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CLINICAL STUDY

High-frequency – Spinal Cord Stimulation

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Abstract

AIM: Our clinical experience with high – frequency SCS for FBSS in patients with predominant low back pain is presented.

MATERIAL AND METHODS: After a trial period, 100 % (21 out of 21) of patients with FBSS with predominant low back pain reported a significant improvement in visual analog scale (VAS) pain score and underwent permanent implantation of the high - frequency SCS system. SCS trials lasted 7–14 days (median 9 days). SCS leads were mostly positioned at the T8–10 or T8–12 vertebral levels . We used both single and dual lead placement. VAS, patient satisfaction, patient performance status, opioid consumption and complication rate were assessed for the period of 12 months.

RESULTS: The mean VAS score before implantation (8.7) compared to VAS 12 months after implantation (4.0) was significantly lower (CI95[3.9–5.4], $p < 0.001$). There was a significant improvement in performance status when comparing PS before implantation (3.0) and 12 months after implantation (1.8) (CI95[0.9–1.6], $p < 0.001$). The mean patient satisfaction scores (PSS) did not differ throughout the whole one year follow-up period.

CONCLUSION: Our group of 21 patients with implanted high - frequency SCS systems reported significant low back pain and leg pain relief within the period of 12 months as well as significant improvement in their performance status. We had a special subgroup of 5 patients with regular change of frequencies between high frequency and conventional frequency (with paresthesia) also with significant leg and low back pain relief *(Tab. 2, Fig. 1, Ref. 8)*. Text in PDF *www.elis.sk.*

KEY WORDS: predominant back pain, failed back surgery syndrome, high - frequency stimulation, spinal cord stimulation.

Introduction

Spinal cord stimulation (SCS) is already a well established method of treatment for failed back surgery syndrome (FBSS) (1). With today's SCS systems, paresthesia coverage is required for pain relief, conventional SCS generates paresthesia (tingling sensation) to cover up pain. The basic principle behind SCS is most probably activation of large myelinated fibers at the dorsal horn which possibly attenuates small fiber activation (2, 3). A mix of nociceptive and neuropathic pain has been known to be difficult to treat with conventional SCS (4). High-frequency spinal cord modulation device was introduced to treat chronic leg and axial back pain. It was co-founded with Mayo Clinic in 2006 and it is planned to become an important therapy for not just chronic pain of neuropathic origin but axial back pain as well. Effectiveness of high stimulating frequencies up to 10 kHz was first described in an animal model of neuropathic pain (5). The exact mechanism of action of high-frequency SCS has not yet been fully understood. It is speculated that it normalizes the behavior of hyperactive or "wind up" second order neurons on the spinal cord (wide dynamic range neurons), returning the system to pre-injury (pre-chronic pain) state, to its physiologic norm. The system should create no paresthesia sensation, just a pure pain relief without tingling or uncomfortable stimulation. Thus the patient does not have to tinker with a remote control of the device to adjust for posture changes and does not need to turn the device off during sleep. The high-frequency stimulation therapy is planned to reduce back and leg pain in comparison to baseline without inducing paresthesia.

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Methods

The preliminary high-frequency SCS study was conducted in four Slovak centers and all implantations were performed by one experienced implanter. Visual analog scale (VAS) pain scores (0–10), opioid use (in mg of morphine sulfate equivalents), patients satisfaction (PSS, 0–10 points) and performance status (PS, 0 normal life – 4 unable to care for self) were determined at baseline, at the end of the SCS trial, and at office visit 3, 6, 9, and 12 months after implantation. Other data collected included such demographics as the patient age, gender, chronic pain duration, type of back pain with pain distribution (legs/back). The

Tab. 1. Patient data.

Number of patients	21
Male vs Female	10 / 11
Average age	44 ± 15
Average pain duration (years)	7.8 ± 5

follow up was done by 4 experienced physicians from all four centers. Spinal cord stimulation trial data also included the type of the lead used, and number of leads used, final position of the lead/leads and tip/tips, lead/leads position (i.e., midline or paramedian), vertebral levels covered and trial duration. Similar data were obtained when SCS system was implanted, along with any associated complications.

Patient selection

Patients had to meet the following criteria to be included in the study: age more than 18 years, primary diagnosis of chronic back pain with or without leg pain, intensity of at least 6 out of ten on Visual Analog Scale (VAS), failure of conventional treatment including pharmacological treatment, physical therapy, epidural injections. The quality of described pain in most of the patients was aching, sharp, and stabbing. All included patients went through psychological and psychiatric assessment to confirm their ability to provide consent, ability to comply with study procedures, visits and evaluations (Tab. 1).

Study design

This was a non-randomised prospective study. After informed consents were provided all patients underwent a baseline evaluation. Within 6 weeks since the baseline evaluation all patients were implanted with percutaneous trial leads, which started the trial phase. The external stimulator was connected to leads under the trial period. The device was programmed to deliver 3 different options to find the most optimal pain relief for each patient (bipolar stimulation up to 10 kHz). VAS levels were assessed on daily basis. Actual SCS trials lasted 7–14 days. At least 50 % of VAS reduction and patient agreement were two basic conditions to proceed to the permanent implantation of pulse generator (Senza™ – rechargeable high frequency system, Nevro Corp, CA, USA). The IPG implant marked the beginning of the permanent phase of the study.

Procedure

For the trial two leads (17 pts) or one lead (4 pts.) were implanted in the epidural space with the puncture site at L1/2 or L2/3 level. Octrode leads were used in all of the patients. The procedure was done under either general or local anesthesia, based on patient's preference using modified Tuohy needles. Leads were positioned in anatomic midline between the T8 and T11 levels, to have a maximum number of contacts over T9–T10 area. There was no intraoperative paresthesia testing or programming performed, the only intraoperative parameter to test were impedances of the system. In case of a successful trial period the permanent IPG implant was done within 14 days since the trial implant. The IPG was placed in the conventional buttock site.

Data collection and analysis

Baseline data were obtained from each patient prior to stimulation with high-frequency SCS system at the time of consent. They included VAS for legs and VAS for back pain, performance status (PS), patient's satisfaction (PSS) and morphine equivalent of the opioid therapy. All data were recorded into special report forms. The data collection was performed by four experienced physicians from 4 different follow up centers. The same data collection was done on all follow up visits three, six, nine and twelve months from the beginning of the therapy. Descriptive statistics were calculated for each analyzed variable. These included number of observations, mean, median and standard deviation. Differences in means were calculated using a two-sided t-test with a 95% confidence interval, the level of significance was set to 0.01.

Results

Complete data were obtained from all 21 patients with FBSS, who were recruited in the trial with high frequency SCS systems through one or two percutaneous eight-contact epidural leads. All 21 patients (10 men, 11 women) completed the trial.

Pain

The mean differences in VAS score before implantation (8.7 ± 0.88) compared to VAS immediately after (3.9 ± 1.13), 3 months (4.4 ± 1.4), 6 months (4.4 ± 1.5), 9 months (4 ± 1.5) and 12 months after implantation (4 ± 1.5) were statistically significant (CI95[4.2–5.5], CI95[3.6–5.1], CI95[3.6–5.1], CI95[4–5.5], CI95[3.9–5.4] respectively, $p < 0.001$). After 12 months, 67 % patients still met the 50 % pre-implant pain reduction criterion (Fig. 1).

Performance status

The mean differences in performance status (PS) before implantation (3 ± 0.38) compared to PS immediately after (2 ± 0.6), 3 months (1.95 ± 0.6), 6 months (1.95 ± 0.6), 9 months (1.95 ± 0.5) and 12 months after implantation (1.8 ± 0.6) were statisti-

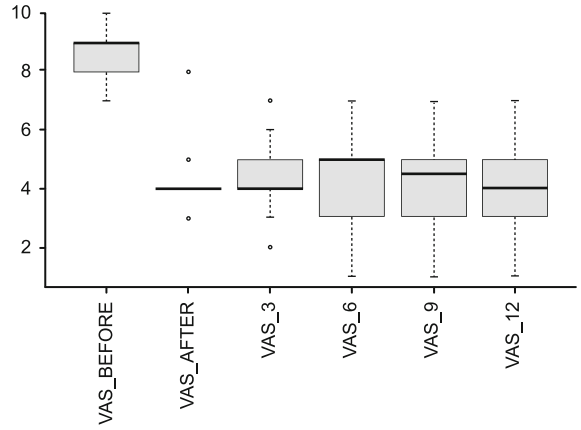

Fig. 1. Box Plot – Visual Analog Scale (VAS) before, immediately after, 3 months, 6 months, 9 months and 12 months after implantation.

Tab. 2. Performance status change.

	Before (No of pts)	6 months (No of pts)	12 months (No of pts)
No symptoms, Normal Life	0	0	0
Able to carry out normal activities, part-time employment	0	4	6
Unable to work, able to care for personal needs	1	14	13
Limited in care for oneself	18	3	2
Unable to care for oneself, confined to bed	2	0	0

cally significant (CI95[0.6–1.3], CI95[0.8–1.4], CI95[0.8–1.4], CI95[0.8–1.4], CI95[0.9–1.6] respectively, $p < 0.001$) (Tab. 2).

Patient satisfaction

The mean patient satisfaction scores (PSS) did not differ throughout the whole one year follow-up period (6.9 ± 3.5 after implant; 6.8 ± 2.9 after 12 months).

Opioid consumption

After 12 months, 65 % of patients had their opioid consumption reduced by a half.

The "special" sub-group

During the one year follow-up period an unexpected group of patients emerged, who were unable to maintain satisfactory pain relief with high-frequency SCS neither with conventional SCS (with paresthesia) alone. These 4 patients had to switch between high-frequency SCS and conventional SCS program every 4 – 5 weeks.

Discussion

We have already had 3 studies available evaluating first clinical results of high frequency spinal cord stimulation (HFSCS). The study by Perruchoud et al concluded that the HFSCS is equal to sham for the primary outcome (improvement of PGIC – patient's global impression of change) as well as for both of secondary outcomes (VAS and EQ – 5D index) (6). This study was performed with conventional implanted pulsed generators (IPG) reprogrammed to deliver a continuous stimulation of 5000 Hz which differs from the frequency of 10 000 Hz used in our study. On the contrary the studies by Van Buyten and Al-Kaisy concluded significant and sustained pain relief on both back and leg pain after twelve months (7) as well as after two years (8). These studies utilized IPGs with a frequency of 10 000 Hz. Compared with the above mentioned studies, our results are definitely showing significant pain relief, patient's status improvement and decrease of opioid consumption after the initial period of one year. Our study did not show any significant improvement in patient satisfaction scores throughout the whole follow-up period. This might partially be attributed to high initial expectations from the treatment in our patients.

The lack of paresthesia with HFSCS allows to create double blinded research protocols. Our study can be criticized for the absence of blinding. The interesting part of our results was a special subgroup of patients (5 patients) where the frequency was changing between 10 000 Hz and a conventional paresthesia frequency. This was because of repeated lack of analgesia after the initial period of good pain relief on both frequencies. The global pain relief in this subgroup was equal to pure high frequency patients. We assume that except for any other questions concerning HFSCS there is a question regarding a possible time limitation of the HFSCS pain relief effect. Continuous overuse of the spinal cord by stimulation with high frequency electrical current might lead to "fatigue" of the stimulated nerve tissue and thus loss of analgesia in some patients.

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