Clinical pain research

Frank Patrick Schwarm*, Marco Stein, Eberhard Uhl, Hagen Maxeiner and Malgorzata A. Kolodziej

Spinal cord stimulation for the treatment of complex regional pain syndrome leads to improvement of quality of life, reduction of pain and psychological distress: a retrospective case series with 24 months follow up

https://doi.org/10.1515/sjpain-2019-0081
Received June 5, 2019; revised September 16, 2019; accepted September 18, 2019; previously published online November 19, 2019

Abstract

Background and aims: Complex regional pain syndrome (CRPS) is a common pain condition which is characterized by pain, functional impairment, and trophic changes. Neurosurgical treatment is not widely offered. In this study the treatment with spinal cord stimulation (SCS) was evaluated over 24 months follow up.

Methods: A retrospective case analysis of six patients with severe CRPS was performed. Pain chronicity was recorded with the Mainz Pain Staging System (MPSS). Pain intensity (NRS), activity level and health-related quality of life (EQ-5D-5L), the actual mood state (ASTS), and treatment satisfaction (CSQ-8) were assessed. All patients received conventional pharmacological treatments including multimodal pain therapy through their local pain therapist or in specialized centers as well as physical therapy. A SCS electrode was implanted for trial stimulation. After successful trial a neurostimulator was implanted and connected to the electrode. Patients were retrospectively analyzed before implantation and 6, 12 and 24 months postoperatively. Statistical analysis was performed using Mann–Whitney *U* and Wilcoxon rank-sum test.

Results: Patients median age was 43 years ($IQR^{25–75}$ 37–43 years). The median MPSS Score was 3 of 3 indicating a high pain chronicity. Median NRS before implantation of the neurostimulator was 8.8 ($IQR^{25–75}$ 7.6–9.3). A reduction to 7.8 ($IQR^{25–75}$ 4.8–8.1; $p=0.14$) after 6 months, 6.5 ($IQR^{25–75}$ 3.8–8.1; $p=0.08$) after 1 year, and 6.8 ($IQR^{25–75}$ 3.8–8.5; $p=0.15$) after 2 years was achieved. Median EQ-5D-5L index value before treatment was 0.27 ($IQR^{25–75}$ 0.25–0.41) indicating a severely lowered quality of life. A significant improvement to 0.53 ($IQR^{25–75}$ 0.26–0.65; $p=0.03$) after 6 months, 0.58 ($IQR^{25–75}$ 0.26–0.84; $p=0.03$) after 1 year as well as after 2 years was seen. ASTS scale showed an increase of values for positive mood, and a reduction in values for sorrow, fatigue, anger and desperation during the whole follow up period. The treatment satisfaction in the whole cohort with a median CSQ-8 value of 29.5 of 32 was very high.

Conclusion: The results of this small case series showed a significant improvement of the EQ-5D-5L after implantation of a neurostimulator. NRS reduction was not significant but a clear tendency towards reduced values was observed. We therefore conclude that SCS is an alternative option to relieve chronic pain and psychological distress originating from CRPS if non-invasive managements of severe CRPS failed. The preoperative selection plays a crucial role for good results.

Implications: CRPS is difficult to treat. SCS is an alternative option to improve the quality of life and relieve chronic pain originating from severe CRPS if conservative treatment modalities fail. Further psychological distress is reduced in long-term follow up. SCS should be kept in mind for therapy refractory cases.

Keywords: complex regional pain syndrome; spinal cord stimulation; multimodal therapy; quality of life; psychological distress.

1 Introduction

Complex regional pain syndrome (CRPS) is a common pain condition which usually occurs after trauma or

***Corresponding author: Dr. med. Frank Patrick Schwarm,** MD, Department of Neurosurgery, Justus-Liebig-University Giessen, Klinikstrasse 33, Giessen 35392, Germany, Phone: +4964198552900, E-mail: fp.schwarm@gmail.com
Marco Stein, Eberhard Uhl and Malgorzata A. Kolodziej: Department of Neurosurgery, Justus-Liebig-University Giessen, Giessen, Germany
Hagen Maxeiner: Department of Anesthesiology, Intensive Care and Pain Therapy, Justus-Liebig-University Giessen, Giessen, Germany

operation on a limb [1]. It can develop from any minor or major trauma (e.g. surgery, burns, peripheral injuries, inflammation) [2]. Characteristic are sensory, vasomotor, sudomotor, and motor/trophic signs and symptoms which are extremely painful and reduce functionality [3–6]. The pain has a distal predominance without any specific nerve territory or dermatome distribution, is variable over time, and seems to be disproportionately in intensity or course to the initiating injury [3]. CRPS is divided into two subtypes: CRPS-I usually develops after a trauma or surgery on the upper or lower limb, without any nerve injury/damage. CRPS-II occurs after injury/damage to a peripheral nerve [7–12]. The permanent disability reduces not only the quality of life, but also affects the social activities and the family life of these patients [5, 13]. CRPS is not a psychological disorder, but psychiatric aspects are important to be recognized as they show a fundamental aspect in the multimodal therapy concept [3, 5, 13]. The diagnosis of CRPS is made clinically based on the updated Budapest Criteria [14]. The underlying pathophysiology is multifactorial and differs from typical neuropathic pain syndromes even if the pain is commonly described as burning and constant [3, 15]. Medical treatment consists of the use of a variety drugs (e.g. analgesics, anesthetics, anticonvulsants, antidepressants, oral muscle relaxants, corticosteroids, calcitonin, bisphosphonates and calcium channel blockers, intravenous immunoglobulin) [3, 16]. Medical treatment is very difficult as CRPS consists of peripheral and central mechanisms, which couldn't be covered all [3]. An altered sympathetic nervous system function, oxidative stress, central and peripheral sensitization, activation of inflammatory- and immune related pathways in additional systems and tissues are only a few examples for this multifactorial process [3, 17–19]. Treatment of CRPS consists of a pharmacotherapy, physical/occupational therapy, psychotherpay, functional restoration, as well as procedures such as sympathetic blocks and if needed sympathectomy [3]. Interventional treatments are often considered for patients with inadequate or partial response to any other therapy to facilitate the patient's functional improvement and pain control [3]. As CRPS is seen as a complex biopsychosocial condition, patients seem more emotionally distressed than non-CRPS pain patients. The prevalence for psychiatric disorders ranges between 24% and 46% [3, 20, 21]. Psychological support plays a crucial role in the multidisciplinary treatment concept for CRPS patients [3]. Emotional distress may have a greater impact on pain intensity with an elevated physiological stress responsiveness in CRPS than in other chronic pain syndromes [22]. Concerning spinal cord stimulation (SCS) as a treatment alternative several retro- and prospective analyses have shown a positive effect in controling pain in patients with CRPS reducing pain by inducing paresthesias and suppressing pain sensation in the affected limb [3, 4, 23]. Neurosurgical treatment is not widely offered in CRPS. In this study the treatment of patients with severe CRPS with SCS was evaluated over 24 months follow up concerning pain intensity (NRS), activity level and health-related quality of life (EQ-5D-5L), the actual mood state (ASTS), and treatment satisfaction (CSQ-8).

2 Methods

A retrospective case analysis of six patients with CRPS was performed. Medical records were analyzed from all CRPS patients treated with SCS at the Department of Neurosurgery between 2012 and 2017. The management protocol was approved by the institutional research ethics board (AZ 165/14). All patients (≥18 years of age) were affected by CRPS of different etiologies and different locations (see Table 1). All patients selected in the present study had received conventional pharmacological treatments including multimodal pain therapy (nonsteroidal anti-inflammatory drugs, co-analgetics, opioids und psychological therapy) through their local pain therapist or in specialized centers as well as physical therapy. SCS was done in two stages: First, the electrode was implanted under local anesthesia epidural and connected to a test

Table 1: Baseline data.

Patient (sex, age at diagnosis)	Indication	Site/region	Electrodes
Male, 43	CRPS hand	Left	8-Pole surgical lead
Female, 43	CRPS lower limb	Left distal	8-Pole surgical lead
Female, 37	CRPS upper limb	Right distal	8-Pole surgical lead
Female, 43	CRPS lower limb	Left distal	8-Pole surgical lead
Male, 36	CRPS hand	Right	8-Pole surgical lead
Female, 43	CRPS upper limb	Right	8-Pole surgical lead

neurostimulator (Restore Ultra® Sure Scan®, Medtronic®, Minneapolis, MN, USA). Intraoperative stimulation was used to verify that the electrode has been correctly placed on the right spinal level. If the patient had a benefit over a trial of several days (3–5), he received a fully implanted system under general anesthesia in a second session. The retrospectively planned evaluation included a detailed medical history, a physical examination, date of electrode- and neurostimulator implantation, type of implants, operative revisions, and various questionnaires. Pain chronicity was determined using the Mainz Pain Staging System (MPSS) [24]. The pain intensity was measured with pain scores on an 11 point (0–10) numeric pain rating scale (NRS) [25]. Activity level and generic health status were assessed using the EQ-5D-5L, the actual mood state with the ASTS questionnaire, a German modified version of the profile of mood states (POMS), and the general treatment satisfaction with the Client Satisfaction Questionnaire (CSQ-8) [26–31]. The EQ-5D-5L health index score was calculated first by mapping the EQ-5D-5L health profiles to the EQ-5D-3L profiles using an algorithm developed by van Hout et al. [32]. Afterwards the EQ-5D-3L value set of Germany was applied. Patients' data were obtained at baseline and 6-, 12- and 24-months postoperatively.

2.1 Statistical analysis

Statistical analysis was performed using Mann–Whitney *U* and Wilcoxon rank-sum test. Treatment success was defined as a long-term pain relief and improvement of quality of life maintained during follow-up period. The data are expressed as mean and interquartile range [25–75] or as percentage. All statistical evaluations were performed with MATLAB (MathWorks®, Natick, MA, USA) and SPSS statistics 24 (IBM corp, Armonk, NY, USA). Descriptive statistics were initially applied to all measures. To calculate the statistical significance of the differences in mean NRS the Mann–Whitney *U* test was used. For EQ-5D5L and ASTS the Wilcoxon rank-sum test was used. A two-sided p-value <0.05 was considered statistically significant.

3 Results

Patients' median age was 43 years ($IQR^{25–75}$ 37–43 years). Diagnoses and patient characteristics are given in Table 1. The median MPSS Score was 3 of 3 indicating high pain chronicity. Median NRS before implantation of the neurostimulator was 8.8 ($IQR^{25–75}$ 7.6–9.3). All patients had a successful trial and subsequent neurostimulator implantation for SCS. A reduction to 7.8 ($IQR^{25–75}$ 4.8–8.1) after 6 months ($p=0.14$), 6.5 ($IQR^{25–75}$ 3.8–8.1) after 1 year ($p=0.08$), and 6.8 ($IQR^{25–75}$ 3.8–8.5) after 2 years was achieved ($p=0.15$) (see Fig. 1). Median EQ-5D-5L index value before treatment was 0.27 ($IQR^{25–75}$ 0.25–0.41) indicating a severely lowered quality of life. A significant improvement to 0.53 ($IQR^{25–75}$ 0.26–0.65) after 6 months ($p=0.03$), 0.58 ($IQR^{25–75}$ 0.26–0.84) after 1 year ($p=0.03$) as well as after 2 years was seen ($p=0.03$) (see Fig. 2). ASTS scale showed an increase of values for positive mood and a reduction in values for sorrow, fatigue, anger, and desperation during the whole follow up period after implantation of the neurostimulator. In detail there was a significant increase of values for positive mood from baseline value 2.0

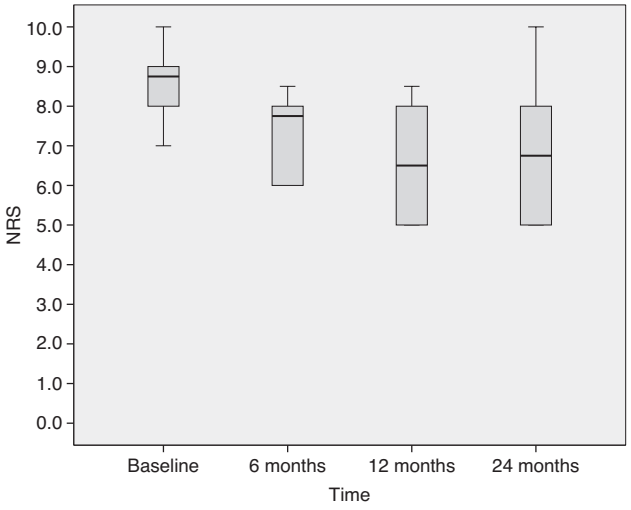

Fig. 1: NRS pain score: Box plots of NRS at baseline, 6-, 12- and 24-months postoperatively.

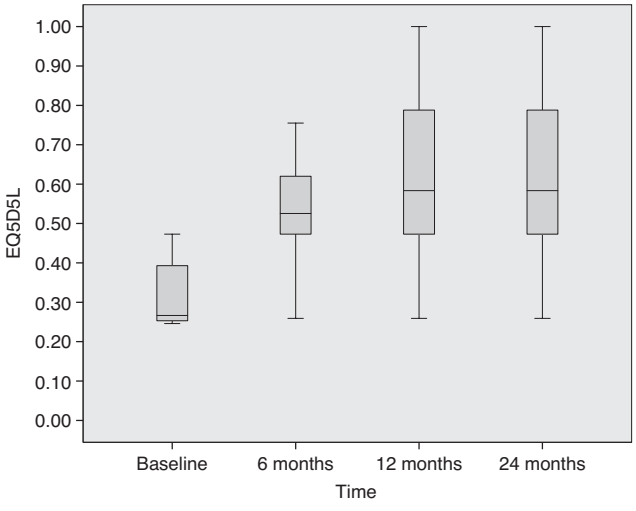

Fig. 2: EQ5D5L: Box plots of EQ5D5L at baseline, 6-, 12- and 24-months postoperatively.

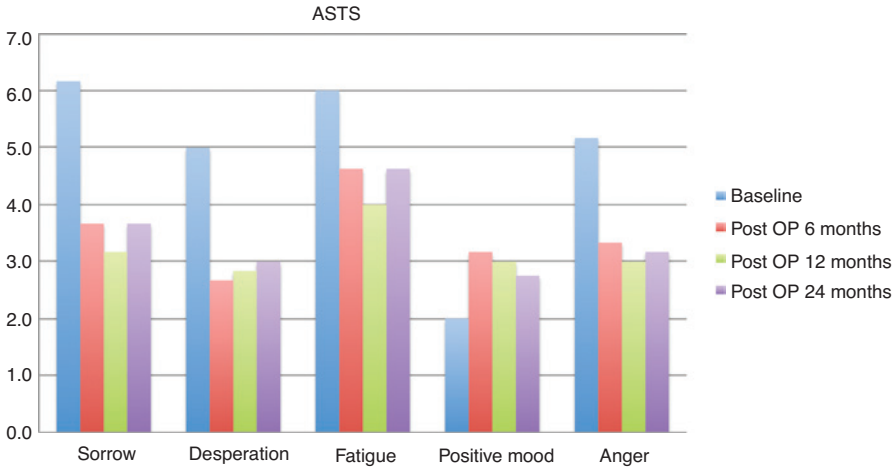

Fig. 3: ASTS mood scale at baseline, 6-, 12- and 24-months postoperatively. ASTS scale showed an increase of values for positive mood, and a reduction in values for sorrow, fatigue, and anger, in the whole follow up period after SCS implantation. The Scale ranges from 0 (not at all) to 7 (extremely).

(IQR$^{25–75}$ 1.65–2.55) to 3.15 (IQR$^{25–75}$ 2.58–4.35; $p=0.043$) after 6 months and 3.0 (IQR$^{25–75}$ 1.68–4.48 $p=0.173$) after 12 months follow up. The values after 24 months showed an improvement to 2.75 (IQR$^{25–75}$ 1.65–4.53; $p=0.225$). A reduction in values for sorrow from baseline 6.15 (IQR$^{25–75}$ 4.55–7.0) to 3.65 (IQR$^{25–75}$ 2.75–6.0; $p=0.068$) after 6 months, 3.15 (IQR$^{25–75}$ 1.98–6.0; $p=0.068$) after 12 months and 3.65 (IQR$^{25–75}$ 1.98–6.0; $p=0.068$) after 24 months was seen. Values for desperation were improved significantly from baseline 5.0 (IQR$^{25–75}$ 2.7–6.48) to 2.7 (IQR$^{25–75}$ 2.15–4.07; $p=0.043$) after 6 months. An improvement to 2.85 (IQR$^{25–75}$ 1.53–5.33; $p=0.249$) after 12 months and to 3.0 (IQR$^{25–75}$ 1.53–4.58; $p=0.249$) after 24 months was seen. Fatigue improved from baseline 6.0 (IQR$^{25–75}$ 4.73–7.0) to 4.65 (IQR$^{25–75}$ 2.98–5.5; $p=0.068$) after 6 and 4.0 (IQR$^{25–75}$ 1.87–6.25; $p=0.138$) after 12 months as well as to 4.65 (IQR$^{25–75}$ 1.87–5.63; $p=0.075$) after 24 months. The values for anger showed a significant improvement from 5.15 (IQR$^{25–75}$ 4.3–6.48) to 3.3 (IQR$^{25–75}$ 2.0–4.85; $p=0.043$) after 6 and 3.0 (IQR$^{25–75}$ 1.53–4.78; $p=0.046$) after 12 months as well as 3.15 (IQR$^{25–75}$ 1.75–4.78; $p=0.046$) after 24 months (see Fig. 3). The treatment satisfaction in the whole cohort with a median CSQ-8 value of 29.5 of 32 was very high and all patients would choose this neuromodulative treatment modality again. All patients regularly took analgesics. One patient took nonsteroidal anti-inflammatory drugs (NSAID) combined with opioids, one patient NSAIDs combined with gabapentin. Four patients took NSAIDs combined with strong opioids and pregabalin. Three patients were able to reduce their pain medication, three stayed at their previous level.

Complications after the surgical procedure developed in two patients. An infection of the implanted lead or neurostimulator occurred in one patient. One patient experienced repeated dislocations of a lead, which had to repositioned surgically.

4 Discussion

In the treatment of CRPS neuromodulation still has a controversial role and is mostly used as the last resort therapy for patients whose long-term treatment was ineffective [4, 13, 33]. Current initial treatment recommendations for CRPS must be chosen interdisciplinary and individualized. They consist of a multidisciplinary management concept, pain control with oral medications such as anticonvulsants, opioids, tricyclic antidepressants, physical and occupational therapy, and psychological support [3, 34]. Many drugs help to reduce the pain, but there is a lack of evidence of the effectiveness of most therapies. Moreover, even effective analgesic drugs may cause tolerance, addiction, and a certain number of undesired side effects [35]. In recent years SCS has proven to be an effective and safe method to treat this painful condition if non-invasive treatment modalities failed. Several retro- and prospective analyses have shown a positive effect in terms of pain reduction, increasement of quality of life, the consumption of analgesic drugs, and improvement of function [3]. Pain control in patients with CRPS is achieved by reducing pain through induction of paresthesia and suppression of the pain sensation in the affected limb [4]. In this retrospective study, six patients treated with SCS experienced pain relief after permanent neurostimulator implantation. The median NRS

before implantation of the neurostimulator was elevated. A reduction after 6 months, 1 year, and 2 years, respectively, was achieved. These results indicate a persistent effect in the whole follow up period in comparison with the baseline data. Kemmler et al. reported about a short-term pain relieving effect after device implantation. This effect was significant in the first 3 years after device implantation, diminished in the further follow up period [13]. Calvillo et al. achieved after 36 months follow up a 53% reduction of initial measured pain on the VAS [36]. Our results did not show any significance, but there was a clear tendency to a pain relieving effect. On the other hand EQ-5D-5L index before treatment indicated a severely lowered quality of life in our study group. A significant improvement over the whole follow up period was achieved. Kemmler et al. did not see a significant influence of quality of life scores by SCS [13]. On the other hand Visnjevac et al. evaluated the effects of SCS on patients with CRPS and supported its role as an effective treatment modality improving CRPS patients' perceived pain relief and quality of life [37].

Besides the significant increase of the generic health status on EQ-5D-5L and the reduction of NRS, an increase of values for positive mood, and a reduction of values for sorrow, fatigue, and anger in the whole follow up period after SCS implantation was seen on ASTS. Pain interference is often associated with a new onset of any mood disorder. The therapy and management of CRPS addresses also psychological evaluation as a depressive mood could be a significant barrier for treatment success [3]. Bean et al. reported, that anxiety, pain-related fear, and disability affect negatively course and severity of the disease and are associated with poorer outcomes in CRPS treatment [38]. Anger suppression or expression could be both associated with elevated chronic pain intensity and emotional distress with an elevated physiological stress responsiveness may have a greater impact on pain intensity in CRPS than in other chronic pain syndromes [22]. In this study all psychological improvements measured by ASTS were persistent during regular follow-up over 2 years in comparison to baseline data. Further a reduction in analgesic medication was seen in 50% of the patients. None of the patients was able to discontinue the complete pain medication. Neurostimulation techniques like SCS have been shown to contribute to the management of pain that is difficult to treat by conservative methods only. The treatment satisfaction in the whole cohort with a median CSQ-8 value of 29.5 of 32 was very high. All patient would choose this treatment again. These results are in accordance with the current literature as Kemmler et al. reported, that 90% of the patients after device implantation indicated a positive treatment response, and 95% would undergo the treatment again for the same result [13].

CRPS is a complex pain condition and difficult to treat. Treatment needs to be multidisciplinary, but neurosurgical treatment is not widely offered [3]. Despite good results with SCS, many patients do not achieve high-level pain relief [39]. Further the efficacy of SCS diminishes over time [13].

As the dorsal root ganglion (DRG) plays an important role in the development and maintenance of neuropathic pain syndromes. In the recent literature DRG-stimulation is described as more precise and selective [39–41]. Deer et al. showed a higher treatment success compared to standard SCS after 3 months (81.2% vs. 55.7%) [41], but there is still a lack of prospective randomized studies, even DRG-stimulation seems to be superior to SCS for CRPS and causalgia of the lower limb [40, 42]. Nevertheless, our study shows an improved quality of life, relieve of chronic pain and reduction of psychological distress originating from CRPS in long-term follow up.

Thus we still see SCS as a useful treatment option if non-invasive managements of severe CRPS failed.

There are several limitations of the present study. First of all there is the retrospective character of the study with the well-known shortcomings of this study design. Further the study population is very small and heterogeneous. However, our data consistently showed relevant pain relief, significant improvement of EQ-5D-5L, and ASTS with SCS during a follow-up of 24 months to restore function, adequate pain control, and stabilization of mood. A careful selection of patients after multimodal treatment and successful test stimulation is essential.

5 Conclusion

SCS proved to be a promising approach for the management of CRPS. Our retrospective study has shown the benefits of SCS with a significant improvement of the EQ-5D-5L after implantation of a neurostimulator for SCS. SCS is an alternative option to relieve chronic pain and psychological distress originating from CRPS if non-invasive treatment modalities failed. The preoperative selection plays a crucial role for good results. If SCS effects do slowly diminish over time, DRG stimulation seems to be a treatment alternative.

Authors' statements

Research funding: Authors state no funding involved.

Conflict of interest: After submission of the manuscript, F.P.S. enrolled in a training program of Medtronic®. Before and during submission there were no relations with industrial sponsors. M.K. receives honoraria for speaking at symposia. The other authors certify that they have

no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

Informed consent: Informed consent has been obtained from all individuals included in this study.

Ethical approval: Approved by the institutional research ethics board (AZ 165/14). The research related to human use complies with all the relevant national regulations, institutional policies and was performed in accordance with the tenets of the Helsinki Declaration, and has been approved by the authors' institutional review board or equivalent committee.

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