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Retrospective Study

Spinal Cord Stimulator Complication Rates: A Single-Institution, 22-Year Study (1999-2021)

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Background: Since the initial introduction in 1967 of spinal cord stimulation (SCS) in the field of neuromodulation, SCS has been utilized to treat a multitude of chronic pain disorders refractory to both conservative and surgical management. Although efficacious when indicated, SCS has associated risks.

Objectives: The goals of this study are to explore the trend of rates of SCS complications in 2 approximately equally sized cohorts (1999-2015 and 2016-2021) within a single institution over a 22-year period.

Study Design: A retrospective cohort study.

Setting: A tertiary care academic hospital.

Methods: A retrospective chart review with pre-existing institutional review board approval was performed on 2 cohorts, one comprising 257 patients between 2016 and 2021 and the other comprising 262 patients between 1999 and 2015, who underwent percutaneous SCS implantation provided by 2 experienced interventional chronic pain specialists. The patients' demographics and complications were recorded in the REDCAP database. Data were collected on complications of both the biological (allergic/foreign-body reactions, dural puncture/leaks, infections, pain over implantation site, poor wound healing, skin erosions, neurological injuries, and subcutaneous/epidural hematomas) and device-related (electrical leaks, inadequate pain coverage, lead fractures, lead migrations, ligamentum flavum stimulation, recharging/battery failures, and unwanted stimulation) varieties. The chart review included records that started 6 months prior to SCS placement and ended at a period of at least one year of follow-up after placement.

Results: Of the patients studied between 2016 and 2021, the mean age was 58.5 ± 13.0 years, with men representing 46.3% and women 53.7% of the patients studied. Of those studied between 1999 and 2015, the mean age was 50.6 +/- 12.3 years, with men representing 42.4% of the patients and women 57.6%. The overall complication rates were 14.0% (36/257) and 38.9% (102/262) for 2016-2021 and 1999-2015, respectively. The rate of biological complications was nearly 3 times lower in the 2016-2021 group than in the 1999-2015 group (4.3% [11/257] vs 12.2% [32/262], $P < 0.001$). In the 1999-2015 group, the leading biological complication was infection, the rate of which decreased in the 2016-2021 group (3.4% [9/262] vs 1.9% [5/257], $P < 0.42$). The rate of device complications was nearly 3 times lower in the 2016-2021 group than in the 1999-2015 group (9.7% [25/257] vs. 26.7% [70/262], $P < 0.0001$). The leading device complication was inadequate pain coverage (12.2% [32/262] vs 7.4% [19/257], $P < 0.08$). No serious neurological injury or death occurred in either cohort.

Limitations: Limitations were inherent to this study's design, since it was a retrospective cohort study.

Conclusion: The rate of SCS-related complications decreased from one group to the next, with

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the most recent group demonstrating a statistically significant decrease in both device and biological complications. Our results are consistent with SCS literature trends that demonstrate decreasing complications, which may be due to technological advancements in SCS device technology and improved complication mitigation strategies. Further prospective research utilizing multicenter data is needed to better define the overall trend of SCS complications.

Key words: Incidence rates, biological complications, device complications, spinal cord stimulation, adverse events

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In the United States, 50.2 million adults, or 20.5% of the population, have reported symptoms of chronic pain associated with reduced quality of life, increased medical expenditures, and increased cost to the economy (1). Since 1967, when spinal cord stimulation (SCS) was introduced to the field of neuromodulation, SCS has been utilized to treat a multitude of chronic pain disorders refractory to both conservative and surgical management (2,3). Rooted in Melzack and Wall's seminal gate control theory of pain, neuromodulation of the spinal cord is based on the principle that the electrical stimulation of larger Aβ fibers inhibits nociceptive signals conveyed by smaller Aδ and C fibers (4). The core components of SCS consist of an implantable pulse generator (IPG), leads, a remote control, and, in most cases, a recharging equipment. The leads are implanted into the epidural space to deliver controlled electrical impulses, mitigating the perception of pain through complex spinal and supraspinal mechanisms (5). While the precise mechanism of action and the electrical targets of SCS therapy remain subjects of ongoing investigation, SCS has been shown to be a safe and effective treatment modality for a plethora of indications, including post-laminectomy syndrome, complex regional pain syndrome, refractory chronic non-surgical back pain, and painful diabetic peripheral neuropathy (5,6).

Although efficacious when indicated, SCS therapy is not without associated risks, which are caused by the surgical implantation procedure and device-related problems (7). These risks include biological complications, most commonly surgical-site infections, hardware pain, and impaired wound healing. The risks also include device complications, which are most often linked to lead migration, lead fracture, and, less frequently, battery failure (8,9). Both biological and device complications can lead to SCS device revision or removal. Biological complications are thought to occur less frequently but may be more severe than device-related adverse events (8,10). Surgical-site infections can be superficial, involving the skin and subcutaneous tissue around the incision, or deep, extending into the fascia and muscle layer around the generator or leads. Deep surgical-site infection most often necessitates device removal and the disruption of therapy to avoid spinal infection or sepsis (11,12). Despite the elective nature and frequent complications of SCS therapy, fortunately few cases of permanent neurological effects or life-threatening complications have been documented as a result of SCS implantation (9,13).

Regardless of the continually expanding body of literature on SCS, data regarding the incidence of biological and device complications vary widely (10-14). Various studies and reviews conducted during the last 3 decades have cited overall complication rates between 28-43%, with the incidence of biological complications ranging from 3-27% and device complications ranging from 10-29% (10,14-20). Continual advancements in SCS systems and best-practice guidelines further underscore the necessity of the periodic reassesment of SCS complication rates (21,22). In 2014 and 2017, the Neurostimulation Appropriateness Consensus Committee (NACC) published recommendations to address several surgical complications, including infection-control

practices meant to reduce the infection rates caused by SCS, which were historically higher than those associated with other implantable devices, and new fixation methods to mitigate lead migration (12,14). Additionally, technological advances now allow for alternative stimulation waveforms and reprogramming options for addressing small lead migrations that would have previously required surgical revision (21). Even with the new recommendations and enhanced technology, it is unclear how the adverse outcomes of SCS have changed. The comprehensive reviews regarding SCS complication rates in the last decade are limited, with a few studies suggesting trends toward decreased rates of common complications, such as infection and lead migration, than those documented in previous literature, but with little available data regarding other incidence rates (23-25). Thus, there is a need for the longitudinal examination and updating of SCS procedures and device-related complications. As such, the goal of this study was to evaluate the incidence of biological and device complications after SCS implantation within a single academic institution in 2 approximately equally sized patient cohorts, one treated during the period spanning 2016 to 2021 and the other treated from 1999 to 2015.

Methods

Study Design and Setting

A retrospective chart review with pre-existing institutional review board approval was performed on 2 cohorts of patients who underwent percutaneous SCS implantation performed by 2 experienced interventional chronic pain specialists at Beth Israel Deaconess Medical Center (BIDMC). One group of patients received treatment between January 1st, 2016 and December 31st, 2021, and the other received treatment between January 1st, 1999 and December 31st, 2015. A registry of all spinal cord stimulator implants in the pain management center was cross-checked with the Current Procedural Technology (CPT) data that gave patient identification. January 2016 also coincided with the introduction of sub-perception stimulation as a therapeutic option in our clinical practice. The chart review included records that started 6 months prior to SCS implantation and ended at up to a minimum of one year of follow-up after placement. Information regarding patients' demographics (age and gender), diagnoses, and any biological and/or device complications were collected and entered into a REDCAP database. The SCS devices utilized were from Medtronic, Abbott, Boston Scientific, and Nevro, and were not analyzed in this study, since the purpose was to evaluate the overall trends in the SCS field.

All patients had failed conservative measures, which included multi-modal analgesia, rehabilitation, injections, or neuroablative techniques where applicable. After being given psychological assessments, all patients received a temporary one-week trial. A successful trial was defined by an average pain intensity reduction of 50%, and those who fit the criteria were implanted with a complete SCS device in the operating room under monitored anesthesia care.

Biological complications included allergic/foreign-body reactions as defined on biopsy results, dural punctures with resultant postural headaches, infections both superficial and deep (including those seen during the trial, the full implantation, and the battery replacement), poor wound healing, skin erosions, subcutaneous/intraspinal hematomas, and a degree of hardware-related pain over the implantation site severe enough to require device removal. Device complications included electrical leaks (defined as burning in the pocket or lead extension site with only the device on), inadequate paresthesia coverage, lead fractures with required replacements, significant lead migration characterized by surgical revision, ligamentum flavum stimulation (defined as an uncomfortable midline stimulation at the level of the lead), recharging failures, and unwanted stimulation. The data were analyzed to determine the biological and device complication incidence rates at a large single-center institution between 2016 and 2021 and between 1999 and 2015.

Statistical Analysis

The differences in the patient demographics were compared using the unpaired t-test for continuous variables (age), the omnibus Fisher's exact test for categorical variables (gender), and the row-wise Fisher's exact test for the diagnosis. The overall differences in the number of biological and device complications between the 2 timeframes were compared using an odds ratio, and the *P* values were provided by the Fisher's exact test. The row-wise Fisher's exact test was used to compare the types of biological and device complications between timeframes. All statistical analyses were conducted in R version 4.2 (R Foundation). The Bonferroni correction for multiple comparisons was not performed, given the exploratory nature of this retrospective cohort study.

Results

Demographics and Diagnoses

During the more recent time interval of 2016-2021, a total of 257 patients underwent percutaneous SCS implantation at our institution. The mean age of the patients was 58.5 ± 13.0 years, with men and women representing 46.3% and 53.7% of the cohort, respectively (Table 1). Between 1999 and 2015, a total of 262 patients underwent percutaneous SCS implantation. The mean age was 50.6 ± 12.3 years, with men and women representing a respective 42.4% and 57.6% of the group. There were no statistically significant differences between the percentage of men and women undergoing SCS implantation within the 2 different timeframes ($P = 0.38$), but there was a statistically significant difference between the mean age ($P < 0.0001$). The 5 most common diagnoses associated with SCS included post-lumbar laminectomy syndrome, complex regional pain syndromes (CRPS) I and II, chronic lumbosacral radiculopathy, and post-cervical laminectomy, and those diagnoses remained stable between the groups over a 22-year time period (Table 1).

Table 1. *Patient demographics and diagnosis.*

Cohort	2016-2021 n = 257	1999-2015 n = 262	*P* value
Gender			
Male	119	111	0.38
Female	138	151	
Age (y), mean (SD)	58.5 (13.0)	50.6 (12.3)	< 0.0001
Diagnosis			
Cervical radiculopathy	1 (0.4%)	3 (1.1%)	0.62
Chronic lumbosacral radiculopathy	23 (8.9%)	11 (4.2%)	0.03
Complex regional pain syndrome 1	28 (10.9%)	61 (23.3%)	0.0002
Complex regional pain syndrome 2	21 (8.2%)	7 (2.7%)	0.006
Post-laminectomy syndrome (back)	154 (59.9%)	140 (53.4%)	0.16
Post-laminectomy syndrome (neck)	20 (7.8%)	5 (1.9%)	0.002
Peripheral neuropathy	1 (0.4%)	4 (1.5%)	0.37
Diabetic neuropathy	1 (0.4%)	3 (1.1%)	0.62
Post-thoracotomy/ intercostal neuralgia	4 (1.6%)	3 (1.1%)	0.72
Other	4 (1.6%)	25 (9.5%)	< 0.0001

Statistical analyses included the Fisher's exact test for gender and diagnoses and the unpaired t-test for age. Other diagnoses for 2016-2021 include gastroparesis, genitofemoral neuralgia, meralgia paresthetica, and sphincter of dysfunction. Other diagnoses for 1999-2015 include angina, brachial plexopathy, chronic surgical pain after total knee replacement, chronic pancreatitis, interstitial cystitis, median nerve neuralgia, peripheral nerve injury, postherpetic neuralgia, post-mastectomy syndrome, spinal cord injury, sural neuralgia, thoracic radiculopathy, ulnar nerve neuralgia, and visceral pain.

Total Complication and Incidence Rate

The overall complication rates were 14.0% (36/257) and 38.9% (102/262) for 2016-2021 and 1999-2015, respectively. Notably, in the 2016-2021 group, one patient experienced multiple device complications (inadequate pain coverage and lead fracture); thus, the incidence rate per patient was 13.6% (35/257). In the 2015-2016 group, 5 patients had 2 complications (one had a lead fracture and poor wound healing, one had an infection and a lead fracture, 2 had dural punctures and inadequate pain coverage, and one had an infection and inadequate pain coverage); thus, the incidence rate per patient was 37.0% (97/262).

Biological Complication Rate

The total biological complication rate was nearly 3 times lower in the 2016-2021 group than in the 1999-2015 group (4.3% [11/257] vs. 12.2% [32/262], $P < 0.001$) (Fig. 1). The 1999-2015 patient cohort was 3.11 times more likely to experience a biological complication than the 2021-2016 cohort ($P = 0.00124$). The most common biological complication in both groups was infection (1.9% [5/257] vs 3.4% [9/262], $P < 0.42$) followed by poor wound healing (0.4% [1/257] vs 2.7% [7/262], $P = 0.07$), dural puncture/leak (0.0% [0/257] vs 1.9% [5/262], $P = 0.06$), pain over the implantation site (0.8% [2/257] vs 1.5% [4/262], $P = 0.69$), allergic/foreign-body reaction (0.0% [0/257] vs. 1.5% [4/262], $P = 0.12$), subcutaneous hematoma (0.4% [1/257] vs. 0.8% [2/262], $P = 0.99$), and skin erosions (0.8% [2/257] vs 1.5% [4/262], $P = 0.62$). No patient in either group had more than one biological complication. There were no seromas, epidural hematomas, or deep spinal infections in either cohort.

Device Complication Rate

The total device complication rate was nearly 3 times lower in the 2016-2021 group than in the 1999-2015 group (9.7% [25/257] vs. 26.7% [70/262], $P < 0.0001$) (Fig. 2). The 1999-2015 patient cohort was 3.38 times more likely to experience a device complication than was the cohort from 2016 to 2021 ($P < 0.0001$). The most common device complication in both groups was inadequate pain coverage (7.4% (19/257)

vs 12.2% (32/262), $P < 0.08$) followed by lead fracture (1.2% [3/257] vs. 5.3% [14/262], $P < 0.01$), recharging failure (0.8% [2/257] vs. 3.4% [9/262], $P = 0.06$), lead migration], (0.4% [1/257] vs. 2.3% [6/262], $P = 0.12$), unwanted stimulation (0.0% [0/257] vs. 1.9% [5/262 $P = 0.06$), ligamentum flavum stimulation (0.0% [0/257] vs 0.8% [2/262], $P = 0.50$), and electrical leak (0.0% [0/257] vs. 0.8% [2/262], $P = 0.50$). No patients in either group experienced more than one device complication. There were no battery failures in either cohort.

Discussion

Overall Complications

Complication rates in SCS therapy have been largely reported to occur in the range of 30-40%, according to the literature of the 1990s and 2000s (7,11,14-16). In our single-institution, retrospective study on SCS complications, the overall incidence for any complication during the 1999-2015 period was 38.9%, which fell within the aforementioned range. Adverse event rates reflect the available technology and procedural techniques of the time periods. A 2021 meta-analysis of the relevant literature revealed a reduction in the overall average complication rate to 21% (27). Our findings are consistent with this trend: the results regarding the 2016-2021 cohort demonstrate a statistical and clinically significant reduction in overall complications to 14%, reflecting declines in adverse events of both the device and biological varieties.

Biological Complications

SCS infections have been reported to occur at a rate of 4-10%, often necessitating the removal of the device and at a higher frequency than other surgical specialties (14,17). Infections are the most common form of biological complication in SCS therapy. At 3.4%, the infection rate experienced by 1999-2015 group is in line with this range. A large retrospective multicenter study published in 2017 determined that the average infection rate in academic practice was 2.88% (28). This finding agrees with our 2016-2021 rate of 1.9 %. In line with the declining infection rates over the 22-year timeframe is the reduction in poor wound healing, probably reflecting the adoption of the improvements in surgical techniques and prevention of surgical-site infections that the NACC began advocating in 2014 (14). A small sample size in conjunction with a low incidence of infection likely accounts for our inability to detect a statistical difference between the 2 groups. We found only a suggested trend.

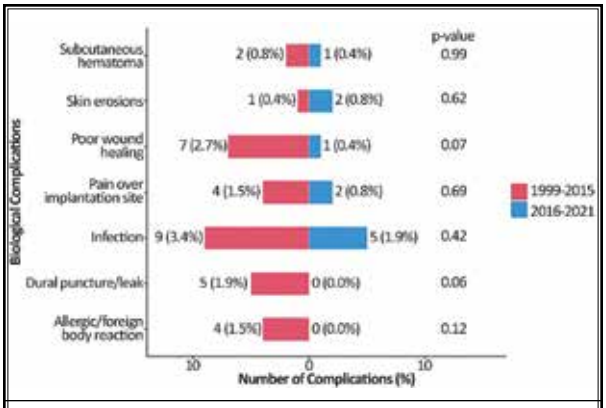

Fig. 1. *Incidence rates of biological complications following SCS implantation. Eleven out of 257 patients had biological complications from 2016 to 2021 (4.3% of patients), and 32 out of 262 patients had biological complications from 1999 to 2015 (12.2% of patients). The differences in the number of biological complications between the 2 time frames were compared using an odds ratio, and the P-values were provided by the Fisher's exact test (odds ratio = 3.11, P-value = 0.00124). Patients from 1999 to 2015 were over 3.11 times more likely to have a biological complication than were patients from 2016 to 2021 (P = 0.001, per the Fisher's exact test).*

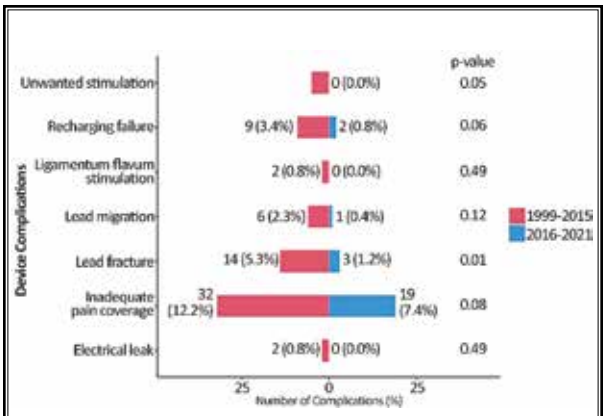

Fig. 2. *Incidence rates of device complications following SCS implantation. Of 257 patients, 25 experienced device complications from 2016 to 2021 (9.7% of patients), and 70 of 262 patients experienced device complications from 1999 to 2015 (26.7%% of patients). The differences in the number of device complications between the 2 time frames were compared using an odds ratio, and the P-values were provided by the Fisher's exact test. The odds ratio was 3.38 (P < 0.0001). Therefore, patients from 1999 to 2015 were 3.4 times more likely to have a device complication than were patients from 2016 to 2021.*

For similar reasons, the rates of other, less frequent biological complications did not show statistical differences in this time frame (Fig. 1). No epidural hematoma or spinal cord injury was detected, but such complications likely would have been found in the current sample size, if previous work was any indication. One study analyzed up to 5,458 retrospective patients and determined rates of 0.75% for spinal hematomas and 2.35% for spinal cord injuries with percutaneous leads (29). A previous report failed to find any epidural hematomas in 2,972 patients and found one spinal cord injury with a paralysis rate of 0.03%, but more recent work suggests the rate of spinal cord injuries associated with SCS percutaneous procedures to be 0.42%, an order of magnitude greater (10,30). Similarly, we did not find seromas to be persistent or significant long-term complications (10).

The true incidence of allergic or foreign-body reactions to SCS device components has been noted to be difficult to determine in the literature (31). The best estimates in the literature were again provided 20 years ago, at 0.1% (10). We cannot explain the higher rate of allergic reactions in the 1999-2015 group compared to the 2016-2021 group other than as the result of random sampling in relatively small cohorts. We suspect that the true incidence is < 1.0% if we combine both groups, but the current sample size likely does not permit the true detection of the rate of this uncommon problem.

Complications such as subcutaneous hematomas and skin erosions presented themselves. Both occurred at a rate of < 1.0%, a finding similar to that of previous studies, and did not seem to change over the course of the present study (10). An intolerable level of pain over the implant site, resulting in surgical intervention, trended downward over time to an extent. Again, however, the rate of this complication did not achieve statistical difference and agreed with prior studies, being found to be ~1.0% (10,13,32). Data from those previous studies likely reported on IPG that were larger than those in our report, suggesting that the current IPG size does not appreciably change the incidence of severe site pain. The incidence rate of inadvertent dural punctures during SCS placement has been estimated, based on 90,952 retrospective percutaneous implants, to be 0.48% (33). The gradual decline by at least an order of magnitude between the 2 groups in the current study has been associated with the use of the contralateral oblique view for guiding accurate epidural needle placement (34). In summary, biological complications overall were reduced with clinical relevance between the 2 groups, but the individual categories of such events were low, and we did not have enough patients to detect statistical differences.

Device Complications

As in many prior reviews, device-related adverse events consistently accounted for the majority of problems encountered in clinical practice (35). Over the 22-year period studied, such events saw a reduction in magnitude similar to the decline in biological complications. Lead breakage was most impacted in the current study (Fig. 2). The literature reports lead fracture rates to be between 5.6-10.0% (9,10,13,34,36). From 1999 to 2015, lead breakage mitigation strategies were undertaken between the years of 2006 and 2007. The strategies included shallow-angle (less than 45-degree) epidural needle placement to minimize angular stress on lead components, silastic anchor nozzles placed through the deep fascia for prevention of lead kinking, nonabsorbable sutures placed only on the anchor so as not to erode lead polyurethane insulation, and a strain relief loop to avoid lead tension (36-38). The 5.3% lead fracture rate incidence observed in the 1999-2015 group is likely related to the employment of these tactics. The further reduction to a very low fracture rate of 1.2% in the 2016-21 group is probably related to the consistent use of fracture reduction strategies and the more consistent use of multi-lumen concentric leads (39).

Similarly, lead migration with clinically meaningful loss of therapy is considered the most common device complication in SCS treatments, with a recent meta-analysis finding an incidence of 9.97% (40). For the first 10 years of SCS treatment that the patients in the 1999-2015 group experienced, lead migration mitigation techniques were based primarily on the nonabsorbable suturing of the anchor to the lead(s) and to supraspinous ligaments, followed by an appropriate amount of strain relief (36). By 2010, surgical approaches were augmented with the use of mechanical anchors meant to prevent the lead from slipping through the main anchor. The 2016-2021 cohort benefited from all lead displacement mitigation strategies, accounting for a 1.2% incidence of lead migration, a finding consistent with the 2.0% rate documented by other experienced authors (41,42).

The remaining reduction in device-related complications resulted from improvements made to SCS programming options and device reliability. The 1999-

2015 group received only a single waveform of tonic stimulation. The 2016-2021 cohort benefited from subthreshold stimulation options, therefore overcoming many of the limitations of paresthesia, including inadequate paresthesia coverage, unwanted paresthesia to non-painful regions of the body, and uncomfortable ligamentum flavum stimulation (LFS). LFS, which occurs because of tonic stimulation by percutaneous leads (43), is a non-radiating discomfort localized to the midline and unaccompanied by muscle contractions. Although not common, LFS as expected would not occur with sub-perception programming. Improvement in the recharging coil in the IPG accounts for the enhanced reliability of the recharging, though we were unable to find a true statistical difference. Lastly, "electrical leak," defined as localized burning at the junction of lead extensions, or, more commonly, at the junction of the IPG site, also trended toward a lower frequency (38). The improvement in the connection between the leads and the IPG likely accounts for the lower occurrence of complications in our current study. IPG technology improved the rates of most of the types of device complications (Fig. 2).

Limitations

The limitations of our study are directly related to its inherent retrospective design, including bias, confounding variables, and the lack of a control group. The study is constrained to a particular time frame at a single institution and the domain of 2 proceduralists whose experience has evolved gradually. The number of years evaluated in each group differed, which can be attributed to the slower earlier phases of SCS adoption. As the providers' experience increased, so did the volume of their patients. Though improvement in complication rates can be seen with increasing provider experience, this factor would have affected this long-term 22-year study only minimally, since the entire study was performed under 2 providers, and the gap in experience would not have played a significant role beyond the first 2 years. Furthermore, we do acknowledge that the rate of complications seen in retrospective "real-world" chart reviews is 2-3 times lower than in prospective studies, since the persons involved in the former type of study are not asked directly about their complaints and complications. There were also minor but statistically significant differences in age and diagnoses between the 2 groups.

Conclusions

The current retrospective analysis suggests that recent improvements in implantation techniques and SCS technology can reduce the overall rate of complications by approximately one-half or two-thirds, bringing it down to 14%. Our results build upon the evolving literature available to support the notion that the incidence rate of SCS complications is declining from the previous benchmark of 30-40%. Future research is warranted to evaluate the incidence rates of both biological and device complications that follow SCS therapy.

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Author Contributions

Johnson Ho, Michael Glicksman, Kyle Kang, Emily X Zhang, Anh Phung, Alexandra Therond, and Alexandra Fonseca are co-first author. Christopher L Robinson and Thomas Simopoulos are co-senior authors. JH, MG, KK, EXZ, ATP, AT, and ACF analyzed the data and wrote and edited the manuscript. AT provided statistical assistance. EB, MES, ADK, JH, CY, JG, and QR assisted in writing, editing, and providing expert guidance. TS and CLR were the primary investigators, planned the project, analyzed the data, and wrote the manuscript.

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