, patient demographics, pre-existing health conditions, and SCS-related data.

Statistical significance was assessed at level alpha = 0.05, and Bonferroni adjustment was used to compare demographics across pre-SCS dose groups. Analyses were conducted using SAS software version 9.4 (SAS Institute Inc, Cary, North Carolina).

## RESULTS

### Patients and Baseline Characteristics

An initial cohort of 27 543 patients was identified, and after application of our exclusion criteria the final cohort for analysis

**TABLE 1. Patient Demographics and Opioid-Related Information by Pre-SCS MME Dose Group**

| | No use | ≤ 20 MME | 20-50 MME | 50-90 MME | >90 MME | Total | *P* value |
|---|---|---|---|---|---|---|---|
| **Patient demographics and opioid-related information by pre-SCS dose level** | | | | | | | |
| Population size, No. | 1457 | 2355 | 1821 | 1066 | 1780 | 8479 | |
| Average daily MME last quarter pre-SCS trial (mg morphine) | | | | | | | <.0001 |
| Mean (SD) | 0.0 (0.0) | 8.8 (5.9) | 33.7 (8.4) | 67.8 (11.3) | 191.1 (93.1) | 58.3 (83.5) | |
| Median | 0.0 | 8.1 | 32.7 | 65.9 | 160.9 | 26.0 | |
| Q1, Q3 | 0.0, 0.0 | 3.5, 13.7 | 26.4, 40.4 | 58.3, 77.3 | 119.2, 240.3 | 4.2, 74.1 | |
| Range | (0.0-0.0) | (0.0-20.0) | (20.0-50.0) | (50.1-90.0) | (90.3-498.2) | (0.0-498.2) | |
| Average daily MME last quarter post-IPG (mg morphine) | | | | | | | <.0001 |
| Mean (SD) | 5.7 (21.6) | 13.3 (27.7) | 37.5 (46.0) | 66.9 (53.0) | 157.3 (111.0) | 54.2 (82.9) | |
| Median | 0.0 | 5.0 | 29.1 | 60.0 | 135.0 | 20.0 | |
| Q1, Q3 | 0.0, 1.7 | 0.0, 15.5 | 11.3, 45.8 | 35.1, 87.3 | 79.2, 225.0 | 0.0, 67.3 | |
| Range | (0.0-281.3) | (0.0-460.8) | (0.0-494.6) | (0.0-485.4) | (0.0-494.9) | (0.0-494.9) | |
| Age at implant | | | | | | | <.0001 |
| Mean (SD) | 60.3 (14.1) | 58.6 (14.4) | 56.1 (13.3) | 54.8 (13.0) | 52.7 (12.1) | 56.6 (13.8) | |
| Median | 60.0 | 58.0 | 55.0 | 55.0 | 53.0 | 56.0 | |
| Q1, Q3 | 51.0, 71.0 | 48.0, 70.0 | 47.0, 65.0 | 46.0, 63.0 | 45.0, 60.0 | 47.0, 66.0 | |
| Range | (18.0-92.0) | (18.0-92.0) | (18.0-91.0) | (18.0-93.0) | (20.0-92.0) | (18.0-93.0) | |
| Sex, No. (%) | | | | | | | <.0001 |
| Male | 629 (43.2%) | 858 (36.4%) | 715 (39.3%) | 425 (39.9%) | 784 (44.0%) | 3411 (40.2%) | |
| Female | 828 (56.8%) | 1497 (63.6%) | 1106 (60.7%) | 641 (60.1%) | 996 (56.0%) | 5068 (59.8%) | |
| Insurance type, No. (%) | | | | | | | <.0001 |
| Employer sponsored private insurance | 809 (55.5%) | 1390 (59.0%) | 1197 (65.7%) | 738 (69.2%) | 1357 (76.2%) | 5491 (64.8%) | |
| Medicaid | 49 (3.4%) | 122 (5.2%) | 110 (6.0%) | 64 (6.0%) | 90 (5.1%) | 435 (5.1%) | |
| Medicare supplemental | 599 (41.1%) | 843 (35.8%) | 514 (28.2%) | 264 (24.8%) | 333 (18.7%) | 2553 (30.1%) | |
| Region, No. (%) | | | | | | | <.0001 |
| Northeast | 189 (13.0%) | 262 (11.1%) | 170 (9.3%) | 85 (8.0%) | 210 (11.8%) | 916 (10.8%) | |
| North Central | 455 (31.2%) | 707 (30.0%) | 523 (28.7%) | 295 (27.7%) | 448 (25.2%) | 2428 (28.6%) | |
| South | 570 (39.1%) | 1012 (43.0%) | 798 (43.8%) | 474 (44.5%) | 733 (41.2%) | 3587 (42.3%) | |
| West | 182 (12.5%) | 235 (10.0%) | 210 (11.5%) | 139 (13.0%) | 289 (16.2%) | 1055 (12.4%) | |
| Unknown (including Medicaid) | 61 (4.2%) | 139 (5.9%) | 120 (6.5%) | 73 (6.8%) | 100 (5.7%) | 493 (5.8%) | |
| Employment status,[a] No. (%) | | | | | | | <.0001 |
| Full time/part time | 434 (29.8%) | 771 (32.7%) | 692 (38.0%) | 445 (41.7%) | 754 (42.4%) | 3096 (36.5%) | |
| Retired | 597 (41.0%) | 836 (35.5%) | 598 (32.8%) | 324 (30.4%) | 424 (23.8%) | 2779 (32.8%) | |
| Dependent/other | 357 (24.5%) | 597 (25.4%) | 391 (21.5%) | 216 (20.3%) | 475 (26.7%) | 2036 (24.0%) | |
| Long-term disability | 20 (1.4%) | 29 (1.2%) | 30 (1.6%) | 17 (1.6%) | 37 (2.1%) | 133 (1.6%) | |
| Medicaid | 49 (3.4%) | 122 (5.2%) | 110 (6.0%) | 64 (6.0%) | 90 (5.1%) | 435 (5.1%) | |
| Long-term use of opioids, No. (%) | 115 (7.9%)[c] | 1342 (57.0%) | 1748 (96.0%) | 1055 (99.0%) | 1773 (99.6%) | 6033 (71.2%) | <.0001 |
| Other pain medication usage, No. (%) | 543 (37.3%) | 1272 (54.0%) | 1171 (64.3%) | 719 (67.4%) | 1199 (67.4%) | 4904 (57.8%) | <.0001 |
| Benzodiazepine use, No. (%) | 299 (22.2%) | 716 (30.4%) | 726 (39.9%) | 461 (43.3%) | 792 (44.5%) | 2994 (35.8%) | <.0001 |
| Concurrent benzodiazepine use, No. (%) | 0 (0.0%) | 573 (24.3%) | 698 (38.3%) | 458 (43.0%) | 786 (44.2%) | 2515 (29.7%) | <.0001 |
| Polypharmacy present, No. (%) | 715 (49.1%) | 1583 (67.2%) | 1382 (75.9%) | 860 (80.7%) | 1457 (81.9%) | 5997 (70.7%) | <.0001 |
| Sleep-disordered breathing, No. (%) | 283 (19.4%) | 507 (21.5%) | 376 (20.6%) | 219 (20.5%) | 399 (22.4%) | 1784 (21.0%) | .2889 |
| Tobacco use disorder, No. (%) | 116 (8.0%) | 231 (9.8%) | 243 (13.3%) | 162 (15.2%) | 265 (14.9%) | 1017 (12.0%) | <.0001 |
| History of spine surgeries in the past year, No. (%) | 76 (5.2%) | 145 (6.2%) | 143 (7.9%) | 92 (8.6%) | 116 (6.5%) | 572 (6.7%) | .0025[b] |
| Chronic pain diagnosis | | | | | | | |
| Post-laminectomy syndrome | 662 (45.4%) | 1041 (44.2%) | 851 (46.7%) | 508 (47.7%) | 870 (48.9%) | 3932 (46.4%) | .0363[b] |
| Complex regional pain syndrome | 103 (7.1%) | 178 (7.6%) | 147 (8.1%) | 64 (6.0%) | 134 (7.5%) | 626 (7.4%) | .3306 |
| Neuritis/radiculitis | 746 (51.2%) | 1241 (52.7%) | 942 (51.7%) | 564 (52.9%) | 911 (51.2%) | 4404 (51.9%) | .7902 |

**TABLE 1. Continued**

| | No use | ≤ 20 MME | 20-50 MME | 50-90 MME | >90 MME | Total | *P* value |
|---|---|---|---|---|---|---|---|
| Degenerative disc disease | 441 (30.3%) | 732 (31.1%) | 574 (31.5%) | 319 (29.9%) | 540 (30.3%) | 2606 (30.7%) | .8660 |
| Back pain | 613 (42.1%) | 1000 (42.5%) | 846 (46.5%) | 512 (48.0%) | 805 (45.2%) | 3776 (44.5%) | .0030[b] |
| Limb pain | 132 (9.1%) | 207 (8.8%) | 178 (9.8%) | 103 (9.7%) | 165 (9.3%) | 785 (9.3%) | .8320 |
| Other chronic pain | 719 (49.3%) | 1231 (52.3%) | 951 (52.2%) | 545 (51.1%) | 928 (52.1%) | 4374 (51.6%) | .4104 |

IPG: internal pulse generator; MME: morphine milligram equivalent; SCS: spinal cord stimulator.
[a]Full time/part time includes active full time, active part time; retiree includes early retiree, Medicare eligible retiree, retiree (status unknown); other includes COBRA Continuee, surviving spouse/dependent, other/unknown.
[b]Bonferroni correction for multiple testing: alpha level = 0.00096
[c]Patients in the pre-SCS trial "No Use" group – a categorization based on opioid usage only during the last 3 mo before SCS trial – may also be considered long-term opioid users because "long-term" was defined as opioid use for >90 d within the entire 1-yr preindex period.

consisted of 8479 patients (Figure 1). The requirement of continuous enrollment for 1 yr pre-SCS trial and 1 yr post-IPG implant was the most prominent reason for exclusion. Baseline characteristics were compared between pre-SCS dose groups (Table 1 ).

## Demographics

Demographics are listed in Table 1. Age was significantly different across the 5 groups (median age ranging from 53.0 to 60.0 years, with the higher dose groups being younger; $P < .001$), as was sex (ranging from 36.4% to 44.0% male; $P < .001$). Insurance type was also significantly different, ranging from 55.5% commercial insurance in the no use group to 76.2% in the >90 MME group ($P < .001$). In all 5 groups, the largest proportion of patients was from the South (consistent with MarketScan's [IBM] relative over-representation of this region[13]), followed by the North Central region, though the overall composition was different across groups ($P < .001$). Employment status was different across groups as well, ranging from 29.8% full time in the no use group to 42.4% full time in the >90 MME group ($P < .001$). Tobacco use disorder varied among groups, ranging from 8.0% in the no use group to 15.2% in the 50 to 90 MME group ($P < .001$).

## Chronic Pain History and Comorbidities

Across the pre-SCS dose groups, there were no significant differences in rates of previous spine surgeries in the 1-yr pre-SCS; for the total cohort, the rate was 6.7% (Table 1). Additionally, chronic pain diagnoses were all similar across groups. The most common chronic pain diagnoses in the total cohort were neuritis/radiculitis (51.9%), postlaminectomy syndrome (46.4%), and back pain (44.5%) (Table 1).

Prevalence of several Elixhauser comorbidities differed significantly across groups (**Table 6**, **Supplemental Digital Content**). These include peripheral vascular disorder (ranging from 7.0% in the >90 MME group to 11.0% in the no use and <20 MME groups; $P < .001$), uncomplicated hypertension (ranging from 52.2% in the >90 MME group to 58.8% in the no use group; $P < .001$), depression (ranging from 24.8% in the no use group to 36.2% in the >90 MME group; $P < .001$), drug abuse (ranging from 3.2% in the no use group to 14.6% in the >90 MME group; $P < .001$), psychoses (ranging from 34.5% in the no use group to 50.2% in the >90 MME group; $P < .001$), and fluid and electrolyte disorders (ranging from 8.6% in the no use and <20 MME groups to 12.6% in the >90 MME group; $P < .001$). There were no significant differences in rates of various other cardiac, pulmonary, renal, neurologic, endocrine, hepatic, infectious, hematologic, or oncologic Elixhauser comorbidities (data not shown), or dementia (from the Charlson Comorbidity Index[14]) (**Table 6**, **Supplemental Digital Content**).

## Nonopioid Pre-SCS Medications

Beyond opioids, there were also significant pre-SCS differences in usage of other pain medications (ranging from 37.3% in the no use group to 67.4% in the 50-90 and >90 MME groups; $P < .001$), use of concurrent benzodiazepines (ranging from 0.0% in the no use group to 44.2% in the >90 MME group; $P < .001$), and presence of polypharmacy (ranging from 49.1% in the no use group to 81.9% in the >90 MME group; $P < .001$) (Table 1).

## Changes in Opioid Use

Long-term use of opioids pre-SCS varied significantly across groups, ranging from 7.9% in the no use group to 99.6% in the >90 MME group ($P < .001$; Table 1). Note that the 1-yr pre-SCS trial period was used to assess long-term opioid usage, and thus patients without opioid use during 3-mo pre-SCS trial period could still be long-term users.

Figure 2 provides a comparison of opioid usage during the last quarter before SCS trial and after IPG implant by dose groups. Of those in the pre-SCS no use group, 71.1% stayed in the no use group 1 yr after IPG implant. As pre-SCS opioid usage increased, the percentage of patients who completely weaned off opioids decreased. Of all the patients on opioids before SCS (N = 7022), 17.0% completely weaned off opioids, and 34.2% moved to a clinically significant lower dose group. Rates of staying in the same dose groups before and after SCS (which

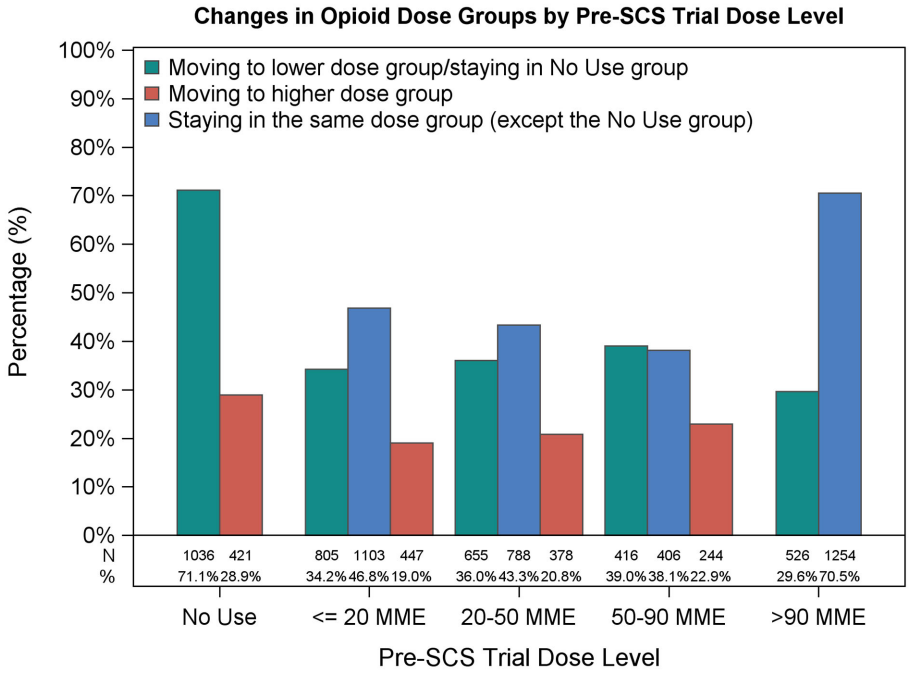


**FIGURE 2.** *Changes in opioid dose groups by pre-SCS trial dose level. The majority of patients either moved to a lower dose group or stayed in the same dose group after SCS (green and blue bars). SCS: spinal cord stimulation.*

**TABLE 2. Patients With Reduction in Daily Morphine Milligram Equivalent by Pre-SCS Dose Level**

| Last quarter pre-SCS MME dose group | Patients with reduction in opioid dose, No. (%) |
|---|---|
| ≤20 MME (n = 2355) | 1400 (59.5%) |
| 20-50 MME (n = 1821) | 1050 (57.7%) |
| 50-90 MME (n = 1066) | 612 (57.4%) |
| >90 MME (n = 1780) | 1177 (66.1%) |
| Any opioid use (n = 7022) | 4239 (60.4%) |

MME: morphine milligram equivalent; SCS: spinal cord stimulator.

may be considered a success when thinking of chronic neuropathic pain as a progressive condition) were as follows: ≤20 MME (46.8%), 20 to 50 MME (43.3%), 50 to 90 MME (38.1%), and >90 MME (70.5%). Table 2 summarizes the percentage of patients with a reduction in average daily MME by pre-SCS dose groups, including those who reduced opioid usage but remained in the same dosage group. Overall, 60.4% of the patients who used opioids during the last quarter prior to SCS trial had some reduction of their opioid usage 1 yr after the IPG implant, with a median change of 16% decrease in daily MME usage (interquartile range, 73% decrease to 27% increase). The percent change in monthly median MME from pre-SCS trial to post-IPG stratified by specific opioid is shown in Table 7, **Supplemental Digital Content**. Notably, median oxycodone MME decreased by 30%; methadone by 40%; hydrocodone, morphine, and fentanyl (transdermal) by 50%; and tramadol and hydromorphone by 100%.

### Regression Modeling of Completely Weaning Off Opioids

Table 3 summarizes the multivariable logistic regression results for completely weaning off opioids using all patients taking opioids prior to SCS trial. Compared to patients in the >90 MME group, the 20 to 50 MME group (odds ratio [OR]: 2.50; 95% CI: 1.93-3.23; $P < .001$) and the ≤20 MME group (OR: 4.85; 95% CI 3.76-6.25; $P < .001$) had significantly higher odds of completely weaning off opioids, after adjusting for other confounders including demographics and Elixhauser comorbidities (Table 3). Variables associated with significantly reduced odds of completely weaning off opioids included long-term opioid usage (OR 0.26; 95% CI: 0.21-0.30; $P < .001$), other pain medication usage (OR: 0.75; 95% CI: 0.65-0.87; $P < .001$), and obesity (OR: 0.75; 95% CI: 0.60-0.94; $P = 0.01$) (Table 3).

## DISCUSSION

### Key Results

Opioid misuse in the USA has become an epidemic. In this national retrospective study of patients undergoing

**TABLE 3. Significant Factors Associated With Completely Weaning Off Opioids for All Patients Taking Opioids During the Last Quarter Before SCS, as Determined by Multivariate Logistic Modeling**

| | Adjusted OR (95% CI) | *P* value |
|---|---|---|
| Pre-SCS trial MME dose group | | |
| ≤20 MME | 4.85 (3.76, 6.25) | <.001 |
| 20-50 MME | 2.50 (1.93, 3.23) | <.001 |
| 50-90 MME | 1.34 (0.97, 1.85) | .08 |
| >90 MME | Reference | – |
| Long-term use of opioids | | |
| Yes | 0.26 (0.21, 0.30) | <.001 |
| No | Reference | – |
| Use of other pain medications | | |
| Yes | 0.75 (0.65, 0.87) | <.001 |
| No | Reference | – |
| Obesity | | |
| Yes | 0.75 (0.60, 0.94) | 0.01 |
| No | Reference | – |

CI: confidence interval; MME: morphine milligram equivalent; OR: odds ratio; SCS: spinal cord stimulator.
Model was adjusted for age, sex, insurance type, region, employment status, concurrent benzodiazepine use, sleep-disordered breathing, tobacco use disorder, history of spine surgeries in 1 yr preceding SCS, chronic pain diagnosis, and Elixhauser comorbidities. Patients who did not use opioids during the last quarter before SCS trial were not included in the model. Sample size for this model is 7022.

SCS for chronic pain, we characterized the demographics of patients with chronic pain undergoing SCS and analyzed the impact of numerous modifiable and nonmodifiable variables on the likelihood of weaning off opioids postoperatively. Factors associated with not weaning off opioids included long-term use of opioids, use of other pain medications, and obesity. Notably, 5.1% to 34.2% of patients, depending on preoperative opioid dose, completely weaned off opioids postoperatively; 40.5% either reduced their postoperative opioid usage or continued to not take opioids at all; and 38.1% to 46.8% of patients taking opioids prior to SCS stayed in the same dose group after SCS (not including the pre-SCS > 90 MME group).

## Interpretation

These results align with a retrospective study by Sharan et al,[15] which showed that patients who retained their implant after 1 yr were significantly more likely to have had a decrease or stabilization (again, with stabilization classified as a successful outcome considering chronic neuropathic pain as a progressive condition) in their opioid dosage, and a previous small prospective study by Gee et al[16] demonstrating that patients undergoing SCS have decreased postoperative opioid usage and pain scores. These results highlight the key role that SCS can play in preventing the escalation of opioid usage in chronic pain patients, thereby reducing the risk of medication-induced side effects, opioid misuse, and associated mortality, as well as the financial costs of treating these consequences.

Further optimization of neuromodulation in the treatment of refractory pain requires a nuanced understanding of patient-level variables that may affect SCS efficacy. In this study, medication-associated variables associated with decreased odds of completely weaning off opioids were long-term opioid usage, other pain medication usage, and belonging to higher pre-SCS dosage groups. Choice of pain medication itself may also play into decision-making here, as oxycodone and methadone may be more difficult to wean off of, while hydromorphone and tramadol may be easier. Additionally, when looking at the entire cohort together in multivariate regression, among all of the Elixhauser comorbidities, the only significant clinical variable was obesity. Previous research from patients undergoing bariatric surgery has demonstrated that $\mu$-opioid receptor availability is lower in obese patients (and could be normalized after weight loss surgery), paralleling the observation in opiate dependence.[17] This may serve as one biological explanation for our findings; further research into this topic is warranted. Regardless, this result emphasizes the importance of optimizing body mass index and considering the biopsychosocial factors impacting a patient's overall health when treating their pain. Notably, after adjusting for several variables in our model, concurrent benzodiazepine usage and chronic pain diagnosis were not statistically significant predictors of outcomes.

## Generalizability

As a large, nationwide analysis, results from this study generalize well to insured American adult patients who suffer from chronic pain and undergo permanent SCS implant. These results demonstrate a need to begin rethinking policies surrounding access to SCS. There is currently a national legislative push to more responsibly care for patients with chronic pain while reducing opioid-related risks.[18] The Administration and Congress, in the recently enacted Support for Patients and Communities Act, have highlighted the development of new, nonaddictive approaches to promoting pain management as a strategy to prevent opioid misuse.[19] Most recently, the National Institutes of Health launched the Helping to End Addiction Long-term Initiative to develop nonaddictive methods for pain control.[20] Current policies by Medicare and other payers designate SCS as a treatment of late and last resort, creating a barrier to access for patients that might benefit from this procedure. Moving forward, it will be even more important to consider SCS because of continuing technological advances improving its efficacy; for example, systems have now transitioned from tonic stimulation toward high-frequency, burst, and closed-loop stimulation with promising results.[21,22] None of these novel waveforms were available for the patients in this cohort only being treated from 2010 to 2015, and we should thus expect future studies to show greater impacts on opioid usage. Given SCS's potential to reduce the risks of long-term opioid therapy, the results presented here lay the groundwork for continued efforts that may ultimately push stakeholders to

reduce payment and policy barriers to SCS, as part of an evidence-based, patient-centered approach to nonopioid chronic pain management.

### Limitations

As with all large administrative claims database studies, interpretations of this work are limited by the clinical granularity of the data. Because of this, our findings should be applied to the use of opioids and utility of SCS at a population level rather than an individual level. However, the generalizability of the large, insured patient population is one of our study's strengths. Additionally, "daily supply," which was used to calculate opioid usage, may also not reflect the actual number of days the opioids were taken. Moreover, it is important to note the observational nature of this study; because the results are correlational without a direct comparison group, we cannot definitively claim a causal relationship between SCS and opioid reduction. The identification of a control group would be unreliable in MarketScan (IBM) for multiple reasons. First, it is impossible to create 2 groups with similar degrees of severity or durations of chronic pain because we cannot accurately query such large claims-based datasets to accurately obtain "number of years of chronic pain" – we can only assess years of pain after patients had insurance claims with chronic pain diagnoses. Additionally, the number of years of chronic pain is also subject to the availability of the years in the database, which may meaningfully truncate the duration of many patients' chronic pain. Nonetheless, the strength of the beneficial correlation observed here with SCS, especially in a patient cohort with high use of opioids and other medications (who have typically already failed to improve with conservative management), does suggest a role for neuromodulation. This is especially true considering that previous systematic reviews have failed to identify high-quality evidence supporting the use of conservative measures in meaningfully reducing opioid use.[23,24] Finally, we only examined one type of SCS outcome. Alternative measures of SCS merit could be pain scores pre- and postimplant, quality of life (PROMIS-29), impact on sleep and mood, and percent pain reduction, although these are currently difficult to acquire on a national scale.

## CONCLUSION

We have characterized the largest and most updated US cohort of patients undergoing SCS and have identified modifiable and nonmodifiable factors associated with significant changes in opioid use following surgery. Notably, 5.1% to 34.2% of patients, depending on preoperative opioid dose, will completely wean off opioids postoperatively. Moreover, 40.5% will either reduce their postoperative opioid usage or continue to not take opioids at all. Long-term use of opioids, concurrent use of other pain medications, and obesity decrease the likelihood of completely weaning off opioids postoperatively. These results will assist clinicians in refining their preoperative assessment of patients undergoing SCS and further inform patient postoperative expectations of pain control. More broadly, this work demonstrates the efficacy of SCS as a strategy to reduce opioid usage, and it thus provides a strong foundation for future efforts ultimately aiming to reduce payment and policy barriers standing between patients and this treatment modality.

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***Supplemental digital content*** *is available for this article at www.neurosurgery-online.com.*

The supplemental digital content contains methods and 7 tables. The Supplementary Methods section expands on the specific details of the methods. Tables 1 to 3 list the ICD-9/10, CPT, and HCPCS Procedure codes we used. Table 4 provides the full list of opioids and corresponding MarketScan (IBM) therapeutic drug class, and Table 5 outlines the morphine equivalence conversion factors. Tables 6 (Elixhauser and Charlson comorbidities by pre-SCS MME) and 7 (average daily MME and dose change breakdown by specific opioid) present other explorations of the relationship between SCS and MME reduction that we could not include in the body of the manuscript.

## COMMENTS

While decreased opioid use after SCS treatment has been documented before, the very large cohort in this study convincingly confirms that SCS patients tend to decrease opioid use over time, sometimes completely stopping them. However, this study is purely observational without a contemporary control group to establish what would have happened to opioid use in this population if SCS had not been applied. It is certainly possible that pain relief from SCS led to reduced reliance on medications, but decrease in use over time might have occurred regardless of SCS since neuropathic pain syndromes treated by SCS are generally not responsive to opioids and sometimes naturally improve over time. No information is available about actual pain outcome, and the fact that SCS had a much smaller effect in the context of higher opioid doses may limit its impact on the opioid crisis since the least benefit was seen in those with the greatest need. These data are hardly sufficient to justify changes in healthcare policy since they do not prove that SCS directly leads to reduction in opioid use, but it is nonetheless reassuring that overall opioid use was seen to decrease after SCS in a very large population.

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The authors analyzed the trend in opioid use over a 1-yr period in a large database of patients who underwent spinal cord stimulation (SCS) placement between 2010-2015. The authors did their due diligence in terms of database screening techniques in order to accurately capture the opioid use in patients implanted with SCS devices. They confirmed what has been observed in the routine clinical practice and shown in previous studies – SCS use does result in reduction or stabilization of opioid usage in majority of patients.

Although the lack of comparison group (ie, explanted SCS or failed trial) makes conclusions less convincing, the ability of SCS to help in fighting the opioid epidemic is hereby underscored. Moreover, since SCS remains an invasive procedure with a small but not-negligible associated complication risk, one must understand that any suggestion to apply this approach in more patients and earlier in their treatment process should be given in association with a consideration in establishing nationwide network of neuromodulation "centers of excellence" and proper training/credentialing of SCS practitioners.

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