ORIGINAL ARTICLE

Spinal cord stimulation in chronic pain treatment – first experiences in Bosnia and Herzegovina

Tatjana Bućma[1,2], Ostoja Savić[3], Tatjana Boškić[1], Lena Arambašić Topić[1], Igor Sladojević[2], Snježana Novaković Bursać[1]

[1]Institute for Physical Medicine and Rehabilitation "Dr. Miroslav Zotović", [2] School of Medicine, University of Banja Luka, [3]University Clinical Center of Republic of Srpska; Banja Luka, Bosnia and Herzegovina

ABSTRACT

Aim To describe results of spinal cord stimulation technique when the conventional multidisciplinary treatment of neuropathic or mixed pain failed.

Methods The research was conducted at the Institute for Physical Medicine and Rehabilitation "Dr. Miroslav Zotović", Banjaluka. Ten patients, who had chronic pain resistant to other therapeutic options and a failed back surgery, were sent for an evaluation. Each patient underwent a 4-week evaluation by a team of medical specialists, phychologist and social workers. Additional diagnostic methods (MRI of the lumbosacral spine, electromyoneurography of lower extermities, congnitive assessment tests) were also performed to establish a proper indication for implantation of the system for spinal cord stimulation. Leads of a system for spinal cord stimulation were implanted percutaneously or surgically at the epidural space. Functional outcome measures (visual analogue scale, Oswestry index, anxiety and depression scales) were taken before the implantation of the system and on several followups.

Results Four patients did not meet critea for the inclusion in the study (two were not ready, two showed psychopathological symptoms). One patient had a percutaneous lead implant, but it was removed after six months due to paresthesia. The remaining five had surgicaly implanted epidural leads and showed significant improvement in pain control, Oswestry index had lower values, and all except one patient had improvement registered by anxiety and depression scales.

Conclusion. Short-term and long-term follow up showed a long lasting pain reduction and improvement of functionality in all patients.

Key words: electric stimulation therapy, failed back surgery syndrome, treatment outcome

Corresponding author:
Tatjana Bućma
Department of Physical Medicine and Rehabilitation "Dr Miroslav Zotović"
Slatinska 11, 78000 Banjaluka,
Bosnia and Herzegovina
Phone: +387 65 531 141;
E- mail: tatjana.bucma@gmail.com
ORCID ID: https://orcid.org/0000-0002-4388-4681

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INTRODUCTION

Spinal cord stimulation (SCS) is a neuromodulation technique that reduces pain by the use of electrical energy to stimulate the dorsal horns of the spinal cord. Perception of pain reduces the quality of life, which leads to anxiety and/or depression, highlighting a significant correlation between pain and the psychological status of the patient. It has been shown that SCS could reduce chronic pain and improve the quality of life (1). Brinzeu et al. showed that two years after the first SCS implantation close to 60% of the patients retained a significant pain reduction and 74% showed improvement in pain scores with significant decreases in drug and non-drug pain treatments (2).

Numerous studies propose Failed Back Surgery Syndrome (FBSS) as the first indication for SCS system implantation.The SCS was proved to be more efficient in the lumbar segment treatment than repeated surgery (1,2). A few years later, studies confirmed that the SCS was more superior to the conservative medical treatment for 6, 12, and 24 months in reduction of leg pain (>50%), improvement of the function and quality of life (3). A significantly larger number of patients with the SCS system and an optimal medical therapy have reduction of pain >50% in the lumbar region in the 6th month from the procedure, compared to patients who received only the medical therapy (4).

The SCS was introduced as a pioneer therapeutic option in Bosnia and Herzegovina in 2018. The aim of this study was to describe the results of SCS in chronic pain reduction and improvement of functional status and symptoms of anxiety and depression when the conventional multidisciplinary treatment of neuropathic or mixed pain failed.

PATIENTS AND METHODS

Patient and study design

Ten patients were referred to an evaluation for the system implantation by the neurosurgeons at the Institute for Physical Medicine and Rehabilitation “Dr. Miroslav Zotović”, Banjaluka (Institute), Bosnia and Herzegovina, in the period February 2018 - June 2021, and no indication was found for a repeated surgical treatment of patients. All patients had had results of magnetic resonance imaging (MRI) of lumbar spine and electromyoneurography (EMNG) of lower extremities beforehand.

Before the final evaluation, the patients spent four weeks at the outpatient hospital for the treatment of chronic pain in the Institute, where any previously undertaken method for the chronic pain treatment (medical or physical therapy, acupuncture, mesotherapy, psychosocial support) was carefully analyzed. If any of these methods had not been applied, and there was a possibility for its justified application, that treatment was applied as well. When a possibility for successful treatment by some other method was ruled out, a team consisting of specialists in neurosurgery, physical medicine and rehabilitation, psychiatry, anesthesiology and clinical pharmacy, together with a psychologist and a social worker conducted evaluation of the patient’s eligibility for the implantation of the system for SCS. Also, the listed contraindications for SCS implantation (inserted pacemaker or some other type of implantable cardiac defibrillator, serious diseases such as immunodeficiency or coagulation disorders, problems with addiction, the changed morphology of the spinal column) had to be taken into the account.

The neurosurgeon obtained insight into the morphological condition of the spinal column, as well as the functional condition of nerves of the lower extremities, while psychiatrist and psychologist carried out a series of tests, among which was the Montreal cognitive assessment/test for rapid cognitive assessment (MoCA test) that determined no diagnostically significant deficits of cognitive abilities (7).

Before the final decision was made, the patients were given detailed information about the implantation procedure, the method of handling the system, what to expect, and they were enabled to contact patients that had already had the system implanted.

The preparation of the patient for the procedure began only after all team members agreed that there was an indication for the implantation of the SCS system in chronic pain treatment.

All patients received patient information and signed an informed consent form that had been approved by the Ethics Committee of the Institute for Physical Medicine and Rehabilitation “Dr. Miroslav Zotović” (Approval number 116-15-12894-1/19).

Methods

There were two options for the selection of a proper lead for spinal cord stimulation. The implantation of percutaneous lead was carried out in local anesthesia, and the lead was implanted into the epidural space alongside the dorsal horns of the spinal cord controlled by C-arm X-ray and with the estimation of a level compared to the pain propagation. The battery with the pulse generator was left externally for four weeks when the system's efficacy was evaluated- whether the pain's intensity was reduced by at least 50% and if the quantity of analgesic medical therapy reduced significantly. The programming of the system was performed with smaller changes during this phase, when the patient was trained to handle the system (turning on and off, and increasing the intensity of the impulse). All the remaining parts of programming and patient follow-up in the following years were in the scope of the trained members of the team. After identifying good results of the implanted system in pain management, the second part of the procedure was the implantation of the permanent RestoreSensor SureScan MRI neurostimulator (Medtronic, Minneapolis, Minnesota, United States) in general anesthesia in the subcutaneous space of the anterolateral abdominal wall.

The procedure for the implementation of surgical leads was performed in general anesthesia, when the surgical leads were implanted into the epidural space under the control of the C-arm, and neurostimulator was implanted into the subcutaneous space of the anterolateral abdominal wall. The programming was performed four days after the surgical procedure.

To manage post-operative pain, the following scheme was used: a day before the surgery gabapentin 600 mg in the evening, also 600 mg on day zero in the evening, and then it was gradually weaned off. Morphine (3-5 mg) was also administered on day zero as a total daily dose. The next day, 1.25 g of metamizole sodium was administered every 6 hours intravenously to manage acute postoperative pain until pain was completely alleviated. Patients' acute pain was managed this way and the system was turned on the fourth day to program.

All the patients were preoperatively monitored (a period of eligibility evaluation for the implantation of the system) for pain intensity according to visual analogue scale (VAS) (8) and Oswestry Disability Index (9) for the functionality assessment. Values of VAS were recorded by a nurse, and the assessment of the Oswestry Disability Index by an occupational therapist.

The psychologist performed the testing with personality inventory scale Beck Anxiety Inventory (BAI) (10) and Beck Depression Inventory (BDI) (11), and interpreted the results as previously descibed (10,11).

The VAS, Oswestry Disability Index, BAI and BDI tests were again done on discharge (two weeks after the surgical procedure). On the last follow-up, the VAS value was redefined (based on the pain records, which were recorded by patients, and intensity average, when the system for SCS was on/off and for how long).

RESULTS

Initially, there were 10 patients with FBSS, but four of them did not meet the inclusion criteria. Two patients (one male and one female), after establishing the proper indication, withdrew from the procedure because they did not feel ready; two patients (two females) were excluded because of the presence of psychopathological symptoms in a degree that represents a contraindication for the procedure.

Six patients who were involved in the implantation process had different duration of complains, several number of surgical procedures, and a different level of implanted electrodes (Table 1).

All patients with surgically implanted leads participated in the follow-up, while one female patient with percutaneous leads was excluded from the monitoring because the system was removed after six months due to difficulty tolerating the paresthesia, despite numerous attempts to set new program parameters. All other patients had no intraoperative, postoperative, as well as any other long-term complications.

Most patients showed the same values of VAS in the follow-up after a half to two and a half years, just like in the follow-up after two weeks, except the patient in case III, who described comorbidity with changes in the spinal cord, which cannot be excluded as the cause of the mentioned pain, although those values are still in the range of good results. The patient in case IV also had a mild increase of pain intensity according to VAS, but

Table 1. Data on patients who had spinal cord stimulation (SCS) system implanted due to failed back surgery syndrome (FBSS)

Case	Age	Gender	Complaints	Former surgical procedures (year)	Month/ year of implantation	Level and method
I	74	F	Lumbar area pain spreading down the right leg since 2008	Interhemilaminectomia L5-S1 (2008); Interhemilaminectomia L4-L5 (2016); System extracted after six months	02/2018	P Th10/11
II	48	M	Lumbar area pain spreading down the legs, dominantly left, since 2011	hemilaminectomia L4-L5 (2012); spondylodesis and stabilisation L5/S1 (2013); foraminotomia L4, discectomia L4, spondylodesis L4/S1 (2013)	04/2018	H Th9/10
III	55	M	Lumbar spine pain spreading down the right leg since 2010	laminectomia L2-L3, disc extirpation (2010); reductio reg.conus medularis (2010).	09/2018	H Th11/12
IV	58	M	Left side lumbar pain, burning pain in the left thigh and upper third of the lower leg	partial endoscopic discectomia L3/L4 (2016); reoperation of the disc L3L4 (2016); discectomia L3L4, transpedicural stabilisation with fusion (2017)	09/2018	H Th9/10
V	45	M	Lumbar area pain, propagation to both legs, more to the left	hemilaminectomia L5-S1 and deliberation of left S1 radix (2018); hemilaminectomia L5-S1 and deliberation of right S1 radix (2018);	11/2019	H Th9/10
VI	54	F	Lumbar region pain, propagation to the left lower extremity	Three surgical procedures for herniated disci L5-S1with transpedicular stabilization (2003, 2004, and 2017).	12/2020	H Th9/10

M, male; F, female; P, percutaneous leads; H, surgical leads

still in the range of good results. These patients used analgesic medication therapy for other pain sources (case VI) or after larger physical activity (case II) or occasionally (opioid) along with the use of co-analgesic medications (gabapentin) (cases III and V) (Table 2). All patients stated that there were periods (during the day, night, or several days consecutively) when they turned the device off because the pain intensity was minor or completely absent.

Table 2. Values of the visual analog scale (VAS) preoperatively, two weeks after the surgery and on follow-up

Case	VAS		
	Preop.	Two weeks postop.	Last follow-up (June 2021)
I	9/10	5	N/A
II	9/10	5	4-6
III	8	0/1	4
IV	6	0	2
V	9	4/5	5
VI	8/9	4	0

preop., preoperatively; postop., postoperatively; N/A, not available;

Functionality, evaluated by the Oswestry Disability Index, showed improvement in all patients after two weeks (Table 3).

Table 3. Functional status of patients measured through Oswestry Disability Index

Case	Oswestry Disability Index		
	Preop.	Two weeks postop.	Last follow-up (June 2021)
I	74	36	N/A
II	84	46	23
III	64	15	28
IV	50	10	22
V	92	46	23
VI	52	42	21

preop., preoperatively; postop., postoperatively; N/A, not available;

All patients, except for the patient in case III (55-year-old male had an improvement on BAI and BDI scales, on both or one of them. The patient in the case III did not have the improvement of the condition compared to the preoperative period, along with mild anxiety without depression (Table 4).

Table 4. Anxiety and depression level according to Beck Anxiety Inventory (BAI) and Beck Depression Inventory (BDI) score

Case	BAI		BDI	
	Before implantation of the system	At the last follow-up (June 2021)	Before implantation of the system	At the last follow-up (June 2021)
I	moderate anxiety	N/A	moderate depression	N/A
II	moderate anxiety	moderate anxiety	moderate depression	bordering depression
III	moderate anxiety	moderate anxiety	no depression	no depression
IV	moderate anxiety	mild anxiety	no depression	no depression
V	no anxiety	mild anxiety	no depression	no depression
VI	severe anxiety	moderate anxiety	severe depression	moderate depression

N/A, not available;

DISCUSSION

This paper shows our first results after the implantation of the SCS system in the treatment of chronic pain. Patients with chronic pain do not get detected by the medical professionals nor understood by the environment. Even though SCS was used for several decades in chronic pain management, there is a lack of high-quality studies on the efficacy of SCS within the largest indication areas such as neuropathic pain and persisting pain after the FBSS (12). Taking into account the

recommendations for SCS system implantation (12), six out of ten of our patients with implanted system had FBSS with several spinal surgical procedures, where the time from the last surgical procedure to the system implantation was 1-8 years.

A workgroup of the European Pain Federation (13) established clear criteria for the SCS implantation. All other modalities of chronic pain treatment had to be exhausted and the patient had the cognitive ability to, after detailed explanation, understand the procedure, benefits, possible risks, and how to handle the system. Anatomically, the patient had at least partially preserved fibers of the dorsal columns of the spinal cord.

All of the specific clinical variables identified in previous studies (12) were included in this study. A broad evaluation must have three dimensions – biological, psychological, and social (14,15). Basic dimensions of the preoperative psychological evaluation are psychosocial risk factors, whether the patient understands the entire procedure, and evaluation of patient's expectations regarding the pain reduction (14).

Also, multiannual pain produces psychological changes that may give distorted perception of the patient's condition, which does not lead to a successful result after the implantation of the system (15). Four of our patients who had passed the evaluation and got into the framework of stated indications and criteria, did not obtain the approval for the system's implantation. The results of the psychological evaluation should not prevent the implantation of the system for SCS, but the psychologist and the doctor have to consult each other directly (14). According to our experience, the multidisciplinary approach has shown to be the key element of success.

In one of our patients, the system was extracted after six months due to paresthesia in the pain region, which she could not bear regardless of numerous attempts to set new program parameters. This could be caused by intolerance to the system, which was impossible to confirm preoperatively (16). Two weeks after the implantation of the SCS system other five patiens had a significant reduction of pain. All patients had a decrease in pain of over 50% two weeks after the implantation of the system and in some cases complete absence of pain. Billet et al. reported that the average pain levels 12 weeks after SCS implantation decreased 61% for back pain and 56% for leg pain with 100% reduction in opioid medication use (17).

The support of self-management training of chronic pain may increase the success in adaptation to the use of the SCS for pain treatment (14). Some patients are unsatisfied even when they experienced at least 50% of pain alleviation. Others expect relief of radicular and back pain, while some are unsatisfied by the system itself regardless of the achievement (16). One part of patients may misinterpret the paresthesia as a relief after pain, while others describe it as discomfort and inability to "bear" such sensations. Patients often "forget" pain they had before the implantation of the system and still report strong pain, but they have far bigger functional capacity compared to the pre-implantation conditions (16).

In a study bu Kumar et al. patients with FBSS and implanted system reported significant pain reduction in the lower extremity (but not in the lower back), improvement of functionality, and improvement of quality of life (5). The revision was necessary for 31% of patients, most of them in the first year after the system implantation. In our case, except for the first patient's request for the system extraction, no revision was required and there were no side effects after the system implantation.

Patients with FBSS, due to pain and longlasting search for a therapeutic option, usually have symptoms of anxiety and depression. After successful implantation of the SCS system, patients have a moderate increase in BAI and BDI scales (18). This was confirmed in our sample except in one case where there was no improvement after the SCS implantation, along with mild anxiety. It is difficult to estimate whether this condition was a result of expectations that did not realize and emerged concern for the future, or this condition caused aggravation of the condition in the last follow-up compared to two weeks after the surgery.

The main limitation of the study was a small sample. Funding of the SCS implantation is limited to five patients annually, and therefore we could not increase the sample size nor make randomization.

In conclusion, successful implementation of the SCS as a therapeutic modality for chronic pain after FBSS reduces pain, improves functionality, and reduces the symptoms of anxiety and depre-

ssion. A careful preoperative selection of patients, selection of the implantation technique and stimulation parameters reduce chronic pain in patients with FBSS. Multidisciplinary approach is a key element for a successful treatment outcome.

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