Rate of perioperative neurological complications after surgery for cervical spinal cord stimulation

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OBJECTIVE Cervical spinal cord stimulation (cSCS) is used to treat pain of the cervical region and upper extremities. Case reports and small series have shown a relatively low risk of complication after cSCS, with only a single reported case of perioperative spinal cord injury in the literature. Catastrophic cSCS-associated spinal cord injury remains a concern as a result of underreporting. To aid in preoperative counseling, it is necessary to establish a minimum rate of spinal cord injury and surgical complication following cSCS.

METHODS The Nationwide Inpatient Sample (NIS) is a stratified sample of 20% of all patient discharges from non-federal hospitals in the United States. The authors identified discharges with a primary procedure code for spinal cord stimulation (ICD-9 03.93) associated with a primary diagnosis of cervical pathology from 2002 to 2011. They then analyzed short-term safety outcomes including the presence of spinal cord injury and neurological, medical, and general perioperative complications and compared outcomes using univariate analysis.

RESULTS Between 2002 and 2011, there were 2053 discharges for cSCS. The spinal cord injury rate was 0.5%. The rates of any neurological, medical, and general perioperative complications were 1.1%, 1.4%, and 11.7%, respectively. There were no deaths.

CONCLUSIONS In the largest series of cSCS, the risk of spinal cord injury was higher than previously reported (0.5%). Nonetheless, this procedure remains relatively safe, and physicians may use these data to corroborate the safety of cSCS in an appropriately selected patient population. This may become a key treatment option in an increasingly opioid-dependent, aging population.

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KEY WORDS cervical spinal cord stimulation; SCS; neurostimulation; neuromodulation

CERVICAL spinal cord stimulation (cSCS) is an important treatment option in the management of pain in the cervical region and upper extremities. In retrospective and prospective multicenter studies, it has been shown to be efficacious in relieving pain and improving quality of life.^{4,7,10,11,14,18,25,28,31,33,35–37} However, comprehensive studies into the safety of cSCS are lacking in the literature.

Complications are taken from case reports and small series and are usually minor and without resultant long-term morbidity. These include hardware malfunction, lead migration, lead fracture, implant site pain, infection, and non-therapeutic stimulation among others.^{4,7,10,11,14,18,25,28,31,33,35–37} Current small patient volume studies limit the detection of rare cSCS related complications and may lead to false safety assurances among implanters, clinicians, and patients.

The most feared complication is perioperative spinal cord injury, and it is rarely reported. In a systematic review, Deer et al.⁷ showed the absence of spinal cord injury in 218 total patients across 11 studies. In our extensive research, we only found a single case report of perioperative spinal cord injuries after cSCS.²⁴ In 2007 Meyer et al. reported a case of quadriplegia after cSCS during a closed percutaneous revision for complex regional pain syndrome. A Tuohy needle had been placed at the T–3 interspace resulting in an inadvertent intramedullary placement of an electrode, with the distal tip at the level of C-2. There is report of significant injury in noncervical spinal cord stimulation,^{1–3,6,12,13,15,22,29,32} but a paucity of literature studying such injuries in the cervical population.

Investigation of the safety of cSCS—outside of the confines of small series and case reports—will ensure more

ABBREVIATIONS cSCS = cervical spinal cord stimulation; DVT = deep venous thrombosis; HCUP = Healthcare Cost and Utilization Project; ICD-9 = *International Classification of Diseases, Ninth Revision*; LOS = length of stay; NIS = Nationwide Inpatient Sample; PE = pulmonary embolism.

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informed decision-making when pursuing cSCS as an option for cervical and upper limb pathology. We examined the Nationwide Inpatient Sample (NIS) from 2002 through 2011 to assess the rate of perioperative neurological complications associated with cSCS.

Methods

The NIS was developed as part of the Healthcare Cost and Utilization Project (HCUP) from the Agency for Healthcare Research and Quality (AHRQ). It is the largest publicly available inpatient hospital database that catalogs discharge data from a stratified sample of approximately 20% of all nonfederal hospitals in the US. For this study, we obtained the NIS data for the 10-year period 2002–2011. Because the NIS is drawn from a sample that includes all patients discharged from sampled hospitals, the data can be used to estimate total annual complications among other variables for all nonfederal hospitals in the US. The dataset presented in this study is thus extrapolated using the weighting variables provided by HCUP.

Patient Population

International Classification of Diseases, Ninth Revision (ICD-9) codes were used to identify discharges with a primary procedure code of implantation or replacement of spinal neurostimulator lead(s) (03.93). Discharges with a primary diagnosis code of cervical pathology were then identified: neck pain (723.1), cervicocranial syndrome (723.2), cervicobrachial syndrome (723.3), brachial neuritis/radiculitis (723.4), other disorders of cervical region (723.8), postlaminectomy syndrome/failed-neck surgery syndrome (722.81), reflex sympathetic dystrophy/complex regional pain of the upper limb (337.21), cervical root lesions (353.2), brachial plexus lesions (353.0), shoulder pain (719.41, 719.51, 719.61, 719.81, 719.91), and upper limb pain (719.42, 719.43, 719.44, 719.52–0.54, 719.62–0.64, 719.82–0.84, 719.92–0.94).

Patient Characteristics

Age, sex, race, income quartile of the patient's zip code, and payer status were coded within the database. Medical comorbidities were defined using a modified version of the Elixhauser comorbidity score,⁸ which excluded the 2 neurological comorbidity variables, "other neurological deficit" and "paralysis" such that the highest possible comorbidity score was 28. Comorbidities of the cervical spine were also identified using ICD-9 codes: ankylosing spondylitis (720.0); cervical spondylosis without myelopathy (721.0); cervical spondylosis with myelopathy (721.1); spinal stenosis in the cervical region (723.0); ossification of the posterior longitudinal ligament (723.7); other/unspecified cervical pathology (723.8–0.9, 722.91); displacement of a cervical disc without myelopathy (722.0); cervical disc degeneration (722.4); intervertebral disc disorder with myelopathy, cervical region (722.71); and myelopathy (336.3, 336.8, 336.9). Payer status was defined by combining the primary and secondary payer variables and placing discharges into the exclusive categories: "private insurance," "Medicaid without private insurance," "Medicare with neither private insurance nor Medicaid," and "other."

Hospital Characteristics

The NIS provides data on hospital size (small, medium, large), location (urban or rural), teaching hospital status, and region (Northeast, Midwest, South, West), as well as annual hospital caseload for a specific procedure by discharge number. Hospital caseload was calculated by annual number of discharge records containing any procedure code of 03.93 with a concomitant primary diagnosis code indicating cervical or upper limb pathology.

Complications/Outcomes Definitions

We identified a number of potential complications resulting from cSCS. The complications included in our analysis and their respective ICD-9 codes are listed in Table 1. As the information within the NIS is based on discharge-level patient information, complications reported are those that occur during the course of in-patient hospitalization.

We examined secondary, short-term safety outcomes provided in the dataset including length of stay (LOS), discharge status, and mortality. Discharges that were to home or home health care were labeled as "routine." Discharges to short-term hospital or skilled nursing facility, or death were referred to as "nonroutine" discharge.

Statistical Analysis

Statistical analyses were performed using built-in and custom scripts (Matlab, Mathworks). The Wilcoxon rank-sum test or a chi-square, with Yates' correction for continuity for tests utilizing 1 degree of freedom, was used. A hierarchical, logistic regression model (SAS procedure GLIMMIX, SAS Institute) was used to analyze variables that predicted the presence of complications. Predictor variables included age, sex, modified comorbidity score, race, income quartile of patient zip code, payer status, hospital experience, size (number of patient beds), region, setting (urban or rural), teaching status, and year of discharge. The unique hospital identification code served as the nesting variable. We accounted for missing data with single imputation based on deterministic regression modeling in an R environment (R Development Core Team). Multinomial logistic, binomial logistic, and linear regression models were used as appropriate, and a $p < 0.05$ was considered statistically significant. Bonferroni Correction for multiple comparisons was used where appropriate. Results are reported $\pm$ standard error of the mean or as a frequency with percentage. Frequency, where presented, is rounded to the nearest whole number patient after application of the HCUP dataset weighting variable.

Results

Patient Characteristics

From January 1, 2002, through 2011, there were 425 discharge records for cSCS; this suggests that the actual number of discharges for cSCS from nonfederal hospitals is an estimated 2053. Table 2 shows the characteristics of patients who underwent cSCS.

The average age of discharged patients was 46.0 ± 0.6 years, and 67.0% were female. The mean modified co-

TABLE 1. Complications by type and ICD-9 code

Complication	ICD-9 Code
Nervous system complications	997.00–997.09
Spinal cord injury	952.00–952.09
Hemiplegia or hemiparesis	342.00–342.92
Nerve root/brachial plexus injury	953.0, 953.4
Sympathetic nerve injury	954.0
Head & neck artery injury	900.00–900.03, 900.82, 900.89, 900.9
Hematoma or hemorrhage complicating a procedure	998.11, 998.12, 997.02
Seroma complicating a procedure	998.13
Mechanical complications	996.2, 996.59, 998.2
Accidental puncture or laceration	998.2
Infectious complications, related to a mechanical device	996.60, 996.63
Infectious complications, postoperative	995.4, 998.51–998.59
Perioperative shock	998.00–998.09
CSF rhinorrhea (CSF leak)	349.81
Dural tear	349.31–349.39
Persistent postoperative fistula	998.6
Wound complication	998.30–998.32, 998.83
Retained foreign body	998.4, 998.7
DVT/PE	415.11–415.19, 451.11, 451.19, 451.81, 453.40–453.42, 995.4
Urinary tract infection	599.0
Pneumonia	486, 997.31–997.32
Other implant-related complications*	
Other complications due to a nervous system device, implant, graft	996.75
Unspecified or other nervous system complication	997.00, 997.01, 997.09
Complications affecting other specified body systems, not elsewhere classified, hypertension	997.91
Complications affecting other specified body systems, not elsewhere classified	997.99
Other & unspecified complications of medical care, not elsewhere classified	999.9
Late effect of complications of surgical & medical care	909.3
Other specified complications of procedures not elsewhere classified	998.89
Unspecified complication of procedure, not elsewhere classified	998.9
Nervous system complications from surgically implanted device	349.1

* The variable “other implant-related complications” was coded as a single variable utilizing all of the subsequent ICD-9 codes.

morbidity score was 1.0 ± 0.1 . With regard to institutional characteristics, hospitals discharging patients with cSCS had an average annual caseload of 2.6 ± 0.1 surgeries for cSCS per year. A majority of procedures were performed at large (68.9%) urban (96.8%) teaching hospitals (60.4%). The average LOS was 2.4 ± 0.1 days. The largest percentage of discharges, 96.8%, were coded as discharged to either home or home health care (routine). Of those discharged “nonroutinely,” 2.7% were transferred to a skilled nursing facility or other long-term care facility, 5.1% were discharged with home health care, and 0.3% were transferred to another hospital.

Complications

Of the patients discharged, 11.7% developed complications during hospitalization, including 0.5% who sustained a spinal cord injury, while 1.1% developed neurological complications of some type, and 1.4% developed

a medical complication. The complications indicated by ICD-9 codes included the following: 1) mechanical complications (5.8%); 2) implant-related complications (2.4%); 3) nervous system complications (0.9%); 4) urinary tract infection (0.7%); 5) spinal cord injury (0.5%); 6) hematoma, hemorrhage, or seroma (0.5%); 7) pneumonia (0.5%); 8) infectious complications of a mechanical device (0.3%); 9) infectious complications postoperative (0.3%); 10) accidental laceration or puncture (0.2%); 11) DVT/PE (0.2%).

No patients died during hospitalization. Table 3 shows the complications associated with cSCS.

Of the discharges associated with a complication, 34.7% were associated with reoperation during the index hospitalization. Eleven patients returned to the operating room for “removal of spinal neurostimulator lead(s)” (ICD-9 03.94). These were associated with nervous system (n = 4) or other complications (n = 7). Six patients returned to the operating room for procedures associated with nervous system

TABLE 2. Characteristics of discharges for cervical spinal cord stimulation

Characteristic	Value (%)*
Total no. of discharges during period	2053
Mean age $\pm$ SEM	46.0 $\pm$ 0.6
Female	1376 (67.0)
Mean modified comorbidity score $\pm$ SEM	1.0 $\pm$ 0.1
Race	
White	1653 (80.5)
Black	184 (8.9)
Hispanic	142 (6.9)
Asian/Pacific Islander	21 (1.0)
Native American	4 (0.2)
Other	49 (2.4)
Patient residential zip codes in	
1st income quartile (lowest)	328 (16.0)
2nd income quartile	498 (24.3)
3rd income quartile	537 (26.2)
4th income quartile (highest)	690 (33.6)
Type of insurance	
Private insurance	1086 (52.9)
Medicaid w/o private insurance	127 (6.2)
Medicare w/ neither private insurance nor Medicaid	300 (14.6)
Neither Medicare, Medicaid, nor private insurance	540 (26.3)
Mean yearly caseload of procedure hospital ($\pm$ SEM)	2.6 $\pm$ 0.1
Teaching hospital	1240 (60.4)
Urban hospital	1987 (96.8)
Hospital size	
Small hospital	248 (12.1)
Medium hospital	390 (19.0)
Large hospital	1415 (68.9)
Location of hospital	
Northeast region	563 (27.4)
Midwest region	327 (15.9)
South region	748 (36.4)
West region	415 (20.2)
Mean LOS ($\pm$ SEM)	2.4 $\pm$ 0.1
Discharge status	
Routine discharge	1987 (96.8)
Short-term hospital transfer	6 (0.3)
Other transfer (includes skilled nursing facility)	55 (2.7)
Home health care	105 (5.1)
Against medical advice	4 (0.2)
Died	0 (0)
Alive, destination unknown	0 (0)

LOS = length of stay.

* Because the NIS is drawn from a sample that includes all patients discharged from sampled hospitals, the sample can be used to estimate total annual data for all nonfederal hospitals in the US. The data set presented here is extrapolated using the weighting variables provided by HCUP. Unless otherwise indicated, values represent number of patients (%). Counts are rounded to the nearest whole number patient after application of the HCUP data set weighting variable.

TABLE 3. Complications of cervical spinal cord stimulation*

Complication	Value (%)
Any complication†	240 (11.7)
Mortality rate	0 (0)
Nervous system complications	18 (0.9)
Spinal cord injury	10 (0.5)
Hemiplegia or hemiparesis	0 (0)
Nerve root/brachial plexus injury	0 (0)
Sympathetic nerve injury	0 (0)
Head & neck artery injury	0 (0)
Hematoma or hemorrhage complicating a procedure	10 (0.5)
Seroma complicating a procedure	0 (0)
Mechanical complications	119 (5.8)
Accidental puncture or laceration	4 (0.2)
Infectious complications, related to a mechanical device	6 (0.3)
Infectious complications, postoperative	6 (0.3)
Perioperative shock	0 (0)
CSF rhinorrhea (CSF leak)	0 (0)
Dural tear	0 (0)
Persistent postoperative fistula	0 (0)
Wound complication	0 (0)
Retained foreign body	0 (0)
DVT/PE	4 (0.2)
Urinary tract infection	14 (0.7)
Pneumonia	10 (0.5)
Other implant-related complications	49 (2.4)
Any neurological complication‡	23 (1.1)
Any medical complication§	29 (1.4)

* Counts are rounded to the nearest whole number patient after application of the HCUP data set weighting variable.

† Includes the percentage of discharges with the presence of any of the complications listed in Table 1.

‡ Includes the percentage of discharges with the presence of any nervous system complication, spinal cord injury, hemiplegia or hemiparesis, or nerve root/brachial plexus injury.

§ Includes the percentage of discharges with the presence of a deep venous thrombosis/pulmonary embolism, urinary tract infection, or pneumonia.

complications (n = 4) and other complications (n = 2) not related to lead removal (ICD-9 03.01, 03.02, 03.09, 03.99).

Hierarchical logistic regression analysis did not find a significant predictor of complications in models for the presence of neurological complications, medical complications, spinal cord injury, or any complication.

Differences Between Discharges With and Without Complications

Table 4 shows the differences between discharges with and without complications. Comparing the patients discharged without complications versus the cohort with complications, the patients with complications had a higher number of males ($p < 0.001$), more often used Medicare ($p < 0.001$), and were from lower income zip codes ($p < 0.001$). Table 5 shows the cervical spinal comorbidities as-

TABLE 4. Characteristics of patients discharged after cSCS

Variable	No Complications (%)	Any Complication (%)	p Value
Total no. of discharges during period	1812	241	
Mean age $\pm$ SEM*	45.9 $\pm$ 0.6	46.8 $\pm$ 1.5	0.15
Female	1,238 (68.3)	138 (57.2)	<0.001
Mean modified comorbidity score $\pm$ SEM	1.0 $\pm$ 0.1	0.9 $\pm$ 0.2	0.54
Race			
White	1440 (79.5)	213 (88.4)	0.02
Black	170 (9.4)	13 (5.3)	
Hispanic	126 (7.0)	15 (6.4)	
Asian/Pacific Islander	20 (1.1)	0 (0.0)	
Native American	5 (0.3)	0 (0.0)	
Other	51 (2.8)	0 (0.0)	
Patient residential zip codes in			
1st income quartile (lowest)*	281 (15.5)	47 (19.6)	<0.001
2nd income quartile*	422 (23.3)	76 (31.4)	
3rd income quartile*	495 (27.3)	42 (17.6)	
4th income quartile (highest)*	614 (33.9)	76 (31.4)	
Type of insurance			
Private insurance*	989 (54.6)	97 (40.2)	<0.001
Medicaid w/o private insurance*	118 (6.5)	10 (4.0)	
Medicare w/ neither private insurance nor Medicaid*	236 (13.0)	64 (26.6)	
Neither Medicare, Medicaid, nor private insurance*	469 (25.9)	70 (29.2)	
Mean yearly caseload of procedure hospital $\pm$ SEM	2.7 $\pm$ 0.1	2.1 $\pm$ 0.3	0.05
Teaching hospital*	1133 (62.5)	107 (44.5)	<0.001
Urban hospital*	1769 (97.6)	219 (90.8)	<0.001
Hospital size			
Small hospital	216 (11.9)	33 (13.6)	0.08
Medium hospital	333 (18.4)	57 (23.5)	
Large hospital	1263 (69.7)	151 (62.9)	
Location of hospital			
Northeast region	497 (27.4)	65 (26.9)	0.44
Midwest region	295 (16.3)	31 (13.0)	
South region	652 (36.0)	97 (40.1)	
West region	368 (20.3)	48 (20.0)	
Mean LOS $\pm$ SEM	2.2 $\pm$ 0.1	3.8 $\pm$ 0.4	0.24
Discharge status			
Routine discharge*	1773 (97.8)	215 (89.2)	<0.001
Short-term hospital transfer*	0 (0)	5 (2.2)	
Other transfer (includes skilled nursing facility)*	34 (1.9)	21 (8.6)	
Home health care*	74 (4.1)	30 (12.6)	
Against medical advice*	5 (0.3)	0 (0)	
Died*	0 (0)	0 (0)	
Alive, destination unknown*	0 (0)	0 (0)	

* Statistically significant association was determined using Bonferroni correction (alpha 0.05/13 comparisons equals a correct alpha of alpha 0.0038). Counts are rounded to the nearest whole number patient after application of the HCUP data set weighting variable.

sociated with discharges with and without complications. Of note, there was a greater percentage of patients with cervical spondylotic myelopathy and cervical spinal stenosis in the cohort with complications ($p < 0.001$ for both comparisons). The cohort with complications more often

received their surgeries at nonteaching hospitals in nonurban locations ($p < 0.001$ for both comparisons). Complications were associated with a greater number of discharges other than to home or home health care ($p < 0.001$). Of note, age, medical comorbidity, spinal comorbidity, and

TABLE 5. Comorbidities associated with cervical spinal cord stimulation

Comorbidity	No Complications (%)	Any Complication (%)	p Value
Any cervical spine comorbidity	228 (12.6)	20 (8.3)	0.05
Cervical spondylosis w/o myelopathy	29 (1.6)	5 (2.2)	0.59
Cervical spondylosis w/ myelopathy*	5 (0.3)	5 (2.1)	<0.001
Cervical spinal stenosis*	5 (0.3)	5 (2.2)	<0.001
Other/unspecified*†	172 (9.5)	5 (1.9)	<0.001
Displacement of cervical disc w/o myelopathy	11 (0.6)	0 (0)	
Cervical disc degeneration	9 (0.5)	0 (0)	
Intervertebral disc disorder w/ myelopathy, cervical region	0 (0)	0 (0)	
Myelopathy	0 (0)	0 (0)	

* Statistically significant association was determined using Bonferroni correction (alpha 0.05/13 comparisons equals a correct alpha of 0.0038). Counts are rounded to the nearest whole number patient after application of the HCUP dataset weighting variable.

† Other/unspecified includes ICD-9 codes for "other syndromes affecting the cervical region" (723.8), "unspecified musculoskeletal disorders and symptoms referable to the neck" (723.9), and "other and unspecified disc disorder, cervical region" (722.91).

yearly cSCS caseload did not have a significant impact on the complication rate.

Discussion

Our study is the largest study reporting short-term complications after cSCS in a multicenter, nonselected hospital setting. Our results reveal that cSCS is associated with higher than previously reported rates of perioperative neurological complications and spinal cord injury (1.1% and 0.5%, respectively). Patients who developed complications more often had cervical spondylotic myelopathy and cervical spinal stenosis; were more often discharged from nonteaching hospitals; and were less likely to be discharged to home or home health care.

Age, medical comorbidity, and hospital caseload did not differ in patients with and without perioperative complications.

As compared with non-cervical-specific SCS, the present study's neurological complication rate is 2-fold higher than the immediate postoperative complication rate of other large database studies. In a study of 395 patients undergoing non-cervical-specific SCS lead implantations, an immediate index hospitalization neurological complication rate of 0.51% was reported.¹ In another study using the FDA Manufacturer and User Facility Device Experience database, Levy and colleagues reported that 239 (0.54%) of a total 44,587 electrode implantation procedures were associated with a neurological complication.²² This confirms that the rate of neurological and spinal cord injury after cSCS is greater than previously reported in the non-cervical-specific SCS population. These findings should serve as a precaution in future discussions with the patient regarding surgical risk and should increase the surgeon's vigilance regarding the treatment planning process. It is important to note, that the present rate of neurological injury refers only the immediate postoperative period. Rates of neurological injury due to cSCS will be even higher with known long-term neurological complications of cSCS including remote spinal cord injury from stimulator mass effect,⁹ local tissue reaction causing cord injury,^{5,16,21,30,34} and lead migration.¹

Aside from direct cord injury, and epidural hematoma, associated neurological deficits remain a concern after cSCS and are described in case reports. Published rates of epidural hematoma in a large, non-cervical-specific SCS study reveal epidural hematoma as a complication of 0.19% of surgeries.²² Our study reveals the hematoma rate alone for cSCS to be similar (0.22%). If the rate of hematoma is summed to the rate of postoperative hemorrhage, the rate of vascular complications is 0.5%. Anatomically, this may be due to a relative increase in size of the epidural space in the remainder of the spine relative to the cervical spine (lumbar 5–6 mm, cervical 1–2 mm) and smaller cervical spinal canal size. Further study into the anatomical and physiological basis of increased hematoma and hemorrhage formation after cSCS relative to SCS should be undertaken.

To avoid neurological complications and spinal cord injury, it may be useful to evaluate spinal imaging prior to cSCS. Patients undergoing cSCS often have medically refractory cervical and upper extremity pain that may be associated with structural cervical degenerative disease. In the present study, the cohort of cSCS associated with complications included a 7-fold greater number of patients who were reported to have cervical spondylotic myelopathy and cervical spinal stenosis at baseline. This suggests that patient selection via measurements of spinal canal size and baseline determination of spinal cord deformation from bony or discal abnormality—as Levy and colleagues²² proposed in their paper "Expert opinion recommendation for safe SCS surgery"—may have a role in selecting the optimal surgical candidate. This bears some significance, as complications in our study were associated with worse short-term outcomes including nonroutine discharge disposition (not to home or home health care) and a trend toward increased LOS. Of note, age, medical comorbidity, and hospital caseload were not factors that were associated with complications. As has been suggested for deep brain stimulation,²³ this may be partially due to the low baseline rate of surgical complications or overall low caseload practice of surgeons offering cSCS. Further study is necessary to elucidate a relationship between these factors and complications related to cSCS.

Our overall complication rate, including medical complications, is 2-fold higher than that reported in a previous large study for SCS for failed back surgery syndrome, in which leads were placed in the thoracic spine. In a retrospective, multicenter, Medicare claim-based database study of 395 cases who underwent either percutaneous or paddle lead SCS implantation, 5.1% of patients had some index hospitalization complication²⁰ as compared with 11.7% in our study. This discrepancy may in part be due to differing anatomy of the thoracic and cervical spine or a more comprehensive capturing of postoperative complications in our study. To this point, our perioperative rate for individual complications such as DVT/PE (0.2%) and pneumonia (0.5%) is similar to that seen in the work of Lad and colleagues (0.3% and 0.8%, respectively).²⁰ In contrast, our rate of infection (0.6%) and wound complication (0%) differs from the aforementioned study (0% and 1.3%, respectively).²⁰ Nonetheless, as is true for SCS, cervical SCS remains relatively safe in the perioperative period with respect to medical and general postsurgical complications.

In summary, our study demonstrates that cSCS is considered safe, with perioperative spinal cord injury and neurological insult occurring rates of 0.5% and 1.1%, respectively. It has been shown to be efficacious^{4,7,10,11,14,18,25,28,31,33,35–37} and long-term complication rates are acceptable for surgery in the appropriate patient. In a systematic review of 180 cSCS patients across 10 studies with up to 88 months of follow-up after cSCS, the rate of hardware malfunction (17.8%), lead migration (13.9%), lead fracture (6.7%), pain over implant site (4.4%), infection (2.2%), over- or understimulation (1.1%), intermittent stimulation (0.5%), and other complications (8.3%) with the absence of any neurological injury supports a low long-term risk of cSCS.⁶ Studies that have evaluated non-cervical-specific SCS have also supported its cost-effectiveness in treating pain.¹⁷ Lumbar SCS for chronic pain after failed back surgery syndrome has been associated with improved outcomes^{19,27} and decreased complications—without an increase in cost²⁶—relative to lumbar reoperation.²⁰ The extent to which these data apply to cSCS should be explored in future studies. Appropriate utilization of cSCS may be key in the treatment of cervical and upper-extremity pain in an increasingly opioid dependent, aging population.

We acknowledge certain limitations of this study. First, the NIS is a retrospective dataset with associated limitations. Second, the NIS complication data are an administrative dataset limited by ICD-9 coding. As a code intended for billing purposes, this scheme may fall short of providing a full clinical picture of the perioperative cSCS patient and the specific nature of a coded complication, such as would be provided with a prospective study. Indeed, as application of ICD-9 codes to hospital discharges is undertaken by individuals, there may be inconsistency in the complication data. Although we conducted an exhaustive search in ICD-9 coding to capture the full breadth of perioperative complications in our dataset, shortcomings and inconsistencies in coding will limit the ability to capture all potential complications from cSCS. For example, we do not cover long-term complications or outcomes (e.g., lead migrations, fractures, revisions/reoperations, local tissue reaction, stimulation effect failure, pain reduc-

tion, and quality of life improvement) of cSCS, which are beyond the scope of the present study. We believe that our complication rates represent a robust minimum periprocedural complication rate for cSCS. Lastly, it remains unknown which method of lead implantation—percutaneous versus paddle leads or anterograde versus retrograde lead placement—was undertaken for each cSCS implantation. The method of electrode implantation, surgeon familiarity with degenerative or complicated anatomy, specialty of proceduralist, and experience with each respective procedure will potentially affect the rate of complications.¹ Still, the literature has only a single report of spinal cord injury after cSCS. The present study reveals that there may be publication bias resulting in an underreporting of spinal cord injury after cSCS. The aforementioned shortcomings should be weighed against the number of cases, utilizing NIS data from the largest database reporting complications using cSCS in the US in a multicenter, nonselected hospital group fashion, beyond the confines of small case reports. Further studies to dissect the rates of complications with respect to the specific cSCS technique (e.g., percutaneous vs. paddle, anterograde vs. retrograde approach) are warranted.

Conclusions

This is the first study to robustly assess the perioperative complication and safety outcomes of cSCS. Prior to this study, there has been only one case report of perioperative spinal cord injury after cSCS. The present study reveals that spinal cord injury and neurological complications are underreported after cSCS, although the rates themselves are reassuringly low. Therefore, cSCS remains an option for the treatment of a variety of cervical pathologies in well-selected patients. Future multicenter prospective studies are needed to provide definitive analysis of efficacy, short-term complications, and, particularly, of long-term complication rates of cSCS.

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Disclosures

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author Contributions

Conception and design: Chan, Jacques. Acquisition of data: Chan. Analysis and interpretation of data: Chan, Winkler. Drafting the article: Chan, Winkler. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Chan. Statistical analysis: Chan. Administrative/technical/material support: Jacques. Study supervision: Jacques.

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