Ali je stimulacija hrbtenjače učinkovita metoda zdravljenja vztrajajoče bolečine v križu in nogi po operaciji? – Naše izkušnje z 21 primeri

Is the Spinal Cord Stimulation an effective treatment for Failed Back Surgery Syndrome? – Our experience with 21 cases

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Izvleček

Namen: *Obravnava bolnikov z vztrajajočo bolečino v križu in nogi po operaciji ledvenokrižne hrbtenice (FBSS) vključuje različne oblike protibolečinskega zdravljenja, vključno z zdravili, kirurškimi metodami in psihološkim zdravljenjem. Pregledali smo izhod pri bolnikih s FBSS, zdravljenih s stimulacijo hrbtnega mozga (SCS).*

Metode: *V retrospektivno študijo smo vključili 21 bolnikov (10 moških in 11 žensk, mediana starost 50 let) s FBSS, ki so bili v obdobju 5 let zdravljeni s SCS na Oddelku za nevrokirurgijo Univerzitetnega kliničnega centra Maribor. Obravnavali smo podatke o jakosti bolečine in spremembi le–te, o omejenih sposobnostih za vsakodnevne aktivnosti, o zaposlitvi, porabi analgetikov in pojavu zapletov.*

Rezultati: *Spremljanje bolnikov po*

Abstract

Purpose: *Management of failed back surgery syndrome (FBSS) is a costly challenge for practitioners of multidisciplinary pain management and for clinicians offering medical, surgical or behavioural therapy. We analyzed the outcome of FBSS treatment with the spinal cord stimulation (SCS).*

Methods: *A retrospective analysis involved 21 patients (10 men and 11 women, median age 50 years) suffering from FBSS. They were treated with the SCS over a 5–year period at the Department of Neurosurgery, University Clinical Centre Maribor. Their pain intensity, clinical alteration in pain relief, functional disability, employment status, analgesics consumption and complications were evaluated.*

SCS je trajalo od 2 do 62 mesecev, mediana vrednost je 24 mesecev. Ocena bolečine po vizualni lestvici (Visual Analogue Scale – VAS) pred SCS je bila med 7 in 10, mediana vrednost 8. Po SCS je bila ocena VAS med 3 in 6, mediana vrednost 4 ($p < 0.0001$). Po posegu se je zmanjšala poraba analgetikov. Vsi zaposleni bolniki so se vrnili na delo. Ocena funkcionalne prizadetosti na podlagi vprašalnika "Oswestry Disability Index (ODI)" je bila med 18 % in 78 % , povprečno 39 % (zmerna prizadetost).

Zaključek: *SCS je metoda izbora za zdravljenje bolnikov s kronično bolečino v nogi v sklopu FBSS, pri katerih ta bolečina vztraja kljub optimalni konzervativni protibolečinski oskrbi. Izboljša se kvaliteta življenja, zmanjša poraba analgetikov in bolniki se lahko vrnejo na delo.*

Result: *The median follow–up after the SCS was 24 months. According to Visual Analogue Scale (VAS) measurement, pain intensity before the SCS was scored between 7 and 10, median value 8. After the SCS, the VAS scores ranged between 3 and 6, median value 4 ($p<0.0001$). A reduction in postoperative drug consumption was evident. All employed patients returned to work. Results of functional disability measured according to Oswestry Disability Index (ODI) ranged from 18% to 78% with the mean value of 39% (moderate disability).*

Conclusion: *The SCS is a treatment of choice for patients with FBSS–associated chronic leg pain, where the pain persists in spite of the optimized conventional pain treatment. It improves the quality of life, reduces drug consumption and enables patients to return to work.*

INTRODUCTION

Medicine has been connected with the art of pain relieving from its earliest beginnings. In everyday pathology, pain still occupies a remarkable place; it has affected humans since their existence. Relieving the pain is therefore an art as old as humanity. To the present day, chronic pain with its complications still presents a frequent cause of morbidity and mortality. It exerts a major burden for the society and a correct and efficient pain management is thus essential (1). Much effort has been focused into pain management with emphasis on the new therapeutic approaches and the development of technologies for acute and chronic pain treatment. Failed back surgery syndrome (FBSS) presents a serious public health problem. Interventional and neurosurgical procedures intended to provide symptomatic relief of chronic pain may be appropriate for some patients. The classical pain treatment has involved ablative interventions, by nature destructive to normal neurological tissues. Among options for chronic pain syndrome treatments, neuromodulation is becoming one of the most often used modalities (1,2). This technique was first reported in 1948 and used initially for psychiatric disorders. It was subsequently developed for electrical stimulation of the nervous system as a pain relieving treatment option (3,4).

Spinal cord stimulation (SCS), practically introduced in 1967 by Shealy and colleagues, was the first clinical application of pain–relieving method that modulated by means of electrical stimulation the function of the nervous system reversibly (3). It initially involved intrathecal implantation of the electrodes through a laminotomy. Nowadays, new technological solutions with smaller implantable electrodes, long–life batteries and programmable electronics have substantially improved neurostimulation procedures of the spinal cord, with a possibility of a reversible, percutaneous electrode placement under local anaesthesia (2,4,5). Numerous theories have been suggested as a mechanism of action for the SCS (1). The first one was a so called Gate control theory, proposed by Melzack in 1965, who suggested that activity in large diameter primary afferents inhibits transmission of pain signals to the brain (4,6,7). Other possible explanations for the neurostimulatory effect include: a) release or activation of neuromodulators, such as gamma–amino butyric acid (GABA), which acts as an inhibitory transmitter in the dorsal columns; b) activation and inhibition of supraspinal mechanisms and c) blockade of signal transmissions in spinothalamic tract (1,5).

FBSS is a common clinical entity where spinal cord stimulation proved to be an effective form of treatment. The condition is defined as failure to improve pain satisfactorily after anatomically successful lower back sur-

gery. Patients suffer from persistent or recurrent back and/or lower extremity pain after spinal surgeries with the aim of pain relieving or correcting neurological or orthopaedic abnormalities (8). The failed–back surgery syndrome patients represent the greatest challenge for the physicians. Despite receiving a variety of therapies, including repetitive operations, oral medications, nerve blocks, corticosteroid injections, physical therapy, chiropractic care and behavioural therapy, lasting pain relief has failed. Before starting treatment in this group of patients, the reasons for prior failures must first be defined. Ten to 40% of patients who undergo spinal surgery will have postoperative complaints (9,10). These are difficult to solve because no specific cause can be identified. There are many reasons for these symptoms, including organic (biological or physiological) and/or psychological (including subtle or overt psychological or psychiatric dysfunction), as well as issues of secondary gain such as socioeconomic factors (11). FBSS is often complicated by depression, financial and personal stress, loss of employment or productivity and diminished self esteem (12).

The diagnostic and therapeutic management of FBSS lacks consistency between individual physicians or treatment centres, and no clear guidelines are established (13). It is important, regardless of whether the ultimate treatment is surgical or non-surgical, that goals of therapy be established before deciding the course of treatment. The outcome objectives should be realistic and the cause for the symptoms recognized. The management of symptoms that persist after lumbar disc surgery varies according to the intensity of the complaints and the temporal relationship to the original procedures. About 30% of patients with FBSS have a definable problem that may be corrected by reoperation (13,14). Many conditions can lead to or contribute to FBSS, including incorrect initial diagnosis, poor patient selection, incomplete decompression, decompression at the wrong level, recurrent disc herniation, segmental spinal instability, facet joint disease, permanent nerve root damage, epidural fibrosis, arachnoiditis (8,13). In approximately two thirds of patients with recurrent complaints, no improvable underlying mechanical cause could be found (14). Surgery is not indicated for patients with nonspecific chronic back pain.

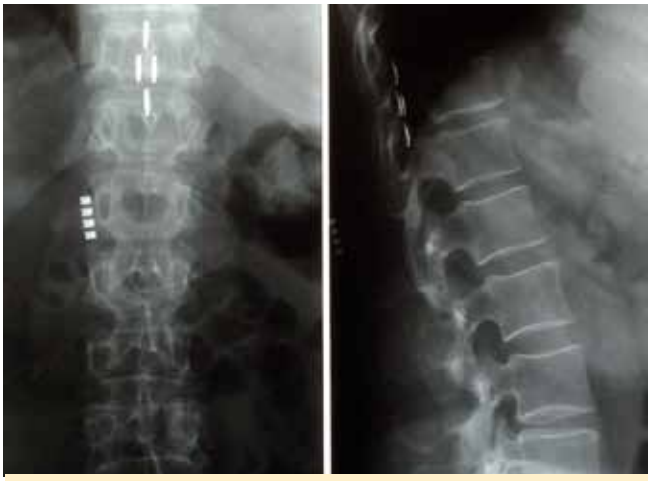

Figure 1. *X ray of the spine with quadripolar electrode in place.*

In this retrospective study, our experience with the first 21 patients suffering from leg pain and treated with the SCS at the University Clinical Centre Maribor between 2003 and 2008 are described. The purpose of this paper is to review demographical factors, pre–treatment evaluation, procedure of the SCS implantation, the rate of complications and patients' outcome.

MATERIAL AND METHODS

Twenty one patients with FBSS were included in the study. They were treated with the SCS at the Department of Neurosurgery and at the Pain Unit, University Clinical Centre Maribor over a 5–year period. Before the SCS treatment, all patients had conventional pharmacological and non–pharmacological management, which did either not alleviate their pain sufficiently or was connected with unbearable side effects. Patients were multidisciplinary evaluated by means of clinical, radiological, electrophysiological and psychological examinations (electromyography (EMG), magnetic resonance imaging (MRI), current perception threshold (CPT), transcutaneous electrical nerve stimulation (TENS)). Magnetic resonance imaging was performed in order to confirm the presence of varying degrees of epidural or perineural fibrosis or arachnoiditis, considered to be

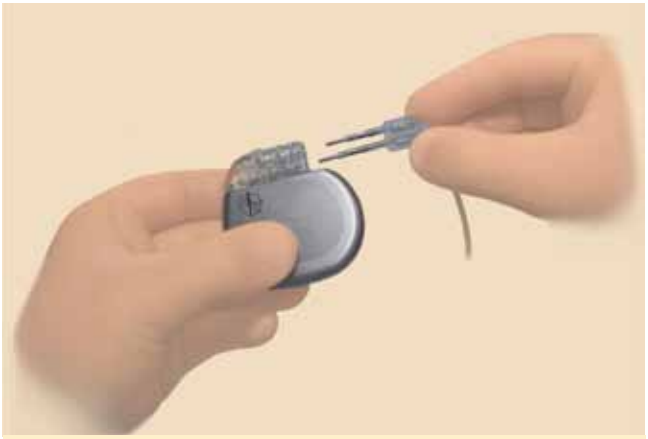

Figure 2a, b, c *Connection of the extensions wires to the pulse generator, which is implanted on the abdominal fascia and secured with sutures. (MEDTRONIC reprinted with permission)*

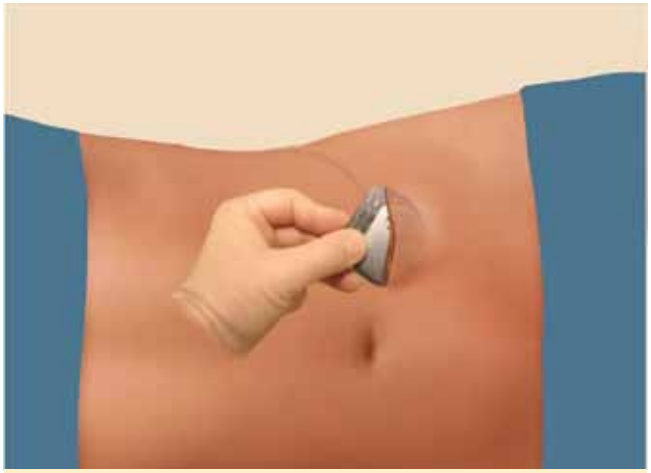

Figure 2b

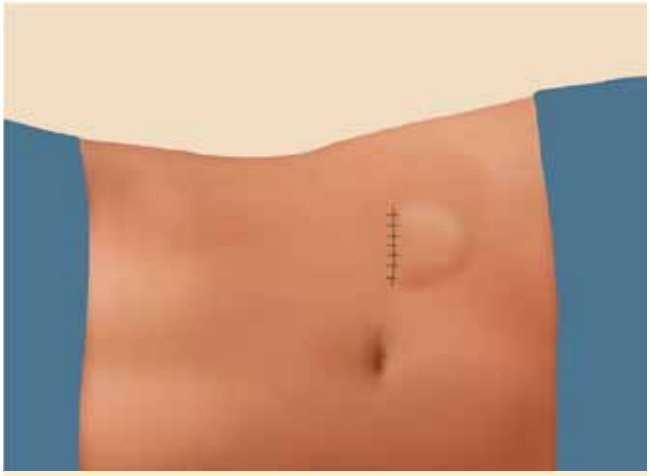

Figure 2c

responsible for their repetitive symptoms. For each patient, previous pain treatment and TENS responsiveness, chronic and neuropathic pain intensity and psychological conditions were evaluated.

The patients' data included sex, age, diagnosis, the number of previous spine operations, the Visual Analog Scale (VAS)–measured pain intensity, chronic pain duration, employment status and medication intake (particularly benzodiazepines and strong analgesics). The inclusion criteria for the SCS procedure were the following: radicular pain persisting after at least one previous spine surgery with intensity of 5 or more according to the VAS scoring (0 = no pain, 10 = the unbearable pain), neuropathic pain refractory to conservative treatment, pain duration of more than six months, pain localisation in an area with no major sensory deafferentation (large myelinated fibres largely intact), no complaints of chronic or recurrent pain above the level of Th 10 dermatome, leg pain with higher intensity than back pain and radiating below the knee, informed consent and suitable psychological evaluation. The general exclusion criteria for the SCS intervention were: evidence of an active disruptive psychiatric disorder, active drug or alcohol abuse, significant personality disorders affecting pain perception, patients younger than 18 years of age as well as patients who did not receive an adequate course of conventional pain treatment (15). The presence of any other clinically significant or disabling chronic pain condition was ground for exclusion. Once a patient has been selected as a candidate for the SCS, the medical team was certain that the patient and the close relative or caregiver have been thoroughly educated about the intended procedure, its potential risks and expected outcomes. On the basis of consistently preoperative patients' selection we abandon the test implant of temporary leads to simplify the SCS intervention and to avoid one procedure.

The procedure of electrode implantation for the SCS was fairly straightforward. All patients were operated by the senior author TS. The SynMix surgical lead with Itrel3 pulse generator (Medtronic, Inc.) was used. The level of electrode placement was chosen preoperatively on the basis of patient's pain distribution (usually Th 10 to Th 12 level). To implant the permanent lead we pre-

ferred small laminotomy instead of percutaneous lead implantation. The technique enables easier handling of lead wires with less probability to kink them. This method offers conspicuous lead insertion even in the presence of obstruction in the epidural space. In addition, it ensures increased lead stability. After laminotomy, electrode insertion in the epidural space followed. One quadripolar electrode (Fig. 1) was anchored to the overlying fascia and the implanted lead wire was tunnelling to the implantable pulse generator (IPG) pocket site. Then, a second incision to the anterior abdominal area was made and above the fascia, a pocket for the IPG was prepared. The extension wire was then connected to the implanted IPG (Fig. 2 a,b,c) (15, 16, 17). The programming of the SCS system was performed soon after the patient awakening from the general anaesthesia. Comfortable stimulation should cover at least 80% of the patient's painful area. Stimulation settings were followed regularly during the postoperative period in order to adjust the amplitude of the stimulation, the frequency and the pulse width. Additionally, education of patients started before the surgical implantation. They were instructed how to use the handheld programmer, to turn the stimulator on and off and to change certain stimulation parameters. At each follow–up examination, the VAS–measured pain intensity was assessed. This allowed patients to quantify their pain objectively both before and after the implantation of the SCS electrodes. The clinical change of pain relief was classified as a very good (50% or more), moderate (30% to 50%) or unchanged (minimal or no pain relief). Functional disability was measured with the Oswestry Disability Index (ODI) 2.0 (18).

For statistical analysis, Statistica for Windows 5.1 programme (StatSoft, Inc. 1996) was used. Variables used included the VAS–measured pain intensity, psychological condition, employment status, analgesics consumption, ODI results and the outcome of the SCS. Descriptive statistical methods and Student's *t* test were used.

RESULTS

From August 2003 to August 2008, twenty–one patients (10 men and 11 women) were included in the retrospective study. The median age of the patients was 50 years (range 33 to 75 years). Patient characteristics are presented in Table 1. All patients suffered from radicular pain, its duration varied from 2 to 16 years, with the median value of 4.0 years. The VAS–measured pain intensity was scored between 7 and 10, median value was 8. FBSS was the most common indication for the SCS in our hospital, with a total of 21 patients (Table 1). Another two patients (not included in the study) underwent SCS at our department – one for transversal lesion of the spinal cord and one for phantom pain. The patients underwent one, two or more previous spinal procedures, namely 7, 11 and 3 patients, respectively. Before implantation procedure, neither signs of epidural or perineural fibrosis nor arachnoiditis were confirmed during preoperative clinical evaluation and on MRI. It was therefore demonstrated that no surgically correctable lesions were present. Psychological screening revealed cognitive disturbances in 2 patients and personality disturbance in 1 patient. The most frequent finding was depression (6 patients), followed by neurosis in 4 patients. At the psychological examination, the remaining 8 patients achieved normal results.

Before implantation, medications for pain control were used regularly by all patients in our series, as presented in Figure 3. In our group, 11 patients were employed, but at the moment of the evaluation for the SCS implant they were on the sick leave (Table 2).

The SCS treatment was performed as described in Patients and methods section. Surgically related complications occurred in two patients; a haemorrhage under concomitant acetyl salicylic acid therapy, which required surgical revision and an infection that was successfully treated with antibiotics. During the five–year period with the SCS at our department, no device–related complications (such as migration of the electrodes) were found. However, one stimulation–induced complication with uncomfortable stimulation paresthesia and leg cramps was recorded in a patient with transversal lesion of the spinal cord (not included in this report). After readjustment of the stimulation parameters, side effects were reduced and a small relive of the segmental pain was achieved.

Table 1. *Patient demographics, anamnesis and outcome of the spinal cord stimulation (SCS).*

No.	Sex	Age (years)	Diagnosis	Duration of pain (years)	Previous surgeries (No.)	Outcome
1	F	48	FBSS	2	2	moderate
2	F	53	FBSS	5	1	very good
3	M	70	FBSS	16	2	very good
4	F	45	FBSS	4	3	very good
5	F	60	FBSS	4	1	moderate
6	F	46	FBSS	6	3	very good
7	M	54	FBSS	3	2	very good
8	M	54	FBSS	7	2	moderate
9	F	52	FBSS	4	2	very good
10	F	47	FBSS	3	2	very good
11	M	75	FBSS	4	1	moderate
12	F	51	FBSS	5	2	very good
13	F	53	FBSS	5	2	moderate
14	M	48	FBSS	3	1	very good
15	M	50	FBSS	5	1	very good
16	M	50	FBSS	2	1	moderate
17	F	47	FBSS	3	2	very good
18	M	56	FBSS	3	2	moderate
19	M	47	FBSS	8	3	very good
20	F	48	FBSS	5	1	very good
21	M	33	FBSS	2	2	very good

Legend: F (female), M (male)

Table 2. *Employment status of the patients before and after the spinal cord stimulation (SCS) procedures.*

Working status	Before SCS	After SCS
	N = 21	N = 21
Retired	7	7
Unemployed	3	3
Shorten work time	1	4
Sick leave	10	0
Easier work	0	5
Same work	-	2

The median follow up in this retrospective study was 24 months and ranged between 2 and 62 months. Primary outcome was estimated by the proportion of patients achieving at least 50% of pain relief in the legs, using the VAS. The VAS–measured pain intensity during the SCS treatment ranged between 3 and 6, the median value was 4. After the SCS implantation, the VAS values were significantly lower, compared to the pre–treatment values (t test, $p<0.0001$) (Fig. 4). In fact, 14 patients out of 21 reported pain relief in the legs of 50% or more. In 7 patients achieved pain relief was between 30% and 49% (moderate success) (Fig. 5). As addendum we report, the failure of SCS in two previous mentioned non FBSS patients, where merely

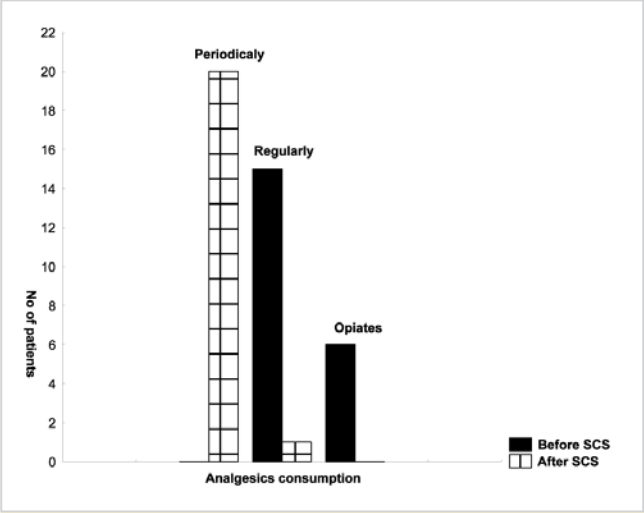

Figure 3. *Reduction of analgesics consumption after the spinal cord stimulation (SCS).*

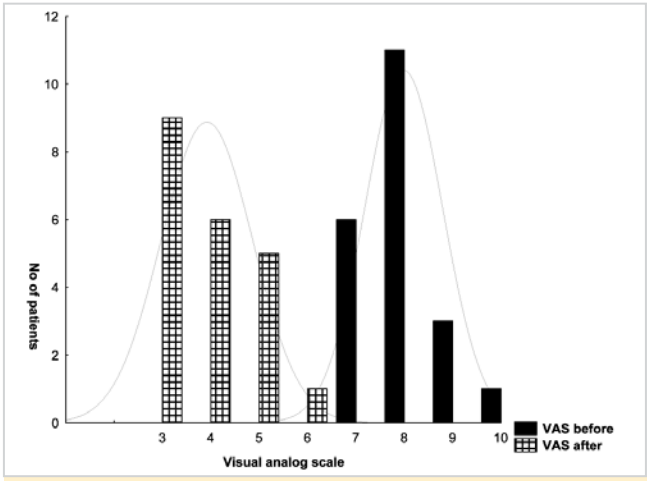

Figure 4. *The Visual Analogue Scale (VAS) -measured pain intensity before and after the spinal cord stimulation (SCS) procedure.*

a minimal effect of the stimulation was observed (1 patient with phantom pain and 1 with transversal lesion of the spinal cord). Both of them have refused the withdrawal of the stimulator, however. All patients had no improvement of the axial pain after the SCS.

A reduction in analgesics consumption following the SCS was evident (Fig. 3). The success of the SCS was reflected also in the working status of the patients. All employed patients returned to work. They started either on an easier working position (5 patients) or with a shortened working time (4 patients). Two patients resumed previous occupation (Table 2). The functional outcome and satisfaction of the patients was evaluated using the ODI. Results of the ODI after SCS treatment ranged from 18% to 78% with a mean value of 39% (moderate disability).

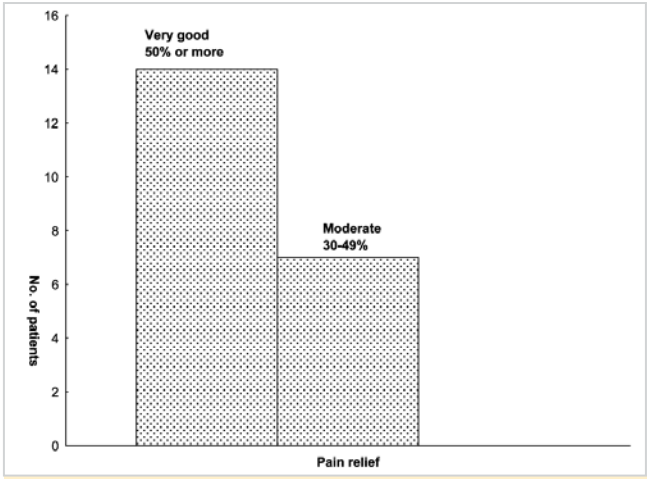

Figure 5. *A bar graph showing effect of spinal cord stimulation (SCS) on the pain relief.*

DISCUSSION

Although the SCS can help patients with persistent neuropathic pain, it does not seem to be useful for nociceptive pain. A major limitation of the SCS in treatment of chronic pain is a difficulty to provide relief of axial (truncal) pain (8). The same limitation was noted in our group of patients where despite a good relive of leg pain, no improvement in low back pain was seen. Our observations are consistent with the most common indication for the SCS in literature, which is back (or neck) radiculopathic pain (16,17,19). In recent years, the SCS has been applied with an increasing effectiveness due to improved patient selection criteria, improved accuracy in electrode placement and technological improvements of the devices (19).

According to different authors, a success rate of 57% to 59% has been reported in long–term observations and both the average pain experienced by the patients as well as the analgesic drug consumption declined significantly (20–24). An efficient pain reduction has been described also after a short–term use of spinal cord stimulation (25). Although a large numbers of

published case series have highlighted the effectiveness and safety of the SCS in the management of FBSS, only few randomized controlled trials reported that the SCS had provided more effective pain relief than reoperation or conventional medical management (CMM), as assessed by at least 50% of pain relief (19,26–28). According to the study of 45 patients, North et al. concluded in 2005 that the SCS was more effective than reoperation as a treatment option for persistent radicular pain after lumbosacral spine surgery (26). Compared with reoperation, the SCS has the advantage of being reversible, minimally invasive and is associated with lower morbidity (27). In 2007, Kumar et al. presented the results of the PROCESS study, which included 100 FBSS patients with predominant leg pain of neuropathic radicular origin (28). They directly compared the effectiveness of the SCS with the CMM. In carefully selected patients with FBSS, the former provided a better pain relief than the CMM alone and improved health–related quality of life (HRQL) as well as the functional capacity. Since 2003, the SCS is being performed also in our country and its clinical effectiveness was evaluated in these 21 patients treated at our institution. We reached satisfactory results without a previous test implant of temporary leads. The indications and especially the long–term efficacy of the SCS continue to be a topic of the debate due to highly variable reports of long–term success rates (29,30). The generally used outcome measurements after the SCS treatment are patients' estimation of pain relief on the VAS and different questionnaires for quality of life, functional capacity, patient satisfaction, need for pain therapies, and number of days absent from work and so on (31). It must be of note that pain is a product of various factors, varying from patient to patient, and that the success rate of the SCS cannot be surely predicted even for the same underlying pathology in two different subjects (19). Although the VAS is a subjective measure, it is understood by most patients and may be readily reproduced on successive presentations (28). It is therefore an internationally recognized and commonly used scale (32). In our patients, a significant decline in the postoperative VAS–measured pain intensity compared to the preoperative values was found. This result reflected the effectiveness of the SCS in reducing leg pain in our group. According to the recommendation from literature, we considered that a reduction of approximately 30% of pain intensity on the numerical rating scale represented a clinically important difference (33,34). Such result was achieved in all FBSS patients from our group. Two thirds of them reported 50% or more of pain relief in the legs. Additionally, patients used significantly less pain medications then before the implantation of the device. Even the working status was changed and employed patients were able to return to the same or easier working position with full or shortened working time. Despite the fact, there was no available ODI data of the included patients before the SCS treatment; we have decided to collect the post–SCS index for the present report. Surprisingly, these results were conflicting with other used outcome measurements, especially with the VAS and the employment status. It was speculated, that the reported ODI after the SCS might be different if the patients have filled the same questionnaire also before the SCS surgery, thus they could themselves make the comparison. On the other hand, the Oswestry low back pain disability questionnaire is considered as a gold standard for lower back functional outcome tools and not for leg pain. In this aspect, the ODI results of our patients after the SCS procedure in the first instance reflected their problems with lower back. It was found in our study, that a chronic pain of long duration (more than 5 years) is not necessary an exclusion criterion. Therefore, a very good outcome may be achieved even after three times longer pain duration.

In accordance with the literature, no serious complications or mortality was documented in our SCS procedures (19). The surgical complication rate (infection, haemorrhage) and the stimulation induced complication rate were similar, as reported in the review of Turner et al. (35) and Burchiel et al. (36), respectively. The incidence of technically– and hardware–related complications is associated with the performance of system implantation (37). No such complications were observed/present during our study. Besides its high effectiveness, the SCS procedure is distinguished also by a low complica-

tion or morbidity rate and a minimal surgical invasiveness. The method is completely reversible. Additionally, the SCS also lacks drug side effects. However, it should be carried out only after a thorough and correct patient assessment (24,38).

CONCLUSION

The current report shows that a successful management of patients with FBSS could be achieved by appropriate patient selection, correct evaluation and follow-up and with proper system implantation. We have been able to achieve comparable results to other studies even without trial stimulation due to proper patient selection and careful preoperative evaluation. The SCS provides documented patient satisfaction, pain relief in the legs, improves independence and quality of life and also enables patients to return to work and resume a normal social life.

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List of abbreviations	
FBSS	failed back surgery syndrome
SCS	spinal cord stimulation
VAS	Visual Analogue Scale
ODI	Oswestry Disability Index
GABA	gamma-amino butyric acid
EMG	electromyography
MRI	magnetic resonance imaging
CPT	current perception threshold
TENS	transcutaneous electrical nerve stimulation
IPG	implantable pulse generator
CMM	conventional medical management
HRQL	health-related quality of life

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