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Original Article

Biological and hardware-related spinal cord stimulation complications and their management: A single-center retrospective analysis of the implantation of nonrechargeable implantable pulse generators in different pain conditions

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ABSTRACT

Background: We present our experience with spinal cord stimulation (SCS) for patients suffering from different pain conditions who subsequently developed hardware-related complications after SCS surgery. The SCS hardware-related complications may compromise the continuous SCS therapy due to partial or total hardware removal. Such situations should be avoided, and possible predisposing factors for their development should be minimized. The present study aimed to evaluate the frequency of hardware-related complications and their proper neurosurgical management.

Methods: The study is designed as a retrospective analysis of all hardware-related complications of SCS procedures for pain patients who underwent the implantation of the nonrechargeable PrimeAdvanced™ SureScan™ magnetic resonance imaging (MRI) neurostimulator (Medtronic, Minneapolis, United States). This neurostimulator allows patients safe access to MRI scans anywhere on the body. The PrimeAdvanced™ SureScan™ MRI neurostimulator can deliver stimulation through one or more leads in the epidural space. From December 2017 to December 2021, 20 patients with SCS implantations and a minimum postoperative follow-up of 3 months were included. All patients were operated on using identical surgical and intraprocedural techniques. The same SCS hardware was implanted (nonrechargeable PrimeAdvanced™ SureScan™ MRI neurostimulator) in all patients. We examined numerous preoperative variables (i.e., sex, age at surgery, diabetes, body mass index, and type of pain syndrome) to detect any correlation between them and the incidence of postoperative hardware-related complications.

Results: Among 20 patients, 8 (40%) patients were affected by hardware-related complications. The most common complications were skin erosion found in 5 patients (25%) and incorrect functioning of the implantable pulse generator (IPG) affecting 2 patients (10%). There were 1 case of an IPG migration (5%) and 1 hardware infection (5%) due to a staphylococcal wound. A total number of 16 revision surgeries were performed to manage all hardware-related complications in these patients adequately. Most of the patients (5 of them) were troubled by more than one hardware-related complication episode. Three patients had 3 revision surgeries, 2 patients had 2 revision surgeries, and 3 patients had 1 revision surgery. Among 8 patients with complications, 3 patients had no further continuation of SCS therapy due to hardware-related complications. Among these 3 patients who stopped their SCS therapy, 1 patient had 3 hardware-related episodes, and the remaining 2 patients were troubled by two hardware-related episodes before discontinuation of SCS therapy.

Conclusion: Our results indicate that patients treated by the SCS technique are at higher risk for the development of skin-related complications, especially skin erosions and less common skin infections, notably in cases when large (high profile) IPGs are utilized. The use of smaller IPGs could reduce the number of these biological as well as hardware-related complications and associated revision surgeries.

Keywords: Complex regional pain syndrome, Failed back surgery syndrome, Hardware-related complications, Skin erosion, Spinal cord stimulation, Visual Analog Scale

INTRODUCTION

The basis for spinal cord stimulation (SCS) has its origin in the gate control theory of pain proposed in 1965 by Melzack and Wall.[26] SCS was applied as a reversible and long-term therapy for complex regional pain syndrome (CRPS) soon after. The goal of classic SCS is to achieve stimulation-induced paresthesia, which is comfortable for the patient but also completely overlaps with their pain topography.[17,32] By stimulating large A-beta fibers, the activation of inhibitory interneurons is achieved, which competitively inhibits the transmission of impulses from small A-delta and C-fibers.[17,26,32]

The main indications for SCS implantations are: failed back surgery syndrome (FBSS) and CRPS.[17,31] SCS is regarded as a last resort treatment for patients affected by pharmacologically resistant neuropathic pain.[35] Nevertheless, SCS is not free of complications. In particular, erosions and infections of the implanted SCS hardware may frequently result in the partial or total removal of the device.[13,18,20,39,40] This situation may become a disaster for the patient by significantly deteriorating his quality of life. The economic aspect of SCS complications is also important. Moreover, SCS is a cost-effective therapy.[39]

This study aimed to determine the frequency of hardware complications and to determine the factors predisposing their development.

MATERIALS AND METHODS

We performed a retrospective evaluation of the clinical outcomes in 20 consecutively treated patients (9 patients with severe, intractable CRPS and 11 patients with FBSS). All patients underwent implantation of a nonrechargeable PrimeAdvanced™ SureScan™ magnetic resonance imaging (MRI) neurostimulator (Medtronic Inc. Minneapolis, *MN*, *USA*) between December 2017 and December 2021.

Due to the retrospective analysis of the presented clinical data, the institutional approval by the Ethics Committee has been waived. All patients were informed about possible complications related to SCS surgery and provided signed, written informed consent before SCS treatment. All patients selected for this study had previously received conventional pharmacological treatment, including multi-modal pain therapy based on multiple pharmacological blockades. All patients were referred for SCS treatment by an experienced pain specialist or a specialized pain center.

Only 16-electrode Specify™ SureScan™ MRI surgical paddle-style SCS leads (Medtronic Inc. Minneapolis, MN, USA) were used. Implantations were performed using the same surgical procedure. SCS treatment was performed in two stages. The same surgical technique was used for all patients. SCS electrodes were implanted under general anesthesia with fluoroscopic guidance for final SCS lead placement in the spinal epidural space. Opening of the spinal canal was achieved by removing the supraspinous, interspinal, and flavum ligaments. Vertebral laminae were not removed. This surgical maneuver allowed for a significant reduction in venous bleeding from spinal bone structures.

On the 1st day following surgery, a stimulation screening was performed to cover the painful area with an acceptable level of SCS-induced paresthesia. During screening, the SCS electrodes were connected to the external stimulator provided by the Medtronic manufacturer. Patients were usually discharged on the 2nd or 3rd postoperative day. Over the next 2 weeks, if the patients showed significant benefit, i.e., at least 50% pain reduction assessed using the Visual Analog Scale (VAS), we proceeded with the implantation of the Prime Advanced Sure Scan™ nonrechargeable implantable pulse generator (IPG) (Medtronic Inc. Minneapolis, MN, USA). Implantation was performed under local anesthesia and with intravenous sedation. The illustration of the final placement of the connected implantable pulse generator, usually in the right buttock area, is depicted in Figure 1. The retrospectively collected data included a detailed medical history, physical evaluation, date of electrode and IPG implants, type of possible adverse events related to SCS therapy, as well as preoperative and postoperative VAS scores. In addition to short-term follow-up, VAS scores were examined over a long-term follow-up period. The clinical characteristics with pre and postoperative VAS scores at the longest follow-up are set out in Table 1.

The patient cohort was comprised of 11 females and 9 males. The mean age of initial diagnosis was 42 years (range: 25–77 years), and the mean duration of disease before SCS treatment was 4 years (range: 1–12 years). FBSS was diagnosed in 11 patients (55%), and CRPS was diagnosed in 9 patients (45%). In 17 patients (85%), the electrode

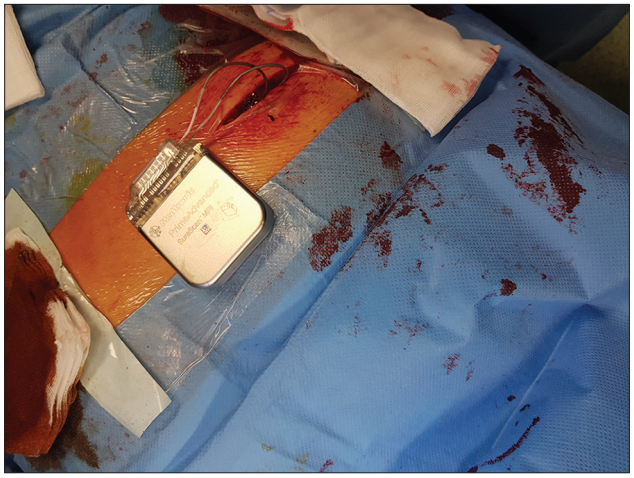

Figure 1: The final placement of the connected implantable pulse generator in the right buttock area.

was placed in the thoracic segment in 3 cases (15%) in the cervical region.

The pain intensity was assessed using VAS scores at baseline, 3 months, and in long-term follow-up in individual patients. A detailed neuropsychological examination was also performed on these patients. For this article, the results of the neuropsychological examination were presented only in relation to the Addenbrooke's Cognitive Examination-III (ACE-III) cognitive function screening scale. The ACE-III cognitive function scores were assessed at baseline, at 3-month follow-up, and the last available follow-up.

Descriptive statistics were applied to all measures, and numerical data were expressed as mean and interquartile ranges. The pain intensity using VAS scores was analyzed using a *t*-test.

RESULTS

Among 24 patients screened and suitable for two-staged SCS therapy, 4 patients failed to respond positively to the SCS 2-weeks trial period. All 4 patients suffered from FBSS. Four patients with the diagnosis of FBSS had their SCS electrodes removed with uncomplicated further follow-up. In contrast, all 9 patients with a preoperative diagnosis of CRPS responded favorably to the 2-week duration stimulation trial period. In 19 cases (96%), the IPG was placed in the buttock area, while in the remaining 1 patient, the IPG was placed in the abdominal wall.

The results of clinical characteristics and individual VAS scores in chronological order in consecutive patients are shown in Table 1. The primary outcome of this study, besides pain assessment and baseline neuropsychological assessment, was documentation of all biological hardware-related SCS complications and their management. The information on different complications with the number of revision surgeries in chronological order in individual patients is provided in Table 2.

In this study, 8 patients (40%) developed postoperative complications. The most common complications in our series were so-called biological complications. The skin erosions were most frequently encountered, which were undoubtedly related to the large dimensions of the nonrechargeable PrimeAdvanced™ SureScan™ MRI neurostimulator. The typical skin erosion and wound dehiscence over IPG are shown in Figures 2 and 3. There were, in total, 8 skin erosion episodes found in 5 patients (25%). Three patients had 2 episodes of skin erosion each; the remaining 2 patients had one skin erosion episode. There was only one skin infection at the IPG site, with subsequent removal of the entire SCS system. The bacteriological examination revealed a *Staphylococcus aureus* infection. This patient refused further proposed reimplantation.

The other hardware-related complications included 2 cases of fast depletion of IPG found in 2 patients with FBSS who required relatively high stimulation settings to provide excellent pain relief. In both cases, the IPG provided the stimulation ranging from 5 to 8 months before depletion. Both patients had replacement surgeries with rechargeable IPG. There was one IPG displacement in the buttock area with possible impending erosion. There was one case of SCS electrode migration with its removal and replacement with a new epidural electrode.

A total number of 16 revision surgeries were performed to manage all 14 hardware-related complications reported in 8 patients adequately. Most of these patients (5 of them) were troubled by more than one hardware-related complication episode requiring revision surgeries. Three patients had 3 revision surgeries, 2 patients had 2 revision surgeries, and 3 patients had 1 revision surgery. Among 8 patients with hardware-related complications, 3 patients had no further continuation of SCS therapy. Among these 3 patients who stopped their SCS therapy, 1 patient had 3 hardware-related episodes, and the remaining 2 patients were troubled by two hardware-related episodes before discontinuation of SCS therapy.

Due to the relatively small sample size, we did not find correlations between preoperative variables (i.e., sex, age at surgery, type of neuropathic pain, diabetes, and body mass index value) and the incidence of biological or hardware-related complications.

We treated two groups of patients affected by intractable pain due to CRPS (9 patients) or FBSS (11 patients). The mean follow-up period for all patients was 35, 4 months (range: 3–60 months). At baseline, unbearable pain intensity (VAS = 10) was reported by 9 patients (45%); 3 patients rated

Table 1: Represents consecutive patients operated for intractable pain conditions like failed back surgery syndrome or complex regional pain syndrome.

Patient's number	Pain duration in years	Implantation level	Sex	Pain condition	VAS preoperative	VAS postoperative 3 months	VAS postoperative last follow-up	Last follow-up in months	Under follow-up
1	3	Th10–Th11	F	FBSS	7	5	7	60	Yes
2	2	Th11–Th12	M	FBSS	8	4	4	52	Yes
3	3	Th9–Th10	M	FBSS	8	4	6	52	Yes
4	3	Th10–Th11	F	CRPS	8	3	4	48	Yes
5	6	Th10–Th11	F	FBSS	7	3	4	48	Yes
6	3	Th11–Th12	M	CRPS	9	4	5	27	Lost for FU
7	6	Th10–Th11	F	FBSS	7	3	4	44	Yes
8	5	Th11–Th12	M	CRPS	10	2	4	47	Yes
9	3	Th11–Th12	F	CRPS	10	4	3	36	Lost for FU
10	1	Th10–Th11	F	FBSS	9	4	5	47	Yes
11	12	Th10–Th11	M	FBSS	8	3	5	47	Yes
12	2	Th11–Th12	F	CRPS	10	3	2	46	Yes
13	3	Th10–Th11	F	FBSS	10	3	5	36	Yes
14	10	C5–C7	F	CRPS	10	4	4	24	Lost for FU
15	3	Th8–Th9	F	FBSS	10	4	5	11	Lost for FU
16	3	Th10–Th11	M	FBSS	10	4	5	36	Yes
17	3	Th11–Th12	M	CRPS	9	4	3	3	Lost for FU
18	7	Th7–Th8	F	FBSS	7	4	5	12	Lost for FU
19	3	C5–C7	M	CRPS	10	5	5	20	Yes
20	6	C3–C4	M	CRPS	10	4	4	12	Yes

The patient's numbers are presented in chronological order. Th: Thoracic, C: Cervical, FBSS: Failed back surgery syndrome, CRPS: Complex regional pain syndrome, FU: Follow-up, VAS: Visual Analog Scale

their pain severity as corresponding to a VAS score of 9, four reported a VAS score of 8, and 4 had a VAS score of 7. The mean pain intensity at baseline was 8.9 (range: 7–10). At short-term follow-up (3 months), the mean pain intensity was 3, 7 (range: 2–5). At the final follow-up, the mean VAS score was 4.4 (range: 2–5). The mean preoperative (ACE-III) cognitive function scores were 86.77 (range: 87–98), at 3 months 91.3 (range: 67–98), and at the last available follow-up 90 (range: 80–100).

DISCUSSION

There is no universal therapeutic procedure for patients suffering from neuropathic pain.[12] The role of SCS in neuropathic pain management remains controversial, and it is most often considered a last-resort treatment.[24] Nowadays, the rate of neurological deficits associated with SCS treatment is low, although hardware-related complications, as well as biological complications, including skin erosions and infections, pose a significant concern in the neuromodulation procedures for pain management.[36]

In our study, 8 (40%) patients developed postoperative biological or hardware-related complications. The total incidence of SCS complications in our study is relatively high when compared to data found in the literature.[18,38,40] For example, lead migration reported by Cameron in a 20-year literature review of SCS therapy in 2,753 patients found 361 SCS lead migrations.[5] The incidence of this complication is relatively high, affecting nearly 13.2% of implanted leads.[36] This means that every 10th-implanted SCS lead will migrate from its original location in the epidural space. In our cohort, this complication occurred in 1 patient (5%) in which we noticed craniocaudal lead migration. Most reviews or clinical studies do not differentiate between craniocaudal (vertical) and horizontal (lateral) lead migration.[11] Fewer lead migrations may be concerned with the paddle-style SCS leads used, which was the only type implanted in our study. Lead migration and positional effects are commonly observed with percutaneous cylindrical leads.[36] Paddle SCS leads used in our center provide more consistent coverage of the painful areas with paresthesia and optimize stimulation efficiency.[29] We considered their use as a more suitable option compared to transcutaneous leads. Paddle SCS leads are also considered more effective by other investigators[2,14,36,43], and their use is identified with lead migration prevention.[3] On the other hand, percutaneous leads have their advantages, with the electrode implantation procedure being less invasive, faster, more comfortable, and associated with a lower rate of complications necessitating surgical revision.[16,27,28,41,42] Mekhail *et al.*,[27] found that among 527 total cases, there were 119 (22.6%) cases of migrated SCS leads. The number of revision surgeries required to continue SCS therapy was

Table 2: Represents patients provided in chronological order troubled by different hardware-related complications.

Patient number	Sex	Cause of SCS implantation	Electrode level	Types of complications	Number of complications	Types of surgical revisions	Number of revision surgeries	The outcome of SCS therapy
3	F	FBSS	Th10/11	Skin erosion over IPG Skin erosion over IPG	2	Wound debridement Removal of SCS system	2	No further SCS treatment
4	F	CRPS	Th10/11	Migration of the epidural electrode	1	Placement of a new SCS electrode	1	Continuation of SCS therapy
5	F	FBSS	Th10/11	Skin erosion over IPG Skin erosion over IPG	2	Wound debridement with implantation of a new IPG Wound debridement with removal of an IPG Implantation of a new IPG	3	Continuation of SCS therapy
6	M	CRPS	Th11/12	IPG migration Skin erosion over IPG	2	IPG revision and relocation SCS system removal	2	No further SCS treatment
11	M	FBSS	Th10/11	Skin erosion over IPG Skin erosion over IPG	2	IPG removal Electrode removal Implantation of a new SCS system	3	Continuation of SCS therapy
15	F	FBSS	Th10/11	Rapid depletion of IPG	1	IPG reimplantation for rechargeable device	1	Continuation of SCS therapy
17	M	FBSS	Th11/12	Skin erosion over IPG IPG site infection Electrode infection	3	Wound debridement Removal of IPG Electrode removal	3	No further SCS treatment
18	M	FBSS	Th7/8	Rapid depletion of IPG	1	IPG reimplantation for rechargeable device	1	Continuation of SCS therapy

The information on different complications with the number of revision surgeries is provided in individual patients with information about further SCS treatment. Th: Thoracic, FBSS: Failed back surgery syndrome, CRPS: Complex regional pain syndrome, IPG: Implantable pulse generator, SCS: Spinal cord stimulation

not reported.[27] Lead migration is also more frequent in the cervical spine compared to incidents in the thoracic segment or thoracolumbar regions because of its high mobility.[3,30] In a study of 410 patients operated over 22 years, lead migrations were found in 88 patients (21.4%) of which 40 were repositioned and 48 were replaced.[19] The incidence of lead migration in this large study was twice as high in the cervical region compared with the lower dorsal region.[19]

IPG may also become displaced. Bench testing data showed that there seems to be a correlation between the site of IPG implantation and the frequency of displacements.[3] The implantation of the IPG in the gluteal region appears to contribute to a greater incidence of migration compared with its placement in the abdominal wall.[7,33]

A well-established solution to prevent migration is appropriate anchoring. Several titanium and plastic anchoring systems have been introduced.[25] McGreevy *et al.*[25] additionally postulated that a Figure 8 loop might be used. However, this configuration can produce lead compromise when only one of the loops absorbs the displacement.[25] Researchers emphasize that the placement of more than one suture may decrease the likelihood of IPG migration.

Another postoperative hardware-related complication is the incorrect functioning of the IPG. This failure was observed in 10% of cases in our study, which is a relatively high malfunction rate of implanted SCS for different pain conditions. Taylor *et al.*[37] noticed an even higher device complication rate, reaching 43% of implanted SCS systems. Cameron[5] reported a hardware malfunction in 2.9% of studied patients. These differences arose due to various inclusion criteria. Some minor issues concerned with the IPG are often not qualified as hardware-related complications.[21]

The incidence of electrode fracture, which did not occur in any of our patients, occurred in 3–9% of cases assessed in the

literature.[1,5,21] The most frequent site of the fracture is the point of anchoring.[5] Electrode fracture is also more often concerned with percutaneously implanted leads.[15,21] This may explain the lack of such complications in our material. Implanting IPG in the abdominal wall instead of the gluteal region can also reduce the risk of electrode fracture.[15,21] Electrode fracture almost always results in a loss of pain relief because of SCS dysfunction, so it is rather easy to recognize.[3]

Biological complications are less frequent than hardware-related problems. Among them, the infection rate is estimated to account for 4–10% of cases.[18,20,27] This represents the costliest complication.[2,3] Fortunately, only 1 patient (4%) developed a *S. aureus* wound infection in our study. Kumar *et al.* postulated that this pathogen is the most frequent.[21] However, this complication is reversible after successful antibiotic treatment, SCS reimplantation, and continued stimulation. Infection appears relatively early, especially in patients who seem to be at an increased risk of infection, for example, those with diabetes, smokers, and those who are obese or immunocompromised.[2,3,8] In our sample, 1 obese patient was diagnosed with type II diabetes mellitus; fortunately, there were no complications in this patient.

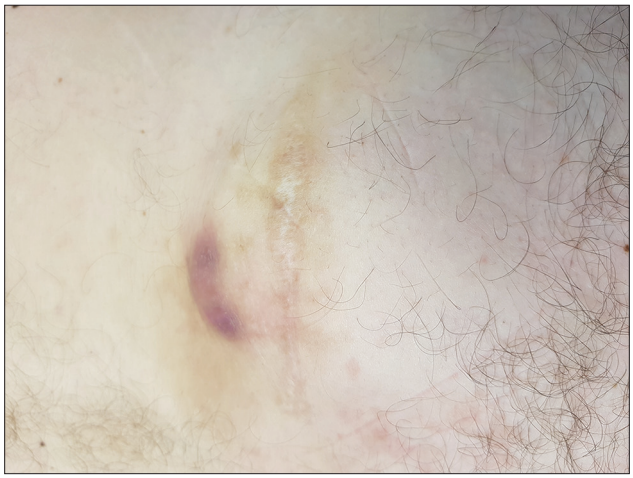

Figure 2: Skin erosion.

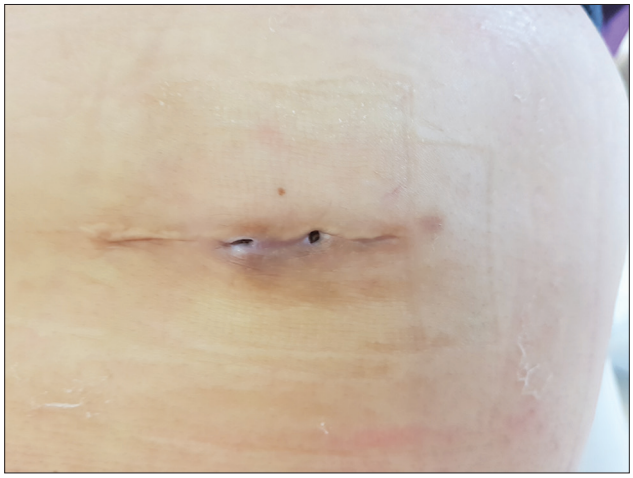

Figure 3: Wound dehiscence.

Postoperative complications, such as intraspinal or epidural hematomas, cerebrospinal fluid leakage, and neurological deficits, are uncommon, and they can be avoided using approaches known to improve intra-procedural safety.[21,22] Modifications to existing operative techniques, for example, minimally invasive paddle lead placement or dorsal root ganglion stimulation, may lower the complication rate and improve overall treatment results.[36,43] Moreover, Blackburn *et al.*[4] reported a lower risk of infection when using percutaneous leads.

In our analysis, 5 patients (25%) developed skin erosions located above the IPG in the buttock area. These complications may have resulted due to the dimensions of the implanted high-profile IPG. There are no studies that correlate the dimensions of the implanted SCS hardware (IPG) to erosions and subsequent infection rates. High-profile IPG without the curvature of the housing may lead to skin erosions. When implanting these relatively large IPGs in the buttock area, the deeper placement of IPG may prevent its mobilization and subsequent development of skin erosions due to its displacement. The implanted Prime Advanced Sure Scan™ nonrechargeable IPG (Medtronic Inc. Minneapolis, MN, USA) had the following dimensions: 15 × 65 × 49 mm regarding thickness, height, and width. The dimensions were larger than the same nonrechargeable IPG from Boston Scientific and St Abbott implanted at that time. The relevant dimensions of Boston Scientific IPG were 11 × 72 × 49 mm and St Jude 9 × 48 × 53 mm, respectively. The dimensions of different IPG from various SCS companies are provided in Table 3. The large dimensions of the IPG implanted in our series can be related to higher erosions and infection rates, as reported in other studies.[3,5,27]

Smaller SCS devices with curved IPG shapes may greatly reduce the incidence of such complications. Verrills *et al.*[41] reported a 7% incidence of hardware erosions. On the other hand, Chaudhry *et al.*[6] hypothesize that only an

Table 3: Size comparison of different types of IPG.

Manufacturer	Device	Size (thickness×height×width) mm
Boston Scientific	Alpha Prime 16	11×72×49
Medtronic	Intellis	6×57×47
	Prime advanced	15×65×49
Abbott/St. Jude	Eon Mini	9×50×57
	Prodigy MRI	9×48×53
Nevro	Senza II	10×56×46

IPG: Implantable pulse generator, MRI: Magnetic resonance imaging

inflammatory response to the SCS components can play a role in their formation. Furthermore, Woźniak-Dąbrowska *et al*.[44] highlight skin allergic reactions as a possible cause of atypical skin erosions in the SCS device area.

The ongoing miniaturization may show the impact of larger device dimensions on the number of postoperative complications.[33,34]

Neurological injury is by far the most dreaded complication of SCS.[22,30] These injuries can result from direct trauma caused by needle puncture, percutaneous lead placement, or during surgery while placing paddle leads.[9] Epidural hematoma formation following the placement of SCS leads can also be a cause of the postoperative neurological deficit. Early recognition and treatment allow functional recovery in most cases.[23] None of our patients experienced this type of complication. Although such a complication is rare,[5] it should always be borne in mind that it may occur.

Our study has several limitations. First, it was a retrospective, single-center study. Second, we used only surgically placed SCS paddle-type electrodes, which tend to be better anchored than subcutaneously placed cylindrical electrodes.[10,11] Third, our group study is relatively small, which did not allow us to draw far-reaching conclusions. Further research is needed to minimize the risk of hardware and biological complications after SCS implantations.

CONCLUSION

Our results indicate that patients treated using SCS are at higher risk for the development of biological and hardware-related complications, especially skin erosions and relative infections, notably in cases when large (high-profile) IPG is utilized. The use of smaller IPG could reduce the number of these types of complications and, hence, revision surgeries.

Ethical approval

Institutional Review Board approval is not required due to the retrospective analysis of the presented clinical data.

Declaration of patient consent

Patient's consent is not required as patients identity is not disclosed or compromised.

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Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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