RESEARCH PAPER

Neurologia i Neurochirurgia Polska
Polish Journal of Neurology and Neurosurgery
2022, Volume 56, no. 4, pages: 371–378
DOI: 10.5603/PJNNS.a2022.0038

ISSN: 0028-3843, e-ISSN: 1897-4260

Spinal cord stimulation for treatment of complex regional pain syndrome: a single-centre retrospective case series study

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ABSTRACT

Introduction. Complex regional pain syndrome (CRPS) is a debilitating disease with limited available treatment options. Spinal cord stimulation (SCS) is a universal option that promises to improve quality of life by reducing intractable neuropathic pain. The aim of this study was to describe the effectiveness and safety of SCS as a treatment for CRPS patients.

Clinical rationale for the study. SCS as an invasive method has relatively recently been introduced to CRPS therapy. We hypothesised that by assessing the effectiveness and safety of SCS, we could justify its early use in the treatment of this debilitating condition.

Material and methods. CRPS is a multifactorial and disabling disorder with complex aetiopathogenesis. The primary goals of CRPS treatment include pain relief, functional restoration, and psychological stabilisation. Early intervention is needed to achieve these objectives. In this study, we performed a retrospective evaluation of clinical outcomes in seven patients with severe, intractable CRPS treated by SCS. All patients underwent implantation of a non-rechargeable prime advanced MRI implantable pulse generator (IPG) (Medtronic, Minneapolis, MN, USA) between December 2017 and December 2020 using identical surgical and intraprocedural techniques.

Results. From a total of 21 patients treated with SCS over the three years in question, seven (33%) were diagnosed with severe CRPS. The duration of chronic pain ranged between two and 12 years. In six cases (86%), an electrode was implanted in the thoracic segment. Good (partial pain reduction) or very good (complete pain relief) treatment results were observed in five patients (72%). In two cases (28%), two revision surgeries were performed for wound debridement. These hardware-related complications were primarily related to erosions located over implanted IPG's.

Conclusions and clinical implications. SCS is the best alternative for patients with CRPS. It should be used immediately after the failure of conservative treatment. Despite the relatively high complication rate in our series, it is the best choice for pain reduction management in this select group of patients.

Key words: complex regional pain syndrome, spinal cord stimulation, visual analogue scale, neuromodulation, intractable pain, health-related quality of life

(*Neurol Neurochir Pol 2022; 56 (4): 371–378*)

Introduction

Complex regional pain syndrome (CRPS) is a rare neuropathic disorder divided into two subcategories: CRPS I, known previously as algodystrophy, and CRPS II, formerly known as causalgia. In CRPS II, a direct nerve injury must be confirmed [1]. The diagnostic Budapest criteria for CRPS [2–4] indicate that both subtypes share similar symptoms, including constant pain, sensory, vasomotor, sudomotor, motor, and trophic changes. Females are affected more frequently than males [5]. The incidence rate of CRPS is 26 per 100,000 people. There is no definitive cure for CRPS, and symptomatic management remains the cornerstone of treatment. Non-invasive treatments are most often used during the initial stages of the disease. There are many conventional strategies used for pain control, including nonsteroidal anti-inflammatory drugs, opioids, and anticonvulsants. Antidepressants, ketamine, bisphosphonates, and thalidomide have also been used [6–8]. None of these

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Received: 28.11.2021 Accepted: 04.04.2022 Early publication date: 20.06.2022

drugs has been accepted as standard care for CRPS, although short-term improvement in symptoms is noticeable. Longer lasting and more pronounced pain relief can be achieved using intra-thecal administration of morphine, baclofen, clonidine, or ziconotide, although this approach is associated with greater side effects [9–11]. Ketamine creams and infusions bring some relief for CRPS patients, but their use is limited by their short period of action [12, 13].

The basis for spinal cord stimulation (SCS) has its origin in the gate control theory of pain proposed in 1965 by Melzack and Wall [14]. It was applied as a reversible and long-term therapy for 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 [15, 16]. By stimulating large A-beta fibres, activation of inhibitory interneurons is achieved, which competitively inhibits the transmission of impulses from small A-delta and C-fibres [14–16]. Novel methods of SCS, including burst stimulation or high-frequency stimulation [15], which do not induce paresthesia, make the procedure more comfortable for the patient.

Material and methods

We performed a retrospective evaluation of clinical outcomes in seven consecutive patients with severe, intractable CRPS treated SCS. All patients underwent implantation of a non-rechargeable PrimeAdvanced™ SureScan™ MRI neurostimulator (Medtronic Inc. Minneapolis, MN, USA) between December 2017 and December 2020.

The institutional approval of our Institute's Ethics Committee was waived due to the retrospective analysis of the presented clinical data. All patients were informed about possible complications related to SCS surgery and provided 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 specialised pain centre.

Only 16-electrode Specify™ SureScan™ MRI surgical paddle-style SCS leads (Medtronic Inc. Minneapolis, MN, USA) were used. Implantations were performed by the same surgeon 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 anaesthesia with fluoroscopic guidance for final SCS lead placement in the epidural space. Opening of the spinal canal was achieved by removing the supraspinous, interspinal, and flavum ligaments. Vertebral laminae were not removed. This surgical manoeuvre allowed for a significant reduction in venous bleeding from spinal bone structures.

On the first day following surgery, a stimulation screening was performed to cover the painful area with an acceptable level of SCS-induced paresthesia. During test screening, the SCS electrodes were connected to the external stimulator provided by Medtronic. Patients were usually discharged on the second postoperative day. Over the course of the next two weeks, if the patients showed significant benefit, i.e. at least 50% pain reduction assessed using the visual analogue scale (VAS), we proceeded with implantation of the Prime Advanced Sure Scan™ non-rechargeable IPG (Medtronic). Implantation was performed under local anaesthesia and with intravenous sedation. 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 pre- and postoperative VAS scores. In addition to short-term follow-up, VAS scores were examined over a long-term follow-up period.

This study included seven consecutively enrolled CRPS patients treated with SCS over three years. The sample comprised four females and three males with refractory CRPS resistant to nonsteroidal anti-inflammatory drugs, selective cyclooxygenase inhibitors, opioids, and psychological therapy. The mean age at initial diagnosis was 37 years (range = 25–45), and the mean duration of disease before SCS treatment was five years (range = 2–12). CRPS type I was diagnosed in five patients (71%), and CRPS type II in two (29%). In six patients (86%), the electrode was placed in the thoracic segment. The most common level of upper electrode tip implantation was Th11/Th12 (71%), while in the remaining two patients the placement of the upper electrode tip was at cervical level C5/C6 and thoracic Th10/Th11. The mean assessment period for long-term follow-up was 33.3 months (range = 24–38). Detailed patients' clinical characteristics before SCS implantation are set out in Table 1.

Descriptive statistics were applied to all measures, and numerical data was expressed as mean and interquartile ranges. Due to the relatively small sample size, we did not examine the linear correlations between preoperative variables (i.e. sex, age at surgery, diabetes, type of pain syndrome, pain distribution) and post-operative pain reduction (i.e. VAS scores at short- and long-term follow-up).

Results

All patients responded positively to the two-week SCS screening period, which led to subsequent IPG implantations in all seven cases. In six patients, the IPG was placed in the buttock area, while in the remaining patient, the IPG was placed in the abdominal wall.

At baseline, unbearable pain intensity (VAS = 10) was reported by four patients (57%); two patients rated their pain severity as corresponding to a VAS score of 9, and one as a VAS score of 8. The mean pain intensity at baseline was 9.4 (range = 8–10). One obese patient (BMI > 30 kg/m^2) was diagnosed with type II diabetes mellitus (DM II). At short-term follow-up

Table 1. Patients' clinical characteristics including location, triggering factor, and duration plus pharmacological medication of CRPS before SCS procedures

Patient number	Sex	Area of CRPS	Triggering or provoking factor	Years of CRPS duration	CRPS type	Types of previous pharmacological or interventional treatment	Pain-reliving medication just before SCS treatment	VAS score before SCS treatment
1.	M	Lower limb	Direct traumatic nerve injury	3 years	II	Multiple pharmacological blockades	No due to ineffectiveness	9
2.	K	Lower abdomen	Multiple operations of ovarian cysts	2 years	I	Subcutaneous neurolysis in integument of abdominal cavity. Multiple pharmacological blockades	Tramadol	10
3.	K	Lower limb	Right ankle sprain with bone structures trauma	3 years	I	Intravenous ketamine and midazolam infusions	Pregabalin, Dulsevia, Ketrel, Morphin	10
4.	M	Lower limb	Right ankle sprain	5 years	I	Pharmacological blockade. Intersection of peroneal nerve	No due to ineffectiveness	10
5.	K	Upper limb	Right forearm trauma	12 years	I	Sympathetic blockade, thermolesion, intravenous ketamine and lidocaine infusions	Oxydolor, Dulsevia, Ketrel	10
6.	K	Lower limb	Resection of neuroma involving peroneal nerve	3 years	II	Multiple pharmacological blockades	No due to ineffectiveness	8
7.	M	Lower limb	Left ankle sprain	5 years	I	Multiple pharmacological blockades	No due to ineffectiveness	9

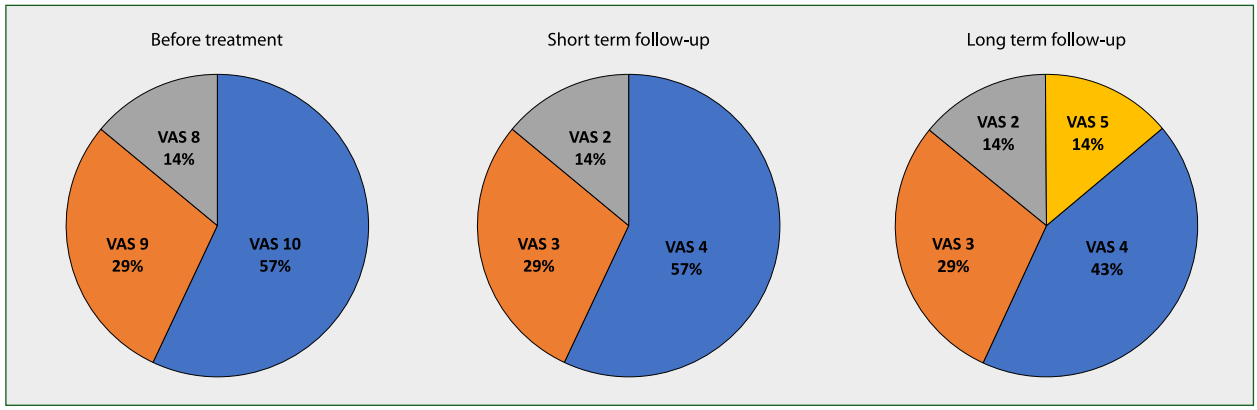

Figure 1. Mean preoperative VAS score before SCS treatment, at short-term (3 months) follow-up and at the long-term follow-up (33,3 months)

(3 months), the mean pain intensity was 3.4 (range: 2–4). A reduction in pain intensity from baseline was found in all cases, with patients achieving lower VAS scores of 4 (n = 4), 3 (n = 2), and 2 (n = 1).

At the last available follow-up, only one patient reported worsening pain intensity, corresponding to an increase in the VAS score from 4 to 5. For the remaining six patients, pain intensity over the long-term remained stable, with a mean VAS score of 3.6 at follow-up (range = 2–5). The VAS scores at baseline, three months, and long-term follow-up are illustrated in Figure 1. In three patients, the need for analgesics was reduced postoperatively. During the study period, two additional operative procedures for skin-related hardware complications (i.e. skin erosions over the IPGs implanted in the buttock area) were performed. In each case, the bacteriological examination was negative, and wound debridement was performed without complication. After a period of empiric antibiotic therapy, the wounds healed properly, and therefore, together with the patients, we decided not to remove the stimulators. An example of erosion is set out in Figure 2. Detailed information

on pain intensity (VAS scores) at baseline, short-term, and long-term follow-up, as well as possible adverse events, are set out in Table 2.

Discussion

There is no universal treatment for CRPS [17]. The role of SCS in its management remains controversial, and it is most often considered as a treatment of last resort [18]. The initial treatment of CRPS should be both interdisciplinary and individualised [18]. This treatment consists of specialised pain control using oral medications, including anticonvulsants, opioids, anti-inflammatory drugs, and tricyclic antidepressants, as well as physical, occupational, and psychotherapy. Pharmacotherapy is effective in reducing pain, but is associated with tolerance, addiction potential, and long-term side effects [17].

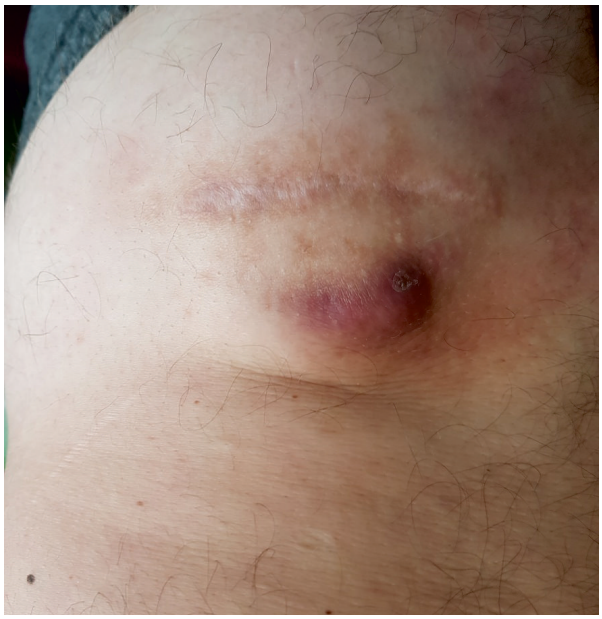

Figure 2. This figure shows an example of erosion. Interestingly, due to the relatively large size of the single-use implantable Prime Advanced MRI Pulse Generator (IPG), erosion appeared above the skin incision due to the upward movement of the IPG from the right buttock area

SCS has emerged as a safe and effective treatment for CRPS, being associated with pain reduction, improved quality of life, and improved neurological function [19]. The rate of neurological deficits associated with SCS treatment is low, although hardware-related complications including skin erosions and infections pose a significant concern in neuromodulation procedures for pain management. In the retrospective analysis, two patients indeed presented with skin erosions located over the IPGs in the buttock area. In both cases, early detection and subsequent wound debridement were successful [20–24]. We suggest that these erosions were related to the relatively greater dimensions of the implanted Prime Advanced Sure Scan™ non-rechargeable neurostimulators. Smaller SCS devices with curved IPG shapes may greatly reduce the incidence of such complications. Other consideration in SCS treatment were hardware-related complications, such as malfunction of IPGs or dislocation of SCS electrodes. These complications can be managed by repeated surgeries. In our sample, we however did not observe such complications over long-term follow-up.

The mechanism whereby pain control in CRPS patients is managed lies in the induction of paresthesia and suppression of pain sensation in the affected limb, which reduces the need for analgesic drugs. This underlines the proposed cost-effectiveness of SCS compared to pharmacotherapy [25–27]. Since the costs of conventional medical management are cumulative in the long run, treatment with SCS should ideally not be postponed [26, 27].

Early initiation of SCS treatment in CRPS can also be considered justifiable since it improves health-related quality of life (HRQoL) [15, 19, 28–30]. Its value in the management of CRPS is superior to that achieved via failed-back surgery

Table 2. VAS scores of individual patients at short-term (3 months) follow-up, and long-term follow-up with adverse events related to implanted SCS hardware

Patient number	Age at surgery	VAS score before SCS treatment	VAS score 3 months after SCS	VAS score at long--follow-up	Pain-relieving medication at final follow-up	Follow-up in months	Adverse events related to SCS
1.	37	9	4	4	None	24	Skin erosion in IPG area
2.	43	10	3	3	Paracetamolum, quit Tramadol	35	None
3.	29	10	4	5	Pregabalin, Dulsevia, quit opioids	34	None
4.	44	10	2	2	None	34	None
5.	25	10	4	4	Considerable reduction of Oxydolor dosesa	33	None
6.	38	8	3	3	None	38	none
7.	45	9	4	4	None	35	Skin erosion in IPG area

IPG – implantable pulse generator

Table 3. Studies reporting clinical outcomes of SCS treatment for CRPS in adult population in which VAS score was used as primary outcome measure of SCS efficacy

Authors of study and year of publication	Number of operated individuals	Male/ female ratio	Mean time in years of CRPS diagnosis to SCS treatment	Mean age at surgery	Mean VAS score at baseline	Mean VAS score at short-term follow-up	Mean VAS score at long-term follow-up	Mean follow-up in months
Forouzanfar et al. (2004) [55]	36	12/24	Not reported	40	7.6	3.6	5.2	24
Kemler et al. 2008 [57]	24	Not reported	6 months	Not reported	7.0	2.8	4.0	60
Sears et al. (2011) [29]	18	9/9	9.6	44	9.2	Not reported	4.7	52
Kumar et. al. (2011) [19]	25	12/13	1	51	8.4	4.8	5.6	88
Geurts et al. (2013) [56]	84	22/62	2.7	35	7.7	4	6	125
Harke et al. (2005) [58]	29	13/16	5.4	50	9.3	1.7	2.1	36
Present study	7	3/4	5	37	9.4	3.4	3.6	33

syndrome (FBSS) [29]. Because the VAS scale used in this study can be reflected in the HRQoL assessment [30], our observations appear congruent with this statement. Goff et al. [28] maintained that patients can be referred directly to SCS, as restoration of normal functioning and adequate pain control can facilitate rehabilitation. Poree et al. [15] and Taylor et al. [32] share this view, with Taylor et al. also emphasising that the best results may be obtained in younger patients with better psychological and functional statuses. Gopal et al. [33] also reported favourable post-operative outcomes at 12 months, insofar as 40% of CRPS patients no longer required any analgesic medications for pain relief. Goto et al. [34] reported an even greater degree of improvement when SCS was combined with intrathecal baclofen treatment, which may be particularly beneficial in refractory cases. This treatment approach also improved dystonic posture and reduced pain fluctuation. The results of treatment can also be optimised by adequately selecting the group of patients. A combination of psychological evaluation and screening is associated with an increase in long-term treatment success by up to 70%. However, Long et al. [35] reported that failure to incorporate psychological evaluation decreases this percentage to only 33%. In contrast, Van de Kelft and De La Porte [36] reported a high success rate (85%) in studies where adequate psychological screening was implemented. Taylor et al. [37] had similar observations. Despite the lack of neuropsychological examination in some of the cases in our study group, the results were satisfactory due to careful patient selection. Nevertheless, appropriate screening plays a crucial role in the exclusion of psychosocial factors exclusion, which can constitute contraindications to neuromodulation treatment [38–40].

Since lead migration and positional effects are commonly observed with percutaneous leads [29], we chose to use only paddle SCS leads in our sample, which provides more consistent coverage of the painful areas with paresthesia and optimises stimulation efficiency [41]. We considered their use a more suitable option than transcutaneous leads. Paddle SCS leads are also considered to be more effective [29, 42–44], and their use is known to prevent lead migration [15, 45]. 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 [46–48]. Despite Blackburn et al. [48] reporting a lower risk of infection when using percutaneous leads, this complication was not evident in our sample, where paddle SPS leads were used. Nevertheless, infection is the most significant complication in patients treated with SCS, the incidence of which can reach 10% [47]. In our sample, one obese patient was diagnosed with type II Diabetes Mellitus, which is a known risk factor for postoperative complications, including infection [47, 49]. However, no complications were evident in this patient. Postoperative complications such as intraspinal or epidural haematomas, cerebrospinal fluid leakage, and neurological deficits are uncommon and they can be avoided by using approaches known to improve intra-procedural safety [15, 50, 51]. Modification to existing operative techniques, e.g. minimally invasive paddle leads placement or dorsal root ganglion (DRG) stimulation, may further improve overall treatment results. DRG stimulation might be more precise and selective compared to SCS after three months (81.2 % *vs.* 55.7%) and a superior option for treating CRPS or causalgia of a lower limb. This still needs to be confirmed in prospective randomised studies [52–54]. Nevertheless, we found excellent outcomes in five CRPS patients with lower limb involvement treated with SCS.

Our study has several limitations. Firstly, this was a retrospective, single-centre study examining the safety and effectiveness of SCS in patients with severe CRPS. All patients included in the study experienced severe, excruciating pain that persisted after unsuccessful pharmacotherapy. Our sample was relatively small when compared to other studies that have examined the clinical outcomes of SCS treatment in CRPS patients [19, 25, 29, 55, 56], as summarised in Table 3. Another aspect is the lack of neuropsychological examination in some of the cases. Now we have included preoperative psychological evaluation in consecutive patients undergoing SCS therapy in our neurosurgical department. Psychological evaluation and neuropsychological support remain mandatory not only in preoperative evaluation but also play an important role in the postoperative care of patients treated for intractable CRPS [55–59]. In the future, we will also use a wider range of scales to evaluate the health-related quality of life, as the VAS scale alone may not be sufficient for an objective HRQoL assessment.

Our patient sample had significant improvements in VAS scores at the last available follow-up, which could be attributable to a shorter postoperative period compared to other studies [19, 25, 29, 55, 56]. Kempler et al. reported a significant pain-relieving effect during the first three years after device implantation, but this diminished over time [57].

Lastly we used only surgically placed SCS electrodes, which tend to be better anchored than subcutaneously placed ones [29, 55, 56].

Despite these limitations, our study confirms the high efficacy and safety of SCS treatment in patients suffering from severe CRPS. We found that the pain-relieving effect of SCS was sustained over a long-term follow-up, and only one patient experienced slight pain worsening beyond 12 months of treatment.

Our results are consistent with previous studies showing favourable clinical outcomes in CRPS patients treated with SCS, as summarised in Table 3.

Conclusions

Our study demonstrated that SCS treatment for CRPS is associated with favourable long-term outcomes. We believe that SCS can be implemented during the early stages of CRPS resistant to pharmacological treatment. In particular, careful selection of patients after multi-modal pain-relieving treatment and successful test stimulation is essential to ensure favourable outcomes in CRPS patients treated with SCS.

Conflict of interest: *None.*
Funding: *None.*

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